WARWICK
THE UNIVERSITY OF WARWICK

A Thesis Submitted for the Degree of PhD at the University of Warwick

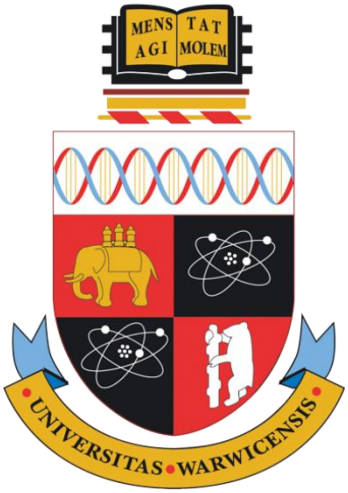
Permanent WRAP URL:
http://wrap.warwick.ac.uk/100532

Copyright and reuse:
This thesis is made available online and is protected by original copyright.
Please scroll down to view the document itself.
Please refer to the repository record for this item for information to help you to cite it.
Our policy information is available from the repository home page.

For more information, please contact the WRAP Team at: wrap@warwick.ac.uk

warwick.ac.uk/lib-publications

Exploring the Potential of Using Mobile Applications in Diabetes Management



Hala Ibrahim Alhodaib

Populations, Evidence and Technologies

Division of Health Sciences, Warwick Medical School

University of Warwick

A thesis submitted for the degree of Doctor of Philosophy, October 2017

Table of Contents

Table of Contents i

List of tables viii

List of figures ix

Acknowledgements x

Declaration xii

Abstract xiii

Abbreviations xiv

Overview of thesis 1

Aim and objectives 1

Rationale and scope 2

Thesis structure 3

Chapter 1 Introduction 6

1.1 Diabetes prevalence and influence worldwide and in the UK 6

1.1.1 Diabetes in general 6

1.1.2 T2D in the UK 7

1.1.3 Diabetes with multimorbidity 7

1.2 The potential for IT in diabetes management 8

1.2.1 Decision-support systems in diabetes management 10

1.2.2 Mobile devices market 11

1.2.3 HCPs' adoption of mobile devices 12

1.2.4 Mobile health (*m*Health) and diabetes management 13

1.2.5 Need for new technology intervention methods 14

1.3 Current state of mobile apps 16

1.3.1 Definition of mobile apps 16

1.3.2 *m*Health apps market 16

1.3.3 Diabetes apps market 17

1.3.4 Medical apps market for HCPs 19

Chapter 2 Background 21

2.1 Use of mobile apps in diabetes care and management 21

2.1.1 Mobile apps for self-management 21

2.1.2 Mobile apps for remote monitoring 22

2.1.3 Mobile apps for clinical practice 22

2.1.3.1 Clinical decision-support apps (*m*Health DSS) 23

2.2 Critical assessment of related work and relation to my own work 24

2.2.1 Previous systematic reviews and meta-analyses 25

2.2.2 Limitations of current systematic reviews and meta-analyses 29

2.3 Issues associated with mobile apps in the literature 30
Chapter 3 Background to thesis methodology 34
3.1 Research framework 34
3.1.1 Application of UCD framework for developing thesis objectives 36
3.2 Research methods 38
3.2.1 Using mixed-methods research design 38
3.2.2 Methods of data collection 39
3.2.2.1 Using quantitative methods 39
3.2.2.2 Using qualitative methods 41
Chapter 4 Systematic review method 45
4.1 Research design 45
4.2 Review aim and objectives 45
4.3 Rationale for undertaking the two systematic reviews 46
4.4 Criteria for considering studies for these reviews 47
4.4.1 Types of studies 47
4.4.2 Types of participants 47
4.4.3 Types of interventions 48
4.4.4 Comparisons 49
4.4.5 Types of outcome measures 49
4.4.6 Settings 50
4.5 Search methods for identification of studies 51
4.5.1 Electronic database search 51
4.5.2 Searching other resources 52
4.6 Data collection and analysis 53
4.6.1 Selection of studies 53
4.6.2 Data extraction and management 53
4.6.3 Quality Assessment of included studies 53
4.6.3.1 Assessment of risk of bias in included RCTs 53
4.6.3.2 Quality assessment of other study designs 54
4.6.3.3 Quality assessment of qualitative studies 55
4.6.4 Measures of treatment effect 55
4.6.5 Dealing with missing data 56
4.6.6 Assessment of heterogeneity 56
4.6.7 Assessment of reporting biases 57
4.6.8 Data synthesis 57
4.6.8.1 Meta-analysis 57
4.6.8.2 Narrative synthesis 58
4.6.9 Other factors relating to data synthesis 59

4.6.9.1 Subgroup analysis 59
4.6.9.2 Sensitivity analysis 59
Chapter 5 A quantitative systematic review and meta-analysis: Results and discussion 60
Design 60
5.1 Results 60
5.1.1 Results of the search 60
5.1.2 Excluded and ongoing studies 64
5.1.3 Included studies 64
5.1.3.1 Study design 66
5.1.3.2 Sample sizes 66
5.1.3.3 Participants 67
5.1.3.4 Interventions 67
5.1.3.5 Comparator 70
5.1.3.6 Outcomes 71
5.1.3.7 Settings 72
5.1.4 Risk of bias in included RCTs 73
5.1.5 Quality assessment of other study designs 77
5.1.6 Effects of intervention 78
5.1.6.1 Clinical outcomes 78
5.1.6.2 Psychosocial outcomes 89
5.1.6.3 Behavioural outcomes 90
5.1.6.4 Knowledge outcome 91
5.1.6.5 Patient-reported outcomes 93
5.1.6.6 HCP-related outcomes 95
5.1.6.7 Miscellaneous outcomes 96
5.1.7 Summary of findings 98
5.2 Discussion 98
5.2.1 Summary of results 98
5.2.2 Quality of evidence 99
5.2.3 Comparison with other reviews 101
5.2.4 Strengths and limitations of review 103
5.2.5 Methodological consideration 104
5.2.6 Implications of the review and future research 105
Chapter 6 A qualitative systematic review: Results and discussion 107
Design 107
6.1 Results 107
6.1.1 Results of the search 107
6.1.2 Included studies 108

6.1.2.1 Data collection methods 109
6.1.2.2 Sample sizes 109
6.1.2.3 Settings 110
6.1.2.4 Participants 110
6.1.2.5 Interventions 110
6.1.2.6 Evaluation 111
6.1.3 Quality of included studies 112
6.1.4 Synthesis of findings 114
6.1.4.1 Patients' experience with intervention components 114
6.1.4.2 Patients' perception on the use of apps 119
6.1.4.3 Patients' needs and requirements for apps 120
6.1.4.4 Usability of apps 122
6.1.4.5 Factors influence patients' acceptance of apps 123
6.1.4.6 HCPs' experience and/or perspective on the use of apps 125
6.2 Discussion 126
6.2.1 Summary of results 126
6.2.2 Quality of evidence 128
6.2.3 Comparison with other reviews 128
6.2.4 Strengths and limitations of review 128
6.2.5 Implications of the review and future research 129
Chapter 7 Diabetes specialist nurses' interview study 131
7.1 Aim and objectives 131
7.2 Research design and setting 131
7.3 Ethics approval 132
7.3.1 Ethical considerations 132
7.4 Eligibility criteria 133
7.5 Sampling and recruitment of participants 133
7.6 Participants 134
7.7 Interview process 134
7.8 Qualitative data analysis 135
7.9 Results 136
7.9.1 Participant characteristics 136
7.9.2 Experience of using apps 137
7.9.2.1 Lack of experience in using clinical support apps 139
7.9.2.2 Lack of knowledge and awareness of available apps that support HCPs 140
7.9.2.3 Tendency towards recommending apps for patients 140
7.9.3 Perceptions and views towards using apps in clinical setting 141
7.9.3.1 Perceived benefits of using apps 141

7.9.3.2 Perceived barriers/limitations to the use of apps 143
7.9.3.3 Perceived concerns of using apps 144
7.9.4 Difficulties in diabetes management that might be supported by the use of apps 146
7.9.4.1 Poor understanding of the concept of decision-support tools 149
7.9.4.2 Basic requirements for clinical support apps 150
7.9.5 Willingness to use apps at the point of care 150
7.9.5.1 Mobile apps are the future 152
7.9.5.2 Apps are self-explanatory 152
7.9.6 One app does not fit all 153
7.10 Discussion 154
7.10.1 Summary of main findings 154
7.10.2 Comparison with other relevant studies 159
7.10.3 Methodological strengths and weaknesses 160
7.10.4 Implications of study results 161
Chapter 8 Design and development of a mobile-based clinical decision-support app 163
8.1 Design rationale and requirements 163
8.1.1 Source of requirements 164
8.1.2 Functional requirements 164
8.1.3 Technical requirements 164
8.1.4 Medical requirements 165
8.2 Design considerations 165
8.3 Development process 165
8.3.1 Prototype development 166
8.3.2 Management pathways (decision algorithms) 166
8.3.2.1 Guidelines used in the development of the management pathways 166
8.3.3 Implementation 167
8.3.3.1 Programming language 168
8.4 Final implemented design 168
Chapter 9 Evaluation of the developed mobile app 174
9.1 Aim and objectives 174
9.2 Research design and setting 174
9.2.1 Pilot randomised controlled experiment 174
9.2.2 Satisfaction questionnaire 175
9.2.3 Usability testing 175
9.3 Ethics approval 176
9.3.1 Ethical considerations 176
9.4 Participants 177
9.5 Recruitment of participants 177

9.6 Session process 177
9.7 Data analysis 179
9.8 Results 179
9.8.1 Participant characteristics 179
9.8.2 Findings 180
9.8.2.1 Pilot randomised controlled experiment 180
9.8.2.2 Satisfaction questionnaire 181
9.8.2.3 Usability testing 182
9.9 Discussion 184
9.9.1 Summary of main findings 184
9.9.2 Comparison with other relevant studies 186
9.9.3 Methodological strengths and weaknesses 186
9.9.4 Implications of study results 187
Chapter 10 Overall discussion and conclusion for the thesis ***189***
10.1 Summary of main findings of the thesis 189
10.2 Contributions to the field 191
10.2.1 Design contribution 191
10.2.2 Methodological contribution 192
10.2.3 Practical contribution 192
10.3 Limitations and challenges 193
10.4 Further research 194
10.5 Future plans and prospects 195
10.6 Conclusion 196
References ***198***
Appendices ***217***
Appendix 1. Search strategy details and results for all electronic databases and journals and grey literature 217
Appendix 2. Example of data extraction sheets for one RCT and one non-RCT 223
Appendix 3. Example of data extraction sheet for one qualitative study 233
Appendix 4. Example of the Risk of Bias assessment for one RCT 239
Appendix 5. Example of the Downs and Black quality assessment for one non-RCT 241
Appendix 6. Example of the CASP methodological quality assessment for one qualitative study 246
Appendix 7. Ongoing and completed trials identified from the online trials registers 248
Appendix 8. Characteristics of included studies tables 257
Appendix 9. Summary of findings tables 275
Appendix 10. Summary of methodological quality of included qualitative studies using CASP assessment tool 282
Appendix 11. Ethics approvals & letters of access 305
Appendix 12. Interview study materials 311

Appendix 13. Decision algorithms and table _____ 317
Appendix 14. App evaluation study materials _____ 326
Appendix 15. Contributions to science and outputs from this thesis _____ 337

List of tables

Table 2.1 Identified reviews on the use of mobile apps in diabetes management. 25
Table 2.2 Identified meta-analyses on the effect of mobile apps on HbA_{1c} (%). 28
Table 4.1 Inclusion and exclusion criteria for study selection. 50
Table 5.1 Distribution of the included studies by different variables. 65
Table 5.2 Key apps' functionalities identified in the included studies. 68
Table 5.3 Design techniques applied in the studied mobile apps. 69
Table 6.1 Distribution of the included studies by different variables. 108
Table 6.2 Classification of included studies into groups according to their main focus of evaluation. ... 112
Table 7.1 Characteristics of participants (N=15). 136

List of figures

Figure 1.1 Global divide on smartphone ownership (Source: Pew Research Centre 2016, p. 16) 12

Figure 3.1 User-Centred Design stages as applied in this project with the data collections methods used in each stage (Adapted from Gulliksen et al. 2003, p. 5). 36

Figure 3.2 Mixed-methods design applied in this project along with the associated research components. 39

Figure 5.1 Flow diagram illustrating selection of studies for inclusion in quantitative and qualitative reviews. 63

Figure 5.2 Risk of bias graph: risk of bias for each domain (percentages across all included RCTs). 75

Figure 5.3 Risk of bias summary: domains for each included RCT. 76

Figure 5.4 Quality assessment result of non-RCTs: sub-scale and overall score by study. 78

Figure 5.5 Forest plot for HbA_{1c} level of diabetes patients who used a mobile app. 80

Figure 5.6 Forest plot for HbA_{1c} level according to type of diabetes. 83

Figure 5.7 Forest plot for HbA_{1c} level according to purposes of intervention. 85

Figure 5.8 Forest plot for HbA_{1c} level according to follow-up durations. 87

Figure 5.9 Distribution of frequently studied outcomes according to diabetes type and intervention effects. 92

Figure 7.1 Themes identified in the study and their relationships 158

Figure 8.1 'Diabetes & CKD' home screen. 170

Figure 8.2 Examples of data entry screens. 171

Figure 8.3 Examples of recommendation screens. 172

Figure 8.4 Additional examples of recommendation screens. 173

Figure 9.1 Frequency of scores for control and intervention groups. 180

Acknowledgements

Firstly, I would like to thank my principal supervisors, Dr Paul Sutcliffe and Dr Krishnarajah Nirantharakumar (*University of Birmingham*) for their unique perspective and valuable help and support over the course of the PhD, providing all the essential relationships that made this research possible. I will be forever grateful for their guidance, assistance, motivation, and confidence in me. This project would never have succeeded without their expertise and constructive criticism. I truly appreciate the time they took in their busy schedule for advising me. Both are exemplars of the true scholar that I aspire to be.

This PhD was funded by a full scholarship covering the studentship and research consumables from my employer *King Saud University*, Riyadh, Saudi Arabia, and I am deeply grateful to their contribution to my education, and for enabling and funding this research project. I owe sincere gratitude to all staff at the *Saudi Arabian Cultural Bureau* in London; their mentoring and support enabled me to attend the *University of Warwick*.

Acknowledgement must also go to all my co-authors who have given my work and me a very important additional element: Professor Wasim Hanif (Consultant - Diabetes and Endocrinology, *University Hospitals Birmingham NHS Foundation Trust*), and Dr Sailesh Sankar (Consultant - Diabetes and Endocrinology, *UHCW NHS Trust*). Without their clinical expertise, knowledge and input, the project could not have been completed. Particular thanks to Dr Antje Lindenmeyer (*University of Birmingham*) for her never-ending enthusiasm and expertise who constantly provided advice about the conduct and analysis of the qualitative parts of this research. Special thanks go to Dr Yen-Fu Chen for his constant support and input throughout the systematic review and meta-analysis.

I extend my deepest gratitude to Xiaofei Gao, the second reviewer in both systematic reviews, for her commitment and hard work. Also, to Joht Chandan, for his effort in organising the controlled experiment session with junior doctors, and Sunjay Paul and Rahul Sethi, in the company recruited to develop the app (*Medic Genie*), for their

commitment to deliver the app on time, and for their patience during the iterative design process.

Big thanks to all the diabetes specialist nurses (DSNs) who took part in this research, and generously gave their time and opinions. Without you, my work could not have been done. Thanks go to all the junior doctors for kindly agreeing to participate into the experiment session and being very patient in providing feedback and answering the questionnaire.

I faced so many ups, downs, and transitions during this doctoral process, personally and professionally, which meant that I lost almost a year that I could have worked productively towards my PhD.

On a personal note, I would like to thank my family who made this journey possible; especially my husband Bandar and children Seba, Lina, and Sultan who have been highly supportive and patient throughout a tough and long journey, when I have had no time for them. Thank you for always believing in me and supporting me in so many ways, and for the constant motivation to reach my goals; I would be lost without you. Thanks also go to my parents for their constant encouragement to have strong faith in God, and for instilling a work ethic in me that when I start something, then I will finish it – no matter what difficulties or obstacles cross my path. I also wish to thank my sisters and brothers for their moral support and constant cheering during these years. I am lucky to have such brilliant siblings.

I am also grateful to my PhD mates. Thank you for sharing your experiences, giving great advice, and team spirit. Finally, a huge acknowledgement to the *Division of Health Sciences*, particularly *PET* unit, for their help in making suggestions to my research project.

Most importantly I thank God for enabling me to complete my degree!

Declaration

I, Hala Ibrahim Alhodaib, declare that the work presented in this thesis is solely my own. Where information or guidance has been derived from other sources, I confirm that this has been indicated by means of reference. None of the work has been previously submitted for any other degree at another university.

Abstract

Background

Diabetes mellitus is a common chronic disease and a leading cause of morbidity, complications and mortality worldwide. The number of people living with diabetes is projected to rise sharply over the forthcoming decades. Diabetes care is complex and can overburden clinicians and nurses. There is a need for innovative, flexible and cost-effective technologies to enable successful diabetes management. This thesis explores the opportunities and challenges of the mobile application (app) technology as a potential tool to support diabetes care and management.

Purpose

The purpose was to develop and evaluate a mobile app that supports healthcare professionals (HCPs) in clinical decision-making.

Methods

A mixed-methods approach was used following the user-centred design (UCD) framework for the design and implementation of all studies. Quantitative and qualitative systematic reviews of studies reporting the use of mobile apps to support diabetes management were undertaken to identify, appraise and summarise available research evidence. An interview study was carried out with diabetes specialist nurses (DSNs), to explore their experiences and views, and to identify user requirements for apps. Lastly, a guidelines-based mobile clinical decision-support app was developed and tested with junior doctors and DSNs in a controlled environment to evaluate its usability and impact on adherence to clinical guidelines, and to explore how participants experienced the app and their suggestions for improvements.

Results

Both reviews found that the existing evidence base for mobile apps is weak and inadequate to draw conclusions about the impact of their use as interventions in diabetes management. The interview study identified that nurses lack experience in using apps in clinical practice, even though they believed it could facilitate and support their work. 'Diabetes & CKD', a simple mobile decision-support app, has been designed and built for the study to assist HCPs in management of patients with diabetes and kidney disease and was tested by 39 junior doctors and 3 DSNs. It had no impact on the accuracy of decisions. Feedback from participants after the pilot session and usability testing indicated a wish to integrate such apps into their clinical practice with a strong willingness to use them in the future.

Conclusions

Application of UCD methods was efficient as the app was well-accepted by both DSNs and junior doctors. Despite the positive views and the strong willingness to use such apps, they are not widely used. There is a need to regulate the use of medical apps in clinical practice. Further research with rigorous methodology is required upon which policymakers and practitioners can base their decision-making.

Abbreviations

AADE7	Seven self-management behaviours recommended by the American Association of Diabetes Educators
ADA	American Diabetes Association
App	Application
ASI	Anxiety Sensitivity Index
BMI	Body Mass Index
BG	Blood Glucose
BNF	British National Formulary
BP	Blood Pressure
BSREC	Biomedical and Scientific Research Ethics Committee
BYOD	Bring Your Own Device
CDSS	Clinical Decision Support System
CES-D	Centre for Epidemiological Studies Depression Scale
CI	Confidence Interval
CKD	Chronic Kidney Disease
CONSORT-EHEALTH	Consolidated Standards of Reporting Trials – Electronic Health
COPD	Chronic obstructive pulmonary disease
CSS	Cascading Style Sheets
DES-SF	Short Form Diabetes Empowerment Scale
DHP	Diabetes Health Profile
DMSES	Diabetes Management Self-Efficacy Scale
DQOL	Diabetes Quality of Life
DQOLY	Diabetes Quality of Life for Youths
DSN	Diabetes Specialist Nurse
DSS	Decision Support System
eGFR	Estimated Glomerular Filtration Rate
eHealth	Electronic Health
EHR	Electronic Health Record
eLearning	Electronic Learning
ENTREQ	Enhancing Transparency in Reporting the Synthesis of Qualitative Research
FBS	Fasting blood sugar
FDA	Food and Drug Administration
GDM	Gestational Diabetes Mellitus
GP	General Practitioner
HADS	Hospital Anxiety and Depression Scale
HbA_{1c}	Glycated haemoglobin
HCI	Human-Computer Interaction
HCPs	Health Care Professionals; including medical and nursing practitioners, and allied health professionals
HEIQ	Health Education Impact Questionnaire
HIS	Hospital Information System
HIT	Health Information Technology
HTML	HyperText Markup Language
ICT	Information and Communication Technology
IDF	International Diabetes Federation
IT	Information Technology
ITT	Intention-to-Treat
LTFU	Lost to follow up
MAST	Model for Assessment of Telemedicine Applications
mHealth	Mobile Health
MMS	Multimedia Messaging Service

NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NR	Not reported
OMDTSQ	Oxford Maternity Diabetes Treatment Satisfaction Questionnaire
OR	Odds Ratio
PAID	Problem Areas in Diabetes
PDA	Personal Digital Assistant
PP	Per Protocol
QoL	Quality of Life
RCT	Randomised Controlled Trial
SCOT	Social Construction of Technology
SD	Standard Deviation
SDSCA	Summary of Diabetes Self-Care Activities
SE	Standard Error
SES	Socioeconomic strata
SF-12	Short Form Health Survey-12
SF-36	RAND 36-Item Short Form Health Survey
SMBG	Self-Management of Blood Glucose
SMS	Short Message Service
SUS	System Usability Scale
T1D	Type 1 Diabetes
T2D	Type 2 Diabetes
UCD	User Centred Design
UK	United Kingdom
USA	United States of America
WHO	World Health Organization

"Healthcare is the last industry that has not adopted digital technology in any major way to help deliver its services. And it's becoming challenging for physicians and consumers to actually manage care without those digital tools." **David Schlanger, Chief Executive Officer, WebMD, 2015**

Overview of thesis

This section outlines the thesis' overall aim and objectives. The scope of the thesis and the rationale for focusing on mobile applications (apps) specifically are then presented, followed by an outline of the thesis structure, which briefly describes the content of each chapter.

Aim and objectives

Developing the aim and objectives of this thesis was an iterative process, in which the objectives evolved while proceeding through the several stages of this research. It began with a primary goal of building and testing a mobile app, and the systematic review findings shaped the direction of this thesis.

The overall aim was to explore the potential role and impact of mobile apps in management of diabetes, with a particular focus on clinical decision-support.

The underlying objectives are as follows:

- To identify, appraise and summarise the available research evidence on the effectiveness of mobile apps in diabetes care and management through a systematic review and meta-analysis
- To identify, appraise and synthesise qualitative research studies exploring patients' and Healthcare Professionals' (HCPs) use of, and perspectives on, mobile apps for diabetes care and management
- To explore the experiences and views of Diabetes Specialist Nurses (DSNs) on the use of mobile apps in clinical practice, to identify needs and requirements of their use
- To design and develop a mobile, clinical decision-support app for the management of patients with diabetes and Chronic Kidney Disease (CKD), based on the findings collected in objectives 1, 2, and 3
- To test the developed mobile app in a controlled setting to evaluate its usability along with its impact on workflow and adherence to clinical guidelines.

Rationale and scope

Mobile health (*m*Health) is an emerging multidisciplinary field. Solid evidence, based on high-quality research, on the impact of *m*Health apps in diabetes care is lacking. There is a paucity of quality research, i.e. research with robust study design, adequate descriptions of methodology and result, statistically-powered sample size and protected against bias and inferential errors, concerning the use of *m*Health apps in diabetes management and their integration in healthcare. This present work aims to make a significant contribution to the existing knowledge. Given the potential of mobile apps to support diabetes management, this thesis seeks to identify the best available evidence on the role of mobile apps in the clinical management of diabetes, add new evidence on how diabetes nurses currently use and perceive the use of mobile apps in clinical practice, and gather further evidence on the feasibility of the developed mobile decision-support app.

Diabetes was selected as the condition for this thesis for several reasons. Diabetes is highly prevalent and costly, and a recent study estimated that the global increase in numbers with diabetes from 2011 to 2030 is 50.7%, at an annual growth of 2.7% (Whiting *et al.*, 2011). The global trends suggest that increases will continue because of population growth, ageing, and rapidly rising numbers of overweight and obese people. The global health expenditure on diabetes treatment and care constitute up to 12% of the total expenditure (International Diabetes Federation, 2015). People with diabetes require at least double the healthcare resources of their peers without diabetes (American Diabetes Association, 1998). Additionally, diabetes care is complex (World Health Organization, 2016) as diabetes professionals deal with additional information: considering the risk of hypoglycaemia, the side effects of medications, comorbid conditions, dyslipidemia, obesity, age, race and gender; all combined to make the treatment options and decision-making even more complex (Childs, 2005). In particular, HCPs face many challenges in caring for patients with diabetes and comorbid conditions. Clinical decision-making is specifically challenging in this population because clinicians have to balance the evidence of benefits and risks along with each patient's preferences. Current individual condition guidelines rarely address

multimorbidities; hence, they can be irrelevant to those with complex treatment regimens (Guthrie *et al.*, 2012). For all these reasons, it is vital to find technological solutions that may assist HCPs in handling the prevalence and complexity of diabetes. Integrating mobile decision-support into a complex care workflow such as diabetes care is essential to enhance adherence to recommended treatments and to improve outcomes for people with diabetes.

In an effort to improve the quality of care and safety of this population, an interactive mobile-based decision-support app for the management of patients with Type 2 diabetes (T2D) and CKD was developed, primarily for research purposes at this stage. The selection of CKD was informed by the patterns of comorbidity that are most common in this population (Deshpande *et al.*, 2008). Nearly three quarters of people with diabetes will develop some stage of kidney disease (Diabetes UK, 2016a). A more complex version of the app, including all the common comorbidities of diabetes, especially major micro- and macro-vascular complications, is planned for development and testing in the future. Based on the intended scope of this thesis, mobile apps referred to throughout this thesis are limited to those developed for, and used on, smart devices, i.e. smartphones, iPods and tablets (not ordinary cellular phone-based systems).

Thesis structure

The thesis has 10 chapters organised as follows:

Chapter 1 provides an overview of the key areas relevant to the wider context of the thesis. It introduces the reader to diabetes status nationally and globally, the use of information technology (IT) to support and enhance the management of diabetes and the increasing global adoption of mobile devices. This will be followed by a summary of the potential of mobile technology in diabetes management with emphasis on the health and medical apps market.

Chapter 2 presents a brief background to the potential use of mobile apps in diabetes care including self-management, remote monitoring and clinical practice. Then, a summary of previous research conditions and limitations, particularly all identified

related systematic reviews, is presented. The chapter concludes with a summary of the main issues associated with mobile apps found in the literature.

Chapter 3 describes the background to the research methodology undertaken in the thesis. The User-Centred Design (UCD) framework is applied to guide the development and structure of thesis objectives and how best to address them. The selected mixed-methods approach is then presented, with the rationale for the choice of quantitative and qualitative data collection methods.

Chapter 4 outlines the methods for the systematic reviews: the research design, the reviews' aims, objectives and rationale. The methods are then presented in three sections: criteria for considering studies for the reviews, search methods for identification of studies, and data collection and analysis.

The following two Chapters (5 & 6) elaborate on the results and discussion of the quantitative and qualitative systematic reviews, respectively. Both chapters state the review aims and objectives, followed by a description of the data analysis strategy. The results are then presented and described, including a summary of included studies, their quality assessment, and the findings. The discussion includes a comparison with other reviews, strengths, limitations and implications of the review, and suggestions for future research.

Chapter 7 presents the interview study methods and results, beginning with the study aim and objectives, and the research design and setting. Next, the ethics and research governance approval are described. The chapter then outlines the eligibility criteria, sampling and recruitment of participants, interview process and data analysis approach. This is followed by describing the results and discussion, including a summary of participant characteristics and the key themes identified. The chapter finishes with a comparison with other relevant studies, methodological strengths and weaknesses, and implications of the study results are discussed.

Chapter 8 provides a brief description of the design and development of the mobile app 'Diabetes & CKD'. This begins with an outline of the rationale for the app design, along with functional and non-functional design requirements. This is followed by a

description of the development process including the decision algorithms. The chapter concludes with a demonstration of the final implemented design of the app.

The evaluation of the developed mobile app is reported in Chapter 9. It begins with a statement of the study's aim and objectives, followed by research design and setting, ethical considerations, eligibility criteria, sampling and recruitment of participants, evaluation process and the data analysis approach. The second half of the chapter reports the results and discussion, including a summary of participant characteristics, followed by a summary of findings. Lastly, methodological strengths and weaknesses and the implications of the study results are discussed.

Finally, the thesis concludes with Chapter 10, which brings together a summary of main findings of the thesis with a general discussion. This chapter then explains how the results from this thesis contributed to the field. It then considers the limitations and challenges of the research. The chapter ends with future plans and the thesis' conclusions.

Chapter 1 Introduction

Chapter overview

This chapter describes the current state of key areas relevant to the wider context of the thesis. It introduces the reader to diabetes status nationally and globally, the use of IT to support and enhance management of diabetes, and the increasing global adoption of mobile devices. This will be followed by a summary of the potential of mobile technology in diabetes management with emphasis on health and medical apps market.

1.1 Diabetes prevalence and influence worldwide and in the UK

1.1.1 Diabetes in general

Diabetes is a lifelong condition in which the blood glucose (BG) level is high as a result of a problem in insulin production. There are three main types: Type 1 diabetes (T1D), Type 2 diabetes (T2D) and Gestational diabetes (GDM). Treatment for diabetes aims to keep BG at normal or near-normal levels (4.0–7.0 mmol/L when fasting), and to reduce risk factors for developing complications, e.g. unhealthy diet, physical inactivity, overweight and obesity, smoking, infections and other environmental influences (International Diabetes Federation, 2015).

Diabetes is one of the most common chronic diseases worldwide (International Diabetes Federation, 2015). The World Health Organization (WHO) estimated that worldwide, 422 million adults had diabetes in 2014 and 1.5 million died from it in 2012, when it was the 8th leading cause of death (World Health Organization, 2016). Diabetes is a public health problem occurring in all countries regardless of their level of development, and its prevalence and burden to patients, families and governments is increasing worldwide (International Diabetes Federation, 2015).

The International Diabetes Federation (IDF) was initiated to raise awareness of the increased prevalence of diabetes (International Diabetes Federation, 2015). The IDF recommends a management programme to provide effective diabetes care by

encouraging patient involvement in their treatment (International Diabetes Federation, 2015). Diabetes therapy is directed at control rather than cure of diabetes. Appropriate management of diabetes requires attention to the education of patients, families and communities about self-management and cooperative care skills (International Diabetes Federation, 2015). These require the development of educational and behavioural interventions and partnership between healthcare providers and patients. Therefore, the priority is to ensure that cost-effective management approaches, which reduce morbidity and mortality, are widely available.

1.1.2 T2D in the UK

In the UK, an estimated 4.5 million people have diabetes (Diabetes UK, 2016a). Public Health England estimated the average prevalence of diabetes in adults was 9% in 2015 (Public Health England, 2016). T2D is the most prevalent form of diabetes, accounting for 90% of diabetes diagnoses (Diabetes UK, 2016a). Only 37.4% of them meet the recommended treatment targets to reduce their risk of developing complications (Diabetes UK, 2016a). Diabetes UK further projected that 5 million people in England are at high risk of developing T2D (Diabetes UK, 2016a).

1.1.3 Diabetes with multimorbidity

People with diabetes often also have other conditions (multimorbidity) (Barnett *et al.*, 2012). There is no standard method for the measurement of multimorbidity, however, number of diseases is the most commonly used measure in primary care and community settings (Huntley *et al.*, 2012). Multimorbidity has a negative impact on patient's self-management, psychological well-being and quality of life (QoL), and considerably increases the use of health services, specifically ambulatory and inpatient care (Marengoni *et al.*, 2011; Smith *et al.*, 2012). There is a strong association between multimorbidity and age; however, multimorbidity is not limited to older persons (Barnett *et al.*, 2012).

People with diabetes are at increased risk of developing one or more long-term complications, including heart disease, stroke, kidney disease, nerve damage,

blindness and amputations, which impact on almost every aspect of life (Diabetes UK, 2016a). Many of these complications are avoidable with regular assessment and management (Diabetes UK, 2016a). However, the rate of complications is increasing as a result of poor management of diabetes, the ageing population and rising numbers of overweight and obese people (Diabetes UK, 2016a). Preventable complications caused by diabetes are costly. The UK National Health Service (NHS) annual spend on diabetes is nearly 10% of its budget (Diabetes UK, 2016a; Diabetes UK, 2016a) and 80% of NHS diabetes spend is for managing avoidable complications (Diabetes UK, 2016a). Good diabetes management reduces the incidence of complications, enhances health-related QoL and reduces hospitalisations (World Health Organization, 2016). Therefore, good management of diabetes has great potential to improve diabetes care and reduce costs.

To date, the number of epidemiological studies on multimorbidity in diabetes is limited (Luijks *et al.*, 2012). Most randomised trials focus on a single condition and exclude multimorbid people (Salisbury, 2012). Additionally, clinical guidelines are essentially established for single diseases rather than multimorbidity (Guthrie *et al.*, 2012). Although guidelines have an important role in diabetes management, co-existing chronic conditions may interfere with management in many ways (Luijks *et al.*, 2012). Understanding the epidemiology of multimorbidity in diabetes is important to help develop future guidelines and design prevention programmes that meet the needs of the population, to improve care for people with diabetes and comorbidities (Luijks *et al.*, 2012).

1.2 The potential for IT in diabetes management

The first step was to consider the wider context of using IT in diabetes management, then specifically discuss mobile technology generally and mobile apps particularly. IT means using digital technologies (e.g. computers, software and the Internet) to transmit, manipulate and store various types of information (Hersh, 2009). Health IT (HIT), also called electronic health (*e*Health), describes the application of computers and technology in healthcare settings (Hersh, 2009).

Attempts to leverage IT in diabetes management go back to the late seventies and have shown promising outcomes (Diabetes UK, 2009). The use of IT to support the delivery of diabetes care has been widely reported (El-Gayar *et al.*, 2013b). Numerous ITs have been found feasible, applicable and effective for diabetes management (Tao & Or, 2013). Most healthcare systems recognise the potential for IT to provide quality care and support for the growing number of people with diabetes which, in turn, may produce clinical and economic benefits.

IT-enabled diabetes management is categorised according to the user: technologies used by providers or by patients. Currently, a wide range of assistive technologies are used by patients and providers in many areas of diabetes management. Examples include: videoconference systems, interactive educational programmes on computers, online diabetes-management resources and social networks for peer support groups; with all becoming vital components of quality diabetes care (El-Gayar *et al.*, 2013b). In particular, the Internet is one of the most common technologies where numerous websites may facilitate patients' daily diabetes care. Widespread and low cost Internet access is reducing geographic, demographic and economic barriers to obtaining health and medical assistance tools online.

Due to changes in population size, age distribution, and ethnic diversity, patients with diabetes often fail to receive the recommended care. In England in 2014-2015, less than half of persons with diabetes met all the NICE-recommended treatment targets for glycated haemoglobin (HbA_{1c}) levels, blood pressure (BP) and lipid control (41% for T2D and 19% for T1D) (Diabetes UK, 2016a). Effective communication between patients and providers is central to this process and the use of IT can improve the quality of care with decreased associated costs (Bellazzi, 2007; Finkelstein & Friedman, 2000). Two reviews have evaluated the potential benefit of IT in diabetes management and found that IT use was associated with an improvement in measures of diabetes care including HbA_{1c}, BP and lipids (El-Gayar *et al.*, 2013b; Siriwardena *et al.*, 2012). Another review investigated IT to promote access and engagement of people with diabetes, and IT increased the frequency of contact between patient and care team (Sutcliffe *et al.*, 2011).

Although studies of IT have addressed some difficulties with the uptake of these interventions (Glasgow *et al.*, 2010), there is, currently, limited evidence documenting adverse effects of IT interventions. IT is not intended to replace the role of HCPs; but to support and complement healthcare. Clinicians commonly use IT systems and tools, including computerised alerts and reminders to care providers, computerised advice on drug dosage, diagnostic support, medical calculators and eLearning materials. Use of such tools aims to help professionals cope with increased workloads. Particularly, a range of computer systems is available to provide help and support for HCPs in decision-making in some areas of diabetes management. The concept of decision-support is highlighted throughout this thesis and, thus, a brief description of decision-support systems is provided in the section that follows.

1.2.1 Decision-support systems in diabetes management

As the specific aim of the thesis is to explore the role of mobile apps in clinical decision-support, it was necessary to first define its concept. Decision-support is defined as the process of utilising medical information and clinical guidelines to convert patient data into decisions and recommendations (Klonoff & True, 2009). Computerised Clinical Decision Support System (CDSS) was defined (Wyatt, 2000) as *'a computer program that provides reminders, advice or interpretation specific to a given patient at a particular time'*. Such systems use the latest medical knowledge along with patient data to generate patient-specific advice, allowing clinicians to make informed decisions. Most CDSS were designed for use on personal computers (World Health Organization, 2011).

CDSS has been widely used in diabetes management, including providing drug therapy recommendations; referral advice to clinicians; follow-up reminders for HbA_{1c}, blood lipid measurements and eye examination; and health alerts including hyperglycaemia (Boren *et al.*, 2009; Cleveringa *et al.*, 2013; Jeffery *et al.*, 2013). One systematic review of 55 clinical trials involving 51 different computer-based CDSS for chronic disease management showed some positive benefits including improved care processes and patient health (Roshanov *et al.*, 2011). Another systematic review assessed the effects of computerised CDSS in ambulatory diabetes management and concluded that CDSS

may improve patients' clinical outcomes, however, the evidence was considered weak due to the inconsistency and risk of bias in most included trials (Jeffery *et al.*, 2013).

Mobile clinical decision-support (*m*Health DSS) is the core of the thesis. A brief account of mobile DSS is presented in the background chapter (Chapter 2, section 2.1.3.1), whereas the following section of this introduction moves on to describe in greater detail the adoption of mobile devices.

1.2.2 Mobile devices market

Mobile phones have diffused very rapidly with 7.5 billion subscriptions worldwide by 2016 (Ericsson, 2016). This represents a penetration rate of over 100%, which means that there are more mobile subscriptions than the population in many countries, primarily due to inactive subscriptions or multiple device ownership (Ericsson, 2016). The vast majority of people in all countries own at least a cellular phone. However, subscriptions for smartphones continue to increase and currently account for 55% of all mobile subscriptions (Ericsson, 2016).

Compared with cellular phones, smartphones offer more advanced functionalities and features such as Internet and email access, installation of a variety of applications, global positioning systems (GPS), Bluetooth and Wi-Fi capabilities, high quality cameras, powerful processers and operating systems, large internal memories and high-resolution touchscreens. Global smartphone ownership approached 43% in 2015, up from just 10% in 2011 (Pew Research Center, 2016). There are 3.9 billion smartphone users globally in 2016, a figure that is projected to double by 2022 (Ericsson, 2016). The rate of smartphone adoption is rapidly increasing, even among low-income groups (Pew Research Center, 2016). Smartphone ownership is relatively high in the UK, with 68% smartphone penetration as demonstrated in Figure 1.1 (Pew Research Center, 2016).

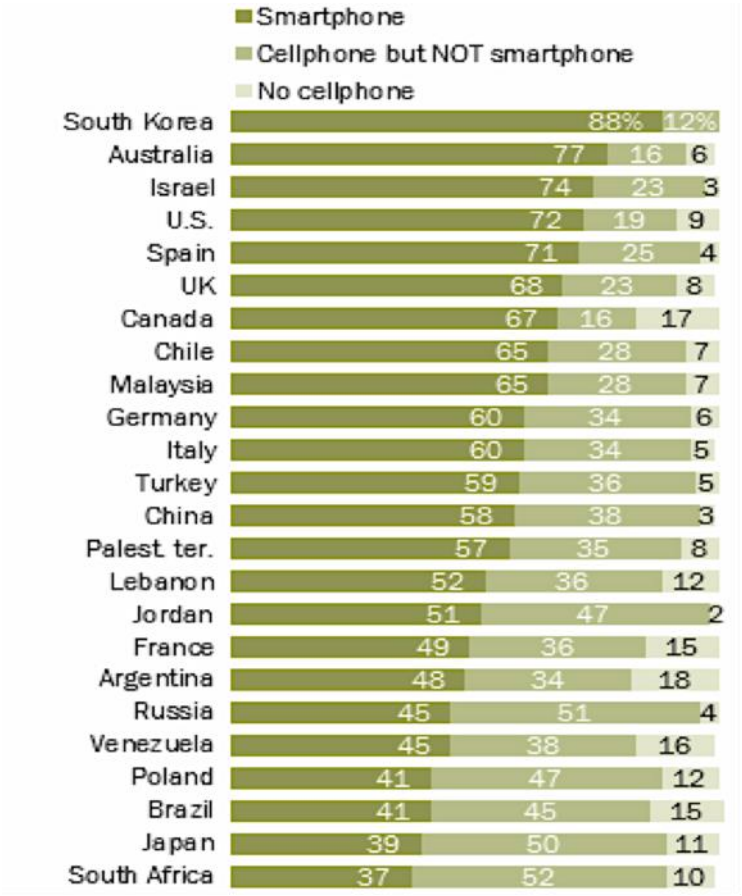


Figure 1.1 Global divide on smartphone ownership (Source: Pew Research Centre 2016, p. 16)

Along with cellular phones and smartphones, people own a range of other mobile devices such as iPod Touch, tablet computers (e.g. iPads), and personal digital assistants (PDAs). Since the tablet launch in 2010, it was the fastest adopted, with its touchscreen, light weight, and blend of smartphone and laptop (Deloitte, 2016). Today, roughly two-thirds of people in the UK have access to tablets (65% penetration of UK homes) (Deloitte, 2016). Most tablets are likely to have cellular mobile connections, which may offer an excellent productivity tool.

1.2.3 HCPs' adoption of mobile devices

After presenting the worldwide figures of various mobile devices' ownership, the next step was to specifically look over the level of mobile devices' adoption among HCPs in clinical setting. HCPs are also adopting mobile devices for patient care, and generally have positive attitudes towards their use in the workplace due to their accessibility and convenience (Koehler *et al.*, 2013). Around 80% of clinicians are adopting smartphones

and tablets and gaining access to mobile-based point-of-care solutions (Moyer, 2013; Research2Guidance, 2013). Smartphone ownership and use in clinical setting has been well-documented across many medical specialties (Almarri & Bhatti, 2015; Buchholz *et al.*, 2016; Hadjipanayis *et al.*, 2016; Jamal *et al.*, 2016; Koehler *et al.*, 2013; Liu *et al.*, 2016; O'Connor *et al.*, 2014; O'Reilly *et al.*, 2014). Clinicians use mobile technology for various tasks, including accessing medical research or drug information (dosage calculators, side effects, interactions, etc.) and communicating with nurses and other staff (MedData Group, 2014).

By contrast, nurses have received limited consideration in this digital revolution (Sedgwick *et al.*, 2016). Today most nurses still rely on pagers and landline communications, which may negatively impact patient care and work efficiency. Consequently, around 67% of nurses are using their own smartphones to support clinical communications and workflow (SpyGlass Group, 2014). BYOD, short for "bring your own device", is increasingly becoming acceptable in healthcare, even though this violates the healthcare regulations and poses major security risks such as cyber-attacks, data breaches and introduces malware and viruses because organisations do not have control of these personal devices and they may not be secured and encrypted (Moyer, 2013).

The potential of various mobile interventions in diabetes management is discussed in the following section.

1.2.4 Mobile health (*m*Health) and diabetes management

Mobile health was first defined by Laxminarayan and Istepanian in 2000, as unwired e-med (Silva *et al.*, 2015). Later, in 2003, the term *mHealth* emerged, referring to the use of mobile devices to support the practice of medicine and public health (World Health Organization, 2011). The WHO considers *m*Health as a component of *e*Health (World Health Organization, 2011). The main goal of *m*Health technology is to support the delivery and management of healthcare from a distance (Akter & Ray, 2010). *m*Health is a rapidly evolving field which has great potential to further improve quality, efficiency and access to healthcare.

The increasing use of mobile devices by clinicians and patients has led to *m*Health solutions being broadly used in many areas such as health promotion and disease prevention, diagnosis, treatment and monitoring (World Health Organization, 2011). *m*Health solutions are categorised as patient-directed or HCPs-directed solutions. The latter do not entail direct interactions with patients but are mainly aimed at increasing healthcare workforce efficiency in delivering patient care.

Chronic conditions including diabetes have noticeably been the focus of *m*Health research (Ali *et al.*, 2016). Studies of mobile interventions published before 2007 predominantly used PDAs, whereas studies published in 2007–2012 mainly used cellular phones as the moderator to enable data flow between patients and care providers (Ali *et al.*, 2016). Studies in this category used basic phone functions as the primary means to manage diabetes, mostly the Short Message Service (SMS) (Holtz & Lauckner, 2012; Liang *et al.*, 2011; Liu & Ogwu, 2012). Other mobile intervention categories included voice or video calls, cameras, media player, Bluetooth technology, Internet and email access (Klasnja & Pratt, 2012).

Mobile devices are increasingly used by patients with diabetes to access relevant information about diabetes and obtain immediate assistance with monitoring their own diabetes (Conway *et al.*, 2015; Dobson & Hall, 2015; Humble *et al.*, 2015; Williams & Schroeder, 2015). The use of *m*Health interventions for diabetes management has shown some positive effects; specifically in diabetes self-management (Kitsiou *et al.*, 2017). However, most interventions relied on text messaging which was examined more extensively in the literature and was successful in improving patients' outcomes (Hamine *et al.*, 2015; Kitsiou *et al.*, 2017; Liu & Ogwu, 2012).

1.2.5 Need for new technology intervention methods

Nurses spend a lot of time directly caring for patients and are responsible for their quality of care. However, nurses face many daily challenges in the hospital setting, e.g. increased paper-based documentation and colleague interruptions, yet they are under increased pressure to communicate, collaborate and coordinate care. Also, there is often a shortage of hospital-based nursing staff; with around 46% of nurses believing

the shortage reduces the amount of time spent with patients (Ergotron Healthcare, 2013). These challenges are expected to increase the risk of errors and reduce the time dedicated to direct patient care. A typical ten-hour nursing shift is spent as follows: up to 35% on documentation, 21% on care coordination, 19% on patient care, 17% on medication administration and 7% on patient assessment (Hendrich *et al.*, 2008). To improve healthcare at the point of patient contact, hospitals need to consider ways to overcome the challenges and provide HCPs with access to tools to address these challenges and deliver top-quality patient care. There are increasing opportunities for mobile technology to support healthcare workers in their role and enhance care provision for patients with diabetes. Providing HCPs with mobile tools may allow them to take action wherever they are, resulting in streamlined productivity and improved patient care quality and safety.

Effective management of diabetes requires multidisciplinary care and self-management by patients, including frequent monitoring of BG levels, use of oral medications or insulin, and adjustment of lifestyle. Mobile technology can potentially offer a simple tool for assessing patients' diabetes control that can be easily applied in real life. Some of the distinct features of mobile technology that make it a particularly promising platform for health interventions are that it is ubiquitous, primarily personal, always available with the person, and context awareness through embedded sensors such as GPS location tracking and accelerometer (Klasnja & Pratt, 2012). All of these allow users to collect considerable medical, physiological, lifestyle, daily activity and environmental data with minimal effort.

The advent of smartphones and tablets has taken the potential for *m*Health to a new level. As these devices have become more user-friendly, affordable and powerful, they became tools that are widely used to enable clinicians and patients to provide or receive healthcare services from anywhere (Finn, 2013). Specifically, mobile applications (apps), which are the focus of this thesis, are a major component of *m*Health today that can deliver tailor-made tools that can benefit both patients and HCPs. A large number of apps are free of charge or available at low cost (Arnhold *et al.*, 2014). Thus, they provide a relatively inexpensive innovative intervention to deliver

better care for more people at lower cost. Since 2013, the amount of *m*Health research directed towards the use of mobile apps on smart devices increased substantially, with most studies (57.8%) targeting chronic conditions (Ali *et al.*, 2016).

Briefly, diabetes complexity and prevalence, current mobile technology penetration, and shortage in healthcare workers are the key drivers for *m*Health apps uptake in diabetes management. A more detailed account of mobile apps is given in the following section of this introduction.

1.3 Current state of mobile apps

1.3.1 Definition of mobile apps

There is no standard definition of *app* found in the literature but in general it refers to any form of application on a computing device (Gröger *et al.*, 2013). Therefore, a mobile app can be defined as software application designed to be installed and run on a mobile device's operating system and often perform a specific task. They are typically available to the public through web-based application distribution markets called A*pp Stores,* for example, Apple App Store, Google Play (Android), BlackBerry App World, Windows App Store and Nokia Ovi Store. For the purpose of this thesis, mobile apps may either have one or multiple components that perform specific tasks to support diabetes care and management, and limited to those developed for, and used on, smartphones, iPods or tablets, rather than ordinary cellular phone-based systems, which are outside the scope of this thesis.

The health and medical apps market is considered in the section below, particularly elaborating on the diabetes apps market and medical apps market for professionals.

1.3.2 *m*Health apps market

As the global market has experienced a tremendous increase in the number of smartphone and tablet users, a parallel increase in the number of apps that consumers are using on their smart devices has been observed. Downloadable health and medical apps for smart devices are a fast-growing element of *m*Health. In 2016 there were nearly 250,000 medical, health and fitness apps available in major app stores around

the world (Fatehi *et al.*, 2017) and only 30% of those apps are targeted at HCPs (Research2Guidance, 2013). It was estimated that 500 million people used mobile apps for fitness, diet and chronic disease management in 2015 (Hood *et al.*, 2016).

1.3.3 Diabetes apps market

Many health-related apps target diabetes (Martinez-Perez *et al.*, 2013), with more than 1,100 apps for the operating systems iOS and Android that are specifically designed for patients with diabetes and HCPs involved in diabetes care (Garabedian *et al.*, 2015; Research2Guidance, 2014). The diabetes segment is the fastest growing in the app market (Research2guidance, 2016) and diabetes apps constitute 42.59% of all chronic condition apps (MobiHealthNews, 2010). Only 7-8% of diabetes apps are provider-directed (Arnhold *et al.*, 2014; Hood *et al.*, 2016). There was a steep increase in the annual release of diabetes apps available on the two major app store Apple and Google Play, from 6 in 2008, to 267 in 2012, to 656 in 2013 (Arnhold *et al.*, 2014). Further, over half (53.7%) were free apps, with €1.90 being the median price for paid apps (Arnhold *et al.*, 2014). The average user rating was 3.6 stars (maximum 5), with no difference in rating between free and paid apps (Arnhold *et al.*, 2014).

On the academic side, many studies reviewed app stores to investigate commercially available apps for diabetes self-management. Three previous assessments reviewed samples of diabetes self-management apps and described issues hindering their usability (Arnhold *et al.*, 2014; Demidowich *et al.*, 2012; Househ *et al.*, 2015), with one specifically evaluating usability among patients aged 50 or older. It concluded that apps were moderate to good in terms of usability (Arnhold *et al.*, 2014). Patients and HCPs should be involved in app development to overcome usability issues (Arnhold *et al.*, 2014). Another set of reviews was restricted to assessing apps' functionalities and features (Brzan *et al.*, 2016; Caburnay *et al.*, 2015; Chomutare *et al.*, 2011; El-Gayar *et al.*, 2013a; Eng & Lee, 2013; Garcia *et al.*, 2011; Hood *et al.*, 2016; Li & 李潔寧, 2014; Martinez-Perez *et al.*, 2013; Nie *et al.*, 2016; Tran *et al.*, 2012). One review showed that there were still gaps between the evidence-based recommendations and the functionalities found in online markets (Chomutare *et al.*, 2011). However, the number of an app's functions was negatively correlated with its usability (Arnhold *et al.*, 2014).

Additionally, a recent study examined the content of self-management apps for the presence of any of the seven self-management behaviours recommended by the American Association of Diabetes Educators (AADE7) (Tomky *et al.*, 2008) and found that most diabetes apps do not adhere to more than two AADE7 behaviours (Breland *et al.*, 2013). Diabetes-related mobile apps rarely integrate clinical guidelines and best practice recommended by diabetes professionals, including the American Diabetes Association (ADA) and the IDF (Brandell & Ford, 2013).

The medical content and safety of commercially-available apps aiming to support people with T1D and containing information on safe drinking of alcohol have been critically appraised (Tamony *et al.*, 2015). Only ten apps were identified, most of which did not meet the minimal educational requirements recommended by clinical guidelines (Tamony *et al.*, 2015). None could serve as an intervention to increase awareness of alcohol-associated risk among young adults with T1D (Tamony *et al.*, 2015). In an attempt to explore the likely risks associated with patient-directed diabetes apps, the accuracy and clinical suitability of insulin dose calculator apps available for iOS and Android have been assessed (Huckvale *et al.*, 2015). Of 46 calculators found, only one app was free of faults, and these apps may recommend an incorrect dose which could harm patients. Hence, HCPs should be very cautious in recommending unregulated dose calculator apps to patients (Huckvale *et al.*, 2015). Lastly, a review examined the privacy and security standards implemented in diabetes apps and found that most analysed apps pose privacy and security threats to users' health data (Knorr *et al.*, 2015). Issues include, but are not limited to, lack of encryption, failure to provide privacy policies and the lack of basic input validation tests; some recommendations for app stores, app developers and consumers were suggested (Knorr *et al.*, 2015).

Of the apps reviewed, very few are considered comprehensive diabetes self-management tools. There is a need for quality apps that support self-management across all skill areas. Recently, efforts have been made to support end-users in selecting trustworthy apps, including a framework to assist HCPs in recommending high-quality self-management apps and matching them to users' needs (Hale *et al.*).

Another novel effort is the development of the Mobile App Rating Scale (MARS), which is a reliable and comprehensive quality assessment tool for *m*Health apps that can be used by researchers, developers and HCPs (Stoyanov *et al.*, 2015).

1.3.4 Medical apps market for HCPs

The demographics of the population necessitate the use of tools such as mobile apps to support HCPs in their role and enhance care provision for patients with diabetes (Kaufman, 2010). A systematic review classified smartphone-based medical apps for HCPs according to their functionalities into seven categories (Boulos *et al.*, 2014; Mosa *et al.*, 2012):

1. Disease diagnosis and drug reference
2. Medical calculators
3. Clinical decision-support tools
4. Literature search
5. Clinical communication
6. Hospital Information System (HIS) client applications and general healthcare applications
7. Medical education and training

The first four categories were reported as most useful by HCPs and medical or nursing students (Boulos *et al.*, 2014; Mosa *et al.*, 2012). Another recent review examined commercially-available apps aimed at HCPs to support hospital prescribing and found 306 apps; 34% of them are intended for use within clinical practice (Haffey *et al.*, 2013). Of these identified apps, 68% are paid for, with an average price of £14.25 per app (range £0.62–£101.90) (Haffey *et al.*, 2013). However, there was little information about any medical or professional involvement in app development (Haffey *et al.*, 2013).

Several studies have examined how HCPs are using smartphones and medical apps in practice (Koehler *et al.*, 2013; O'Connor *et al., 2014*). Up to 80% of clinicians and medical workers are regularly using medical apps to record and access patient information from anywhere, or as disease management and drug administration tools

(Research2Guidance, 2013). More than half of nurses who own smartphones or tablets have downloaded free or paid-for nursing apps (Springer Publishing, 2013). The main reasons for clinicians' adoption of *m*Health apps are time and cost efficiency, improving care quality and continuity, and improving communication with patients (MedData Group, 2014). Clinicians clearly take advantage of medical app availability to enable rapid access to clinical information and communication among clinical staff. The use of medical apps among clinicians has a great potential in facilitating their workflow and connection with their patients.

Chapter 2 Background

Chapter overview

This chapter provides a background to potential uses of mobile apps in diabetes care including self-management, remote monitoring and clinical practice (critical assessment of the literature in Chapters 5 & 6); a summary of previous research especially systematic reviews; and a summary of the main issues associated with mobile apps found in the literature.

2.1 Use of mobile apps in diabetes care and management

*m*Health apps are becoming increasingly available and popular, especially for patients with long-term conditions, and diabetes was the most investigated condition in mobile app research (Martinez-Perez *et al.*, 2013). They offer a highly accessible and cost-effective approach for delivering quality, tailored care for patients with diabetes, e.g. education, management and prevention. However, there is a lack of systematic consideration around the impact and safety of using diabetes apps (Goyal & Cafazzo, 2013; Istepanian, 2015).

2.1.1 Mobile apps for self-management

Self-management is the process by which a person develops the skills to manage their condition, which involves collecting information, reviewing it, and taking action independently. The five key self-management diabetes-specific components are education, monitoring, medication/insulin, and adjustments of diet and exercise (Baron *et al.*, 2012). Successful self-management requires patient education with information and tools that enable active participation in self-care (Baron *et al.*, 2012). Technologies have been applied to behaviours including physical activity, diet, medication adherence and continuous monitoring, that are facilitated by the ubiquitous nature of mobile devices (Baron *et al.*, 2012; Goyal & Cafazzo, 2013), and allow patient self-care between provider visits, access to information, data input and progress tracking without location restriction.

Mobile apps offer low-effort data collection by tools such as electronic diaries, medication reminders, calculators for insulin dose/carbohydrate counting, and food databases for nutrient optimisation at meals. Often the main goal for diabetes self-management is to maintain BG levels within the target range, so monitoring BG level is the core function in most apps. Self-monitoring of BG reduces HbA_{1c} levels, especially for T1D (Tao & Or, 2013). Access to personalised self-management apps supports daily self-tracking activities, facilitates adherence and enhances patient involvement (Årsand *et al.*, 2012). A recent study provided recommendations for diabetes self-management app developers (Brzan *et al.*, 2016). However, limited research has identified apps as a distinct intervention category for diabetes self-management.

2.1.2 Mobile apps for remote monitoring

Remote monitoring is the use of any form of information and communication technology (ICT) to enable a patient's monitoring outside a clinical setting (World Health Organization, 2011). The terms *telemonitoring, telehealth, telemedicine, telecare, teleconsultations and telenursing* are interchangeably used in the literature, encompassing a wide definition of the delivery and management of healthcare over distance (Busey & Michael, 2008). Remote monitoring involves two-way professional-patient communication; patients capture and send healthcare providers information required to facilitate management between scheduled clinic visits, allowing clinicians to monitor patients' control of diabetes and modify care plans accordingly, offering an opportunity to improve patient–provider interaction and feedback.

It especially benefits patients with barriers to healthcare e.g. distance or disability (Akter & Ray, 2010), and can improve quality and efficiency of diabetes care (Baron *et al.*, 2012). Yet, limited research evaluates mobile apps for remote diabetes monitoring (Baron *et al.*, 2012).

2.1.3 Mobile apps for clinical practice

The growing prevalence of diabetes will absorb more time from HCPs. Professionals should explore the opportunities offered by the use of mobile clinical practice apps, and adopt apps as innovative mobile solutions for diabetes management and support

(Brandell & Ford, 2013), including clinical communication and workflow, problem-solving and decision-making in diabetes diagnosis, treatment and prognosis (MedData Group, 2014). Nurses, in particular, require applications that assist them to interpret and act on patient information rapidly.

Prior research largely focused on the development and clinical evaluation of patient-directed mobile diabetes apps (Okazaki *et al.*, 2012), with limited research on apps for HCPs. The evidence is not robust, and predominantly used PDAs, although they have shown improved access to information, performance and quality of care, evidence-based decision-making, engagement with learning, and reduced medical errors, (Free *et al.*, 2013a; Free *et al.*, 2013b; Guo *et al.*, 2015; Moyer, 2013; Prgomet *et al.*, 2009). PDAs are outdated and are being increasingly replaced by smart devices e.g. smartphones and tablets.

This thesis explores the role and impact of introducing a clinical decision-support app, outlined here.

2.1.3.1 Clinical decision-support apps (*m*Health DSS)

Doctors spend nearly 64% of their online time searching for information to support clinical decisions (Ventola, 2014). The use of mobile devices for clinical decision-support allows HCPs to make rapid and more accurate decisions (Ventola, 2014). However, global adoption of mobile decision-support systems is low, with few studies documenting implementation and evaluation, indicating that this is an emerging field within *m*Health (World Health Organization, 2011), although one of the most widely-used categories of medical apps is for clinical decision-support (Boulos *et al.*, 2014; Mosa *et al.*, 2012).

Limited studies have investigated the use and development of decision-support systems solely for mobile apps in diabetes care (World Health Organization, 2011). A recently-published study has developed a prototype for a clinical decision-support application for mobile devices based on the Brazilian guideline for diabetes (Klein *et al.*, 2016). The prototype was tested and evaluated by three medical experts, with promising results (Klein *et al.*, 2016). The development and use of *m*Health DSS for

smoking cessation, found that this can be integrated into nurses' workflow (86% of nurses used it and more than 60% perceived it as useful) (Hyun *et al.*, 2013). Furthermore, the smoking tool increased patients being screened, helped nurses to successfully support patients quit smoking (Cato *et al.*, 2014), helped address health disparities, and educated nurses about available resources (Cato *et al.*, 2014). For future studies, the authors recommended evaluating the use of smartphone-based tools on clinical workflow and patient outcomes (Cato *et al.*, 2014).

2.2 Critical assessment of related work and relation to my own work

To set the scene for the thesis, a narrative overview of the literature is presented in this section, including how the literature has evolved, the available systematic reviews and their limitations.

A scoping search was undertaken using combinations of a few terms: ''mobile app'', ''mobile application'', or ''smartphone'', with ''diabetes'', to explore previous research conducted in the field of *m*Health apps and diabetes. The aim was to explore existing studies and the types of populations, interventions, comparisons and outcomes assessed. The initial search revealed that clinical effectiveness studies were inconsistent in study design, intervention and the purpose of the intervention. Few randomised controlled trials (RCTs) have been completed (Kirwan *et al.*, 2013; Quinn *et al.*, 2011), whilst pilot studies with few participants dominated (Årsand *et al.*, 2010; Cafazzo *et al.*, 2012a; Tatara *et al.*, 2013b; Waki *et al.*, 2012). The quality of *m*Health research for diabetes is poor, with only 21% of published studies providing robust evidence about the effectiveness of mobile interventions (Garabedian *et al.*, 2015). Limited small-scale quantitative efficacy studies evaluate HCPs' use of mobile apps in diabetes care, although studies have become much more numerous from 2014.

In contrast, several qualitative studies have explored diabetes patients' perspectives and preferences for using mobile apps (Årsand *et al.*, 2008; Frøisland *et al.*, 2011; Harris *et al.*, 2010; Waite *et al.*, 2013), including usability (Holtz & Lauckner, 2012; Okazaki *et al.*, 2012). Limited research has explored HCPs' perspectives and intention to adopt mobile technology (Holtz & Lauckner, 2012; Okazaki *et al.*, 2012), suggesting

that the perceived benefits and value are the primary predictors of physicians' intention to use mobile diabetes monitoring (Okazaki *et al.*, 2012). HCPs' use and views of CDSS on mobile devices have reported positive and negative views related to their use in clinical practice (Wan *et al.*, 2012; Weber, 2010).

2.2.1 Previous systematic reviews and meta-analyses

Several systematic reviews and meta-analyses on the use of mobile technology to support diabetes management were found (Baron *et al.*, 2012; de Jongh *et al.*, 2012; El-Gayar *et al.*, 2013b; Frazetta *et al.*, 2012; Herbert *et al.*, 2013; Holtz & Lauckner, 2012; Krishna & Boren, 2008; Liang *et al.*, 2011; Liu & Ogwu, 2012; Patterson, 2013; Saffari *et al.*, 2014; Tao & Or, 2013; Tatara *et al.*, 2009). None of them was particularly focused on smartphone or tablet apps. Past reviews on the effectiveness of mobile interventions in diabetes care have produced inconsistent results. Additionally, they did not distinguish between different modalities of mobile technology i.e. SMS, apps, voice calls, games, emails and Internet, despite the differences in the intervention components in both diabetes management and the use of technology. Only nine out of 24 reviews provided robust evidence about the effectiveness of mobile interventions and they were mostly focused on text messaging interventions rather than apps (Garabedian *et al.*, 2015). Evidence from these reviews is outdated as most included studies were published before 2010, with interventions functioning on mobile phones and not smartphones or tablets (Garabedian *et al.*, 2015).

Reviews and meta-analyses published from 2014 are summarised in Table 2.1 and Table 2.2, respectively.

Table 2.1 Identified reviews on the use of mobile apps in diabetes management.

Study	Design	Intervention	Population	No. of studies	Result	Comments
(Li & 李潔寧, 2014)	Systematic review	Mobile apps	Adults with T1D or T2D	5 RCTs	Mixed results, with positive effects on patient outcomes, mainly with reductions in HbA_{1c} similar to usual care	Did not assess the quality of included trials

(Wang et al., 2014)	Integrative review	Smartphone interventions	Adults with long-term conditions	16 studies, 5 for diabetes	With the help of apps, patients participated in their own health management more effectively, felt secure that their illnesses were closely monitored and that they were taken good care of even outside the hospital/clinic	Did not assess the quality of included trials Most of the included trials did not report power calculations
(Deacon & Edirippulige, 2015)	Systematic review	Mobile interventions	Adolescents with T1D	13 studies, 4 examined mobile apps	Evidence is weak for HbA_{1c}, with limited quality in the included studies, and mixed result for other outcomes	Most studies use text messages as the intervention tool
(Garabedian et al., 2015)	Systematic review	*m*Health technologies	Adults with T1D or T2D	20 studies	Majority of studied interventions showed short-term improvement on primary outcomes including HbA_{1c}	Studied 16 interventions, only 9 were smartphone-based but were not limited to apps
(Majeed-Ariss et al., 2015)	Systematic review	Mobile apps	Adolescents with long-term conditions	4 studies, 2 were targeted at T1D	Result was inconclusive, dearth of studies and the small overall sample size emphasizes the need for future studies	Two feasibility studies that have not been powered to detect statistical significance
(Tamony et al., 2015)	Systematic review	Mobile apps to support safe drinking of alcohol	Young people with T1D	7 studies	There was a limited literature focusing on the specific research question with mixed results	Studies either used qualitative approaches to explore app usability and user experience or focused on the features and content of apps

(Cui et al., 2016)	Systematic review	Smartphone apps	Adults with T2D	13 RCTs	Moderate beneficial effect on glycaemic control and no clinically relevant effects were found on BP, serum lipids, or weight	Most included studies utilised mobile phone-based systems rather than apps on smart devices
(Sun et al., 2016)	Systematic review	Smartphone apps	Adults with T1D	8 studies, 4 focused on stand-alone apps	No significant improvement in HbA_{1c}, but two studies indicated significant improvements in adherence to BG monitoring	Conference abstract; no full text review was identified Considered both stand-alone apps and apps plus text messaging
(Whitehead & Seaton, 2016)	Systematic review	Mobile apps	Adults with long-term conditions	9 RCTs, 5 addressed diabetes	4 studies showed statistically significant improvements in HbA_{1c}	
(Hood et al., 2016)	Systematic review	Mobile apps	Adults with T1D or T2D	13 studies	Some clinical benefits but mostly tended to be insignificant due to the lack of statistical power	Most studies are uncontrolled with small sample sizes
(Bonoto et al., 2017)	Systematic review	Mobile apps	Adults with T1D or T2D	13 RCTs	Moderate beneficial effect on glycaemic control, and no significant differences with respect to secondary outcomes, but positive impacts on diabetes perception of self-care and self-efficacy	

(Kitsiou et al., 2017)	Overview of systematic reviews	*m*Health interventions	Adults with T1D or T2D	15 systematic reviews	Mobile technology interventions improve HbA_{1c} by as much as 0.8% for T2D and 0.3% for T1D, particularly in short term	Most reviews had important limitations in methodological quality
(Greenwood et al., 2017)	Overview of systematic reviews	Technology-enabled intervention	Adults with T1D or T2D	25 systematic reviews	18 studies reported significant reduction in HbA_{1c}	Reviews evaluated multiple types of technology, and mobile phones and secure messaging dominated

The pooled effect size on HbA_{1c} ranged between -0.36% and -0.49% (Table 2.2). This is a clinically significant difference, especially because the intervention, in some of the included trials, was the *m*Health technology alone whereas the control was usual care by a clinician. Therefore, the equivalence of outcome would be a good result. *m*Health apps have a potential role to play when compared to the effect of medications, specifically, if they were improved further to give more clinical effect.

Table 2.2 Identified meta-analyses on the effect of mobile apps on HbA_{1c} (%).

Study	Intervention	Population	No. of studies	Pooled effect size	Comments
(Cui et al., 2016)	Smartphone apps for self-management	T2D	6 RCTs	-0.40% (CI: -0.69 to -0.11%; p=0.007)	Most studies utilised mobile phone-based systems rather than apps on smart devices
(Hou et al., 2016)	Mobile apps for self-management	T1D and T2D	14 RCTs	T2D: -0.49% (CI: -0.30 to -0.68%; p<0.01) T1D: -0.36% (CI: -0.87 to 0.14%; p=0.16)	4 studies targeted T1D, therefore, inadequate data to describe the effectiveness of apps Moderate GRADE of evidence Subgroup analyses indicated that younger patients were more likely to benefit, and the effect size was enhanced with HCP feedback

(Bonoto et al., 2017)	Mobile apps for self-management	T1D and T2D	12 RCTs	-0.44% (CI: -0.59 to -0.29%; p<0.001)	Subgroup analysis was performed according to diabetes type, and both subgroups showed favourable results of HbA_{1c} control to intervention compared with control

A systematic review being planned (Huckvale *et al.*, 2011) on the use of mobile apps for diabetes self-care aims to examine the clinical, informational, behavioural and economical facets. Yet, it is restricted to the aspect of self-management, limited to patients' use and excluded diabetes during pregnancy.

In regard to HCPs' use of mobile apps, a systematic review aimed to assess the effect of *m*Health interventions on healthcare delivery processes (all specialities, not specifically diabetes) and concluded that trials investigating mobile interventions for HCPs' support have reported some promising results for clinical management, appropriate testing, referral, screening, diagnosis, treatment and triage (Free *et al.*, 2013b). Another systematic review explored classification of smartphone-based healthcare apps (not solely diabetes-related) according to their functionalities, but was limited to MEDLINE literature (Mosa *et al.*, 2012). Thus, the use of mobile apps to support HCPs involved in diabetes care has not yet been explored in a systematic review.

2.2.2 Limitations of current systematic reviews and meta-analyses

To date, there is no robust evidence on the effect of mobile apps specifically, rather than mobile interventions more generally. Most previous reviews and meta-analyses have found inconclusive and heterogeneous evidence of clinical effectiveness or other outcomes, and they did not distinguish between the different functionality of mobile apps in calculation of the overall effect size.

Limited reviews specifically focused on smartphone or tablet apps' effectiveness, as distinct from mobile apps, which may include mobile phone-based systems, for diabetes management and care. As *m*Health is an emerging field, most mobile app studies were published after 2013 and, although some existing reviews covered

publications up to 2016, they were limited to studies with such robust research design as RCTs. Moreover, many included studies in these reviews were published prior to 2010 when the *m*Health industry was significantly different from today, while even those published between 2010 and mid-2013 evaluated mobile phone systems rather than smartphone or tablet apps.

Existing systematic reviews largely examined self-management of diabetes, mostly in patients with T2D and fewer T1D, but none with GDM.

Additionally, past reviews have limitations in transparency of methods and rigour. No qualitative systematic review was identified that particularly considered the quality impact of using mobile apps in diabetes management and care, and no reviews considered the cost-benefits of mobile apps. Little is known about the uses of *m*Health apps by diabetes care-providers since no review considered their use in clinical practice and decision-making.

To conclude, the number, sample size and quality of clinical effectiveness trials so far provide inadequate evidence of mobile apps as an effective means of delivering healthcare within the care pathways for people with diabetes. All reviews helped to enrich the discussion part of the systematic review result reported in Chapters 5.

The final section of the background chapter addresses issues and concerns about existing apps documented in the literature, and the need for regulatory control due to new technology.

2.3 Issues associated with mobile apps in the literature

There is limited evidence documenting adverse effects of mobile interventions. Yet, there have been well-established concerns over the accuracy and safety of the medical content of mobile apps (Lewis & Wyatt, 2014). The information source is unclear in many apps, which might question the credibility and reliability of those apps and the consequences for patient safety, as some may provide patients with conflicting advice or incorrect management practice. The National Health Service (NHS) in England has launched an online library of approved mobile health apps in response to concerns

about the quality of *m*Health apps (Boulos *et al.*, 2014). The IMS Institute for Healthcare Informatics analysed over 40,000 consumer health apps currently available to download from the U.S. Apple App Store, which can be used as a reference to assist consumers deciding which app to use (IMS Institute for Healthcare Informatics, 2013). Additionally, Lewis & Wyatt have developed a generic risk framework that helps consumers and stakeholders assess the potential risks of medical apps (Lewis & Wyatt, 2014).

*m*Health apps are not regulated by specific guidelines in many countries, raising uncertainty about their quality and validity. There is a need to establish appropriate regulatory guidelines by government health authorities on *m*Health apps for clinical use to promote accountability, best practice and quality in patient care. Some regulatory bodies do regulate mobile medical apps, e.g. the U.S. Food and Drug Administration (FDA) Medical App Guidance (U.S. Food & Drug Administration, 2013), for medical apps that convert a mobile platform into a medical device, and the European Commission has also issued legislation aiming to certify the compliance of medical app developers with those regulations (European Commission, 2010). Happtique, a U.S. *m*Health solutions company, released a voluntary app certification scheme 'Happtique Health App Certification Program' (HACP) but only for apps available in the U.S. market (Boulos *et al.*, 2014). Considerations regarding safety and reliability must be balanced by a timely certification and approval process. Buijink et al. proposed a number of strategies that could control the medical app market and minimise unnecessary procedures that may hinder app development (Buijink *et al.*, 2013).

Further concerns arise around data protection, including the privacy and security of health data. The transfer of patient data, electronically, through mobile apps may risk hacking or data breaches e.g. if the device is lost or stolen.

Mobile solutions aim to support and complement healthcare beyond traditional settings such as hospitals and clinicians' offices. However, remote-care technological interventions, although not specific to mobile apps, may introduce new risks for patients and/or providers. Some possible adverse effects of this technology were

discussed by Finkelstein and Friedman (Finkelstein & Friedman, 2000), including the following:

- Where manual data input is used, there is a risk of inaccurate data entry and the patient taking the wrong action accordingly
- Patient receiving wrong advice or misinterpreting the information and guidance
- Risks related to technical issues of the technology; e.g. limitations of coverage area, delayed or lost messages
- Patient inability to use the technology, e.g. due to visual or literacy problems
- Breaking down the healthcare practitioner-patient relationship due to reduced contact
- Data generated by remote monitoring may create an additional workload for HCPs and increase the proportion of time clinicians spend on daily care.

Still, compliance can be made possible and some of these risks may be overcome. Manual data entry, for example, can be replaced with automatic or wireless transmission. Further, basic security safeguarding techniques such as encryption of data and appropriate authentication mechanisms can easily be implemented to ensure patient safety and confidentiality.

The development of medical apps is *ad-hoc* and is often undertaken without involving end-users in their design (Boulos *et al.*, 2014). An assessment of expert involvement in *m*Health app design and development found a low level of medical professionals' involvement in development and content (Subhi *et al.*, 2015). Moreover, it is crucial that medical apps are updated when new clinical evidence arises. Therefore, it has been suggested that medical apps should be peer-reviewed by clinicians and that the established guidelines should be used by app developers and reviewers to ensure their quality and reliability.

A report on *m*Health apps classifies the growing health and medical app market into three phases: an initial trial phase, a commercialisation phase and an integration phase (Research2Guidance, 2013). The current commercialisation phase requires regulations on *m*Health in order to enter into the integration phase where apps are projected to

be integrated into treatment plans and paid for by health insurance companies (Research2Guidance, 2013). Medical app regulation is one of the main issues in *m*Health field that needs to be addressed for *m*Health apps to meet their potential and become an integral component of healthcare in the future.

Chapter 3 Background to thesis methodology

Chapter overview

This chapter provides the background to the methodological approach used in this thesis: The User-Centred Design (UCD) framework and justification for its use, application of the UCD for developing thesis objectives, the mixed-methods approach, and quantitative and qualitative data collection methods.

3.1 Research framework

*m*Health is an interdisciplinary research field, primarily at the intersection of Health Sciences and Computer Science. As the goal is to design and develop a mobile app, a well-accepted framework widely used in the field of Human-Computer Interaction (HCI) was utilised. HCI is a discipline which emerged in the early 1980s. It studies how people interface with computers (Lazar *et al.*, 2010). The User-Centred Design (UCD) framework is a generic, multi-disciplinary, iterative, user-oriented approach to software development (Noyes & Baber, 1999), putting the intended users, their needs and requirements at the centre (Gulliksen *et al.*, 2003; Noyes & Baber, 1999). Its utilisation in healthcare has gained an increased interest over the years.

The term User-Centered Design was first coined by Norman and Drapers in 1986 (Norman & Draper, 1986). Several definitions of UCD have been proposed over the years. For instance, a simple definition was proposed by Karat in 1996 (Karat, 1996):

"For me, UCD is an iterative process whose goal is the development of usable systems, achieved through involvement of potential users of a system in system design."

Key principles that underlie the UCD process are (Gulliksen *et al.*, 2003):

- The design should be guided from the beginning by understanding users, tasks and environments
- Users should be actively involved throughout the entire design and development process
- The design is refined by user-centred evaluation

- The development process is iterative where the software design is modified and tested repeatedly
- The resulting design should address the whole user experience
- A multidisciplinary team should be involved throughout the design and development process.

Medical app developers may not fully understand the medical context (Boulos *et al.*, 2014), and app development may not involve end-users (Boulos *et al.*, 2014). UCD can improve design quality and increase user acceptance and usage of the tool (Gulliksen *et al.*, 2003). A design process study was considered important in the current thesis to guide the design and development of an app that drew upon the clinical experience and needs of HCPs.

The UCD framework involves three key stages of the design process (Gulliksen *et al.*, 2003). Figure 2.1 illustrates the phases of UCD and the data collection methods in each phase.

1. **Requirements gathering:** Identify the primary users of the tool, their requirements, tasks and the context of use

2. **Design and development:** An iterative process of software design and development based on the specified user's needs and requirements; building from a simple prototype to complete executable software

3. **Evaluation:** User-based assessment of the software usability, functionality, and acceptability to gather critical data that feed back into the overall design process.

These stages are repeated until software usability objectives have been attained.

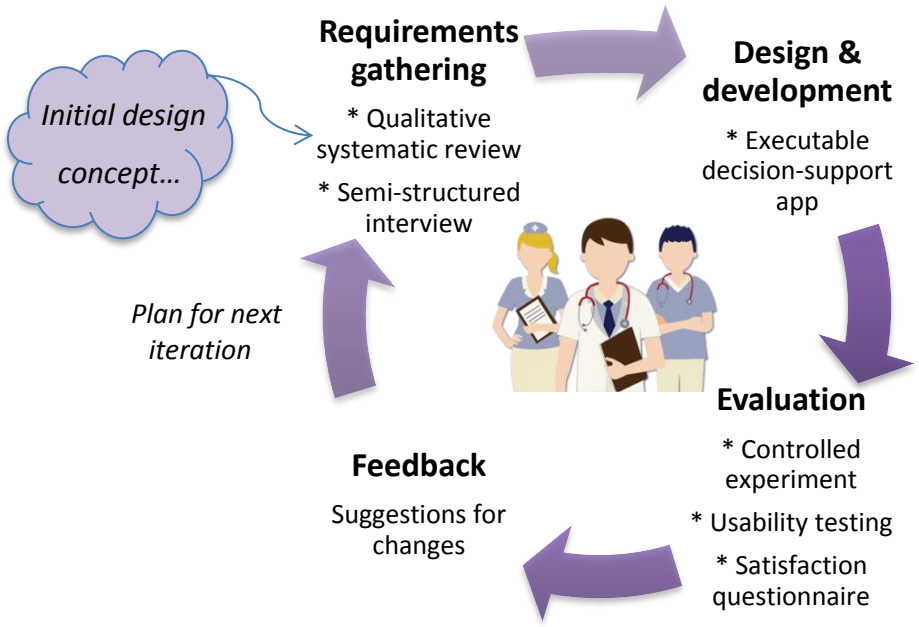


Figure 3.1 User-Centred Design stages as applied in this project with the data collections methods used in each stage (Adapted from Gulliksen et al. 2003, p. 5).

3.1.1 Application of UCD framework for developing thesis objectives

UCD is a design philosophy which aims to develop software fulfilling users' requirements, without forcing them to change their behaviour to fit around the product (Noyes & Baber, 1999). Using the UCD framework to guide the objectives and methods ensures that the development of the mobile app is systematic and that the results could help further development and evaluation of mobile apps. This section describes the application of UCD methods to the process of developing and evaluating a decision-support mobile app. Although multiple UCD cycles are needed, only one cycle was feasible within the timeframe of this research project.

Five objectives were developed to address the thesis aim. The first objective was devised following the need for a systematic review that was outlined in the background chapter (Chapter 2, section 2.2.2). Furthermore, identifying the extent of the evidence base concerning mobile apps in diabetes management was proposed as a starting point to help further in deciding the purpose and functional specifications of the app planned to be developed. This was addressed by carrying out a systematic review and meta-analysis.

1. *To identify and summarise the available research evidence on the effectiveness of mobile apps in diabetes care and management through undertaking a systematic review and meta-analysis.*

The guidance provided by the UCD framework concerns the planning, development and evaluation stages (Noyes & Baber, 1999). An initial design concept for a mobile decision-support app was proposed, with a goal to build an app that is evidence-based, user-oriented and well-suited to practice, with high potential for adoption (in this case by HCPs). This involves researching about users (HCPs) and their tasks and needs, and using the findings to help design and refine the software; investigative methods include focus groups and interviews (Noyes & Baber, 1999). The UCD guidance relating to the 'requirements gathering' stage helped in deciding on the second and third objectives, which were addressed using qualitative systematic review, and semi-structured interview.

2. *To identify and synthesise qualitative research studies that have explored patients' and HCPs' use of, and perspectives on, mobile apps for diabetes care and management*
3. *To explore the experiences and views of DSNs on the use of mobile apps in clinical practice, with a view to identifying needs and requirements of their use.*

The fourth objective relates to the 'design & development' stage and was addressed by developing decision pathways and using programming technologies.

4. *To design and develop a mobile, clinical decision-support app for the management of patients with diabetes and CKD, based on the findings collected in objectives 1, 2, and 3.*

Finally, objective five relates to the 'evaluation' stage, and was addressed using a randomised controlled experiment, usability testing and a satisfaction questionnaire.

5. *To test the developed mobile app in a controlled setting to evaluate its usability along with its impact on workflow and adherence to clinical guidelines.*

Research methods addressing the objectives are outlined in the next section (textbooks referred to as sources are cited at the end of individual paragraphs).

3.2 Research methods

3.2.1 Using mixed-methods research design

There are three empirical components, illustrated in Figure 2.2, using a mixed-methods design, as neither quantitative nor qualitative methods are adequate alone (Cameron, 2009). Qualitative methods are prioritised to understand end-users' needs and experiences (Gulliksen *et al.*, 2003).

There are a variety of designs for mixed-methods research. Triangulation of methods (QUAN + QUAL) is one of the most common approaches, where one method is combined with another in attempt to confirm, cross-validate, or discard findings within a study. Another approach is the complementary (QUAN + QUAL), which involves combining two different methods to seek elaboration, enhancement, or clarification of results from one method with results from another. A nested approach (QUAN (qual) or QUAL (quan)) involves one method embedded into another giving priority to one method to guide the project. This approach is typically used to seek information from different levels. An increasingly used approach is the sequential (QUAN → qual or QUAL → quan), whereby two or more methods are implemented sequentially, as one method is used to facilitate and inform the development of another. This strategy is useful when developing and testing a new instrument (Cameron, 2009; Creswell, 2014; Pope & Mays, 2006). Therefore, this thesis has applied a combination of complementary, sequential and nested designs, where the findings obtained from the quantitative and qualitative components assisted in designing and developing the app, which then was evaluated both quantitatively and qualitatively. The overall research design is demonstrated in Figure 2.2.

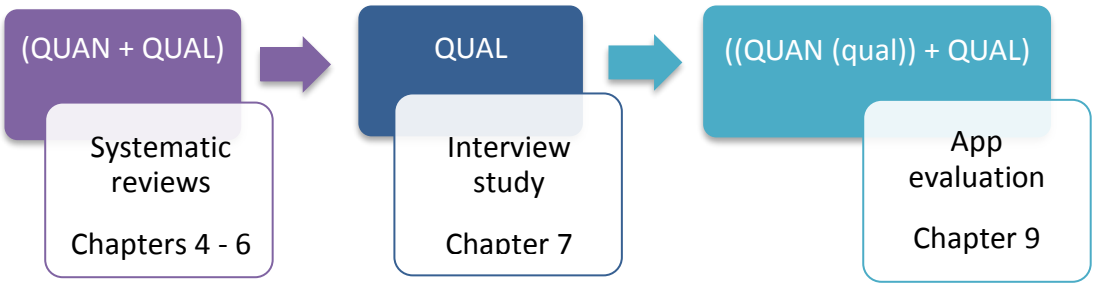


Figure 3.2 Mixed-methods design applied in this project along with the associated research components.

3.2.2 Methods of data collection

The UCD process uses several quantitative and qualitative data collection methods (Maguire, 2001), described next with the rationale for their selection and in later chapters in greater detail. As UCD falls within HCI, it is crucial to ensure consistency with HCI guidance, which further assisted in selecting the most appropriate methods to address the objectives (Lazar *et al.*, 2010).

3.2.2.1 Using quantitative methods

Quantitative research is used to measure variables, test hypotheses, predict future results, or investigate causal relationships. It is an objective approach where the researchers take a neutral position in conducting the research. Quantitative methods try to answer a clearly-defined question and have a structured, replicable design. Quantitative data are in numerical format and, thus, use statistical and mathematical methods for analysis. Findings can be generalised across groups of people to explain a particular phenomenon (Creswell, 2014; Robson & McCartan, 2016).

Quantitative research design has been broadly classified into two categories: descriptive and experimental. Descriptive studies may include large samples with hundreds or thousands of subjects who are usually measured once, with attempt to establish associations between variables. Experimental studies involve small samples of subjects who are generally measured before and after a particular intervention, to establish causality between variables (Creswell, 2014).

The quantitative methods used in this thesis include systematic review, meta-analysis and a randomised controlled experiment.

Systematic review & meta-analysis

A systematic review is a secondary research method that aims to identify, evaluate, and summarise all the existing research evidence relevant to a particular research question or topic area. It is possible to combine results of separate but similar quantitative studies using meta-analysis to produce a more reliable and precise numerical estimate of the overall effect of an intervention than from single studies. Well-designed systematic reviews are at the top of the traditional hierarchy of evidence for intervention studies, and examine the best available research evidence about a particular intervention, or identify any gaps in knowledge, and thus suggest areas for future research (Glasziou *et al.*, 2001; Tacconelli, 2010).

However, systematic reviews are more reliable and comprehensive than traditional literature reviews (Creswell, 2014), as they follow pre-specified, standardised and reproducible methods that limit any potential source of bias. They are typically conducted according to a predefined protocol that describes the research question, inclusion/exclusion criteria and the search strategy, that aims to detect as much relevant literature as possible. Additionally, they use critical appraisal tools to assess the quality of evidence in each individual study (Glasziou *et al.*, 2001; Tacconelli, 2010).

The systematic review for this thesis was carried out following rigorous guidelines for undertaking systematic reviews (Higgins & Green, 2011; Tacconelli, 2010). This systematic review assessed all the available evidence on mobile apps for diabetes management and was not restricted to any study design. However, it was split into two systematic reviews, a quantitative review with meta-analysis and a qualitative narrative review. The method for both reviews is detailed in Chapter 4, including the methods and criteria for identifying and selecting relevant studies, extracting and analysing data.

Randomised controlled experiment

An 'experimental' design tests hypotheses or theories. It is used to assess the quantitative impact of introducing a treatment or intervention on an outcome, while controlling for all other factors. A controlled experiment is a trial that includes

a control group to increase the reliability of the results through direct comparison between groups (Creswell, 2014; Lazar *et al.*, 2010).

One weakness of the experimental design is the inability to control, completely, for all other confounders that might influence the outcome. Findings can be misinterpreted as the experiment may additionally measure something different. The overall effect could exceed the treatment effect. One method to control confounders is to randomly assign individuals to groups. Well-designed and executed controlled experiments with complete randomisation can give confidence in the findings (Creswell, 2014; Lazar *et al.*, 2010).

The UCD framework supports a range of methods in the 'evaluation' stage, mostly qualitative (described below) (Maguire, 2001). Other quantitative methods were considered in deciding how best to measure the impact of using the app. However, it was important to make use of the randomised controlled experiment to ensure reliable and valid assessment. The randomised controlled experiment conducted with junior doctors, a major group of targeted users, to assess the effect of using the app on performance measures, is described in Chapter 9 (section 9.2.1).

3.2.2.2 Using qualitative methods

Qualitative research is primarily exploratory. It aims to provide insights into a problem, gain an in-depth understanding of a context, or develop hypotheses for potential quantitative research. It is a more subjective approach and the results may be researcher-dependent. Qualitative methods ask broad questions, focus on meanings and the sample size is typically small. The collected data often involve text but may also include pictures or observations. Qualitative methods mostly use unstructured or semi-structured techniques to generate rich and detailed data. Data analysis mostly involves structuring and coding data into groups and themes. Findings can be transferred to other contexts or settings (Creswell, 2014; Robson & McCartan, 2016).

Suitable qualitative approaches for this thesis include qualitative systematic review, semi-structured interviews, usability testing and satisfaction questionnaires.

Qualitative systematic review

Traditionally, systematic reviews rely on evidence from quantitative studies only. There is an argument around the feasibility of synthesising qualitative evidence despite the increasing utilisation of qualitative research in healthcare decision-making processes. Consequently, there has been a rise in efforts to include qualitative research in systematic reviews when appropriate (Pope & Mays, 2006).

Qualitative research may be expressed using narrative synthesis (a "story-telling" approach), using words and text to summarise and explain the findings from multiple quantitative or qualitative studies, one after another (Pope & Mays, 2006; Rodgers *et al.*, 2009). Narrative synthesis helps gather insights about the topic area and identify key themes that served as evidence, infer user needs and requirements for mobile apps in clinical practice, and then use them to inform app design and development. Also, narrative synthesis produces straightforward findings that are directly relevant to policymakers, practitioners and designers of the interventions (Barnett-Page & Thomas, 2009). The method for the qualitative review is outlined in Chapter 4.

Semi-structured interviews

Capturing user perspectives in healthcare decision-making is growing in importance. Qualitative feedback from potential users is a critical component, which provides valuable information on acceptability of interventions, user preferences, requirements, barriers and facilitators (Pope & Mays, 2006). The UCD framework was used to select the appropriate method for the 'requirements gathering' stage. The most commonly-used UCD methods for requirements gathering are interviews and focus groups to gain a more detailed understanding of an area or specific requirements (Maguire, 2001; Noyes & Baber, 1999).

A focus group is a form of interview but in a group context, which allows the collection of a broad range of viewpoints from participants within a short time (Lazar *et al.*, 2010; Robson & McCartan, 2016). However, scheduling a focus group with DSNs was difficult due to constraints of time and location, and participants' unique points of view can be explored in detail using individual interviews. Face-to-face interview with DSNs was

chosen to gain insight into individuals' perceptions, viewpoints and challenges. The goal was to obtain a sample of nurses' needs and preferences for mobile apps within their work context and to identify emergent themes to inform the next stage of this research. Any possible misunderstandings between the interviewer and the participants could be identified and immediately addressed. All the interviews were semi-structured and guided by an interview schedule. Semi-structured interviews have a flexible structure with a fixed set of open-ended questions in order to allow the interviewee's responses to direct the flow of the interview rather than the questions themselves, and to keep the discussions within the boundary of the research objective. This is a pragmatic choice, because semi-structured interviewing allows for depth of questioning with probing and detailed exploration of individual statements (Lazar *et al.*, 2010; Robson & McCartan, 2016). Additionally, one-to-one interviews fit better within the busy schedule of nurses. The method for the interview study is outlined in Chapter 7.

Usability testing

Usability testing is another common method that can be used at the end of a design cycle for the 'evaluation' stage. It involves inviting a number of end-users to attend a testing session and asking them to perform a series of tasks using the design and talking aloud as they use it. The session can be audio or video taped and a moderator may take notes of any difficulties encountered. It represents an excellent method to identify functionality, the most likely usability problems, and user attitudes at early stages. Undertaking usability testing in a group setting is considered important to create a space that stimulates discussion and elicits ideas, in particular, around the app's design and features. Usability testing requires some form of design to be available to test - whether a fully working version of the software or a paper prototype. It focuses primarily on gathering verbal feedback on the software design. However, collection of numerical performance measures, such as time taken to complete a task, is possible during usability testing (Lazar *et al.*, 2010; Noyes & Baber, 1999).

The DSNs tested the app in controlled conditions, performing representative tasks using case scenarios, to evaluate the app qualitatively with another group of potential users (Chapter 9, section 9.2.3). The nurses were asked to follow the 'think-aloud' protocol, i.e. verbalise what they are doing while they are doing it.

Satisfaction questionnaires

As part of the controlled experiment, participants completed a qualitative questionnaire. A questionnaire is a widely used method for the 'requirements gathering' and 'evaluation' stages (Lazar *et al.*, 2010; Noyes & Baber, 1999; Robson & McCartan, 2016).

A satisfaction questionnaire is a type of exploratory questionnaire comprising open-ended questions to capture users' subjective impressions following their experiences using a piece of software or a prototype. It is often group-administered, typically at the end of an experiment, to provide subjective data to complement and support the objective data collected. It can be administered on paper or electronically, e.g. online, and provides a simple, quick and inexpensive way of obtaining subjective feedback from users with a high response rate (Lazar *et al.*, 2010; Maguire, 2001). Questionnaires were given to junior doctors who participated in the experimental group. They were instructed to complete the questionnaires as comprehensively as possible (Chapter 9, section 9.2.2).

Chapter 4 Systematic review method

Chapter overview

This chapter outlines the methods used in conducting two systematic reviews, quantitative and qualitative: research design; aim and objectives; rationale; criteria for considering studies for the reviews; search methods for identification of studies; data collection and analysis.

4.1 Research design

Two systematic reviews were undertaken, a quantitative review with meta-analysis of randomised controlled trials (RCTs) and a qualitative review. Their results are presented separately in Chapters 5 and 6, respectively.

The reviews were carried out in conjunction with five co-authors: Dr Paul Sutcliffe, academic supervisor; Dr Krishnarajah Nirantharakumar, academic supervisor (University of Birmingham); Dr Yen-Fu Chen, Xiaofei Gao and Qing Fang.

The protocol for the systematic reviews has been completed and registered at the PROSPERO website on April 2014 (available from: http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42014009211). PROSPERO is an international database of registered systematic reviews in health and social care funded by the National Institute for Health Research, England, the Department of Health, Public Health Agency, Northern Ireland and the National Institute for Social Care and Health Research, Welsh Government.

4.2 Review aim and objectives

The review's aim was to systematically assess quantitative and qualitative evidence on mobile apps for diabetes care and management, to provide patients, clinicians and decision-makers with a robust evidence base concerning the effectiveness and impact of mobile apps.

The objectives of the quantitative review were to identify, appraise and summarise available research evidence on the effectiveness of mobile apps in diabetes care and management, identifying outcomes in the literature and areas for further consideration.

The objectives of the qualitative review were to identify, appraise and synthesise qualitative research studies that have explored patients' and HCPs' use of, and perspectives on, mobile apps for diabetes care and management, to identify HCPs' needs and requirements.

4.3 Rationale for undertaking the two systematic reviews

A growing body of literature is examining the use of mobile apps in diabetes management, making a systematic review of their impact very timely. Due to the rapid advances in technology, early mobile devices quickly become out-dated. In this fast-changing field, existing systematic reviews of mobile apps require updating. The rationale for conducting a systematic review with a broad scope of selection criteria was due to the scarcity of studies when developing the protocol. The current review:

- Closes gaps within the literature by focusing specifically on smartphone and tablet apps and including studies of apps designed to support people with any type of diabetes and HCPs
- Provides an up-to-date review, including studies up to December 2015[1]
- Combines evidence from quantitative and qualitative research to strengthen and add value to the limited evidence base (Pope & Mays, 2006)
- Avoids the weaknesses in quality found in past reviews by applying a high-quality and rigorous methodology following the Cochrane Collaboration standards for the conduct and reporting of systematic reviews and the Centre for Reviews and Dissemination (CRD) guidance for undertaking reviews in healthcare (Higgins & Green, 2011; Tacconelli, 2010).

[1] An updated search is being conducted and the result will be published (see Chapter 10, Section 10.5)

Previous reviews differ from this one by considering a broader definition of mobile apps; being limited to patient-directed self-management apps; primarily reviewing effects on glycaemic control; and being conducted some years ago.

4.4 Criteria for considering studies for these reviews

A complete list of all inclusion and exclusion criteria for study selection is presented in Table 4.1.

4.4.1 Types of studies

Eligible study designs included:

- Randomised controlled trials (RCTs), including randomised crossover studies and cluster randomised trials
- Quasi-experimental studies, including interrupted time series (ITS) studies
- Controlled before and after (CBA) studies
- Observational studies, including cohort, case-control and cross-sectional studies
- Pilot single group studies
- Qualitative studies e.g. interviews, focus groups
- Partially published work, e.g. conference abstracts, only if it was linked to a full-text report.

Non-RCTs and pilot studies were included because the initial scoping search revealed that most identified trials were small-scale pilot studies, and to understand how variations in trial design and duration may influence their results.

4.4.2 Types of participants

Eligible populations include:

1. Individuals with diagnosed diabetes mellitus (T1D, T2D or gestational), or their parents or caregivers. Studies examining mobile apps for a broad population of patients, e.g. those with chronic diseases, with subgroup analysis for patients with diabetes, were included.

2. HCPs involved in diabetes care (e.g. general practitioners (GPs), consultants, DSNs and diabetes dieticians).

No participant was excluded on the basis of any socio-demographic characteristic (e.g. age, gender; ethnicity; marital status; geographic location; employment status; education; income or health status) in any care setting.

4.4.3 Types of interventions

Definition of the intervention

The intervention (mobile apps) was defined in Chapter 1 (section 1.3.1).

Studies which examined a broad range of interventions, e.g. ICT-based apps, for diabetes management, with subgroup analysis for mobile apps, were included. The review was restricted to studies of mobile apps that support one of the following aspects:

1. *Telemonitoring:* facilitating remote monitoring of patients with HCPs at a distance, involving information exchange, i.e. two-way communication between patient and provider. Care provider feedback may include (but is not limited to) treatment recommendations, medication adjustment, reminders, advice, encouragements and corrections to lifestyle.

2. *Self-care:* developing or supporting at least one of the seven diabetes self-care behaviours as defined by the American Association of Diabetes Educators (AADE7) (Tomky *et al.*, 2008):

    a. Healthy eating
    b. Being physically active
    c. Self-monitoring of BG and other biometrics
    d. Medication adherence
    e. Problem solving skills
    f. Risk reduction behaviours and preventive care
    g. Healthy coping skills and maintaining motivation.

Apps in this domain may include one or more functions designed to initiate or reinforce those behaviours without the help of HCPs at a distance.

3. *Clinical practice:* Medical apps that target HCPs engaged in diabetes care in a clinical setting. These include apps that provide on-demand, and instant clinical support in treatment, diagnosis and decision-making at the point of care, or facilitate care coordination between the care team.

4.4.4 Comparisons

The review considered studies comparing mobile apps with:

- Usual care or any other control intervention; or
- Other intervention variant.

Studies without comparators were eligible for inclusion.

4.4.5 Types of outcome measures

All reported outcomes related to patients or HCPs were considered. No study was excluded based on the reported outcomes.

Examples of outcomes related to patients include (but are not limited to): glycated haemoglobin (HbA_{1c}), BP, cholesterol level, body mass index (BMI), QoL, hypoglycaemic episodes, hospital admissions, knowledge, self-efficacy and adherence.

Examples of outcomes related to HCPs include (but are not limited to): adherence to clinical guidelines, prescription errors and time spent with patients.

Examples of outcomes related to both patients and HCPs include (but are not limited to): usability, satisfaction, acceptability, accessibility, preferences, perceptions and experiences.

Outcomes measured at the completion of the intervention or at any subsequent time points (follow-up) were included; short-term follow-up was defined as within 30 days of the completion of the intervention, medium-term as 30 days–6 months, and long-term more than 6 months after the completion of the intervention.

4.4.6 Settings

All settings were considered, with no restrictions by country or healthcare system type.

Table 4.1 Inclusion and exclusion criteria for study selection.

	Inclusion	Exclusion
Study design	▪ RCTs, including randomised crossover studies and cluster randomised trials; ▪ Quasi-experimental studies, including ITS studies; ▪ CBA studies; ▪ Observational studies, including cohort, case-control, and cross-sectional studies; ▪ Qualitative studies.	▪ Systematic review/meta-analysis; ▪ Literature review/review paper; ▪ Descriptive paper, e.g. studies that describe a design or prototype of a mobile app with no testing on individuals; ▪ Editorial or commentary paper; ▪ Conference abstracts with no full-text report; ▪ Full-text article was not available.
Populations	1. Individuals with diagnosed diabetes mellitus (T1D, T2D or gestational); 2. Parent of, or caregiver for, a person with diabetes; 3. HCPs involved in diabetes care	▪ Individuals with pre-diabetes; ▪ Medical and nursing students
Interventions	Mobile apps that support one of the following aspects: Telemonitoring, Self-care and Clinical practice	▪ Mobile apps as co-intervention, i.e. another primary intervention besides the app; ▪ Mobile apps as a secondary intervention or a minor component of a broader intervention programme; ▪ Mobile web-based apps that can only can be accessed online through a web-browser, even though it was accessed using a smartphone or tablet; ▪ Mobile apps with adapter attached to the smartphone/tablet; ▪ Artificial Pancreas (AP) technology, since this is still under development and no AP is commercially available; ▪ Mobile apps on ordinary mobile/cellular phone or if not clear whether the app was functioning on mobile phone or smartphone; ▪ Apps on PDAs, netbooks, laptops or desktop computers; ▪ Smartphone-based interventions other than apps, e.g. SMS, Internet, and social networks; ▪ Insufficient details of the intervention or the trial; ▪ Mobile apps for medical training or continuing medical education; ▪ Mobile apps for complementary or

	Inclusion	Exclusion
		alternative medicine; ▪ Mobile apps for preventive care.
Comparisons	▪ Usual care or any other control intervention; ▪ Other intervention variant; ▪ No comparison.	None
Outcomes	All outcomes related to patients or HCPs	Technical evaluation, or validation of the accuracy of a mobile app
Settings	Any setting	None

4.5 Search methods for identification of studies

All searches were limited to studies published from 2008, due to the relatively new innovation of smart devices and apps. The first-generation Apple iPhone was introduced in 2007 and the first mobile app store, the iOS App Store, was launched in July 2008 (Gröger *et al.*, 2013). Since then, mobile apps became available to the public to download and use. Prior to that, mobile software applications were distributed directly by manufacturers.

4.5.1 Electronic database search

The following databases and journals were searched for relevant studies from 2008 onwards:

- The Cochrane Central Register of Controlled Trials (CENTRAL, The Cochrane Library)
- MEDLINE (OVID)
- EMBASE (OVID)
- PsycINFO
- IEEEXplore
- Web of Science
- Journal of Medical Internet Research (JMIR)
- Journal of Mobile Technology in Medicine (JMTM)
- Journal of Diabetes Science and Technology (JDST).

There were no language restrictions.

Initially, a detailed search strategy was devised for MEDLINE and then was adapted as appropriate for other databases. The search strategies were checked and refined by an academic support librarian. The detailed search strategies and the results for all databases and journals are in Appendix 1.

Auto Alerts was set up to send weekly or monthly updates for new literature in most databases.

4.5.2 Searching other resources

Grey literature was searched through the following sources:

- Google Scholar
- ProQuest Dissertations
- EThOS - Electronic Theses Online Delivery Service
- DART-Europe Portal
- Conference Proceedings: Conference Papers Index (ProQuest), Papers First, Proceedings First, Web of Science Core Collection – Proceedings Paper, Zetoc.

Also, databases of completed and ongoing trials were searched in the following resources (2008-present without language restrictions):

- NIH ClinicalTrials.gov (*http://www.clinicaltrials.gov/*)
- Current Controlled Trials (*http://www.controlled-trials.com/*)
- The WHO International Clinical Trials Registry Platform (ICTRP) (*http://www.who.int/ictrp/en/*).

Grey literature sources only allow for simple and short searches (Appendix 1).

Additional studies were sought by searching the reference lists of retrieved primary trials, systematic reviews and meta-analyses.

4.6 Data collection and analysis

4.6.1 Selection of studies

To determine the eligibility of studies, one author (HA) assessed all titles and abstracts retrieved from electronic searches. A second author (QF) independently assessed a random sample comprising 20% of all identified studies due to the vast amount of potentially relevant literature. Agreement on inclusion was calculated using the Cohen's kappa statistic to ensure consistency, and disagreement about any particular study was resolved by discussion. Next, HA investigated the full-text of all papers identified at the abstract sift and the reasons for exclusion were recorded. A third author, the academic supervisor (PS), was sought for their opinion about any uncertainty about inclusion.

4.6.2 Data extraction and management

Two review authors (HA and XG) each extracted data from half the included studies, and checked the extraction of the other author's half for accuracy. Standard data extraction templates were used, with any disagreements resolved by discussion and, when required, by a third party. In the case of duplicate publications and companion papers of a primary study, to maximise yield of information, all available data were extracted simultaneously. Examples of data extraction sheets for quantitative and qualitative studies are in Appendices 2 and 3, respectively.

4.6.3 Quality Assessment of included studies

Quality assessment was independently undertaken by two review authors, HA and XG, and were compared, with any disagreements resolved by discussion, or with consultation of a third party.

4.6.3.1 Assessment of risk of bias in included RCTs

To evaluate the methodological quality of included RCTs, the Cochrane Collaboration's Risk of Bias Tool was used (Higgins & Green, 2011). This method uses the following bias criteria:

- Random sequence generation (selection bias)
- Allocation concealment (selection bias)
- Blinding of participants and personnel (performance/detection bias)
- Blinding of outcome assessors and data analysers (performance/ detection bias)
- Incomplete outcome data (attrition bias)
- Selective outcome reporting (reporting bias)
- Other possible sources of bias, e.g. baseline imbalance, intention-to-treat analysis, possible contamination between groups, validity and reliability of outcome measures.

Risk of bias criteria were judged as low, high or unclear risk, using a template. Where insufficient information was available about a specific domain, that domain was judged as 'unclear.' An example of the risk of bias assessment sheet is in Appendix 4.

The risk of bias was described and illustrated in each study using a 'Risk of bias graph' and a 'Risk of bias summary' figure. This was followed by an overall assessment of the risk of bias for each of the criteria across all included studies with the possible impact on the overall effect size.

4.6.3.2 Quality assessment of other study designs

A Downs and Black checklist (Downs & Black, 1998) (Appendix 5) was used to assess the methodological quality of other quantitative, non-randomised studies (non-RCTs). Where a study used a mixed-methods approach, only the quantitative element was assessed using this instrument. The validity and reliability of this instrument meet accepted standards. The checklist contains 27 items distributed across five sub-scales, and provides an overall numeric score for study quality out of a possible 28 points. Each item is scored: yes=1, no=0, unable to determine=0, partially=0.5, except one item in the reporting subscale, which is scored: yes=2, no=0, unable to determine=0, partially=1. The five sub-scales are (Downs & Black, 1998):

1. Study reporting –10 items to assess if sufficient information was provided in the paper to enable unbiased evaluation of findings
2. External validity –3 items to assess generalisability of findings to the wider

population

3. Internal validity (study bias) –7 items to address potential bias in the intervention and outcome measures
4. Internal validity (confounding) –6 items to address potential selection bias
5. Power of the study –1 item to determine if the findings are due to chance.

The assessment for all included non-RCTs is illustrated in a graph with an overall score for each study and a profile of scores for all sub-scales, along with commentary about each sub-scale.

4.6.3.3 Quality assessment of qualitative studies

For the appraisal of qualitative research, the quality criteria defined by Critical Appraisal Skills Programme (CASP) was used (Appendix 6). This is a widely-used tool in appraising primary qualitative studies. Where a study used a mixed-methods approach, only the qualitative element was appraised using this tool. The checklist contains ten items to systematically assess a study reporting methodology, reflexivity, ethical issues and overall value. There are three possible answers for each item: 'yes', 'no', and 'can't tell' but studies were not given a weight based on this assessment (Critical Appraisal Skills Programme (CASP), 2013).

All included studies were assessed and the relative value of insights was described in the synthesis process.

4.6.4 Measures of treatment effect

Dichotomous data were reported as odds ratios (OR) or risk ratios (RR) with 95% confidence intervals (CIs). Continuous data were reported as a mean difference (MD) or standardised mean difference (SMD) with 95% CI, depending on whether the outcomes were reported on similar measurement scales or not.

This review looked at a broad range of outcomes to help understand the nature and extent of examined outcomes. As the review was carried out, it emerged that outcomes have not been measured and reported in a standard way across all studies.

Many of the included studies had missing data, poor reporting of data, or uncertainty in the treatment effect estimates.

It was not possible to standardised data for any outcome. Data were used according to the study report.

4.6.5 Dealing with missing data

Study authors were contacted in order to obtain relevant missing data whenever possible, however, none was obtained, so they were calculated, e.g. standard deviation (SD) using parametric data such as standard error (SE), CI, and p-values, or the interquartile range (IQR) for non-parametric data, using a tool (template in Microsoft Excel), comprising formulae presented in the Cochrane Handbook (Higgins & Green, 2011), or imputed using baseline and follow-up scores using a formula reported in Follmann *et al.* (Follmann *et al.*, 1992). A statistician was also consulted.

4.6.6 Assessment of heterogeneity

Heterogeneity describes differences among studies in a systematic review. There are three different types of heterogeneity; clinical, methodological, and statistical. Clinical heterogeneity comprises variability in the participants, interventions and the outcomes studied; methodological heterogeneity refers to variability in study design and risk of bias; and statistical heterogeneity refers to variability in the observed intervention effects in the different studies (which may be a consequence of clinical or methodological heterogeneity or both) (Higgins & Green, 2011).

The degree of statistical heterogeneity across studies was identified through inspection of the forest plots and employing the I^2 statistic (Higgins & Thompson, 2002; Higgins *et al.*, 2003), where an I^2 statistic greater than 50% indicates a considerable level of inconsistency (Higgins & Green, 2011). When heterogeneity was identified, the potential reasons for it were sought by examining individual study and subgroup characteristics. The impact of clinical, methodological and statistical heterogeneity on the review is described in the Chapter 5.

4.6.7 Assessment of reporting biases

Reporting bias arises when the nature and direction of study results influence the likelihood of it being disseminated, e.g. publishing only results with positive significant findings. This may include, but is not limited to, rejected or delayed publication of results and selective reporting of some outcomes in a study.

To detect reporting biases, a number of strategies were undertaken, including searching the trials registries and conference abstracts to identify studies that have been registered/presented but not published; and assessment of selective outcome reporting. The original study protocol was sought for all included studies to compare the reported methods and outcomes against the original plan. If this was not possible, and the missing data were suspected to introduce serious bias, a sensitivity analysis was used to investigate the impact of excluding such studies from the overall results.

When appropriate, if 10 or more studies were pooled (Sterne *et al.*, 2011), publication bias was assessed through visual inspection of funnel plots with respect to plot asymmetry and use of linear regression tests, and a regression slope of zero was interpreted as no publication bias. There are a number of explanations for the asymmetry of a funnel plot and thus, results should be carefully interpreted (Lau *et al.*, 2006; Sterne *et al.*, 2001).

4.6.8 Data synthesis

4.6.8.1 Meta-analysis

To pool the effect of the intervention in measures of clinical outcomes in diabetes, such as BG control, the study design was restricted to RCTs. Depending on the level of heterogeneity; a meta-analysis was conducted for any of the outcome measures where at least two studies were identified. Heterogeneity, in terms of study design, reported outcomes, outcome measures, intervention function and age group, prevented the conduct of meta-analysis for several outcomes. The number of meta-analyses was determined by discussion amongst review authors. Where appropriate, a meta-analysis was performed according to the statistical guidelines for meta-analyses

of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins & Green, 2011). Subject to the level of heterogeneity, pooling was carried out using an inverse variance random-effects model. Statistical analysis was performed using RevMan 5.3 (The Nordic Cochrane Centre, 2014).

4.6.8.2 Narrative synthesis

Where meta-analysis was considered unsuitable due to the heterogeneity and/or the small number of studies, a narrative overview of the findings of included studies was presented, with tabular summaries of extracted data where appropriate. Narrative synthesis can be applied to both quantitative and qualitative reviews (Rodgers *et al.*, 2009).

For the quantitative evidence synthesis, a narrative synthesis was carried out for all included quantitative studies. Study design, intervention, population and outcomes were summarised in text and tables. Outcomes were grouped into clinical, psychosocial, behavioural, knowledge, patient-reported, HCP-related and miscellaneous outcomes. Data were presented in tables, graphs and text primarily split by outcome group and stratified by diabetes type and/or study design, and the results for each outcome were presented in text individually and linked in text and summary tables.

The choice of synthesis approach is highly dependent on the purpose of the review (in this case, to summarise and integrate all the available qualitative evidence in relation to mobile apps for diabetes) and the number of relevant studies and the nature of the available evidence (Pope & Mays, 2006). Planning the synthesis approach at the protocol stage is very important to help the review authors to avoid highlighting some findings above others, even unintentionally. At the protocol stage, the qualitative analysis was planned using the thematic synthesis approach, although during the review, the organisation and presentation of the data, and method of synthesis, evolved based on the findings into a narrative synthesis for studies that used qualitative methods of data collection and analysis, whether stand-alone studies or part of mixed-methods studies (Thomas & Harden, 2008). Narrative synthesis arranges

studies into homogenous groups and then summarises their primary data in a structured format and lastly puts into context the extracted data. Therefore, studies assessing the same outcome were first grouped together. Study characteristics, setting, quality and findings were reported in text and summary tables, with similarities and differences compared across studies. Information was structured according to the population (patients or HCPs) and then stratified according to the type of diabetes and/or intended purpose of the intervention (self-care, telemonitoring or clinical practice).

4.6.9 Other factors relating to data synthesis

Where it was possible to pool the data from included studies in a meta-analysis, subgroup and sensitivity analyses were both considered.

4.6.9.1 Subgroup analysis

When considerable heterogeneity was found (I^2>50%), the following subgroup analyses were considered to explore further the effect of certain variables on the pooled intervention effects:

- Diabetes types (T1D or T2D)
- Purpose of intervention (telemonitoring, self-care)
- Follow-up duration (3, 6 or 9 months)
- Age groups (18-50 years, >50 years).

4.6.9.2 Sensitivity analysis

Sensitivity analyses examined the influence of the following factors on the pooled effects of the intervention:

- Excluding studies with a high or unclear risk of bias across various domains
- Restricting the analysis to large studies to establish how much they dominate the results
- Excluding studies with results which differ significantly from other studies.

Chapter 5 A quantitative systematic review and meta-analysis: Results and discussion

Chapter overview

This chapter describes the findings from the quantitative systematic review and meta-analysis, including the search results, characteristics of included studies, risk of bias and quality assessment (using figures and tables), effects of interventions are presented (text, tables and meta-analysis). The discussion section summarises the results of the review, the quality of the evidence, comparison with relevant reviews, strengths and limitations, methodological considerations and the implications and impact of the review on future research.

Design

This systematic review adopted both meta-analysis and narrative approach (Chapter 4). The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist was used to ensure systematic reporting of the review (Moher *et al.*, 2009).

5.1 Results

5.1.1 Results of the search

One search was undertaken for both the quantitative and qualitative systematic reviews, run between August and September 2014, covering studies published from 2008 until September 2014. The electronic database search found 7253 records and an additional 1059 records were identified through grey literature search. The reference management software EndNote (Thomson Reuters Corporation, 2013) was used to combine and de-duplicate the search results, leaving 5435 records to be screened at title and abstract level. A random sample of 1088 records was screened by two reviewers independently and the strength of agreement on inclusion was found to be 'very good' (kappa=0.800; SE=0.033; 95% CI: 0.735 to 0.865). Next, 646 records were assessed for eligibility at full-text level.

An additional 6016 records were received through databases' Auto Alerts considering publications until December 2015.[2] These records were screened against inclusion criteria in a similar way. Finally, 80 records fulfilled the selection criteria and were included, comprising 34 quantitative studies and 20 qualitative studies. Figure 5.1 shows an adapted PRISMA study flow diagram for the selection of studies in both reviews.

The quantitative studies were published in the following formats:

- three studies each had one individual thesis or dissertation (Min, 2013; Nielsen, 2013; Sarala, 2014);
- two each had a thesis plus one published journal article (Årsand, 2009; Årsand *et al.*, 2010; Williams, 2015; Williams & Schroeder, 2015);
- one had a thesis plus two published articles (Tatara, 2013; Tatara *et al.*, 2013a; Tatara *et al.*, 2013b);
- one had three published articles (Holmen *et al.*, 2014; Ribu *et al.*, 2013; Torbjørnsen *et al.*, 2014);
- five each had one published article plus one published abstract (Cafazzo *et al.*, 2012a; Cafazzo *et al.*, 2012b; Franceschi *et al.*, 2014; Humble *et al.*, 2014; Humble *et al.*, 2015; Miele *et al.*, 2015; Waki *et al.*, 2015; Waki *et al.*, 2011; Waki *et al.*, 2013; Waki *et al.*, 2014);
- one had two published articles plus one published abstract (Frøisland *et al.*, 2011; Frøisland & Årsand, 2015; Frøisland *et al.*, 2012);
- one had two published articles plus three published abstracts (Holl *et al.*, 2014; Neubauer *et al.*, 2014a; Neubauer *et al.*, 2015; Neubauer *et al.*, 2014b; Spat *et al.*, 2013);
- one had three published articles plus five published abstracts (Gibson *et al.*, 2013; Hirst *et al.*, 2015a; Hirst *et al.*, 2014; Hirst *et al.*, 2015b; Loerup *et al.*, 2013; Loerup *et al.*, 2014a; Loerup *et al.*, 2014b; Mackillop *et al.*, 2014);

[2] An updated search is being conducted and the result will be published (see Chapter 10, Section 10.5)

- one study had four published articles plus three published abstracts (Benhamou *et al.*, 2010; Charpentier *et al.*, 2011; Franc *et al.*, 2012a; Franc *et al.*, 2014; Franc & Charpentier, 2015; Franc *et al.*, 2012b; Penfornis *et al.*, 2010);
- and the remaining 18 studies each had individual published articles (Alanzi *et al.*, 2014; Chomutare *et al.*, 2013; Conway *et al.*, 2015; Dobson & Hall, 2015; Drion *et al.*, 2015; Hong *et al.*, 2015; Hsu *et al.*, 2015; Hunt *et al.*, 2014; Istepanian *et al.*, 2014; Kim *et al.*, 2014; Kim *et al.*, 2015; Kirwan *et al.*, 2013; Logan *et al.*, 2012; Pellegrini *et al.*, 2015; Rao *et al.*, 2010; Tiefengrabner *et al.*, 2014; Wayne *et al.*, 2015; Wayne & Ritvo, 2014).

Several studies were published by the same authors or groups, for example, Årsand 2010, Frøisland 2012, Tatara 2013, Chomutare 2013 and Holmen 2014 were all affiliated with the Norwegian Centre for Integrated Care and Telemedicine, University Hospital of North Norway, Tromsø, Norway (Årsand *et al.*, 2010; Chomutare *et al.*, 2013; Frøisland *et al.*, 2012; Holmen *et al.*, 2014; Tatara, 2013).

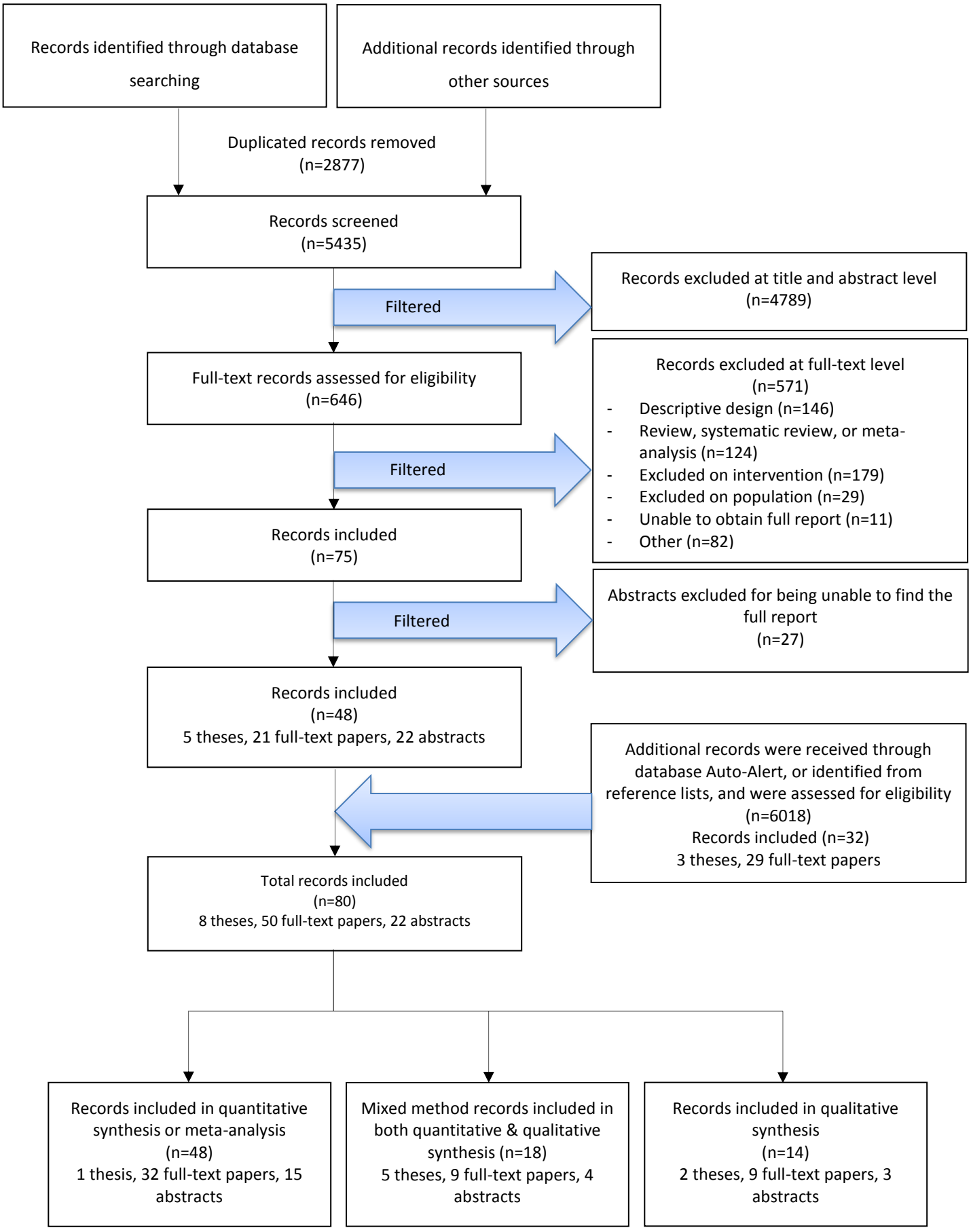


Figure 5.1 Flow diagram illustrating selection of studies for inclusion in quantitative and qualitative reviews.

5.1.2 Excluded and ongoing studies

Many studies did not fit the design inclusion criteria at full-text level and, thus, were excluded, mostly because studies were descriptive in nature, including those which described a design or prototype of a study-specific mobile app with no testing on individuals (n=146) or reviews of mobile apps (84 narrative overview/literature review; 25 systematic review/meta-analysis; 15 reviews of commercial apps).

Ineligible interventions were: 11 text messages; 44 telemedicine/telemonitoring systems; 16 computer/web apps; 14 PDA apps; 63 apps not functioning on smart devices or device unclear; 11 not specific to apps or no separate result for apps; 16 Artificial Pancreas (AP) technology (i.e. continuous glucose measurement systems linked to an insulin pump where the smartphone was used as a hub running the closed loop control algorithm); and four studies tested an app that utilised a device camera or wearable computing device, e.g. smartwatch, as the primary intervention, whereas the app was a secondary component.

Few studies were excluded based on their population (21 not specific to diabetes or no separate result for diabetes; 8 targeted pre-diabetes). Other reasons for exclusion included study outcomes that were not related to the user, e.g. studies which tested a mobile app's accuracy or its technical validation (n=14); studies with insufficient reporting of the result for outcomes of interest or insufficient information on the intervention or the trial itself (n=24); studies with outcomes that were assessed only at baseline with no further assessment at the end of the study (n=1); duplicated records (n=44); studies in which the full-text report was unavailable (n=11), or study abstracts where no full paper was found (n=27).

Online trials registers were searched on September 2014 and a list of all identified ongoing and completed trials is in Appendix 7.

5.1.3 Included studies

48 quantitative records and 18 mixed-methods records were included, comprising 34 studies, published 2009–2015, with a notable increase in more recent studies. Table

5.1 presents the distribution of the included studies by different variables. Characteristics of included studies tables are in Appendix 8, including country, design, description of the mobile app and its purpose and function, comparator, sample size, mean age, study duration and outcomes.

Table 5.1 Distribution of the included studies by different variables.

	No of trials, n	Percentage, %
Study design		
RCT	9	26
Crossover, repeated measures design	1	3
Pre-post design with control	1	3
Pre-post design without control	6	18
Single group post-only design	10	29
Cross-sectional	6	18
Case report	1	3
Sample size		
< 70	25	74
≥ 70	9	26
Study duration		
< 6 months	23	68
≥ 6 months	11	32
Country		
USA & Canada	12	35
Europe (UK, Norway, Netherlands, France, Italy, Austria, Denmark)	13	38
		18
Southeast Asia (Korea, Japan, India)	6	6
Middle East (Iraq, Saudi Arabia)	2	3
Australia	1	
Study setting		
Primary care	6	18
Secondary care (outpatient and inpatient)	15	44
Tertiary care	3	9
Community and non-medical setting	10	29
Age group		
Younger age group < 18	3	9
Older age group ≥ 18	31	91
Population		
Patients	32	94
HCPs	2	6
Type of diabetes		
T1D	7	21
T2D	18	53
T1D/T2D	8	23
GDM	1	3
Intervention purpose		
Self-care	18	53
Telemonitoring	14	41
Clinical practice	2	6
Study focus		
Disease management	11	32
Behaviour change	9	26
Adherence	0	0

Education	0	0
Usability	4	12
App utilisation	3	9
Current use of apps and preferences	5	15
Clinical decision-support	2	6

5.1.3.1 Study design

The 34 included studies were:

- interventional studies:
  - RCTs (Charpentier *et al.*, 2011; Drion *et al.*, 2015; Holmen *et al.*, 2014; Hsu *et al.*, 2015; Istepanian *et al.*, 2014; Kirwan *et al.*, 2013; Logan *et al.*, 2012; Waki *et al.*, 2014; Wayne *et al.*, 2015), of which two (Charpentier *et al.*, 2011; Holmen *et al.*, 2014) were 3-armed but the third arm was not eligible as it involved a co-intervention combined with the mobile app; one study (Istepanian *et al.*, 2014) was not described as an RCT, but met RCT criteria and was classified as an RCT within this review; and
  - non-RCTs: pre-post design with control (Kim *et al.*, 2014) or without control (Cafazzo *et al.*, 2012a; Chomutare *et al.*, 2013; Frøisland *et al.*, 2012; Pellegrini *et al.*, 2015; Sarala, 2014; Wayne & Ritvo, 2014), post-only design (Alanzi *et al.*, 2014; Årsand *et al.*, 2010; Mackillop *et al.*, 2014; Miele *et al.*, 2015; Min, 2013; Neubauer *et al.*, 2015; Rao *et al.*, 2010; Tatara, 2013; Tiefengrabner *et al.*, 2014; Waki *et al.*, 2015), crossover repeated measure design (Hunt *et al.*, 2014) and case report (Hong *et al.*, 2015); and
- cross-sectional observational studies (Conway *et al.*, 2015; Dobson & Hall, 2015; Humble *et al.*, 2015; Kim *et al.*, 2015; Nielsen, 2013; Williams & Schroeder, 2015).

5.1.3.2 Sample sizes

The RCTs (n=9) included a total of 670 participants. Study sizes ranged from 12 to 121 (mean=74.4, median=72, SD=35.85). All RCTs used power calculations except one pilot feasibility study (Istepanian *et al.*, 2014) with 12 participants.

The non-RCTs (n=17) comprised a total of 343 participants. Study sizes ranged from 5 to 73 (mean=20.2, median=14, SD=19.15). Only one study (Kim *et al.*, 2014) involved a comparison group. Most (n=14) were pilot studies with very small sample sizes (n<25). Two other non-RCTs (Neubauer *et al.*, 2015; Sarala, 2014), with HCPs as the main user of the intervention (102 HCPs and 99 patients), were analysed and discussed separately.

A total of 1058 participant were included in the observational studies (n=6). Study sizes ranged from 42 to 588 (mean=176.3, median=75, SD=214.17).

5.1.3.3 Participants

The participants in 31 studies were aged 18-65 years (mean 35 years for T1D and 55 years for T2D participants); a few studies clearly targeted adults but did not report the age distribution (Mackillop *et al.*, 2014; Min, 2013; Sarala, 2014; Williams & Schroeder, 2015); and three non-RCTs (Cafazzo *et al.*, 2012a; Frøisland *et al.*, 2012; Miele *et al.*, 2015) involved a total of 47 children and young adults with T1D (aged 4–18 years; mean=13, SD=4.40).

Patients were the target population in nearly all studies, except two non-RCTs (Neubauer *et al.*, 2015; Sarala, 2014) involving HCPs, of which one also included patient participants.

More studies targeted patients with T2D only (n=16) than T1D only (n=7), whereas GDM only was studied in one non-RCT (Hirst *et al.*, 2015b; Mackillop *et al.*, 2014). Eight studies included both T1D and T2D; although four of them (Humble *et al.*, 2015; Kim *et al.*, 2015; Logan *et al.*, 2012; Nielsen, 2013) did not identify the diabetes type. In total, the patient-directed studies (n=32) involved 2070 participants (T1D=493, T2D=1106, GDM=59, NR=412).

5.1.3.4 Interventions

In the 28 included interventional studies, 53% of studies examined apps aiming to support diabetes self-care, 41% examined apps aiming to facilitate patients'

telemonitoring, whilst only 6% considered apps supporting clinical practice. Nine key functionalities of mobile apps were identified, summarised in Table 5.2.

Table 5.2 Key apps' functionalities identified in the included studies.

Functionality	Description
Diabetes-related data collection	Enables users to track and monitor their condition by collecting various biometrics (e.g. BG & BP readings), symptoms, medication, weight, diet, physical activity, or healthy behaviours
Insulin/medication management	Helps users to adhere to their medication regimen and independently initiate or adjust insulin doses
Diet evaluation and management	Helps users to modify their diet and build healthy eating habits by using different techniques
Communication and remote monitoring	Allows care providers to monitor patients and give personalised feedback (e.g. treatment recommendations, medication adjustment, reminders, advice, encouragements and corrections to lifestyle) remotely, and enables patients to communicate with HCPs
Coaching	Allows care providers to provide patients with active coaching through virtual interactions with the primary purpose of behaviour change, motivation, and education
Reminder	Reminds users to engage in daily management activities; e.g. taking medications, self-monitoring or behaviour change
Education	Provides patients with diabetes-related education pertinent to disease outcomes, self-monitoring, interpretation of measurements, benefits and risks of healthy behaviors, and medication and side effects
Social Support	Involves use of social media to enable users to communicate with other users, with similar health status, about health-related information or sharing self-management progress, to engage family members and friends
Clinical decision-support	Utilises clinical guidelines and patient's clinical parameters to generate personalised recommendations that assist HCPs in making informed decisions

Studies varied in their main focus, with most (n=11; RCT=7; non-RCT=4) focusing on disease management; specifically, two (Charpentier *et al.*, 2011; Hsu *et al.*, 2015) focused on medication management. Other studies emphasised behaviour change (n=9; RCT=2; non-RCT=6; cross-sectional=1), with one study (Pellegrini *et al.*, 2015), in particular, focusing on increasing physical activity. Another area of focus was the app usability and user satisfaction (non-RCT=4), app utilisation and usage trends (non-RCT=3), and clinical decision-support (non-RCT=2). None of the included studies focused essentially on patient education or adherence to the management regimen.

Most of the studies examined a study-specific mobile app, except five studies which tested a freely-available diabetes self-management app, or did not report sufficient details of the app. Two studies featured multi-faceted interventions (Kirwan *et al.*, 2013; Sarala, 2014). In Sarala (2014) the patients received an intervention package,

including a nurse coordinator and counselling services besides the mobile app and, thus, outcomes specific to the patients were excluded and only the HCPs' outcomes relating to the app use were included. However, in Kirwan *et al.* (2013) the participants in the intervention arm used a separate text messaging software to communicate with a diabetes educator and received regular feedback and therefore this was treated as a telemonitoring study.

Most studies (n=20) provided participants in the intervention group with a smartphone or tablet, while few studies (n=3) required smartphone ownership for inclusion. In some studies (n=15), participants were also provided with additional equipment necessary to use the app, e.g., glucometer, Bluetooth adapter, BP monitoring device, wireless scale, pedometer or accelerometer to allow collection of various health-related parameters. Data entry, in most studies, was automatic from the connected devices; in particular, data were often transmitted wirelessly using Bluetooth technology. Few studies explicitly reported covering the cost of the mobile service during the trial. Some studies placed no restrictions on the use of the intervention, whereas others specified a required frequency for use. Some intervention group participants were trained on how to use the app, while other studies did not report offering any training or instructions.

Frequently-applied techniques in diabetes-related apps were diaries, visual graphs, trend reports and information export, while gamification and rewards were the least-implemented techniques. Studies, particularly those involving remote monitoring, used a web interface linked to the app. This involved a secure, web-based dashboard/portal which allowed care providers to review and monitor patients' data remotely. Patient-provider communication was mostly achieved through text messages, except in a few studies where phone calls or virtual video visits were used.

Table 5.3 Design techniques applied in the studied mobile apps.

Technique	Description
Electronic diary/logbook	Allows users to log health data automatically or manually and save them for later review
Visual graphs and trend reports	Provides summary graphs and reports based on logged health data to support users in problem-solving and decision-making
Information export	Allows users to export logged health data *via* email or other means of communication

Technique	Description
Web-based dashboard/portal	Allows care providers to review a patient's logged health data remotely and provide feedback accordingly
Automated feedback	Provides users with automatically-generated feedback based on logged health data, e.g., feedback on how a patient's values compare with a clinical guideline
Alerts	Enables users to set pre-determined or customisable reminders triggered by logged health data
Text messages	Involves the delivery of messages to users on a recurring basis for various purposes, including delivery of educational and motivational messages
Goal setting	Allows users to set individualised goals/targets for treatment or behaviour change to motivate them to engage better with their management
Food database	Allows users instantly to browse a large amount of food and retrieve information on nutritional composition, reference intake or portion size
Estimation of food nutritional value	Allows users to upload photographs of meals (using a phone camera) and receive instant automatic dietary assessment and advice
Other dietary management techniques	Additional techniques to support diet management including nutrition quizzes, calorie counter, and healthy recipes
Calculator	Uses validated algorithms to help users perform calculations using logged health data, such as bolus calculator
Gamification	Uses games or game-like elements to condition users to perform particular tasks
Rewards	Integrates incentives (points or collectibles) to help sustain user engagement with their management tasks

Observational studies (n=6) did not involve an intervention, and mainly included surveys to explore patients' current use and preferences for mobile apps in diabetes self-management, except one (Kim *et al.*, 2015) which explored the role of apps in patients' behaviour change. Two studies (Dobson & Hall, 2015; Humble *et al.*, 2015) explored the use of *m*Health technology more broadly, however, the mobile apps' result was analysed and reported separately.

5.1.3.5 Comparator

The RCTs compared the intervention group, generally access to a mobile app in addition to usual care, with a control group of usual care, with or without a standard paper diary/logbook. Control participants in one study (Wayne *et al.*, 2015) additionally received Health Coach Support for selecting and progressing toward goals. Another study (Hsu *et al.*, 2015) gave control participants access to high standard care at the clinic in initiating and titrating insulin, with interim face-to-face visits, as well as telephone/fax communication with educators and clinicians. Logan et al. (Logan *et al.*,

2012) provided control participants with an identical-appearing home BP device without built-in Bluetooth capability for home BP monitoring.

Two non-RCTs involved a comparison group; in one (Kim *et al.*, 2014), control participants received usual care, while in the other (Hunt *et al.*, 2014), they received a paper journal to log diabetes self-management activities. The remaining non-RCTs did not have a control group.

5.1.3.6 Outcomes

The most common primary outcome in both RCT and non-RCTs (n=17) was glycaemic control. Other frequently-studied outcomes included body composition, self-management behaviour, QoL, self-efficacy and usability/utilisation of the intervention. Assessed outcomes in each study were all included and presented in this review, grouped as described below.

Clinical outcomes

All examined patient-related clinical outcomes; these included glycaemic control measures including HbA_{1c} level, average BG level, fasting BG level, proportion of patients reaching the HbA_{1c} target, and frequency of hypoglycaemic episodes. Other clinical outcomes included: BP, proportion of patients reaching the BP target, cholesterol levels, body composition (weight, BMI, waist circumference), and change in medication.

Psychosocial outcomes

This set included: QoL, depression and anxiety, diabetes-related distress, diabetes-related self-efficacy, positive and negative affect, satisfaction with life, satisfaction with diabetes treatment, and comfort with self-monitoring.

Behavioural outcomes

This group included: Diabetes self-management, frequency of self-monitoring, logging behaviour, lifestyle change (physical activity, dietary habits), and performance of physical activity.

Knowledge outcomes

This was knowledge about diabetes and diabetes management.

Patient-reported outcomes

This included satisfaction and usability of the intervention, and (primarily in the observational studies) participant's current use of apps, preferences, attitudes, and intention to use apps.

HCP-related outcomes

Few HCPs' outcomes were reported, including user errors and workflow anomalies, usability of intervention and compliance with given recommendation.

Miscellaneous outcomes

This group contained outcomes not included in any other group, e.g. number of GP visits, time spent on consultation visits, and utilisation and compliance with intervention use.

Few studies (n=4) addressed adverse events, and this was mainly in the discussion, rather than as an outcome (Frøisland et al., 2012; Holmen et al., 2014; Kirwan *et al.*, 2013; Neubauer et al., 2015).

Studies varied in duration from a week to 12 months (mean for RCTs=6.6 months [range=3–12 months]; non-RCTs=4.6 months [range=1 week–12 months]); three non-RCTs (Alanzi et al., 2014; Min, 2013; Rao et al., 2010) did not report the duration of intervention use or follow-up.

Outcomes studied are outlined in the 'Characteristics of included studies' tables in Appendix 8.

5.1.3.7 Settings

The included studies took place in the USA (n=6), Canada (n=6), Norway (n=5), UK (n=2), Austria (n=2), Netherlands (n=1), France (n=1), Denmark (n=1), Italy (n=1),

Australia (n=1), Korea (n=3), Japan (n=2), India (n= 1), Saudi Arabia (n=1) and Iraq (n=1).

Settings included primary, secondary and tertiary care and in the community. Most RCTs (n=5) were set in secondary care, specifically in diabetes outpatient clinics. Of the four remaining studies, three (Istepanian *et al.*, 2014; Logan *et al.*, 2012; Wayne *et al.*, 2015) were in primary care and one (Hsu *et al.*, 2015) was in a tertiary centre specialising in diabetes care.

Similarly, most non-RCTs (n=10) were in secondary care, two were in primary care (Sarala, 2014; Wayne & Ritvo, 2014), and two were in tertiary care (one in an inpatient setting of a tertiary care hospital (Neubauer *et al.*, 2015) and the other in a pregnancy and diabetes clinic (Mackillop *et al.*, 2014)). The remaining studies (n=5) were set in the community or other non-medical settings.

Four observational studies were conducted in non-medical settings and recruitment was primarily either online (noticeboards, health websites, social networks) or national diabetes registries. Of the remaining two studies, one (Dobson & Hall, 2015) was set in a community-based organisation providing diabetes education and the other (Humble *et al.*, 2015) was in primary care.

5.1.4 Risk of bias in included RCTs

Risk of bias assessments were based on published reports only. The domains being sequence generation and allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias), and other potential sources of bias. All of the included RCTs featured some bias. Figure 5.2 summarises the risk of bias for each domain across all included studies and Figure 5.3 summarises the domains for each included study.

Seven studies used adequate sequence generation, using computer-generated block randomisation, shuffled envelopes, or a schedule randomly arranged and administered by a person not directly involved in the study. In two studies (Hsu *et al.*, 2015;

Istepanian *et al.*, 2014), sequence generation was not reported. Five studies reported adequate allocation concealment (using sealed, non-transparent envelopes kept by an independent researcher, or varied blinded block sizes and blinded allocation order within blocks) with the remaining studies not providing information on this domain.

All studies were at high risk of bias in the domain of blinding of participants and personnel except two (Hsu *et al.*, 2015; Istepanian *et al.*, 2014), which did not provide information on blinding. Participants could not be blinded in any of the studies due to the nature of the intervention, which required apparent participation. The blinding of personnel was discussed in some studies and was considered unfeasible, as participants may use the device during visits to their care providers. Thus, HCPs who delivered the intervention knew participants' allocated groups. Blinding of outcome assessors was not discussed in most studies and, therefore, studies were assessed based on their primary outcome. In seven studies, this was change in glycaemic control (assessed by HbA_{1c}), which was generally measured by a pathology laboratory and forwarded to the research team, so was unlikely to be influenced by the lack of assessors' blinding. The primary outcomes in the remaining two studies (Drion *et al.*, 2015; Logan *et al.*, 2012) were change in QoL, measured by a validated tool, and change in mean daytime ambulatory systolic BP, respectively, both considered unlikely to be influenced by the lack of assessors' blinding.

Four studies were free of attrition bias (one study had no missing data; one had one withdrawal but an intention-to-treat analysis (ITT) was carried out to account for the missing data; in two studies, missing data was imbalanced between groups but an ITT analysis gave comparable results to completers-only analysis and an adequate description of missing participants was provided). In the remaining five studies, the risk of bias was assessed as 'high' due to high and uneven dropout rate; many withdrawn participants and data presented for completers only; insufficient information provided to assess whether an ITT analysis was carried out; or no attempt made to describe or investigate missing participants.

Six studies had a trial protocol, whereas published protocols were unavailable for the remaining three (Drion *et al.*, 2015; Istepanian *et al.*, 2014; Waki *et al.*, 2014). Four

studies were judged as free of selective outcome reporting. All primary and secondary outcome measures were pre-specified in their trial protocols and they presented all outcomes outlined in their protocol. One study (a conference paper), was assessed as having a high risk of selective reporting; the study protocol was not found and only the result of the primary outcome (HbA_{1c}) was reported, while other outcomes were only summarised. The remaining four studies were judged unclear with study protocols not identified or incomplete results for some outcomes.

Six studies had an unclear risk of other sources of bias, including potential concerns about imbalance in baseline characteristics, lack of adjustment for confounders, recall bias, intervention group compliance, technical issues and poor study reporting.

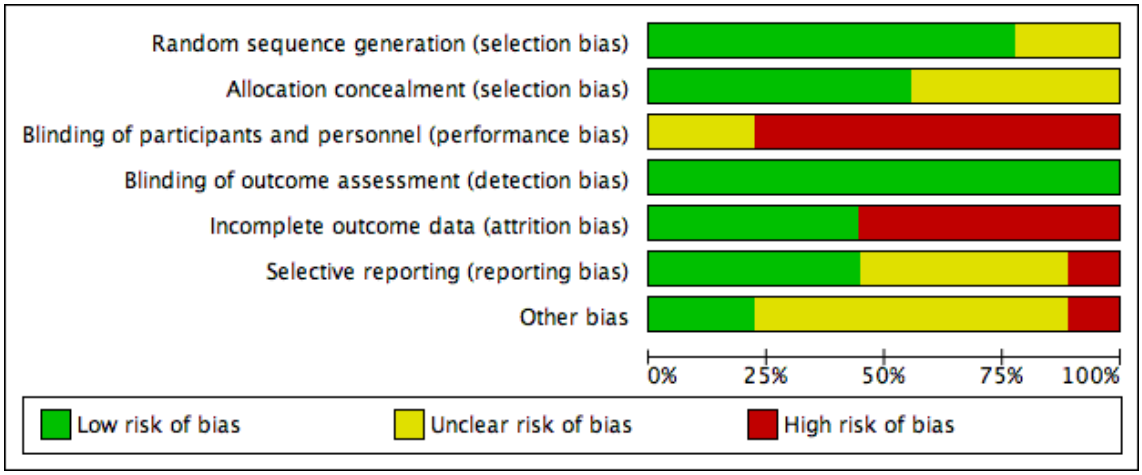


Figure 5.2 Risk of bias graph: risk of bias for each domain (percentages across all included RCTs).

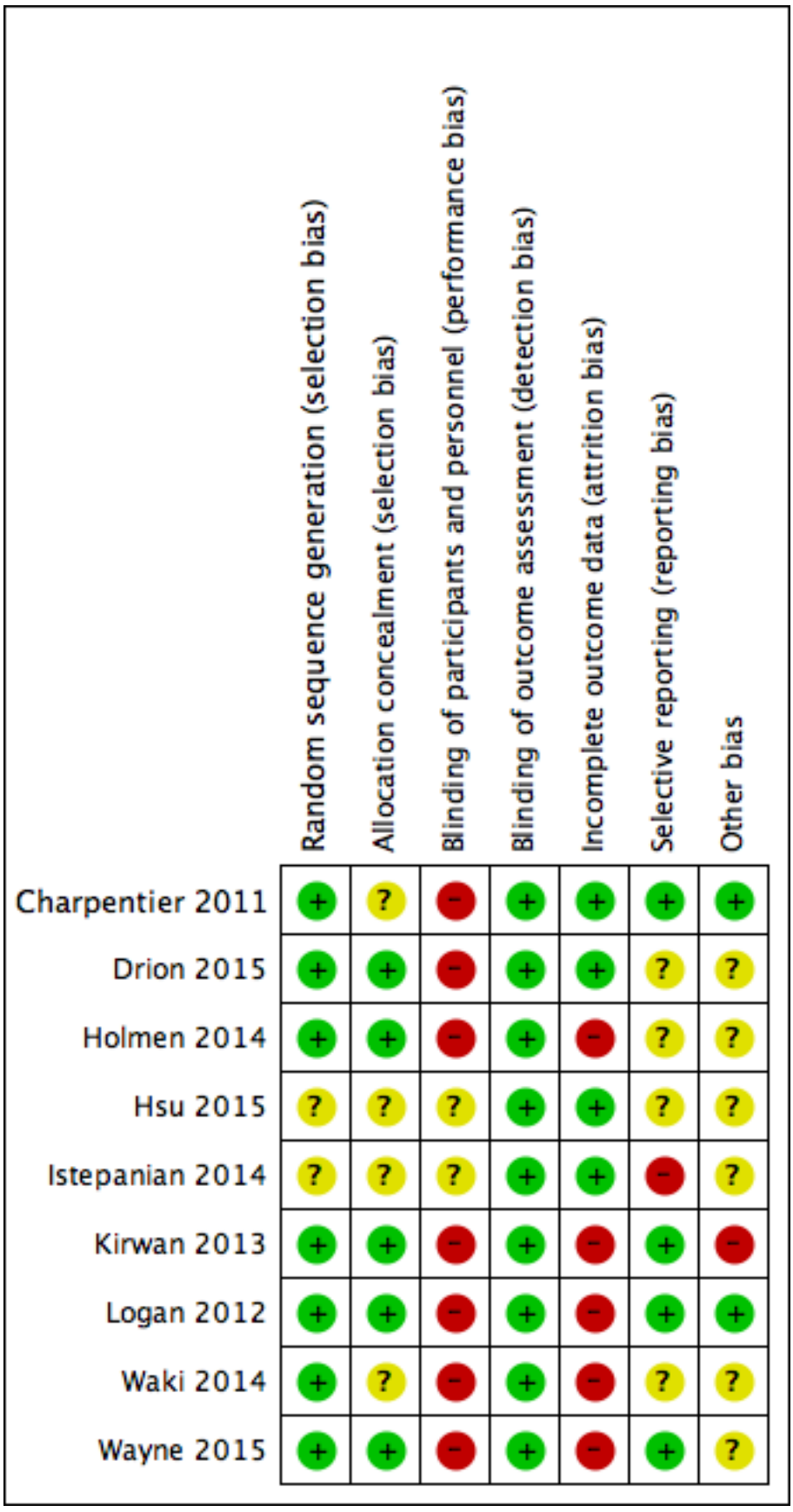


Figure 5.3 Risk of bias summary: domains for each included RCT.

5.1.5 Quality assessment of other study designs

For the Downs and Black assessments (Figure 5.4), the non-RCTs, including the observational studies, scored a median of 16/28 overall (range 8–22). High scores indicate good quality, but only one study scored >20/28; 21 studies scored 10–20 and three scored <10.

For study reporting, median was 7/11 (range 4–11). Nearly all had a clear hypothesis/aim/objective and main outcomes and clearly described the intervention. However, the characteristics of participants and the distributions of principal confounders were partially described in many studies. Only eight studies provided sufficient information to enable unbiased evaluation of their findings.

For internal validity, the median was 4/7 (range 2–5) for bias and 2/6 (0–4) for confounding. No study scored highly in these two sub-scales, representing a high potential for bias/confounding. For external validity, the median was 1/3 (0–3) and seven studies scored 0, indicating limited generalisability of results.

For power, the median was 0 (0–1)/1; only one study was sufficiently powered to detect a clinically important effect, whereas the remaining pilot/feasibility studies lacked the power to detect any difference.

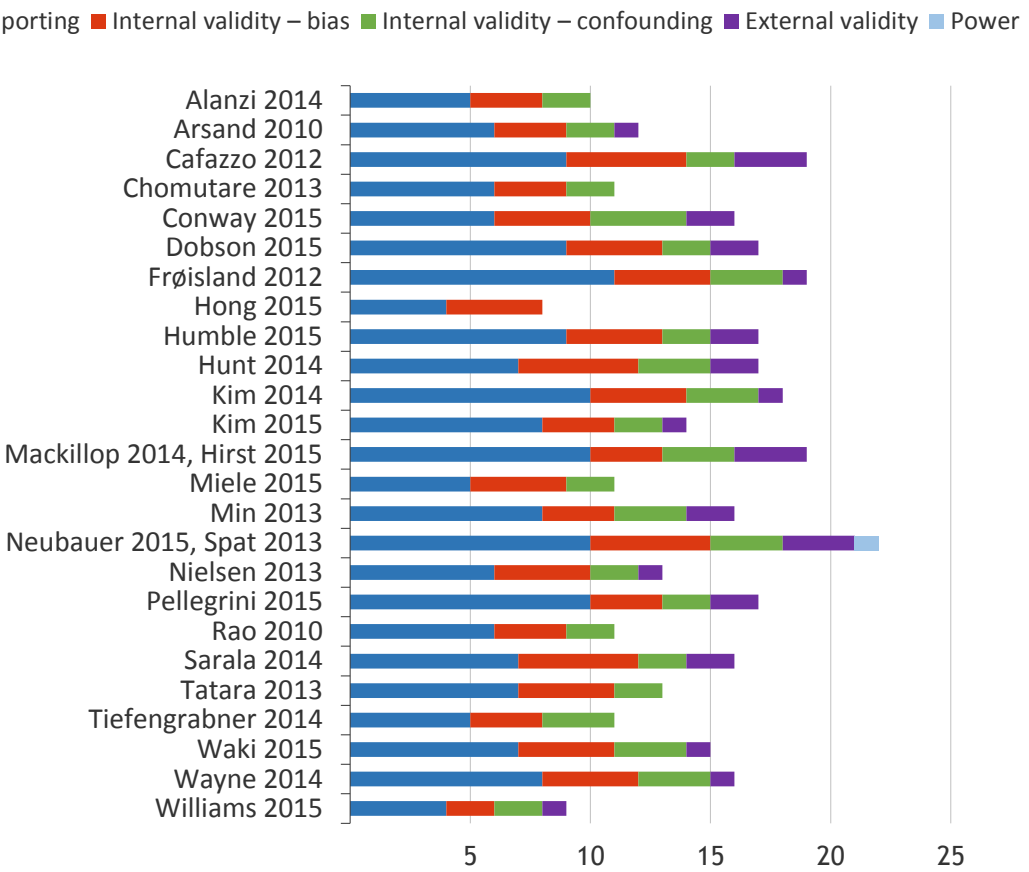


Figure 5.4 Quality assessment result of non-RCTs: sub-scale and overall score by study.

5.1.6 Effects of intervention

This section presents the effect of mobile apps including a meta-analysis of RCTs and a narrative synthesis of the evidence from all the study designs for all the outcomes, grouped into categories.

5.1.6.1 Clinical outcomes

Glycaemic control

Only HbA_{1c} was reported in enough RCTs (Charpentier *et al.*, 2011; Drion *et al.*, 2015; Holmen *et al.*, 2014; Hsu *et al.*, 2015; Istepanian *et al.*, 2014; Kirwan *et al.*, 2013; Waki *et al.*, 2014; Wayne *et al.*, 2015) for meta-analysis (n=549 participants: T1D=232, T2D=317; intervention=271, control=278) (Figure 5.5). Data extracted included the sample size, mean change of HbA_{1c} or mean±SD HbA_{1c} at baseline and endpoint. Where data points were missing, values were estimated. A random-effects model was used as clinical heterogeneity was expected, and $p<0.05$ was considered statistically

significant. Heterogeneity was examined with I^2 test, and I^2>50% and p for heterogeneity<0.10 were considered significant heterogeneity.

There was a statistically significant effect of mobile apps on glycaemic control versus usual care (mean difference [MD] -0.45%, 95% CI: -0.85 to -0.04%; P=0.03; $I^{2=}$76%). Although the evaluation favoured apps, there was substantial heterogeneity in the effect.

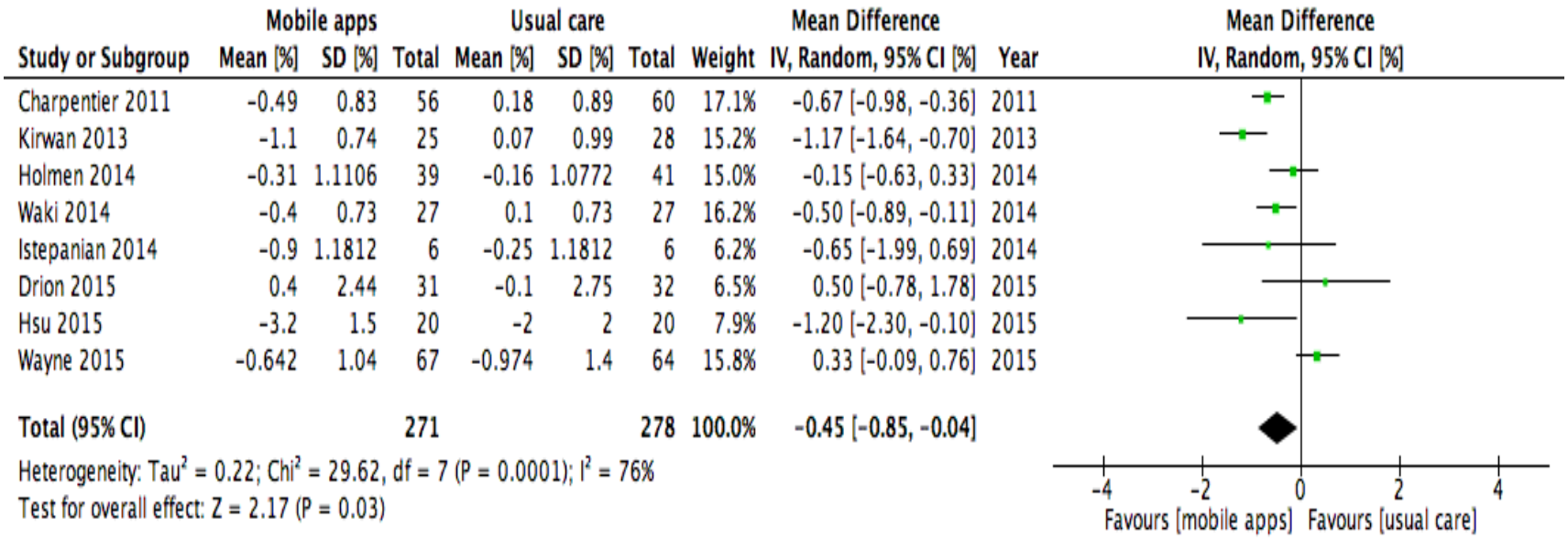


Figure 5.5 Forest plot for HbA_{1c} level of diabetes patients who used a mobile app.

There was a statistically significant difference in the reduction of HbA_{1c} favouring the intervention group in 4/8 of the RCTs (Charpentier *et al.*, 2011; Hsu *et al.*, 2015; Kirwan *et al.*, 2013; Waki *et al.*, 2014). Only two of the seven non-RCTs that measured HbA_{1c} (Hong *et al.*, 2015; Wayne & Ritvo, 2014) found that mobile apps were associated with a significant reduction in HbA_{1c}, whereas three studies (Årsand, 2009; Chomutare *et al.*, 2013; Kim *et al.*, 2014) reported positive but non-significant improvement, and two (Cafazzo *et al.*, 2012b; Frøisland *et al.*, 2012) reported no difference (Appendix 9).

Other measures of glycaemic control were assessed in some studies: percentage of subjects reaching the HbA_{1c} target in two RCTs (Charpentier *et al.*, 2011; Hsu *et al.*, 2015) (no statistical difference between the groups); percentage of BG values in the target range in one study (Neubauer *et al.*, 2015) was increased when using the mobile app and was significantly higher (P=0.001) than the criterion value derived from a recent best-practice study (Umpierrez *et al.*, 2013). Two non-RCTs (Hong *et al.*, 2015; Waki *et al.*, 2014) measured fasting BG level which significantly declined (P=0.015) in one study and increased in the other. Average BG reduced in two studies (1 RCT; 1 non-RCT) (Hsu *et al.*, 2015; Mackillop *et al.*, 2014; Neubauer *et al.*, 2015) and one non-RCT (Mackillop *et al.*, 2014) found positive significant change for women with new diagnoses of GDM and non-significant result for women with previous GDM. The frequency of hypoglycaemic episodes did not differ between groups for the duration of study was reported in two RCTs (Charpentier *et al.*, 2011; Hsu *et al.*, 2015).

For some non-RCTs, several data points were missing or had only descriptive results of changes in BG after using the intervention. For instance, one study (Hunt *et al.*, 2014) aimed to evaluate HbA_{1c} but only collected baseline values and no further measures were available during the study period.

Subgroup analyses

As considerable heterogeneity was found (I^2=76%), subgroup analysis was performed to assess whether changes in HbA_{1c} differed by type of diabetes (T1D/T2D; Figure 5.6), intervention purpose (telemonitoring/self-care; Figure 5.7), and follow-up duration (3/6/9 months; Figure 5.8).

Apps significantly reduced HbA_{1c} for patients with T1D (MD -0.69%; 95% CI: -1.28 to -0.09%; P=0.02; $I^{2=}$71% but not T2D (-0.29%; 95% CI: -0.75 to 0.18%; P=0.23; $I^{2=}$67%).

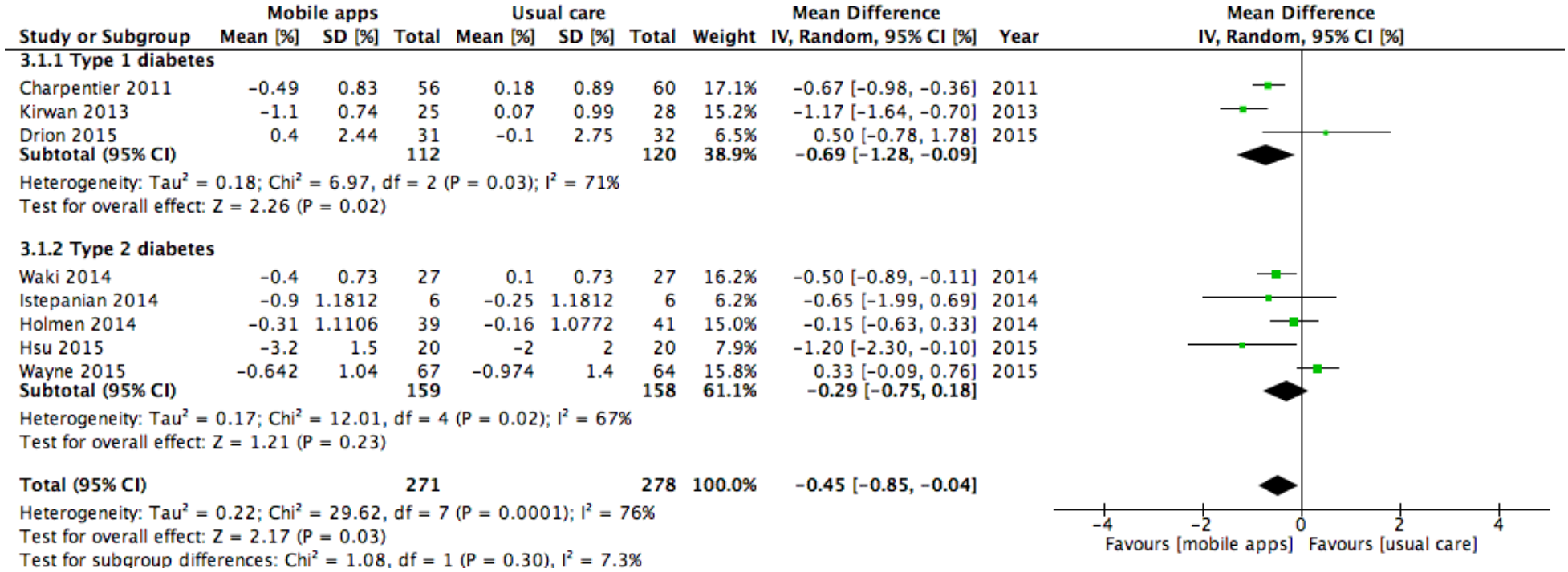


Figure 5.6 Forest plot for HbA_{1c} level according to type of diabetes.

Telemonitoring apps reduced HbA_{1c} (MD -0.59%; 95% CI: -1.06 to -0.11%; P=0.02; I^2=80%), but self-care apps did not (-0.07%; 95% CI: -0.52 to 0.38%; P=0.76; I^2=0%).

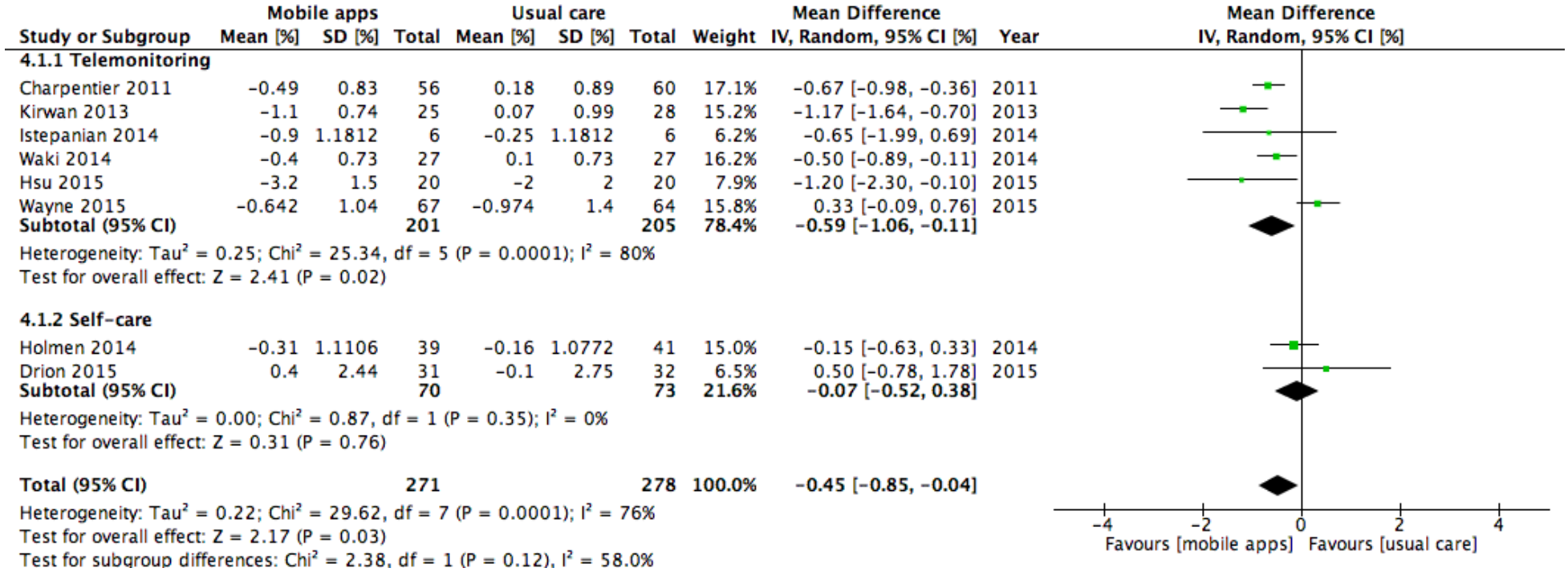


Figure 5.7 Forest plot for HbA_{1c} level according to purposes of intervention.

The effect of apps on HbA_{1c} was not significant at any individual time point but was significant when pooled together.

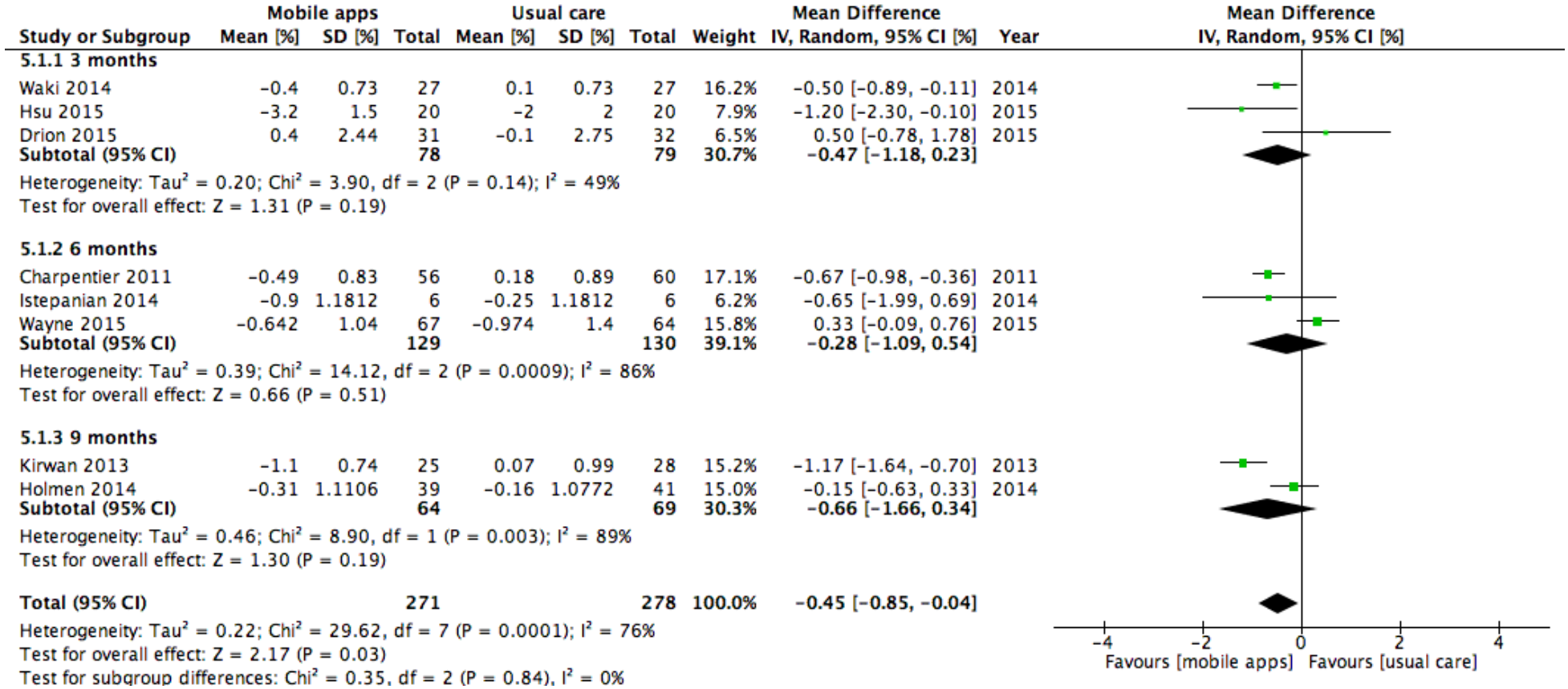


Figure 5.8 Forest plot for HbA_{1c} level according to follow-up durations.

In all these subgroup analyses, there was no statistically significant difference between the subgroups (p for heterogeneity: 0.30; 0.12; 0.84, respectively).

A sensitivity analysis was performed to investigate possible reasons for heterogeneity, excluding one study at a time and checking the changes in values of I^2 and P. However, no notable change was observed on the total pooled effect or the heterogeneity.

BP

In 1 RCT and 1 non-RCT (Kim *et al.*, 2014; Waki *et al.*, 2014), systolic and diastolic BP remained similar without significant difference between the groups. However, one RCT (Logan *et al.*, 2012) found a significant decrease in mean daytime systolic (P<0.0001) and diastolic (P<0.005) BP only in the intervention group. Additionally, they reported that 51% of intervention subjects achieved the guideline-recommended target BP versus 31% of controls (P<0.05).

Cholesterol levels

In three studies (RCT=2; non-RCT=1) (Istepanian *et al.*, 2014; Kim *et al.*, 2014; Waki *et al.*, 2014), there were no changes in total cholesterol, triglycerides, or high- or low-density lipoprotein.

Body composition

Of the studies that assessed at least one body composition measure (weight, BMI or waist circumference), four (2 RCTs; 2 non-RCTs) (Hong *et al.*, 2015; Waki *et al.*, 2014; Wayne *et al.*, 2015; Wayne & Ritvo, 2014) reported improvements of varied magnitude; the other three (2 RCTs; 1 non-RCT) (Holmen *et al.*, 2014; Hsu *et al.*, 2015; Kim *et al.*, 2014) found no difference between groups.

Change in medication

Changes in medication from baseline were evaluated in 4 RCTs (Charpentier *et al.*, 2011; Hsu *et al.*, 2015; Logan *et al.*, 2012; Waki *et al.*, 2014), which reported no between-group differences in the total number of medicines or in their dosages. Only

the case report (Hong *et al.*, 2015) showed that the medication dose was reduced at 3 months follow-up and it was stopped at 6 months.

5.1.6.2 Psychosocial outcomes

QoL was assessed in six studies (RCT=5; non-RCT=1) using the Diabetes Quality of Life (DQOL) (Kirwan *et al.*, 2013), the Diabetes Health Profile (DHP) (Charpentier *et al.*, 2011), the RAND 36-Item Short Form Health Survey (SF-36) (Drion *et al.*, 2015), the Short-Form Health Related Quality of Life-36 (SF-36) (Holmen *et al.*, 2014), the Short Form Health Survey-12 (SF-12) (Wayne *et al.*, 2015) and the Diabetes Quality of Life for Youths (DQOLY) (Cafazzo *et al.*, 2012a). One study (Wayne *et al.*, 2015) found improvements in QoL for both intervention and control groups, but the remaining five studies found no influence of the diabetes diary app on QoL (Appendix 9).

Three RCTs evaluated depression and anxiety using the Hospital Anxiety and Depression Scale (HADS) (Wayne *et al.*, 2015), the Centre for Epidemiological Studies Depression Scale (CES-D) (Holmen *et al.*, 2014) or the Anxiety Sensitivity Index (ASI) with HADS (Logan *et al.*, 2012). The change in depressive symptoms did not differ significantly between the groups in one study (Holmen *et al.*, 2014). Another study (Wayne *et al.*, 2015) reported similar improvements for both intervention and control groups in the HADS depression subscale. In the third study (Logan *et al.*, 2012), a trend toward worsening using the HADS depression was detected in the intervention group, with a significant between-group difference (P=0.032). This study also found a worsening in participants' comfort with BP self-monitoring in both groups. One RCT (Drion *et al.*, 2015) found no difference between groups in diabetes-related distress using the Problem Areas in Diabetes (PAID) questionnaire (Appendix 9).

One RCT (Wayne *et al.*, 2015) found significant between-group differences favouring the intervention group (p=0.007) for the negative affect subscale of the Positive and Negative Affect Schedule, and significant within-group improvements in life satisfaction were found in both groups on the Satisfaction with Life Scale. One RCT reported a statistically significant difference (p=0.01) between groups on the Diabetes Treatment Satisfaction Questionnaire (DTSQ) (Hsu *et al.*, 2015). One non-RCT (Hirst *et*

al., 2015b) demonstrated that women's overall satisfaction on the Oxford Maternity Diabetes Treatment Satisfaction Questionnaire (OMDTSQ) was high; 45 of 49 women agreed their care was satisfactory and felt it had been the best for them, and 47 agreed they had a positive relationship with the maternity diabetes team, particularly the diabetes midwife.

Diabetes-related self-efficacy was assessed in four studies (RCT=1; non-RCT=3) using the Short Form Diabetes Empowerment Scale (DES-SF) (Chomutare *et al.*, 2013; *Kirwan et al.*, 2013), the Diabetes Management Self-efficacy Scale (DMSES) (Hunt *et al.*, 2014) or the Diabetes Family Responsibility Questionnaire (Cafazzo *et al.*, 2012a). One study (Cafazzo *et al.*, 2012a) found slight improvements in both the parent and adolescent scores. No significant changes were reported in self-efficacy in the remaining studies (Appendix 9).

5.1.6.3 Behavioural outcomes

Six studies (RCT=3; non-RCT=3) assessed diabetes self-management using the Summary of Diabetes Self-Care Activities (SDSCA) (Kim *et al.*, 2015; Kirwan *et al.*, 2013), Diabetes Self-care Activities-Revised (SDSCA-Revised) (Hunt *et al.*, 2014), the Japanese version of SDSCA (Waki *et al.*, 2014), the Health Education Impact Questionnaire (HeiQ) (Holmen *et al.*, 2014) or the 14-Item Self-care Inventory (Cafazzo *et al.*, 2012a). Significantly improved self-care activities for at least one item were reported in two studies (Holmen *et al.*, 2014; Kim *et al.*, 2015). Non-significant improvements in exercise were found in an additional study (Cafazzo *et al.*, 2012a). In the remaining studies, participants' scores remained similar between the two groups (Appendix 9).

In one non-RCT (Cafazzo *et al.*, 2012a), the daily average frequency of BG self-monitoring was significantly increased (p=0.006), whilst it did not differ significantly between groups in the two RCTs (Charpentier *et al.*, 2011; Drion *et al.*, 2015). In one non-RCT (Hunt *et al.*, 2014), self-management activity logs stayed the same, whereas another non-RCT (Tiefengrabner *et al.*, 2014) reported varying percentages of increase in logging behaviour for the different parameters.

In one RCT (Holmen *et al.*, 2014) using self-reported questionnaires, there were no statistically significant differences between groups in physical activity or diet. One non-RCT (Årsand *et al.*, 2010) reported an increase of 20% in step count during the study. Another non-RCT (Pellegrini *et al.*, 2015) showed significant changes in sedentary behaviour and physical activity during the one-month follow-up, with 87.5% of participants reducing sedentary time and increasing light-intensity physical activity.

5.1.6.4 Knowledge outcome

One non-RCT (Frøisland *et al.*, 2012) found the knowledge test scores on a 27-item questionnaire based on the Norwegian National Health Informatics' diabetes quiz remained nearly the same before and after the study. One RCT (Istepanian *et al.*, 2014) found the level of knowledge on a questionnaire adapted and translated into Arabic from The Diabetic Knowledge Test [Michigan Diabetes Research and Training Centre] was significantly increased after the intervention.

Figure 5.9 summarises the narrative synthesis results for the commonly-studied outcomes, demonstrating the distribution of outcomes according to diabetes type and intervention effects. Statistically significant positive effect indicates significant between-groups improvement or significant pre/post improvement; at least in one measure or subscale, while positive effect indicates non-significant improvement or pre/post improvement but not significant; at least in one measure or subscale. No effect indicates no difference between-groups or no change in a single group. Negative effect indicates any negative impact between-groups or pre/post, either significant or not.

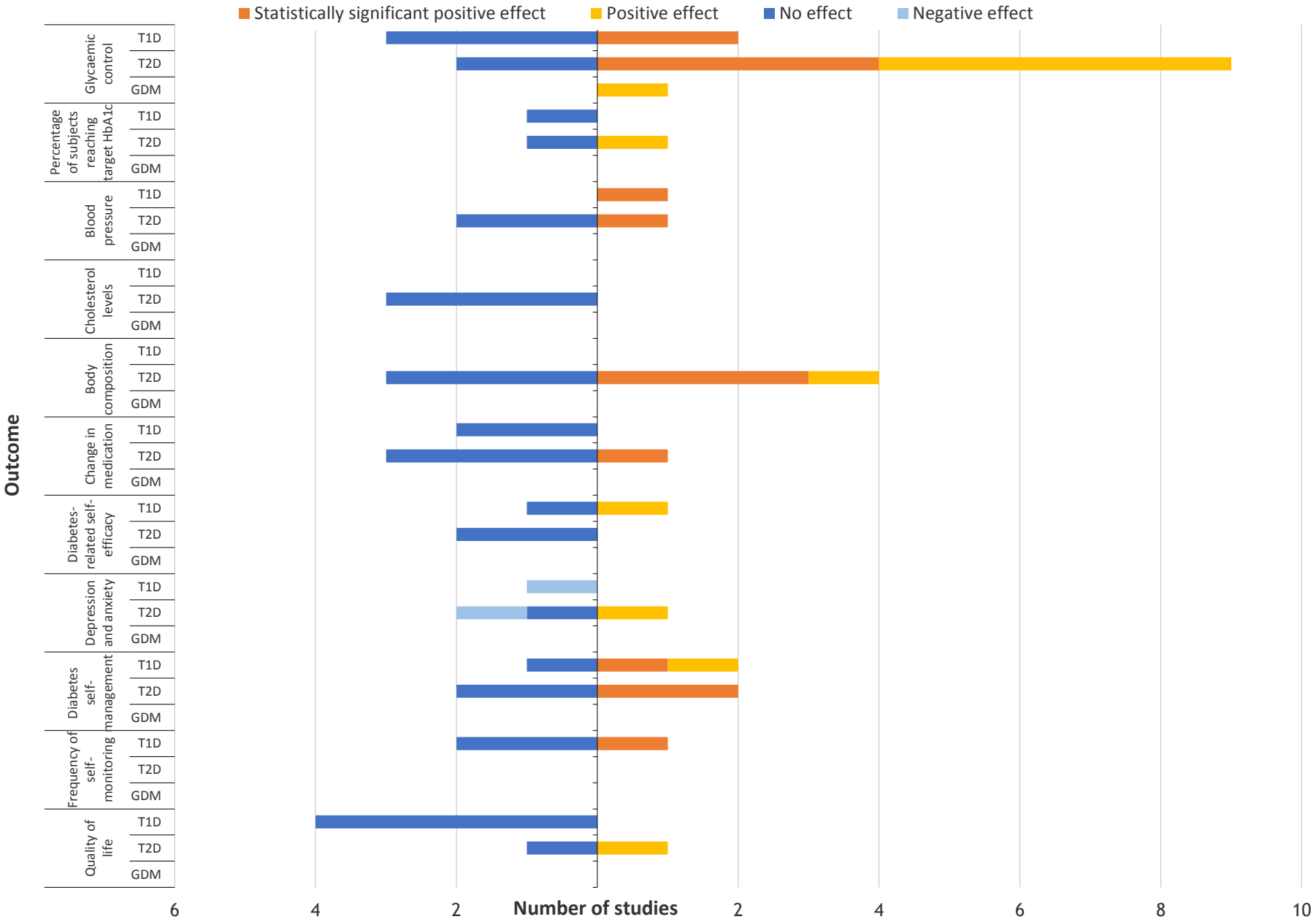


Figure 5.9 Distribution of frequently studied outcomes according to diabetes type and intervention effects.

5.1.6.5 Patient-reported outcomes

Five studies (RCT=1; non-RCT=4) used custom-made questionnaires including items on satisfaction, convenience willingness to use the app in the future and to recommend it to others. In the RCT (Charpentier *et al.*, 2011), 77% of intervention participants were satisfied/very satisfied with the app and 67% were willing to continue using it. User satisfaction was high in two non-RCTs (Cafazzo *et al.*, 2012a; Hirst *et al.*, 2015b); 88% of participants in the former study would continue using the app, while the remaining 12% suggested that it needed to be integrated with their insulin pump to continue using it. In the latter study, 48 of 49 women agreed that the app plus associated equipment was both convenient and reliable, even though four had problems transferring their readings automatically due to poor network coverage. The remaining two studies (non-RCT=1; cross-sectional=1) showed high user satisfaction, and improvements in HbA_{1c} or self-management activities were greater in the satisfied group (Kim *et al.*, 2014; Kim *et al.*, 2015). In one study, 27 of 35 participants were satisfied, while 8 were less satisfied, with most complaints related to data transfer errors (Kim *et al.*, 2014). In the other, almost 87% were satisfied with app structure and nearly 97% were willing to continue use and to recommend it to others (Kim *et al.*, 2015).

App usability was assessed in ten studies (RCT=2; non-RCT=8) using the System Usability Scale (SUS) (Årsand, 2009; Chomutare *et al.*, 2013; Drion *et al.*, 2015; Frøisland *et al.*, 2012; Hong *et al.*, 2015; Min, 2013; Tatara, 2013), the Questionnaire for User Interaction and Satisfaction (QUIS) (Alanzi *et al.*, 2014), or custom-made questionnaires (Rao *et al.*, 2010; Waki *et al.*, 2014) (Appendix 9). SUS scores range from 0–100, with a score ≥70 considered acceptable and <70 is below average (Bangor *et al.*, 2009). SUS scores range from 72–92.5, indicating high satisfaction with usability, ease or learning and user-friendliness. Still, many usability problems were reported with apps, including inconvenience of manual data input, short battery life, and problems with the touch screen. Studies using QUIS indicated a positive impression and good levels of satisfaction. In studies using custom-made questionnaires (composite ease of use score across eight parameters (Rao *et al.*, 2010) or frequency of

participants in agreement with statements given (Waki *et al.*, 2014)), apps were easy to use, useful and requiring least time.

Other self-reported outcomes, primarily explored in observational studies, included participants' current use of apps for diabetes management, preferences, attitudes and intention to use them. Six studies assessed these outcomes (non-RCT=1; cross-sectional=5) using custom-made questionnaires. All studies were targeting both T1D and T2D, apart from one (Dobson & Hall, 2015) aiming at T2D. Results from one study (Rao *et al.*, 2010) indicated that ease of use and connectivity with a glucometer were the most desirable features in BG tracking apps (frequencies 100% and 90%, respectively). Use of diabetes apps, specifically glucose tracking apps, among Latinos was investigated in another study (Williams & Schroeder, 2015). They found that only 3.1% (18/588) used diabetes apps, 50% of them reported that tracking of oral medications and reminders were the most frequently used functionalities, followed by tracking of BG (44%). In a third study (Conway *et al.*, 2015), *m*Health preference scores were skewed into high (7-10) preference category, nearly 70% of respondents agreed or strongly agreed that a smartphone app to manage diabetes would be a positive development and approximately 55% would prefer to use apps to manage their diabetes. The most preferred feature was password protection (56%), whereas social media was the lowest rated functionality (20%). Diabetes type influenced respondents' preferences, with people with T1D showing a higher preference for a ratio wizard, logging of insulin and glucose monitoring; age, gender and diabetes type were significant confounders for *m*Health preferences in diabetes management. Use of, and interest in, mobile apps were also assessed in underserved populations with less access to technology (Humble *et al.*, 2015). High interest in using apps to help manage diabetes was found (57%) but only 36% thought that they would be extremely helpful in diabetes management. Users showed a greater preference for apps providing BG, BP, exercise tracking and reminders. Younger patients were more often smartphone owners and were more interested in using apps to manage their diabetes. In Denmark (Nielsen, 2013), 75% of patients surveyed were using apps to support diabetes control, with carbohydrate counting as the most-used functionality (75%), followed by insulin/medication tracking (21%), BG (17%), and BP monitoring (13%). Seventy-five

per cent of users were interested in sharing their collected data with their doctors and receiving feedback on their progress, and stated that they would feel safe if the app was recommended by their HCPs. On the users' general perception of apps, 50% would trust the technology, and 63% did not have any concerns about confidentiality of their data. In another study (Dobson & Hall, 2015), 92% were not using their mobile phones in managing their diabetes, however 58% indicated their intention to use apps in the future. Most respondents expressed interest for tracking BG (90%), dietary planning (87.5%), and communication with HCPs about their diabetes (85.7%), and again younger people had more favourable attitudes and intentions to use apps in diabetes self-management.

5.1.6.6 HCP-related outcomes

One non-RCT assessed usability of a decision-support app using a custom-made questionnaire, with two samples of clinical staff (trial 1: nurses=12; physicians=6); trial 2: nurses=51; physicians=14). Most participants in both trials (95% & 91%) felt safe and confident in using the app to support the glycaemic management of their patients; 95% and 85% stated that glycaemic control was more efficient when using the app; 100% and 80% reported that using the app helped prevent errors associated with insulin dosage or drug prescription; 89% and 89% believed that the app was practical to use in daily clinical routine; 95% and 86% stated that the app supported independent clinical decision-making and, thus, physicians were consulted less often. HCPs had mixed views about workload when using the app, 55.5% and 20% indicated workload was increased; 16.7% and 50.8% indicated workload was decreased; 27.8% and 18.2% indicated no change in the workload, while the remaining 11% in trial 2 did not answer the question. In general, the app was highly acceptable to HCPs on different clinical wards.

HCPs' compliance with given recommendations from the decision-support apps was assessed in two non-RCTs (Neubauer *et al.*, 2015; Neubauer *et al.*, 2014b; Sarala, 2014). Adherence rates to the suggested insulin doses by physicians and nurses was very high in one study (range 95–98%). However, in the other study, 73% of

prescriptions in both the community health centres and the outpatient departments matched app recommendations, versus 63% at specialist clinics.

HCPs' errors and workflow anomalies were evaluated in one retrospective study (Spat *et al.*, 2013). The study used real-life data from a previous clinical trial, including 1190 decision-support action points, for simulation with the app. They compared the results generated by the app with those in the clinical study using a paper-based algorithm. Only four errors by the app were identified, versus 144 errors by physicians and nurses in the paper-based study, as well as ten workflow anomalies, such as adjustment of the daily insulin dose without any BG measurement.

5.1.6.7 Miscellaneous outcomes

The number of GP and specialist visits was assessed in one RCT only (Logan *et al.*, 2012), collected from medical records and patient self-reporting, which revealed no significant difference between groups in GP visits or combined visits to GPs and specialists.

The time spent on consultation visits was evaluated in two RCTs. In one study (Hsu *et al.*, 2015), the duration of virtual visits in the intervention group was electronically tracked whilst, for the control group, face-to-face interaction time was obtained from the subjects' medical records. The intervention group required less total interaction time (average 65.7 minutes, excluding app training time, versus 81.6 minutes for controls). Still, the intervention group required additional time for training to use the mobile device. For the other study (Charpentier *et al.*, 2011), the duration of visits was recorded as well as the time spent by participants coming for hospital visits. There was no difference between groups for the total time spent on visits, whether face-to-face or by telephone. However, face-to-face visits required more than half a working day traveling to and from the hospital, versus no additional time for the app.

App utilisation and compliance with its use were reported in 12 studies (RCT=4; non-RCT=8), using data logged in the app server, e.g. number and value of transmitted BG readings, inputted diet and exercise data, date and time. The extent and frequency of app use clearly varied among participants across the studies, some used it regularly or

as instructed, whereas others used it less frequently. A number of studies demonstrated high usage and excellent compliance with the app. In one study (Mackillop *et al.*, 2014), 85% of women were compliant with the recommended frequency of BG monitoring (≥18 measurements/week). Two studies (Waki *et al.*, 2015; Wayne *et al.*, 2015) reported relatively high compliance, ranged between 81-90%, for both BG measurements and diet input but not for exercise. The rate of use was also very good in another study (Charpentier *et al.*, 2011; Franc *et al.*, 2014) with the insulin dose being calculated with the app for an average of 67% of meals throughout the study period. In a few studies, the data were extracted from the logs of the database and analysed for the purpose of identifying participants' usage trends and patterns. A study (Tatara, 2013) confirmed a statistically decreasing ($P<0.05$) usage trend among participants. They concluded that individual usage patterns varied and changed over time with different magnitudes. BG measurement rate and input rate for diet and exercise declined to around 50% or more by the end of one study (Waki *et al.*, 2014), with the exception of morning BG measurements which stayed over 70%. Another study (Kirwan *et al.*, 2013) also reported a decline with time in the number of BG logs and the number of text messages sent to the diabetes educator. By contrast, use in another study (Holmen *et al.*, 2014) was low during the first month, then increased during the second month and remained about the same until the end-point. However, only 39% of participants were substantial users. The degree of usage for each app function was diverse too. One study (Kirwan *et al.*, 2013) indicated that 54% of logged data were related to BG levels, followed by insulin (33%), whilst exercise was the least (1%). BG monitoring was the highest in another study also, with an average use of 3 times/day (Chomutare *et al.*, 2013). Usage of the social networking functionality was generally very low (Cafazzo *et al.*, 2012a; Chomutare *et al.*, 2013). Gamification and reward techniques were used in one study (Cafazzo *et al.*, 2012a) where they helped to sustain participants' use and engagement with the app. Lastly, two studies (Miele *et al.*, 2015; Pellegrini *et al.*, 2015) did not aggregate the usage data.

Very few studies (RCT=2; non-RCT=2) addressed adverse events and this, mainly, was in the discussion, rather than as an outcome (Frøisland *et al.*, 2012; Holmen *et al.*,

2014; Kirwan *et al.*, 2013; Neubauer *et al.*, 2015). Those that did report adverse events stated that, for the participants, there were no unintended effects related to the app use or the study overall. One study (Holmen *et al.*, 2014) explained that some participants incurred high mobile costs for using the app while travelling abroad, however, participants were informed of this risk before starting the trial.

5.1.7 Summary of findings

The outcome matrix summarising the narrative synthesis of all studied outcomes, the number of supporting trials for the intervention effects, and a summary of the results of the outcomes that were reported in at least three studies in the review are provided in Appendix 9 (Tables 1–8).

5.2 Discussion

5.2.1 Summary of results

The present review focuses on identifying, appraising and summarising all the available evidence about the use of mobile apps with respect to all reported outcomes. The result shows that the extent of the evidence for mobile apps in diabetes management and care is inadequate and weak. It is not possible to draw any conclusion thus far on their impact as an intervention either for patients or HCPs.

A wide range of outcomes was reported in the included studies. HbA_{1c} level was the most commonly assessed outcome. Evidence from meta-analysis showed that mobile apps may have a positive impact on HbA_{1c}, as the pooled effect significantly favoured apps versus usual care. Subgroup analyses were conducted to investigate possible sources of the high heterogeneity found, but without finding significant differences in effects between the subgroups.

Limited evidence of added benefits or mixed results were found for other clinical outcomes, psychosocial, behavioural or knowledge outcomes. Still, for the majority of outcomes when positive results were indicated, there were no significant differences found between groups or pre/post.

Utilisation of apps in diabetes management among participants is low, despite having access to the required technology. Both patients and HCPs have mixed views toward app usability, but generally scores were high. They expressed some satisfaction with apps and are willing to use them in routine care.

Most studies focused on adults with T2D and patient-related outcomes. Evidence of the effectiveness of mobile apps for HCPs in clinical practice and for women with GDM is much more limited.

5.2.2 Quality of evidence

The review identified, appraised and summarised available evidence about the use of mobile apps, and found that the evidence base in diabetes management is inadequate. Findings should be interpreted with caution as the included RCTs had a high or unclear risk of bias across many domains, and many of the non-RCTs were uncontrolled with very small sample sizes (n≤25). In particular, there were studies with high risks of performance, attrition and reporting bias, and many had missing data, selectively presented data, or high or unclear dropout rates. Double-blinding was absent in all studies: as with most lifestyle interventions with modern technology, blinding of participants is not feasible; the open character may have introduced bias. Consequently, the decline in HbA_{1c}, or any other observed effects, may not be attributable to the mobile app. Instead, it could be attributed to the special attention the participants may have received from their care providers when joining the study. By contrast, blinding of personnel may have been possible; specifically in those studies that examined self-care apps, as personnel may be masked to treatment group. With remote monitoring apps, personnel involved have to use a linked web portal to review participant's data and provide feedback accordingly.

Sample sizes in the RCTs were small (range 12–121) often leading to inadequate power to detect differences.

Generally, non-RCTs scored low on the Downs and Black checklist (median 16/28). Most included non-RCTs were small (n=5–21) uncontrolled studies investigating the feasibility, acceptability, and the preliminary effectiveness of the apps. Nearly all

reviewed non-RCTs were neither statistically nor methodologically robust. This indicates limited generalisability to the wider population.

Changes in technology over time

Although the current review excluded studies that examined apps functioning on ordinary mobile phones, many of the included studies provided participants with first or second-generation smartphones when the technology was less developed than today. Advances in technology have occurred since their publication, which may make their results less relevant today. The smartphones provided in those studies, for example, were not integrated with Bluetooth technology or motion sensors. They required the use of supporting devices to help collecting certain health data. Thus, participants were provided with additional devices, such as Bluetooth adapters and external accelerometers, which posed challenges for participants owing to the requirement for multiple devices.

Technical problems were reported by many participants across the studies, including trouble with the Bluetooth pairing, data transfer errors and difficulties in using the devices. This may have led to less satisfaction and decreased use of the app in the earlier studies. Therefore, this needs to be taken in consideration when evaluating the evidence.

Mobile technology is rapidly evolving and, with developments through the years, smart devices have become smarter, and every new phone has superior features than the previous generation phone. Still, there is a great expectation for future possible development in the next generation of smart devices. Hence, findings are very likely to change after future research. This fact may limit the applicability of the findings from these studies.

Wider settings

The generalisability of findings from the included studies is quite limited. The patients, providers and practices in these studies were variable. The study durations, ranging between 1-12 months, were inconsistent as well, which may had an impact on the

glycaemic control measures reported across the included studies. Most studies took place in high-income countries, and all were published in English. Therefore, the applicability of their results to wider settings is questionable.

Participants' compliance

Only one third of the studies tackled participants' compliance with app use by using logged data; the remaining two thirds did not evaluate compliance. This raises uncertainties about whether detected effects were attributable to the use of the app.

Overall, despite multiple trials examining the use of mobile apps in diabetes management, the standard of the evidence to date is poor. This highlights the need for large-scale, high-quality experimental research conducted in this area.

5.2.3 Comparison with other reviews

As outlined in the discussion on existing systematic reviews and meta-analyses presented earlier in this thesis (Chapter 2, section 2.2.1), several recent reviews have addressed the use of mobile apps in diabetes management but their approaches differed.

The present review conducted a meta-analysis with a pooled effect on HbA_{1c} reduction of -0.45% (95% CI: -0.85 to -0.04%; p=0.03; $I^{2=}$76%), indicating a moderate benefit on glycaemic control, consistent with some earlier meta-analyses (Bonoto *et al.*, 2017; Cui *et al.*, 2016; Hou *et al.*, 2016). One study (Cui *et al.*, 2016) was restricted to T2D and showed that the pooled effect on HbA_{1c} reduction was -0.40% after the use of self-care apps. In a second study (Hou *et al.*, 2016), the pooled effect on HbA_{1c} reduction for T2D was -0.49%, whereas for T1D was -0.36%. Another study (Bonoto *et al.*, 2017) reported a mean decrease in HbA_{1c} of -0.44%. These results were mostly associated with considerable heterogeneity.

Subgroup analysis was performed according to diabetes type in two of these review (Bonoto *et al.*, 2017; Hou *et al.*, 2016), and both T1D and T2D showed non-significant HbA_{1c} reduction with apps. Unlike those reviews, this review found a significant effect favouring T1D (P=0.02). This could be attributable to the younger age of people with

T1D (mean age 35 years vs. 55 years for T2D); this is in accordance with a study (Hou *et al.*, 2016) which indicated that younger patients were more likely to benefit from apps (HbA_{1c} reduction 1.03% for ≤55 years versus 0.41% for >55 years).

The subgroup analysis showed a larger and significant reduction in HbA_{1c} for apps that involved interaction with HCPs. This provides some support for previous claims that apps are more effective when combined with feedback from HCPs (Cui *et al.*, 2016; Garabedian *et al.*, 2015; Hou *et al.*, 2016). A possible rationale for this is the added benefit of closer monitoring, even outside the clinic, in addition to the facilitated interaction at any time between patients and HCPs. Yet, the exact relationship between apps, feedback and positive outcomes is not clear. People with diabetes expressed interest and willingness to use apps that involve interaction with HCPs.

Subgroups by follow-up duration did not differ significantly, possibly due to insufficient number of studies at each time-point. Other studies found a non-significantly larger reduction in HbA_{1c} with a shorter follow-up duration (<6 months) than with a longer duration (>6 months) (Garabedian *et al.*, 2015; Hou *et al.*, 2016; Kitsiou *et al.*, 2017).

Existing reviews did not distinguish between the different functionalities of mobile apps (e.g. helping patients adjust insulin doses, track BG levels or support healthy lifestyles) despite the differences in the intervention components in both diabetes management and the use of design techniques. One exception is a study which performed subgroup analysis by the number of functions available in the app. However, both subgroups showed significant favourable results in HbA_{1c} control (Bonoto *et al.*, 2017). Within the included studies, various functionalities of apps were not always shown to support glycaemic control. It was not feasible to carry out a subgroup analysis by app functionality due to the small number of included RCTs. The functionality of apps needs to be standardised in future research to enable the assessment of their impact.

On other outcomes, there appear to be early indications of improvement from the use of apps but the final results tended to be insignificant and inconclusive (Bonoto *et al.*, 2017; Cui *et al.*, 2016; Deacon & Edirippulige, 2015; Hood *et al.*, 2016). Some of the

past reviews examined mobile interventions more generally, rather than apps specifically, with significant heterogeneity existing among the trials included.

Unlike the previous reviews, the present review addresses the use of apps by HCPs in clinical practice and decision-making, and apps that support women with GDM.

5.2.4 Strengths and limitations of review

There is no standard definition of a diabetes mobile app and studies may have defined it differently. This review made a clear definition of a mobile app before commencing the study, which may be considered as a strength. The present review is the first to evaluate the impact of mobile apps, functioning on smartphones and tablets. It expands the evidence base by bringing together studies of apps designed to support people with diabetes or HCPs in diabetes care and by assessing both clinical and non-clinical outcomes. It also contributes to the emerging literature of *m*Health app usability and acceptability. It further highlighted the lack of research with HCPs and women with GDM.

The breadth of review scope, with a wide range of participants, settings and all reported outcomes, is a strength of this review, although this heterogeneity in study objective, design, age range, diabetes type and variation in app functionality all made clear comparisons difficult.

This review was not limited to the English language. Moreover, a broad search strategy was carried out using variety of terms. As well as searching the main medical and computer science databases, searches were also carried out in the grey literature and trial registers. Additionally, setting up the Auto Alert in most databases enabled the inclusion of many more studies that were published after the search was conducted. Two authors were involved in making the decisions for study selection and for data extraction and quality assessment in order to avoid bias and improve reliability.

This review had several limitations too. Problems were encountered regarding the selection of studies for inclusion, since some studies did not describe their intervention clearly, in particular, whether or not it was functioning on a smartphone/tablet,

causing a problem about deciding whether they should be included. As a result, there is a chance of missing a number of trials. Contacting study authors for clarification on their interventions was attempted in a few instances to ensure that the inclusion criteria were adhered to thoroughly. In addition, authors were contacted for missing data whenever possible. One weakness of evidence is that it was not always clear if the measured effect was entirely attributable to the use of apps since compliance with its use was not ensured in all studies; or perhaps, it could be attributed to other factors such as HCPs feedback.

The main limitation of the meta-analysis was the substantial heterogeneity between the included studies. Thus, it only provided an overall estimate that suggests areas for future research. Data for other outcomes could not be pooled in a meta-analysis. Due to the inconsistencies in the outcome measures among the included studies in this review, it was not possible to standardise all the data for any single outcome. Although a number of studies assessed the same outcome, they were measuring it in different ways; for instance, QoL was assessed in many studies but using different instruments with varying numbers of scales and sub-scales. Therefore, a narrative synthesis was carried out for other outcomes by grouping them into categories which was deemed the most appropriate way to present such huge and variable data to allow the reader easily to capture the extent of the evidence base and the variability among the different studies and their measures.

The findings from this review would have been more useful if the studies were classified into groups by app functionality to allow reliable comparison and help identify the most effective app functionality. However, a subgroup analysis by app functionality and stratifying the results of synthesis by app functionality was found to be infeasible due to the small number of RCTs included and the significant heterogeneity among studies.

5.2.5 Methodological consideration

Two of the included RCTs (Charpentier *et al.*, 2011; Holmen *et al.*, 2014) had three arms and for the purposes of this review, only two arms, the mobile app group and the

control group, were included for comparison. Any statistical analysis undertaken in these studies was between the three groups rather than between the two groups of interest. For that reason, it is important to recognise that any between-group comparisons presented are representative of a difference between all three groups and not precisely between the two groups.

5.2.6 Implications of the review and future research

The findings of the present review did not provide adequate evidence about mobile apps' effectiveness. Therefore, the main implications of this review arise from the dearth of evidence in relation to apps.

Need for additional research

Small-scale pilot and feasibility studies with post-only, or pre-post with no control designs were the dominant forms of apps trials. This indicates scope for further research, requiring large scale and good quality as the central characteristics of any future studies, especially methodologically rigorous and adequately-powered RCTs with longer follow-up. Further empirical research is needed to examine the effectiveness and costs of introducing apps for both patients and HCPs. Additionally, research exploring the impact of apps on clinical practice outcomes is needed.

Future research should also consider the use of apps by adolescents and women with GDM. Most teenagers are 'technology savvy'; they are more inclined to use apps than adults and, thus, are anticipated to benefit more. Apps may also have high potential to contribute to the care of GDM due to the short-term nature of the condition that occurs during pregnancy. Given that the purpose and functionality of apps were diverse across the heterogeneous studies included, establishing standardised app functionalities may assist in identifying the most effective functionality and facilitate the interpretation of future research findings.

Implications for app developers

Not all studies agreed on the most desired app functionalities and features. However, in general, diabetes education was the least offered functionality in diabetes apps at

present, but was rated the highest, whereas social support was the least utilised functionality. Other repeatedly recommended functionalities included automatic data input, reminders and glucometer connectivity. Incorporating these functionalities and features into diabetes apps may maximise their potential benefits.

In some studies, the app mainly supported one task of diabetes management, while in others it supported multiple tasks. Due to the lack of integration in apps' functionality, some users were using more than one app, each with a specific task, to supplement each other. This may underline a need for more comprehensive apps that help patients manage different aspects of their condition. However, with multiple tasks app, their usability may be negatively impacted.

Apps targeting patients' remote monitoring were more likely to be effective. This suggests that HCPs feedback is a key functionality in future diabetes apps, helping to achieve greater improvements in glycaemic control and compliance.

Implications for practice

Mobile apps can potentially add to diabetes care in clinical practice. The lack of robust evidence makes implications for clinical practice difficult to determine. Before widespread implementation of mobile apps into practice to complement the care for the growing number of people with diabetes, more research on the effectiveness, cost-effectiveness and acceptance by both patients and HCPs is needed.

Patients and HCPs in the included studies generally expressed interest and satisfaction with apps, so increasing patients' and HCPs' awareness of the available diabetes apps with their potential benefits is important. There remains a need for patients, clinicians and policy-makers to understand whether the use of apps should be considered for diabetes care and management. As the *m*Health field matures, policies that integrate mobile apps into healthcare management and services will become more likely.

Chapter 6 A qualitative systematic review: Results and discussion

Chapter overview

This chapter describes the findings from the qualitative systematic review, including the search results; characteristics of included studies; quality assessment; narrative synthesis (text and tables); summary of the results; discussion on the quality of the evidence; a comparison with relevant reviews; strengths and limitations; methodological considerations; and the implications and impact of the review on future research.

Design

This systematic review adopted a narrative approach to synthesise the findings of qualitative studies. This deductive method allows an exploratory analysis which fits well with the aim of describing the literature on how mobile apps are perceived and experienced. The ENTREQ checklist (Enhancing Transparency in Reporting the Synthesis of Qualitative Research) was used to ensure systematic reporting of the review (Tong *et al.*, 2012).

6.1 Results

6.1.1 Results of the search

Detailed description of the search results and the flow diagram for the selection of studies were provided in the previous chapter (Chapter 5, section 5.1). Eighty records fulfilled the selection criteria, comprising 34 quantitative studies and 20 qualitative studies, the latter of which were published in the following formats:

- four studies were represented by individual theses or dissertations (Min, 2013; Nielsen, 2013; Sarala, 2014; Skinner, 2015);
- two had one thesis and one published journal article (Årsand, 2009; Årsand *et al.*, 2010; Harris *et al.*, 2010; Le, 2008);

- one had one thesis and two published articles (Tatara, 2013; Tatara *et al.*, 2013a; Tatara *et al.*, 2013b);
- three had one published article and one published abstract (Cafazzo *et al.*, 2012a; Cafazzo *et al.*, 2012b; Franceschi *et al.*, 2014; Miele *et al.*, 2015; Waki *et al.*, 2015; Waki *et al.*, 2011);
- one had two published journal articles and one published abstract (Frøisland *et al.*, 2011; Frøisland & Årsand, 2015; Frøisland *et al.*, 2012);
- one had two published articles and three published abstracts (Hill & Masding, 2013; Pulman *et al.*, 2012; Pulman *et al.*, 2013a; Pulman *et al.*, 2013b; Pulman *et al.*, 2013c); and
- the remaining eight studies were represented by individual published articles (DeShazo *et al.*, 2010; Garnweidner-Holme *et al.*, 2015; Hsu *et al.*, 2015; Lehocki *et al.*, 2012; Owen *et al.*, 2015; Pellegrini *et al.*, 2015; Pludwinski *et al.*, 2015; Scheibe *et al.*, 2015).

6.1.2 Included studies

The 20 studies (published 2008–2015) fell within two broad design approaches: nine were entirely qualitative and 11 utilised mixed-methods designs. Table 6.1 presents the distributions of the included studies by different characteristics. Details of included studies (country, data collection method, intervention purpose and functionality, sample size, study aim/objectives and analysis method) were extracted and summarised in the tables 'Characteristics of included studies' in Appendix 8 (Table 4).

Table 6.1 Distribution of the included studies by different variables.

	No of trials,	Percentage, %
Data collection method		
Interview	18	90
Focus Group	3	15
Questionnaire	5	25
Think-aloud	2	10
Field-testing and user feedback	1	5
Country		
USA & Canada	8	40
Europe (UK, Norway, Slovak Republic, Italy, Germany, Denmark)	10	50
Southeast Asia (Japan, India)	2	10

Study setting		
Primary care	4	20
Secondary care (outpatient and inpatient)	7	35
Community and non-medical setting (Non – clinical)	8	40
Tertiary care	1	5
Age group		
Younger age group <18	4	20
Older age group ≥ 18	16	80
Population		
Patients	16	80
Children/adolescents patients with/without parents	4	20
HCPs	2	10
Type of diabetes		
Type 1	8	40
Type 2	7	35
Type 1 & 2	4	20
GDM	1	5
Intervention purpose		
Self-care	13	65
Telemonitoring	6	30
Clinical practice	1	5

6.1.2.1 Data collection methods

Qualitative elements of the included studies used five data collection methods, with several studies combined multiple methods. Interview (semi-structured, structured, in-depth, ethnographic and structured written) was the most frequently-used method (18 studies) (Årsand, 2009; Cafazzo *et al.*, 2012a; Frøisland *et al.*, 2012; Garnweidner-Holme *et al.*, 2015; Harris *et al.*, 2010; Hsu *et al.*, 2015; Miele *et al.*, 2015; Min, 2013; Nielsen, 2013; Owen *et al.*, 2015; Pellegrini *et al.*, 2015; Pludwinski *et al.*, 2015; Pulman *et al.*, 2013a; Sarala, 2014; Scheibe *et al.*, 2015; Skinner, 2015; Tatara, 2013; Waki *et al.*, 2015). Focus group was employed by three studies (Årsand, 2009; DeShazo *et al.*, 2010; Tatara, 2013), whereas questionnaire was utilised within five studies (Årsand, 2009; DeShazo *et al.*, 2010; Nielsen, 2013; Pellegrini *et al.*, 2015; Tatara, 2013). Two studies used think-aloud method (Garnweidner-Holme *et al.*, 2015; Harris *et al.*, 2010) and one study employed field-testing and user feedback (Lehocki *et al.*, 2012).

6.1.2.2 Sample sizes

The studies (n=20) included a total of 357 participants (287 adult patients, 50 children/adolescent patients with their parents, and 20 HCPs; study sizes ranged from 5–52 [median=13]).

6.1.2.3 Settings

Studies were conducted in the USA (n=5), Canada (n=3), Norway (n=4), UK (n=2), Germany (n=1), Italy (n=1), Denmark (n=1), Slovak Republic (n=1), Japan (n=1) and India (n=1).

Studies were conducted in primary care (Harris *et al.*, 2010; Lehocki *et al.*, 2012; Pludwinski *et al.*, 2015; Sarala, 2014), secondary care (Cafazzo *et al.*, 2012a; Frøisland *et al.*, 2012; Garnweidner-Holme *et al.*, 2015; Miele *et al.*, 2015; Min, 2013; Pulman *et al.*, 2013a; Waki *et al.*, 2015), tertiary care (Hsu *et al.*, 2015), and community and non-medical settings (Årsand, 2009; DeShazo *et al.*, 2010; Nielsen, 2013; Owen *et al.*, 2015; Pellegrini *et al.*, 2015; Scheibe *et al.*, 2015; Skinner, 2015; Tatara, 2013).

6.1.2.4 Participants

Participants in four studies (Cafazzo *et al.*, 2012a; Frøisland *et al.*, 2012; Miele *et al.*, 2015; Skinner, 2015) were children or adolescents with, or without, their parents; the remaining 16 studies included adult patients, and of these, two studies (Nielsen, 2013; Sarala, 2014) included both patients and HCPs.

More studies targeted patients with T1D only (n=8), followed by T2D only (n=7), while only one study examined women with GDM (Garnweidner-Holme *et al.*, 2015). Four studies considered both T1D and T2D (DeShazo *et al.*, 2010; Harris *et al.*, 2010; Nielsen, 2013; Scheibe *et al.*, 2015), of which two (Nielsen, 2013; Harris *et al.*, 2010) did not report the distribution of diabetes type.

6.1.2.5 Interventions

Different types of mobile apps were examined: six studies explored apps aiming to facilitate patients' telemonitoring (Hsu *et al.*, 2015; Lehocki *et al.*, 2012; Miele *et al.*, 2015; Nielsen, 2013; Pludwinski *et al.*, 2015; Waki *et al.*, 2015), whilst only one considered an app supporting clinical decision-making (Sarala, 2014). The remaining studies (n=13) examined apps supporting diabetes self-care. Studies varied in their main focus, functionalities and applied design techniques.

Other studies did not involve an intervention; generally they explored participants' perceptions, needs and views on apps for diabetes management.

6.1.2.6 Evaluation

Studies evaluating the same outcome were grouped together.

1. Patients' experience with intervention components

This group of studies commonly employed mixed-methods designs and, thus, involved app trialling followed by exploration of participants' experiences with the intervention components (e.g. acceptability, accessibility, satisfaction, and use and utilisation).

2. Patients' perception on the use of apps

Studies explored participants' perceptions and views on the use of apps to support diabetes management.

3. Patients' needs and requirements for apps

These studies identified, from participants' experience with diabetes and their views, the needs and requirements of the target users in order to assist in the early design and development of an app. This also included participants' preferences and desired apps features and, thus, some studies further provided a number of ideas and suggestions for apps functionalities and enhancements to help guide app developers.

4. Usability of apps

These studies evaluated the usability of an initial design of the app (second step of design phase) to identify potential issues in workflow and further refine the design.

5. Factors influence patients' acceptance of apps

This group identified factors influencing participants' acceptance and use of diabetes apps.

6. HCPs' experience and/or perspective on the use of apps

These studies explored HCPs' experiences with intervention components or perspectives on the use of apps to support diabetes management.

Table 6.2 shows studies in to each group.

Table 6.2 Classification of included studies into groups according to their main focus of evaluation.

Evaluation	Study reference
Patients' experience with intervention components	Årsand 2009, Frøisland 2012, Tatara 2013, Sarala 2014, Miele 2015, Pludwinski 2015, Hsu 2015, Owen 2015, Pellegrini 2015
Patients' perception on the use of apps	Nielsen 2013
Patients' needs and requirements for apps	Harris 2010, Deshazo 2010, Cafazzo 2012, Min 2013, Pulman 2013, Skinner 2015, Garnweidner-Holme 2015
Usability of apps	Harris 2010, Deshazo 2010, Lehocki 2012, Tatara 2013, Waki 2015, Garnweidner-Holme 2015
Factors influence patients' acceptance of apps	Scheibe 2015
HCPs' experience and/or perspective on the use of apps	Nielsen 2013, Sarala 2014

6.1.3 Quality of included studies

The application of CASP critical appraisal tool across the 20 studies showed variable results. In all studies, a clear statement of the research aims was provided and qualitative methods were considered appropriate to address their aims and objectives. All except four studies (Miele *et al.*, 2015; Scheibe *et al.*, 2015; Tatara, 2013; Waki *et al.*, 2015) gave sufficient description of the sampling strategy and/or recruitment process but only five provided some rationale for the selection of participants (Lehocki *et al.*, 2012; Nielsen, 2013; Owen *et al.*, 2015; Sarala, 2014; Skinner, 2015). Only five studies reported potential reasons for non-participation (Nielsen, 2013; Pellegrini *et al.*, 2015; Pludwinski *et al.*, 2015; Skinner, 2015; Tatara, 2013). Data collection method was reported in all studies but with variation in the degree of detail given. The setting was described in nine studies (Årsand, 2009; Frøisland *et al.*, 2012; Garnweidner-Holme *et al.*, 2015; Harris *et al.*, 2010; Min, 2013; Nielsen, 2013; Sarala, 2014; Scheibe *et al.*, 2015; Skinner, 2015), while who carried out the data collection was stated in ten studies (Årsand, 2009; Cafazzo *et al.*, 2012a; DeShazo *et al.*, 2010; Garnweidner-Holme *et al.*, 2015; Lehocki *et al.*, 2012; Min, 2013; Nielsen, 2013; Pellegrini *et al.*, 2015; Sarala, 2014; Skinner, 2015). Only five studies provided justification for the selection of data collection methods (Min, 2013; Nielsen, 2013; Pulman *et al.*, 2013a; Scheibe *et*

al., 2015; Skinner, 2015). Data saturation was only discussed in four studies (Cafazzo *et al.*, 2012a; Pludwinski *et al.*, 2015; Sarala, 2014; Skinner, 2015).

Reflexivity was adequately discussed in three studies (Årsand, 2009; Min, 2013; Sarala, 2014) where they critically examined researchers' roles and any potential influence and bias in the formulation of research question, sampling, data collection or analysis. An additional six studies (Harris et al., 2010; Lehocki et al., 2012; Nielsen, 2013; Scheibe et al., 2015; Skinner, 2015; Tatara, 2013) partly reflected on potential bias of researchers at some stages of the study.

Five studies (Lehocki *et al.*, 2012; Miele *et al.*, 2015; Nielsen, 2013; Owen *et al.*, 2015; Pulman *et al.*, 2013a) did not report details on ethical approvals from research ethics committees or participants' consent. An additional three studies (DeShazo *et al.*, 2010; Harris *et al.*, 2010; Scheibe *et al.*, 2015) did not explicitly discuss either the approval or the consent, whereas the remaining (12 studies) sufficiently discussed obtaining approvals and written consent from all participants before the commencement of any data collection. Only four studies (Owen *et al.*, 2015; Pellegrini *et al.*, 2015; Sarala, 2014; Skinner, 2015) described how the study was explained to participants. Likewise, four studies (Owen *et al.*, 2015; Pludwinski *et al.*, 2015; Sarala, 2014; Tatara, 2013) discussed how confidentiality was maintained.

Half of the studies (n=10) provided adequate description of data analysis method but the extent of information given was variable (Cafazzo *et al.*, 2012a; Frøisland *et al.*, 2012; Min, 2013; Nielsen, 2013; Pellegrini *et al.*, 2015; Pludwinski *et al.*, 2015; Sarala, 2014; Scheibe *et al.*, 2015; Skinner, 2015; Tatara, 2013). An indication of involvement of multiple researchers in the analysis process was given in only four studies (Cafazzo *et al.*, 2012a; Frøisland *et al.*, 2012; Harris *et al.*, 2010; Min, 2013). Sufficient primary data, i.e. quotations from participants, were presented to support findings in ten studies (Årsand, 2009; Frøisland *et al.*, 2012; Nielsen, 2013; Owen *et al.*, 2015; Pludwinski *et al.*, 2015; Pulman *et al.*, 2013a; Sarala, 2014; Scheibe *et al.*, 2015; Skinner, 2015; Tatara, 2013). Findings in most (15) studies were explicit and clearly discussed in relation to other published research, but five studies (DeShazo *et al.*, 2010; Hsu *et al.*, 2015; Lehocki *et al.*, 2012; Miele *et al.*, 2015; Pulman *et al.*, 2013a)

were very limited in their presentation of findings. Only six studies considered the credibility and validity of their findings (Årsand, 2009; Frøisland *et al.*, 2012; Nielsen, 2013; Pulman *et al.*, 2013a; Sarala, 2014; Tatara, 2013). The assessment result for all studies is in Appendix 10.

6.1.4 Synthesis of findings

A narrative overview of the findings of studies, using the above classification by main study focus, is shown with illustrative quotations from the primary studies.

6.1.4.1 Patients' experience with intervention components

Although nine studies (presented in Table 6.2) explored participants' experience following a completion of an intervention trial, these interventions were diverse in their main functionality, purpose and design. Three studies (Årsand, 2009; Frøisland *et al.*, 2012; Tatara, 2013) examined different versions of the same app 'Few Touch'; yet, the studies were different in their focus and population.

Disease management was the main focus in four studies (Frøisland *et al.*, 2012; Hsu *et al.*, 2015; Owen *et al.*, 2015; Pludwinski *et al.*, 2015). Of these, two (Frøisland *et al.*, 2012; Owen *et al.*, 2015) examined apps supporting self-care for patients with T1D, whereas the other two (Hsu *et al.*, 2015; Pludwinski *et al.*, 2015) examined apps involving remote monitoring of patients with T2D. Of these four, one (Frøisland *et al.*, 2012) explored adolescents patients' experience, while the remaining targeted adults. Behaviour change was the primary focus in two studies (Årsand, 2009; Pellegrini *et al.*, 2015) which examined apps supporting self-care in patients with T2D. Understanding and describing app usage patterns and utilisation was the focus in two studies (Miele *et al.*, 2015; Tatara, 2013). One targeted remote monitoring of children with T1D (Miele *et al.*, 2015), while the other supported self-care for patients with T2D (Tatara, 2013).

Similarities emerged between studies' findings. In three studies (Frøisland *et al.*, 2012; Owen *et al.*, 2015; Pludwinski *et al.*, 2015), the app enabled participants to capture relevant health-related information in the form of images. Integrating trend graphs

and/or a photo-based diary gave young people and adults a better visual understanding of their diabetes and how physical activity, food intake and insulin dosage interact and affect BG levels (Årsand, 2009; Frøisland *et al.*, 2012; Hsu *et al.*, 2015; Owen *et al.*, 2015; Pludwinski *et al.*, 2015; Tatara, 2013). This assisted individuals in trend spotting, self-reflection, and self-awareness of habitual behaviours.

> *'That one gets it visually – the combination of all the efforts you do – it's incredibly important for further motivation.'* (Årsand, 2009)
>
> *'Before, I really thought that the blood sugar was one thing and giving insulin was one thing and eating was one thing, but now I see more all three of them as a whole, that they all belong together.'* (**Tom**, Frøisland *et al.*, 2012)
>
> *'I understand the reasons behind the decision (of changing insulin dose) much better.'* (Hsu *et al.*, 2015)

In addition, capturing and saving meals' pictures gave them a visual understanding of their own unhealthy diet (Frøisland *et al.*, 2012), and increased awareness of portion size and carbohydrate intake (Pludwinski *et al.*, 2015). Image capture was more likely to be used in unusual events and during moments of change as it enabled in understanding the impact of new factors (Owen *et al.*, 2015).

> *'I just photographed the food I usually eat, but I thought during the process that I should apply more healthy eating habits, because I saw I had a lot of unhealthy canteen food in school.'* (**Erik**, Frøisland *et al.*, 2012)
>
> *'If I can see a picture of what I have eaten it gives me a better idea of what my blood sugars are doing and why… I had a couple of hypos and I looked back at the photographs and saw that I had a coffee and a muffin and had really overestimated the insulin.'* (**Holy**, Owen *et al.*, 2015)

In studies that involved any type of interactions with care providers, participants described the app as a 'sought-after' tool that gave them a feeling of access and security (Frøisland *et al.*, 2012). Additionally, the involved HCPs were perceived as always watching them (Pludwinski *et al.*, 2015).

> *'The fact that you have someone to support you—someone who knows the subject, and if you get into difficulties you can get an answer—it gives a certain feeling of security.'* (**Oda**, Frøisland *et al.*, 2012)
>
> *'(Smartphone) was my watcher. Somebody is watching you through your eyes . . . it was so interesting'* (**Participant #9**, Pludwinski *et al.*, 2015)

In a similar way, participants in studies that involved telemonitoring (Hsu *et al.*, 2015; Pludwinski *et al.*, 2015) shared positive experiences about the interaction with their HCPs, and they felt that the connectivity with their HCPs helped reduce anxiety and the feeling of isolation, and the feedback received was specifically identified as motivating.

> *'It's comforting to know that they [clinician coaches] are always there.'* (Hsu *et al.*, 2015)

> *'I think this study helped me emotionally a lot, more than physical, I feel emotionally happy. That is important to me'* (**Participant #9**, Pludwinski *et al.*, 2015)

Participants felt empowered through the connectivity with their HCPs, e.g. in making insulin adjustments (Hsu *et al.*, 2015). Others became more critical of their own behaviours related to food and exercise (Pludwinski *et al.*, 2015)

> *'I feel more equal with the coach in making decision about my health.'* (Hsu *et al.*, 2015)

The use of apps appeared to have increased participants' sense of control and confidence to deal with, and interpret, their information in meaningful way (Owen *et al.*, 2015; Pludwinski *et al.*, 2015; Tatara, 2013). Some participants reported notable changes to their management regime (Owen *et al.*, 2015). One stated that the use of the app helped reduce his medication (Årsand *et al.*, 2010):

> *'Even though I admit that the blood glucose measurement system made me stressed, I also see that when using it, I reduced my medication by one tablet a day.'* (Årsand *et al.*, 2010)

Another participant said:

> *'I did not eat so much sweet food in the Christmas season. Instead, I ate a lot of fruits and a little bit of cake every now and then.'* (**P03 at Meeting 3**, Tatara, 2013)

Participants in studies that were supporting lifestyle changes (Årsand *et al.*, 2010; Pellegrini *et al.*, 2015; Tatara, 2013) reported that they were motivated by the challenge to trying to reach their own goal; i.e. achieve a smiley face for attaining food habit goal or the red line for reaching the target daily steps.

> *'The motivation increased again when we got the step counter. I have tried not to take the bus, but instead walked back and forth to my work.'* (Årsand *et al.*, 2010)

Moreover, they found the diet tracking functionality useful, particularly as a learning resource; however, they reported that the need to manually record food intake several times a day was tiring (Årsand *et al.*, 2010).

> *'This is a tool that can help you to learn more about yourself, but sometimes I become tired of recording what I eat each day.'* (Årsand *et al.*, 2010)

Participants who underwent an intervention aiming to increase physical activity (Pellegrini *et al.*, 2015) stated that the app made them more aware of their sitting time and motivated them to stand up and take more breaks from sitting.

> *'It would remind me that I had been sitting for a period of time, without having to think about it.'* (Pellegrini *et al.*, 2015)

Two studies described patterns of use among participants (Miele *et al.*, 2015; Tatara, 2013). One study (Miele *et al.*, 2015) concluded that one size does not fit all, pointing to the fact that users have heterogeneous needs and, thus, no-one used all the provided functions and nobody used only a single function. The second (Tatara, 2013) concluded that there were significant variations in usage patterns and level of engagement and they changed over time. They explained that motivation to use the app is a result of balance between efforts required to use it and benefits attained. In general, participants' usage and interactions with the app decreased over study periods and the novelty of using the app wore off with time (Owen *et al.*, 2015). Tatara (2013) outlined two main reasons for the decrease in usage: 1) attrition of motivation after obtaining a sense of control over diabetes, and 2) experience of problems in using the app.

> *'I have not used the application in the last four months since the summer holidays. But the HbA_{1c} went down from the last time. I believe that I have gained a better understanding about myself, and now I don't have to use it daily as I did before. I was eager at the beginning. Even though I don't use it, I think over what I eat and things like that anyways.'* (**P11 at Meeting 6**, Tatara, 2013)

In terms of overall experience across studies, positive experiences indicated in the majority of studies as participants generally were satisfied and found apps to be highly usable and useful.

> *'The program is a big motivation in my life… it's a positive thing for me… with all that's going on I need positive things.' (***Participant #6**, Pludwinski *et al.*, 2015)

Contrary to that, participants encountered some technical problems that required resolution; mostly related to WiFi/network connectivity (Frøisland *et al.*, 2012; Hsu *et al.*, 2015). Other participants experienced malfunctions with the supporting devices such as a glucometer or a step counter (Årsand, 2009; Pellegrini *et al.*, 2015; Tatara, 2013).

> *'Yes, the project was tailored to me, but it could have been better on the glucose transmission [from the glucometer to the phone] because it didn't work all the time.'* (**David**, Frøisland *et al.*, 2012)

Few participants, particularly those with highly structured and predictable routines, struggled to integrate the app into their management routine. The reported reasons were either that the app interrupted their habits and routines (Owen *et al.*, 2015) or that there was a mismatch between app design concepts and reality (Tatara, 2013).

> *'I think it takes a bit more time for something like this to become part of a routine, I have been using paper and an insulin pump since 2001.'* (**John**, Owen *et al.*, 2015)

Participants expressed some concerns around the use of photo capture or data entry during social situations (Owen *et al.*, 2015; Tatara, 2013).

> *'I entered results every time, except when it was rude to get my phone out then I would retrospectively add them.'* (**Sarah**, Owen *et al.*, 2015)

Sarala 2014 (Sarala, 2014) was distinct from others, that it interviewed 33 patients with T2D who underwent an intervention; a smartphone-based decision-support app used by HCPs. The study explored their experience and how they perceived the use of a 'smart phone' by nurses and physicians in the middle of the consultations. The app gained high acceptance among patients; the majority felt the smartphone was of use to them and the recording of their data through the app was useful. A 46-year-old female patient was of the opinion that:

> *'The nurse enters data into the phone in front of me. I think recording data is for patient care.'* (Sarala, 2014)

6.1.4.2 Patients' perception on the use of apps

Only one study (Nielsen, 2013) explored patients' perceptions and preferences on the use of smartphone apps to enhance adherence to remote diabetes monitoring and self-management. The study showed that most people with diabetes in Denmark are using apps to support the monitoring and self-management. The overall perception was positive; participants have already adopted and accepted the technology. They believe that it could be used as a tool to help change their lifestyle and improve diabetes control, though different social group of users have variable meanings and opinions about the use of apps. The potential risks related to safety and security of apps do not seem to prevent respondents using apps for diabetes management.

Most participants are willing to engage their HCPs in the monitoring and self-management of diabetes through using apps. However, there is controversy on the extent that they should involve HCPs in their diabetes control. They do not perceive apps as a replacement for face-to-face visits with their doctors; they prefer a combination of both personal and digital interaction with their doctors. They stated that they would feel safe if apps were recommended by their physicians.

Despite the satisfaction with some of the available apps' features and functions, respondents expressed a lack of interest in using certain functionalities. Some users are not interested in the alert functionality which allow them to set reminders, for instance, to take medication. In addition, few participants are interested in social media networking with respect to their diabetes. The author interpreted this as 'one-size-does-not-fit-all' with regards to apps' features and functions, meaning that users have different preferences as individuals. Most participants would prefer an 'all-in-one-place' app. Yet, most participants tend to use more than one app to complement each other.

On the negative side, lack of synchronisation with other devices, such as the glucometer, or with their doctor's system, and with other websites, were indicated as limitations of currently available apps.

6.1.4.3 Patients' needs and requirements for apps

Users' needs and requirements were explored in seven studies to inform more patient-centred design and development of apps supporting diabetes management. Of these, four (DeShazo *et al.*, 2010; Garnweidner-Holme *et al.*, 2015; Harris *et al.*, 2010; Min, 2013) targeted the needs of adults with T1D, T2D or GDM. Two (Cafazzo *et al.*, 2012a; Skinner, 2015) targeted children and adolescents with T1D and their families, while the remaining one targeted young people aged 18–21 with T1D (Pulman *et al.*, 2013a).

Participants expressed their need to share diabetes-related information with close family members (Min, 2013; Skinner, 2015). Although most have social network accounts, i.e. Facebook, Twitter, etc., they further explained that they are not interested in discussing diabetes matters with online communities (Min, 2013). Children and teens are willing to share their data with parents (Cafazzo *et al.*, 2012a; Skinner, 2015), and parents valued the idea of sharing information through an app; they felt this would make them comfortable and more secure (Skinner, 2015). For example, one parent stated:

> *'I think it would be cool, because then especially when he's not around, I can know and then I can check in with him or not bug him if I don't need to.'* (**Parent 2**, Skinner, 2015)

Children and teens liked the idea of an app that connect them with their friends and allow them to share data to compare progress and provide support (Cafazzo *et al.*, 2012a; Skinner, 2015).

> *'I feel like it would be useful, and it would be fun to like communicate with others and learn more about it.'* (**Child 2**, Skinner, 2015)

However, one parent stated that even though connecting with peers with similar condition would be helpful, she expressed concerns about her child using social media and talking with strangers (Skinner, 2015).

> *'When your kids are younger, the fact that you want them talking to social media with people that you don't know and they don't know from all over is a scary thought.'* (**Parent 4**, Skinner, 2015)

Ease of logging data and the summary of data graphics were the most-liked features by most participants across several studies (Cafazzo *et al.*, 2012a; Harris *et al.*, 2010; Min, 2013; Pulman *et al.*, 2013a; Skinner, 2015).

> *'It's just easy to log in your information, and it keeps it all for you. You don't have to worry about paper or pencil. You just punch it in. It's as easy as sending a text or writing a text or email. It's just all very convenient and in one spot.'* (**Parent 4**, Skinner 2015)

> *'Cause again that's something then you're looking at that's more visual, that you can see oh ok, maybe it's not as good as I thought, whereas just doing it, doing your sugars once every day and just seeing the numbers…'* (Pulman *et al.*, 2013a)

Recording of data was regularly described as exhausting and time-consuming, therefore, participants reported that the key parameters that they needed to track are BG, carbohydrates, insulin and activities. Additionally, they requested that the app provides real-time feedback on their BG levels (Garnweidner-Holme *et al.*, 2015), specifically, receiving a notification of abnormally high or low readings is helpful (Harris *et al.*, 2010; Min, 2013). Moreover, participants showed a strong desire towards an app that connects them with their HCPs (Harris *et al.*, 2010). One study explored participants' needs for mobile games that deliver diabetes education, however, some participants thought games should be targeting the younger population (DeShazo *et al.*, 2010). An additional requirement outlined by some participants is the need for individualised app content (Garnweidner-Holme *et al.*, 2015; Pulman *et al.*, 2013a).

> *'No one, no two people are the same with diabetes, everybody is different.'* (Pulman *et al.*, 2013a)

Adolescents, in particular, expressed a need for automated and fast transactions that only takes seconds in order to avoid social embarrassment when testing in public places (Cafazzo *et al.*, 2012a). They further asked for decision-support prompts and alerts for testing BG to support accurate and timely management of their condition.

One parent emphasised the need for the app to be engaging to increase the likelihood of being used by adolescents; otherwise, the novelty of a new app will wear off with time (Skinner, 2015).

> *'I think it's going to be like anything – in the beginning it's going to be a novelty, and they're doing to do it right away.'* (**Parent 4**, Skinner, 2015)

Skinner (2015) suggested several features for apps' design to best benefit young people (Skinner, 2015). This includes the ability to synchronise data between multiple accounts and devices and to their medical records. Another important feature was having customisable settings, and this is because families have children at different ages and, thus, their needs would be different. Furthermore, Pulman (2013) provided a list of apps' ideas and enhancements to improve currently available apps functionalities based on young people views and experiences (Pulman *et al.*, 2013a).

6.1.4.4 Usability of apps

Six studies (DeShazo *et al.*, 2010; Garnweidner-Holme *et al.*, 2015; Harris *et al.*, 2010; Lehocki *et al.*, 2012; Tatara, 2013; Waki *et al.*, 2015) carried out usability testing to examine an initial design of the apps and identify usability impediments, then use the collected feedback to refine the design. Participants in most studies were provided with the devices, smartphones or tablets, to test the app and, therefore, participants expressed preference to use their own devices with which they would be more familiar (Lehocki *et al.*, 2012).

Most participants perceived the wireless upload of BG readings through the app as convenient and easier than their current practice (Garnweidner-Holme *et al.*, 2015; Harris *et al.*, 2010; Lehocki *et al.*, 2012; Tatara, 2013)

> *'This is way easier, so I mean it would take me, what, five seconds?'* (Harris *et al.*, 2010)

A woman with GDM made the following statement:

> *'I think it is very good. You get inspired to do things right. It's pretty easy, yes, because you have your phone with you all the time. I always forget about the registration booklet and have to find a pen.'* (Garnweidner-Holme *et al.*, 2015)

Most participants in one study felt that receiving more than 2–4 reminder messages per day for compliance to self-management activities was annoying (Lehocki *et al.*, 2012). Participants in another study felt that the automated messages were irrelevant to them (Harris *et al.*, 2010). They thought receiving 1–2 messages per day is

reasonable, and suggested adding an option allowing them to turn off automated messaging.

> *'I don't need a stock answer. I need somebody to say okay, this person is in trouble. I need to call her.'* (Harris *et al.*, 2010)

In terms of mobile games that deliver nutritional education, participants generally found the information relevant to them and reported that they enjoyed playing (DeShazo *et al.*, 2010). However, they suggested shorter games since this type of game is usually played to pass time while waiting for something or commuting. Participants in a study that examined the usability of meal-photo input function (Waki *et al.*, 2015), which provides patients with real-time feedback for diet modification, appreciated the app and described it as convenient, helpful, quick and easy to use.

> *'I could know nutritional values of my meal immediately after I input extract images.'* (Waki *et al.*, 2015)

In general, positive feedback was reported on design interface, navigation structure and data presentation in most studies (Lehocki *et al.*, 2012; Tatara, 2013; Waki *et al.*, 2015) except one where confusion was reported respecting the use of language and small picture sizes (Garnweidner-Holme *et al.*, 2015). Other frequent usability problems included the short battery life; touch-screen or camera did not function well, or connectivity issues with other devices (Harris *et al.*, 2010; Tatara, 2013). Finally, Tatara (2013) identified five major factors associated with usability of the app over time (Tatara, 2013): integration with everyday life with a minimal effort; automation of data transfer; balance between accuracy and meaningfulness of data with manual entry; intuitive and informative feedback; and rich learning materials, especially about foods.

6.1.4.5 Factors influence patients' acceptance of apps

Only one study (Scheibe *et al.*, 2015) identified several factors that influence the acceptance of diabetes apps among people aged ≥50. The study identified seven acceptance factors which were classified into two categories; the main impact factors are: perceived ease of use and perceived additional benefit, while the secondary impact factors include: previous knowledge and experiences, available support,

current state of health, trust in own technical abilities/insecurities in utilisation, perceived data security and expected reliability/fault tolerance and joy of use.

Low degree of apps' usability was shown among participants in the study as they encountered difficulties understanding the menu labelling and navigation. The main barriers were related to the small font size and representations plus the low colour contrast. This target group were generally not aware of the additional benefits provided by using apps compared to their current management practice. Hence, a diabetes app should provide users with written statements of the advantages of using the app.

> *'As long as the alternative doesn´t provide me with a technical advantage or true advantage, I won´t put any efforts into mastering this, I mean, a smartphone requires a certain amount of practice, so yeah, I haven´t gotten around to doing this as I don´t see the personal advantage.'* (Scheibe *et al.*, 2015)

Participants with no prior experience in using smartphones and tablets required more assistance during the session and this was identified as negatively influencing the group intention to use apps. This group of users needs support in using modern technology; therefore, having a personal contact person available to answer their technical questions is important. Family members, in particular children, grandchildren and partners, were their first choice. Most participants were concerned regarding the protection of their health data or incorrect data input, for example, one participant stated:

> *'…an inhibitional threshold where one could make a mistake and that data, personal data, could get lost, or that any involuntary payments might be necessary that were hidden somehow.'* (Scheibe *et al.*, 2015)

Health status was a factor impacting on perceived additional benefits and, thus, the acceptance of apps. For example, patients with insulin therapy may gain more benefit from using an app than patients with oral medications. The lack of interest and joy in using new technologies also emerged as a factor influencing app utilisation among the target group.

Finally, the authors concluded that the needs of elderly users with diabetes are considerably variable due to the variations in their level of knowledge, age, type of

diabetes and treatment. As a result, they recommended that diabetes apps should be adaptable to individual needs in order to raise acceptance among target users.

6.1.4.6 HCPs' experience and/or perspective on the use of apps

Two studies (Nielsen, 2013; Sarala, 2014) explored HCPs' experiences or views on the use of apps for diabetes management. Sarala (2014) (Sarala, 2014) examined the feasibility of a smartphone-based decision-support app for clinical practice, and then explored opinions and satisfactions of the involved HCPs with regard to app use. Participants reported that using the app helped in making patient evaluation more systematic, and reduced the chance of missing important patient data such as clinical parameters or medical history. A Medical Officer stated:

> *'One change I can see is that we are ruling out the chance of missing any comorbidities.'* (Sarala, 2014)

Another Medical Officer said:

> *'The software takes care of these medical updates and that way the new system is very useful.'* (Sarala, 2014)

With respect to HCPs' compliance to the given clinical management plan by the app, Medical Officers admitted that they were sometimes unable to follow the recommendations generated from the app, mainly due to the mismatch in the availability of medicines in drug supply or the affordability of medicines for patients. For example, a nurse stated:

> *'Our doctor writes mostly the drugs as per the guideline. For poor patients he gives drugs available in the supply which is free rather than advising medicines suggested by the software.'* (Sarala, 2014)

However, specialist physicians were deviating from the suggestions more often as most of their patients have complications or comorbidities, therefore, they tended to prescribe newer and expensive medicines. They felt that the given recommendations were incompatible with their complicated patients and asked for more advanced version of the app.

Lastly, participants indicated that the small screen size of the smartphone was a limitation and suggested using a tablet as alternative. A specialist physician said:

> *'Probably you should give these girls a notebook or tablet, because it is difficult for them to feed data into phone from large number of patients. There is too much strain to the eyes. After two years, she will be wearing big spectacles. Nowadays tablets are very cheap. You will get it for 12000, 15000 rupees. That would be a better option.'* (Sarala, 2014)

Nielsen (2013) (Nielsen, 2013), on the other hand, interviewed one Endocrinologist to explore his perception and opinion about the use of apps for remote monitoring of diabetes patients. His general perception is positive as he expressed interest in using apps for monitoring and interacting with patients, and acknowledged that he recommends such apps for his patients. The Endocrinologist further reported that receiving patient data from an app potentially improves treatment options as suggested in the following statement:

> *'We already have patients sending mails with their glucose measurements, and it provides us with improved treatment options. Integrating an app in our system would improve this further.'* (Nielsen, 2013)

He believed that information received from apps would not represent a burden to HCPs' daily workflow. Additionally, he thought that the risk of issues related to safety and security of apps will not undermine the utilisation of the technology in diabetes care.

> *'There is always some resistance to change – but I also think there would be a lot of interest in such a new app. Depending on HCP personality.'* (Nielsen, 2013)

6.2 Discussion

6.2.1 Summary of results

This systematic review identified, appraised and summarised available literature on how mobile apps were perceived and experienced by patients with diabetes and their HCPs. Twenty primary studies met the inclusion criteria and were reported using a narrative synthesis approach. Studies were grouped according to their main focus of evaluation: patients' experience with intervention components, patients' perception

on the use of apps, patients' needs and requirements for apps, usability of apps, factors influence patients' acceptance of apps, and HCPs' experience and/or perspective on the use of apps.

Although studies were very heterogeneous in term of their aim, population, intervention purpose and main functionality, the findings of the studies were closely linked whether they were exploring experiences, perceptions or needs. The general perceptions on the use of apps of both patients and HCPs were positive. Yet, app users have different preferences and needs as persons and patients. The results indicate a need for more individualised app design, where users can customise apps according to their personal preferences and needs.

The most appreciated and desired app features and functionalities among diabetes patients were the wireless automatic transfer of BG readings, visual summary graphs and connectivity with their HCPs. Apps that integrated visual elements helped diabetes patients in their self-management, enabling them to see their glucose levels as a historical trend graph on their smartphones or tablets. Implementing a visualisation tool is an important contribution for people with diabetes, facilitating reflective learning and helping patients better understand the link between their food choices, physical activity and insulin dosage and its impact on BG levels.

Apps provided a convenient tool to capture and analyse contextual information about their condition. Thus, the use of apps had a motivational effect on some users. However, patients were engaging in the app use for various reasons and in different ways. Generally, patients decreased use over time, suggesting that apps might be more suitable for the short term.

It is impossible to draw a definite conclusion on apps' impact as an intervention either for patients or HCPs. Most studies focused on patients' experiences and perspectives. Evidence on HCPs' use of apps in clinical practice and for women with GDM is limited.

6.2.2 Quality of evidence

All studies had a clear description of research aims and design but few gave explicit rationales for the sampling strategy. Data collection methods were reported in all studies, but only half clearly and sufficiently described the analysis method. Not all studies addressed obtaining ethical approval and participants' written consent. Most studies did not include any consideration of reflexivity, however, findings in most studies were presented clearly.

Studies which sufficiently met most quality criteria were either theses or dissertations where the word limit is much more compared to the restricted limits in journal publications. This certainly limits the degree of detail provided in journal articles, especially for studies that were part of mixed-methods research, since they need to fit in both quantitative and qualitative results. The CASP tool assesses the reported quality of studies rather than their actual quality; therefore, a study could be of good quality but poorly reported.

6.2.3 Comparison with other reviews

To the best of the authors' knowledge, this review is the first to consider qualitative research exploring patients' and HCPs' use of, and perspectives on, mobile apps for diabetes care and management. As *m*Health apps is an emerging field in diabetes management, the only identified reviews examining the effectiveness of apps in diabetes management were quantitative.

6.2.4 Strengths and limitations of review

The present review considered the impact of using apps functioning specifically on smartphones and tablets. It brought together the existing qualitative evidence on the use of apps by both people with diabetes and HCPs in diabetes care. It highlighted the lack of research with HCPs and women with GDM. The breadth of review scope, with a wide range of participants and all perspectives and experiences, is a strength of this review. However, this may be considered as a limitation as well, due to the variations

between included studies in study aim, participant's age range, diabetes type and differences in apps main functionality; all made synthesis of findings more challenging.

A comprehensive electronic database search was conducted including the main medical and computer science databases. Moreover, searches were also carried out in the grey literature. The search was not limited to the English language. Additionally, Auto Alert was set up in most databases which enabled the inclusion of more studies that were published after the search was conducted. Two authors were involved in making the decisions for study selection, data extraction and quality assessment to avoid bias and improve reliability.

This review had limitations too. The main weakness is that most included studies were poorly reported, although no study was excluded based on its quality. Problems were also encountered in the selection of studies for inclusion due to the insufficient reporting of study details. As a result, eligible studies might have been missed. In the study protocol, a thematic synthesis approach was planned. However, the qualitative research literature was too heterogeneous to permit identifying any consistent themes. Therefore, it was necessary to change the method of synthesis to fit with the nature of the available evidence.

6.2.5 Implications of the review and future research

The findings of the current review provided inadequate evidence about the impact of using apps due to the scarcity of qualitative evidence in relation to apps.

Need for additional research

There is scope for further qualitative research in the area. Little is known with respect to app use in clinical practice. In particular, researchers need to consider HCPs' acceptance of apps and whether they are interested in interacting with their patients by use of apps, as this would involve change in their workflow, specifically, regarding time and resources. There is a demand to identify HCPs' needs and requirements for apps' use, tasks that would be best served by apps, and any potential obstacles to integrating apps into diabetes care. Future research should also consider the

perspectives and preferences of women with GDM. The different social groups, young people, adults and elderly, have different perceptions and preferences of apps. Most patients with chronic conditions today are older people. They require an app design that is compatible with their needs. Therefore, another implication for future research involves discovering whether apps are accessible and acceptable to elderly patients.

Implications for app developers

This review highlighted the needs and preferences of people with diabetes and the highly-appreciated and desired functionalities and features. Also, it provided target users' suggestions for apps' ideas and enhancements to existing apps. Integrating these ideas, features and functions into diabetes apps may increase their acceptance and adoption.

Implications for practice

The lack of valuable qualitative evidence makes the implications for clinical practice difficult to define. Before there is widespread implementation of mobile apps into practice to complement care for people with diabetes, more research on the perspectives and acceptance by both patients and HCPs is needed.

Chapter 7 Diabetes specialist nurses' interview study

Chapter overview

This chapter presents the interview study aim and objectives, research design, setting, ethics and research governance approval, methods (eligibility criteria, sampling/ recruitment of participants, interview process and data analysis approach), results (participant characteristics and key themes) and discussion (comparison with other relevant studies, methodological strengths and weakness and implications).

7.1 Aim and objectives

This chapter addresses the third objective of this thesis, relating to the 'requirements gathering' stage of the applied UCD approach (Chapter 3, section 3.1). The overall aim is to explore DSNs' experiences and views on the use of mobile apps in clinical practice to draw on their clinical experience and vision to help design and develop an app that supports them in managing patients with diabetes.

Specific objectives are to:

- Explore how apps are currently being used among DSNs
- Explore DSNs' perceptions and preferences for mobile clinical support apps with particular attention to decision-support
- Identify potential benefits and barriers of using apps at the point of care
- Investigate current challenges facing DSNs in managing patients with diabetes that might be assisted by the use of apps
- Explore DSNs' willingness to use apps in the clinical setting.

7.2 Research design and setting

This was an exploratory qualitative study using face-to-face semi-structured interviews with DSNs from hospitals and community health centres across West Midlands. Details on the interview method and justification for its selection were provided previously (Chapter 3, section 3.2.2.2).

7.3 Ethics approval

Research ethical approval was granted from the Biomedical and Scientific Research Ethics Committee (BSREC) at the University of Warwick (reference number REGO-2014-786). As this study involved undertaking research on the premises of NHS organisations with NHS staff, it was necessary to obtain Trusts' permission before carrying out any interview. Several NHS Trusts across West Midlands were approached, including: University Hospitals Coventry & Warwickshire NHS Trust, Sandwell & West Birmingham Hospitals NHS Trust, Walsall Healthcare NHS Trust, Shropshire Community Health NHS Trust, The Dudley Group NHS Foundation Trust, Heart of England NHS Foundation Trust and South Warwickshire NHS Foundation Trust. However, most considered this study as service evaluation and therefore did not require any further approval or permission. Only two Trusts classed this study as research and thus applications were submitted and NHS Trusts' permissions were obtained from these Trusts, and letters of access were issued. The ethical approval letter along with the obtained access letters are in Appendix 11.

7.3.1 Ethical considerations

Nurses were fully informed of the study by given the 'participant information leaflet' and the 'participant consent form' (see Appendix 12). Filled consent forms were collected from nurses who agreed to participate at the beginning of each interview. Nurses' contact information was not collected unless they were willing to take part in the second phase of this research. To ensure the confidentiality of participant, each nurse was anonymised. Participants had the right to withdraw from the study freely at any time, however, nobody did.

Collected study information (including recorded interviews and consent forms) was only accessed by the research team. The study information was retained securely by the researcher; electronic copies of the interviews were stored on university-owned computers with access passwords, while paper records of the consent forms were stored in a locked cabinet in the office at the University of Warwick. Data will be

retained for a period of 10 years in line with the University of Warwick's policy on published data.

7.4 Eligibility criteria

To be eligible, DSNs were required to have a minimum of two years' experience of working with people with diabetes. This criterion was indicated in the invitation of potential participants. For practical reasons, only DSNs living in the West Midlands were considered. However, variations in socio-demographic characteristics such as age and gender, and the years of experience were desirable. There were no further restrictions on DSNs' eligibility for participation.

7.5 Sampling and recruitment of participants

Convenience sampling was used in this study: DSNs who work at local NHS facilities were selected because they are accessible. It is the most common method of sampling because it is fast, easy and inexpensive (Green & Thorogood, 2009). Although the use of convenience sample has many disadvantages, such as the lack of transferability of findings to the entire population and the high risk of selection bias (Farrokhi & Mahmoudi-Hamidabad, 2012), yet, it was used for practical reasons.

One main approach was undertaken in recruiting DSNs. Once the NHS Trusts' permissions were obtained, an email was sent by the researcher to the Research & Development Department in each trust asking for a list of emails for all DSNs. Next, invitation emails were sent by the researcher to the provided mailing lists of DSNs with two documents attached: the 'participant information leaflet' and the 'participant consent form' (Appendix 12). Nurses interested in taking part were invited to contact the researcher by using the contact information given at the bottom of the information leaflet or by replying directly to the email. Follow-up emails were sent in some instances when no response was received. Moreover, two diabetes and endocrinology consultants were approached who were able to help circulate the invitation to all DSNs in their department, either via email or via word-of-mouth, to encourage participation.

DSNs who participated in the study were given a £20 Amazon.co.uk voucher as a reimbursement of their time, and were eligible to claim any travel expenses that they incurred through participating in this study.

7.6 Participants

The study was intended to include a variety of HCPs involved in diabetes care. However, due to the limited timeframe of this research, DSNs were chosen as the study population because they have more direct responsibility for diabetes clinical care, education and on-going support. Their role involves working closely with patients and their families and spending more time caring for them.

A sample size estimate of ten DSNs was provided on the ethical approval application with intention to continue sampling until saturation point. Data saturation occurs when additional interviews do not add 'new' insights or themes relating to the study objectives (Green & Thorogood, 2009; Strauss & Corbin, 1990). According to Bowen (2008) (Bowen, 2008):

"Saturation is reached when the researcher gathers data to the point of diminishing returns, when nothing new is being added."

Saturation was reached in the study within all interview questions after 15 interviews and, thus, the recruitment was discontinued.

7.7 Interview process

Once eligibility of a potential participant was confirmed, an interview was scheduled at a convenient date/time and location. Interviews lasted an average of 24 minutes (range 15–33 minutes). Fourteen interviews took place in a meeting room/office at the hospital or practice where the nurses work. One nurse was interviewed in her home. All interviews were recorded using a digital recorder. Participants were informed and consented to be recorded.

A semi-structured, but flexible, discussion guide was used in all interviews (Appendix 12). The interview topic guide was prepared with six open-ended questions concerning

the use of mobile clinical support apps that assist nurses in managing aspects of diabetes, with particular attention to decision-support apps. Open questions were supported with a number of possible probes that could be explored further. At the beginning of each interview, a brief description of mobile apps and the concept of decision-support, along with some examples, were provided. Then, some demographic questions, such as age and gender, along with other relevant questions (e.g., medical profession, level of clinical experience in years, and smartphone/tablet ownership), were included. Questions related to previous experience of using mobile apps, perceived value and subjective norms, benefits and barriers of using apps, challenges in clinical diabetes management that might be supported by the use of apps, and intention to use apps at the point of care. At the end, the interview concludes with one generic question; 'is there anything else you would like to add before we end?' as a prompt for further ideas related to the topic.

7.8 Qualitative data analysis

The analysis of interview data began during the data collection phase, to inform ongoing interviews and to help in determining when the saturation point was reached. Interview recordings were transcribed verbatim by the researcher. Computer-assisted qualitative data analysis software NVivo (QSR International, 2012) was used to assist in the analysis process.

Thematic analysis is the most common approach for analysing qualitative research in healthcare (Pope & Mays, 2006), and was used. The process of data analysis was iterative, involving several cycles. The first cycle involved reading and re-reading all the transcripts for the purpose of familiarisation with the data. The next cycle involved coding and re-coding data items for emerging patterns. Coding methods applied in the analysis process followed the guidance provided in the coding manual for qualitative research (Saldaña, 2013). Once the coding scheme was produced, codes were then grouped, linked and sorted under categories or themes. Next, an initial set of recurring themes were identified, and repeatedly refined. Completion of further interviews led to a confirmation or adjustment to these themes. Data were mostly approached inductively; that is, themes emerged gradually from the data, and less often

deductively, where themes were anticipated or predetermined. As this was an exploratory study, the analysis proceeded by simply reporting and describing themes, with attempt to examine how the themes may be related by mapping them into a diagram to facilitate interpretation. In attempt to minimise bias in the interpretation of the data, Dr Antje Lindenmeyer (University of Birmingham), who is an experienced qualitative researcher, was consulted on the conduct and analysis of this research. The codes and themes were checked by her and discussed until consensus was achieved.

7.9 Results

7.9.1 Participant characteristics

Fifteen DSNs were interviewed from four hospitals and two community health centres across West Midlands. All were female; 11 were aged 40-60 three aged 30-39 and one aged 20-29 years. Two were paediatric DSNs, one was diabetes service lead and the remaining 12 were DSNs. Most participants (n=9) were working in both the community and hospital settings, whilst four were hospital-based and two community-based only. The period of clinical experience ranged between 2 and 18 years of working with diabetes patients. Eleven were nurse prescribers; that is qualified to prescribe medicines for patients with diabetes, and four were not (see Table 7.1).

Device ownership

Nearly all nurses (n=14) own a personal smartphone (Apple iPhone=11; Samsung=2; Blackberry=1), and all had a personal tablet (Apple iPad=12; Samsung=2; Kindle HD=1). However, NHS Trusts did not all provide their nurses with smart devices. Five nurses were only provided with basic mobile phone, one was not provided with any device, while the remaining nine nurses were provided with at least one smart device or both (Table 7.1).

Table 7.1 Characteristics of participants (N=15).

Factor	N
Gender	
Male	0
Female	15
Age group (years)	
Range	29–57

Factor	N
Mean	44.8
20–29	1
30–39	3
40–49	6
50–59	5
Work experiences with diabetes (years)	
Range	2–18
Mean	9.5
2–5	4
6–10	5
11–15	5
16–18	1
Profession	
Paediatric DSN	2
DSN	12
Diabetes service lead	1
Work setting	
Community-based	2
Hospital-based	4
Both	9
Prescribing qualification	
Nurse prescriber	11
Not qualified	4
Device ownership	
Smartphone	14
Tablet	15
Trust devices	
Provided with basic mobile phone only	5
Provided with smartphone only	3
Provided with tablet only	3
Provided with smartphone and tablet	3
Not provided with any	1

The following sections present the themes arising under the four main areas that addressed the objectives of this study:

- Experience of using apps
- Perceptions and views towards using apps in clinical setting
- Difficulties that might be supported by the use of apps
- Willingness to use apps at the point of care (Figure 7.1).

7.9.2 Experience of using apps

Nearly all nurses had prior experience in using mobile apps but only for personal purposes such as news, weather, games, travel and shopping. This indicates that nurses are experienced in using apps, For example:

'I use quite a lot of apps for personal purposes…' (Nurse 1)

'I do use apps, mobile applications on my phone for personal use.' (Nurse 7)

On the contrary, nurses had limited experience in using apps for clinical purposes, although this experience was recent, they generally were satisfied with their use.

'I am very much a novice, so in terms of my work life, I don't use them at all, except for the BNF app on my own private iPhone.' (Nurse 8)

'Um at work I have had experience with using apps for diabetic ketoacidosis in the wards, and also for patient information in respects to diet… um very limited in terms of what I have used within the workplace.' (Nurse 15)

DSNs who were provided with the smart devices by their trust reported that apps were not utilised on these devices at all. Provided iPads were exclusively used for accessing the hospital local system for referrals and retrieving/documenting patient information.

'I have an iPad but we haven't downloaded any app.' (Nurse 5)

'…now with the iPhones when we're in hospital, we can access patient information, some patient information systems, so you got that for the iPhone, you got it for the iPad. It is certainly easier to view on the iPad. We can look at patient's blood test results, we can look at the observations, they are on the ward, so I can sit here, log in and look at my patient's blood glucose levels that have been measured in the ward.' (Nurse 14)

By contrast, provided smartphones were mainly used for the purpose of communication with their patients using phone calls, texts or emails, in addition to the facility to access the local system. They were very satisfied with their use and reported that providing them with the smartphones enabled them to access the Internet and app stores when patients ask about some apps.

'I use the smartphones and tablet is mostly to communicate with patients usually through emails, texts or phoning them that's what I use that for. Mostly it's with emails and text when I'm on the go. Just for communication, it's not for apps or anything like that I don't use that at the moment… For me personally it's made a difference having the smartphone and the tablet mainly easy communication with both patients, their carers and other healthcare professionals.' (Nurse 12)

Generally speaking, nurses had experience with using apps for personal purposes but lack the experience in using apps for clinical practice. Consequently, three main themes were arising here: the lack of experience in using clinical support apps, the lack

of knowledge and awareness of available apps that support HCPs and the tendency towards recommending apps for patients.

7.9.2.1 Lack of experience in using clinical support apps

Most nurses reported no experience at all in using work-related apps.

> *'…we just have no experience with them at the moment… I haven't had any experience using apps at all for work.'* (Nurse 2)

> *'Um but nothing for work to be honest. Personal really.'* (Nurse 4)

This lack of experience among DSNs was due to several reasons that were identified from the discussions. Lack of resources, e.g. smart devices or WiFi, was the most frequently stated reason, specifically by those nurses who were not provided with the devices by their trust.

> *'…unfortunately, in the clinical setting because the trust doesn't supply smartphones with apps, obviously we don't use them.'* (Nurse 1)

> *'I haven't got access to them.'* (Nurse 5)

Moreover, nurses were not willing to use their personal devices for work-related tasks.

> *'Clinical, we don't use mobile apps. I don't have a smartphone for work…. Because it's personal. I wouldn't pay and charge myself.'* (Nurse 2)

> *'Oh, never use my personal ones for work, no. No, there's boundary's.'* (Nurse 14)

Some nurses described themselves as not being technology-minded and this was attributed either to their older age or to the lack of interest and knowledge in using technology. They further pointed out that nurses are experienced clinically, but may not be experienced in technology.

> *'Probably I'm just old school and we just know what we know really…'* (Nurse 4, 40-49)

> *'I don't, I'm not, to be fair, I'm not of a generation where I'm used to using loads of apps and loads of technology.'* (Nurse 5, 40-49)

> *'None at the moment. We use no mobile applications because I can't figure them out.'* (Nurse 12, 40-49)

> *'…when I was at school they didn't; we didn't do computers. So it's like a self-learning thing with the apps and the mobile phones.'* (Nurse 13, 50-59)

In the same context, the next theme is the lack of knowledge and awareness of available apps that support HCPs.

7.9.2.2 Lack of knowledge and awareness of available apps that support HCPs

Most nurses were only aware of apps that support patients in self-care and monitoring of their diabetes. Most nurses lack knowledge about available apps in the market that may support them in clinical work.

> *'I don't know if there's any app out there to use them.'* (Nurse 3, 50-59)

> *'I wasn't aware that there were this sort of thing, and then when you mentioned about wanting to meet to discuss today, I just thought, oh ok, so I had a little look... I know that there are lots of patient ones, I wasn't aware that there were more out there for professionals… But I did have a little bit of a search to see, and I did come across some other ones, which I felt um I found quite useful, actually.'* (Nurse 7, 30-39)

Few nurses were unable to envisage how an app could fit around their work or what it is capable of.

> *'I don't really know how my work would fit around an app… I just don't know what there is in an app that I'm going to use in clinic.'* (Nurse 5, 40-49)

> *'…I don't really know what they are capable of, um so I think it would be just, for me, a greater awareness really.'* (Nurse 8, 50-59)

As a result, nurses suggested that there is a need to advertise the existing clinical support apps and raise HCPs' awareness and encourage their use.

> *'I think having an awareness of it to advertise it that would be needed to be done.'* (Nurse 3)

> *'Just sort of um raise the fact that or advertise the right word, or put it out there that these are available.'* (Nurse 12)

7.9.2.3 Tendency towards recommending apps for patients

Most nurses tend to recommend the use of trusted apps to their patients. The commonly recommended app was the Carbs & Cals, which supports in carbohydrate counting. Other apps included Fitness Pal and Health Fabric; both for tracking exercise, and Dafne which is a patient education program for T1D. In return, nurses would

expect some feedback around the app from their patients so they could pass the information to other patients.

> *'I do direct patients to use apps themselves.'* (Nurse 1)

> *'We recommend Carbs & Cals to our Type 1 for carbohydrate counting.'* (Nurse 4)

Other nurses exercised extreme caution in recommending any app unless it was certified by recognised body such as Diabetes UK.

> *'I am quite cautious about recommending apps for patients...'* (Nurse 8)

Nurses also noted that some patients, specifically the younger population, were asking for apps to use in supporting self-management.

> *'It's something that the teenagers always ask us, you know, if there are any apps that can help them.'* (Nurse 2)

7.9.3 Perceptions and views towards using apps in clinical setting

There were mixed views towards the use of apps in clinical practice. For instance, time was perceived as a benefit in some cases, by helping clinicians to save time, and a barrier in other situations mostly due to the limited consultation's time. However, in general, DSNs believed that the benefits of having a good app may outweigh its hindering.

> *'That would be both, a bit of both really. More beneficial. But it's again, if I'm somewhere on a ward and I'm struggling to get a signal, that's a hinder a limitation...'* (Nurse 4)

> *'…so it's mixed, but overall, I would say, it's far more powerful to have an effective app working for you.'* (Nurse 6)

Three subthemes derived under the perceptions and views of DSNs: perceived benefits, perceived barriers/limitations and perceived concerns of using apps in clinical setting.

7.9.3.1 Perceived benefits of using apps

Nurses have clear ideas about several potential benefits of using apps in clinical practice. The commonly reported benefit was the convenience and accessibility of

apps due to the mobility of these devices, in particular for nurses working in the community since part of their work involves going to patients' homes and schools. So they can access them wherever they are and all times; they would not be dependent on a computer or a workstation. It could also save them from carrying around loads of papers or materials.

> *'…it just makes things really accessible to you quickly… We work in the community as well so; my job takes me to schools and home visits and things. So, obviously when I'm out in the community, I don't have my computer with me so, I don't have access to that.'* (Nurse 2)

> *'Mobile apps, access to them at all times morning, noon, and night...'* (Nurse 3)

> *'I have always got my phone in my pocket, I don't have to carry around bits of paper… It is more of a convenience than anything.'* (Nurse 9)

In particular, nurses value the potential of apps to save them some time in many different ways, instead of wasting time in seeking assistance or retrieving information.

> *'It's quick, it's accessible immediately, you know, because we are not always hospital-based, that would be a huge benefit… So, it would be a bit of a time-saver for us as well maybe.'* (Nurse 2)

> *'I think it can potentially speed up the consultation processes of patients.'* (Nurse 9)

> *'It does definitely saves time… If you can access information there at your fingertips...'* (Nurse 14)

One nurse pointed out to one advantage of using apps over other written materials; that is the ability to update its content easily.

> *'I think when it comes to the app they probably would be updated a bit more quicker than say anything that's written down in paper… So that would be another advantage with the app...'* (Nurse 12)

More generally, nurses foresee a potential for apps to help improve patients care; particularly to help HCPs in providing standardised care to all patients.

> *'…you'd all be giving the same information… you're all going to be giving the same advice and so yeah, quality of care, consistent advice as well.'* (Nurse 2)

> *'So from that point of view, again I guess it standardises care...'* (Nurse 11)

7.9.3.2 Perceived barriers/limitations to the use of apps

Lack of resources, including the smart devices, funding and Internet access, was further reported as a barrier that needs to overcome in order for nurses to be able to use apps.

> *'Out in the community, if you couldn't access the app, if you didn't have Internet, that would be a bit of a downfall.'* (Nurse 2)

> *'We need to have the equipment. You know, I'm not using my own mobile phone to download apps for work. You know, I'd want a separate device specifically for work.'* (Nurse 5)

Other limiting factor stem from the fact that nurses had experienced technical issues related to WiFi connection, network coverage and poor signal in the hospital.

> *'Sometimes it's hard to get a signal on some of the areas because there's blind spots.'* (Nurse 4)

> *'Um getting a good signal… there's one of the wards where the Wi-Fi pick up isn't so good.'* (Nurse 14)

The cost of the app itself could be a hurdle as one nurse noted:

> *'And if there's a cost implication. Because if it's freeware obviously it's okay, but if they have to pay for it. That might be a bit of a turning off point.'* (Nurse 12)

The busy schedule for nurses and their limited time in clinic setting may introduce time as a barrier rather than a benefit, as exemplified by the following comments from one nurse:

> *'I suppose haven't got the time in my consultations to spend looking at the app.'* (Nurse 8)

Interest in technology and the ability or intellect to use technology, especially with older people, were reported as possible barriers to the use of apps.

> *'Um some of the older consultants might not even want to use it. You can't have that happening.'* (Nurse 1)

> *'Um I mean there's always resistance to technology with a cohort of people.'* (Nurse 11)

Related to that is the small screen size of some devices made it inappropriate to be used by people with visual impairment, as another nurse stated that:

> *'It's the screen size with me really, cause my eyesight.'* (Nurse 13)

However, some reported no barriers at the present time to their use in clinical practice.

> *'I don't think there will be barriers now. I notice there is quite a lot of hand held devices, certainly in this Trust.'* (Nurse 15)

7.9.3.3 Perceived concerns of using apps

Confidentiality and information governance were on top of the list of concerns, in particular, around apps that involve storing or accessing patients' data.

> *'I would be concerned about accessing patient records, because of the confidentiality… if you put patient's information on there, it would be, that would be the main concern, because you are out and about with it.'* (Nurse 14)

Nurses were keen to ensure, before using or recommending any app, that it came from a reliable source, and that it was validated and safe to use. They emphasised that despite the availability of loads of apps to download from app stores, they would never use any random app unless it was endorsed by a recognised agency.

> *'I'd like to see if it was approved by somebody within the medical profession...'* (Nurse 12)

> *'You want to know that it's come from a neutral source and it's not linked in with any pharmaceutical companies and buyers…'* (Nurse 13)

> *'Very important that you want to know, that it was trustee… I suppose you would want to have some sort of approval, that you know, it is approved by the NHS, if you know what I mean. You would want to know that it is reliable.'* (Nurse 15)

IT is always a potential source of concern; therefore, some nurses expressed their concern in placing too much trust in technology. They indicated that they should not count on apps to work correctly all the time as they may fail to work or crash and stored data might be lost.

> *'If the app crashed or maybe it failed for whatever reason… that would be a bit of a negative.'* (Nurse 2)

'…when you rely on systems, you rely on the fact that they are going to work and everything is going to be running right at the time for you that you needed.' (Nurse 15)

With regard to patients' perception, nurses expressed some feelings that using the mobile devices in clinical setting may not be socially acceptable. Patients may not be aware that they were used for work-related tasks.

'I hope people don't think I'm sitting playing on my phone, because I'm actually not. So maybe it's not quite, so socially acceptable to just whip out your phone and start fiddling about, maybe people don't understand that you're actually using it for professional use, not playing on your phone.' (Nurse 7)

Another nurse pointed out to the importance of having eye contact with patients, and how the use of apps during the consultation may break this communication.

'I hate it when people are looking at screens and not making eye contact and listening. Um in most the communication is non-verbal and you pick so much up, if one tapping on an app, or even on a tablet, you know into a consultation, I am breaking that, I'm putting barriers up to them sort of communicating with me. I tend to do most of my inputting after the consultation.' (Nurse 8)

Safety of the equipment was brought up as another concern. Smartphones and tables are small, portable and expensive devices, as a result, there is high potential to be lost, broken or even stolen.

'There maybe some places where you don't want to be taking out things, expensive piece of equipment. It might not be a safe area.' (Nurse 14)

'… that it doesn't get stolen and then it doesn't get broken and things like that. So there is also issues with regard to the mobile as well.' (Nurse 15)

Nurses worry about the possibility that some apps may have an out-dated content. They demanded that clinical support apps should be updated regularly to correspond with the latest evidence-based clinical guidelines.

'…who would be responsible for keeping the apps updated. Um making sure that the information that we had access to on the app was current and you know, wasn't out of date… because it's you know, guidelines and things that's constantly changing.' (Nurse 2)

Another concern among nurses was that they may become very much reliant on technology on daily basis and thus, they may lose their clinical skills and judgements.

'My worry would be maybe people would get a little bit deskilled in making that decision process for themselves, relying on an app... I think it's important that we still keep up our skills in being able to make decisions as professionals ourselves.' (Nurse 2)

'It's an obvious concern isn't it, that people rely so much on technology, that they lose the common sense to make a decision.' (Nurse 5)

One nurse, who described apps as self-learning tools, stated that she would be concerned about the potential of misunderstanding or misinterpreting the given advice or recommendation and acting upon them.

'There would be a slight concern because we all when we're self-learning, can misunderstand and misinterpret things, sometimes incorrectly... It says do this, or they've read it wrong, or they've done it wrong.' (Nurse 3)

7.9.4 Difficulties in diabetes management that might be supported by the use of apps

Clinical challenges facing DSNs were discussed in the context of those that might be assisted by the use of apps. Nurses expressed positive views towards the potential of apps to help overcome several difficulties, and they proposed a number of app's ideas. As the focus of this study was mainly around decision-support, challenges and suggestions were specifically considered in this context. Nurses admitted that clinicians are extremely busy and certainly do not have the time to read lengthy guidelines and thus, they welcomed the idea of decision-support app which they described as an abbreviated and interactive version of the clinical guidelines. They considered such apps to be a promising alternative to help HCPs in making a proper clinical decision and improve patient's safety by promoting the correct procedures and protocols that need to be followed.

'People haven't got time these days to sit down and read guidelines… at the moment, people don't even look at the guidelines that are already written to follow instructions.' (Nurse 5)

'I think it would maybe reduce drug errors. It would probably, possibly reduce length of stay, or any complications that diabetes can bring in hospital...' (Nurse 7)

'Um I guess there is a place for sort of care pathways and decision-making and so on.' (Nurse 11)

Most nurses were prescribers, and they use the British National Formulary (BNF) to look up drug prescriptions and support decisions regarding treatment compatibility.

> *'Because at the moment when I'm looking up prescribing medication, I look in the BNF to see is this medication going to be okay with the other medications...'* (Nurse 11)

Decision-support apps were considered useful in some settings, particularly in hospital wards. They potentially reduce the number of referrals received from all over the hospital, and may help prompt nurses to ask the right questions.

> *'I think that would probably help us, maybe we wouldn't get such irrelevant referrals, if there was actually a mobile app that they could use, that could assist on caring for their patients...'* (Nurse 7)

> *'… it gives help to make your decision quicker, rather than you looking up the information, and it would help also in prodding you to um when asking questions. To ask the right questions in the shortest period of time…'* (Nurse 12)

One of the nurses' biggest challenges is the volume of patients with diabetes versus the small number of DSNs. To overcome this challenge, a major part of DSNs' role is to train others, such as district nurses, in specialist care. Therefore, it was suggested that decision-support apps might be of great help in particular for practice nurses, district nurses, junior doctors, GPs and professionals from other specialties who do not necessarily have specialist diabetes knowledge.

> *'We're a specialist diabetes team so our nurses have got a wealth of experience but obviously you've got other health care professionals who are treating people with diabetes but they aren't themselves are not necessarily specialists in diabetes. So for example, the district nurses. So they've got knowledge of diabetes but not specialist knowledge. So I guess if there was something to help them, not necessarily make the call with regards to prescribing, but perhaps when to refer, whom to refer to. That could be useful.'* (Nurse 11)

> *'I think as well for the practise nurses that are prescribing and doing a lot more diabetes and GPs really it would be useful.'* (Nurse 13)

> *'I think, certainly to help with maybe juniors who are not so familiar with protocols.'* (Nurse 15)

Many nurses expressed their interest in having educational apps, specifically, nurses working in the community as they described their job role as educator. They are educating patients or carers and school staff to help them to understand the condition.

'…because we do go out at home visits and school visits, um we would like to create a kind of e-learning package. And we've put in for funding for an iPad or tablet of some description that we would be able to carry that out with us into the community.' (Nurse 2)

'… um but I think I probably would see myself using it more as an education sort of tool in terms of helping patients to understand their condition rather than a decision-making one for myself.' (Nurse 8)

Nurses highlighted several clinically relevant apps' suggestions that might help such as dose adjustments, insulin titration, medication prescribing including the timing for medication and hypo management.

'…we have another patients at home who have insulin delivered by district nurses. So, at the moment the district nurses have to faxing information to us about blood sugars, insulin if they want us to titrate up the dose. So, if there is an app that the district nurse could access when she is out in the home, that would be a good one.' (Nurse 1)

'I think dose titration information would be really beneficial on the wards, especially for like, junior doctors, or you know, the doctors on the ward as well, because we get a lot of our referrals are for like, simple dose titration of insulin… that could just be done on the ward, without us having to go up and advise. And prescribing information as well. So the timings that the medication should be given, because that's another big issue that we come across on the wards, if medication's being prescribed at the wrong times, it's causing problems with the hypos, etc.' (Nurse 7)

'Dosing maybe, so insulin dosage. So I would use a wide base dose if I was starting somebody on insulin, but if a doctor was prescribing maybe in a GP practise or in a ward or in a nursing home, they might do it slightly differently… and the other thing is converting… Swapping people from say a BD mixture to three times a day or swapping people from a BD to basal bolus.' (Nurse 9)

Nursing home was specifically deemed as a big area for decision-support as they may lack the speciality in diabetes, which is critical in most cases that they deal with.

'…having something that they can regularly use with a very structured app, I think would be very good to have for the nurses in the care homes. They're very good at the nursing care, but the diabetes side, they're much more nervous about. I'm not saying they're not good at it, but they're a lot more anxious about, and knowing the difference from the Type 1 and Type 2 is quite fundamental in in getting the balance right of the insulin…' (Nurse 6)

'…they are complex care patients, and actually they are being cared for by people again who don't necessarily have specialist knowledge of diabetes. So whilst we

go into nursing homes and undertake training for the staff that is a real area which I think could be massively supported by decision-making apps.' (Nurse 11)

Decision-support apps that provide high-level advice on the management of diabetes patients with comorbidities was suggested. For instance, nurses indicated that many of their patients have renal problems, which is challenging to decision-making since new drugs are always coming out, and they need to remember renal cut-off points specific for each drug.

'…we have got quite a large diabetic renal population here. They are quite a challenging group… they need to monitor a lot, so not just blood sugars, but blood pressure and pulses as well.' (Nurse 9)

'With a lot of our patients certainly that we see in our clinics, they have other health problems as well… so apps that may be, could be flexible in terms of not just covering diabetes, but other long-term conditions as well, all built into one… I do diabetic renal clinic, so an app with you know, with hypotensive medications and sort of protocols for diabetic renal disease would be really useful for me to have personally.' (Nurse 15)

The following themes arose among DSNs:

7.9.4.1 Poor understanding of the concept of decision-support tools

Although nurses were given a brief description of decision-support tools with examples at the beginning of each interview, some nurses were still unable to envisage how apps could support their clinical decision-making process. They generally presumed that decision-support apps meant to replace the presence of human being, and that they will make a definite decision to be taken forward. However, clarification was given that these apps will only provide some suggestions based on clinical guidelines, and the clinical judgement of HCPs will still be needed; the app will not eliminate this. At the end, HCPs may agree with the given advice or just discard it, so those apps are only used as a mean of reinforcement.

'Oh do you mean people can't work it out for themselves; is it going to prompt you to make a decision? I don't think so really… Well, nothing can teach you to look after patients, you need that exposure and you need that experience, that clinical experience… And if you're always relying on technology, where's your experience, where's your clinical skill going to go?' (Nurse 5)

'… it is more as an aid isn't it? Rather than telling you what to do… um but I think you've just gotta be careful not to rely on it and not lose your own clinical judgement.' (Nurse 13)

7.9.4.2 Basic requirements for clinical support apps

Most nurses urged for apps that are simple, short and to the point. Clinical support apps need to work across multiple mobile platforms, and not to require WiFi connection in order to suit the setting where nurses work, whether it was in the hospital, which got poor signal reception, or in the community where they had no Internet access. Further, clinical apps need to be approved by, for example, the wider NHS, and their use must be restricted to NHS staff. Nurses prefer a small app that does one specific task rather than having one big and complicated app that does multiple tasks.

'… when it comes to the app rather than having a lot of information on one app it would probably be split into certain sections so you might have an app which tells you section about drugs to use for certain conditions and then another one which tells you about how to treat a hypo and stuff like that. So you don't have a big app which tells you a lot of information. But just small… Quick and easy to get to.' (Nurse 12)

Clinical apps need to be customised locally, e.g. based on local guidelines, rather than having a generic app, which would be less relevant.

'You know, it's no good giving me a generic thing because then it's not going to be locally recognised.' (Nurse 3)

'If it is a clinical app, it has to follow local or national guidelines in respect to the information that it is giving.' (Nurse 15)

And lastly to be visual, interactive and does not require inputting too much details.

'Pictorial, would be better... I'm happy to input information as long as I don't have to write an essay.' (Nurse 5)

7.9.5 Willingness to use apps at the point of care

Overall, nurses expressed strong willingness to use apps in clinical practice. However, willingness was very much dependent on the benefits they get, and the simplicity of the app.

'Yeah, very likely. As long as it was user friendly…' (Nurse 2)

'As long as it's just simple, simple information, I think that people are more likely to use it.' (Nurse 7)

'Um just ease of use bearing in mind the time restrictions.' (Nurse 11)

'Just make it really simple, mobile app for dummies.' (Nurse 14)

Nurses are not willing to embrace change in work routine that requires many efforts, unless it supports their job role, and makes better use of it.

'I guess change is always a little bit difficult to implement in your working routine when you're used to doing things a certain way… I think yeah, absolutely, we would use mobile apps. I think we've got to embrace the change.' (Nurse 2)

'If it's going to do a job and it's helping me do what I need to do, then fair enough.' (Nurse 5)

Willingness and adoption of apps may be impacted by user age. Nurses emphasised that young people are more into technology and very much interested in using apps, while older people are not much interested in technology and may encounter some difficulties in using them.

'It's whether you are of that generation that uses apps and are quite comfortable with using that technology. Quite a lot of older people are experienced clinically but not experienced in this technological age where they have a different way of working.' (Nurse 5)

'I think, you know, in terms of like junior doctors. They are probably really familiar with using lots of apps and they use them all the time, so I think they would be more likely to be using that, but possibly if you were looking at older people who are not familiar with using apps… they might be a bit frightened about the technology or not know how to access things...' (Nurse 15)

When nurses asked whether they would prefer to use apps on a mobile device or on a traditional computer, nurses were generally more likely to use mobile-based apps but that depended on the situation. Nurses working in the community expressed preference for mobile apps due to the nature of their work, whereas nurses based in the hospital explained that when they are in the wards, they will have to keep going back to the office to use their own computer, or they will have to find a computer that is free, but then, getting hold of access to a computer is difficult sometimes within the clinical area.

'Out in the community, definitely mobile… You know 50-60% of our job isn't based in the hospital so that would really, really help us.' (Nurse 2)

'Mobile device definitely… most people have got the phone so the mobile will be better.' (Nurse 12)

'I think certainly within a clinical area, it would better to be mobile, because getting hold of access to PC's is difficult some times, within the clinical area…' (Nurse 15)

7.9.5.1 Mobile apps are the future

Even though nurses indicated that there would be always resistance to technology and/or change with some people, mobile apps were conceived as the future. Nurses agreed that there is a place for apps in their clinical work. Nearly all thought that technology, specifically mobile apps, ought to be the way forward for NHS Trusts. They further believed that it is only a matter of time before mobile apps are integrated into their clinical practice as an essential tool.

'It is abnormal not to use them I would say… that's the way forward… I see that as the future.' (Nurse 1)

'I think yeah, there is definitely a place for it… for us, we see the future is definitely going into mobile because that's where we are a lot of the time…' (Nurse 2)

'I'm sure you know people have to move forward with the technology and that's the way it has to go… Everybody's always walking around like this, although with their phones.' (Nurse 5)

7.9.5.2 Apps are self-explanatory

The majority of nurses reported having self-learning experience with apps. They think that apps do not require any training to use them. Some nurses stated that instructions contained within the app would definitely be sufficient. Others preferred to have someone in the first place to at least run through it, to make sure they will access it correctly and use it in the right way.

'I'm quite fine with using apps… I like to just work things out myself really. You know, when I get a new phone, I'll never read the instruction book, just press all the buttons until I find out how it works, and that's probably a bit how I would.' (Nurse 1)

'Surely apps are pretty self-explanatory.' (Nurse 3)

'Well, I'm not that daft. I can probably manage to download an app and work my way through it.' (Nurse 5)

'I don't think I would need training, no. I don't think most people need training; I think it's quite self-explanatory… I like to try… with new things I am a bit of a trier.' (Nurse 7)

Depending on the complexity of the app, nurses aged 45 and over were more likely to think that they may need training to use it.

'It depends on how complicated it is. Yeah, I probably just need a little bit. But if it's straightforward, that's okay.' (Nurse 4, 40-49)

'Depends on how easy, you know, it would be good to have from the experts, an idea of what was expected of it, and how to deliver it.' (Nurse 6, 50-59)

'Probably. Just to see how it works just at first.' (Nurse 13, 50-59)

7.9.6 One app does not fit all

This theme emerged throughout the interviews but did not fit under any of the four main investigated areas. People have different needs and preferences, range of skills and varying degree of motivation. They will interact and engage with apps in different ways. No one particular app will fit all, as believed by most nurses. Having a good app design would not necessarily make it successful. Two apps might be doing exactly the same function, but only one becomes popular. It was clearly shown in this study that apps should meet DSNs' needs in order to be adopted and used, but their needs and preferences varied according to their role.

'Not every app will fit all, and some will become quite popular.' (Nurse 3)

'I think it's very specific to the person. It's a broad spectrum of skills that people have and use them in in very different ways… which part of the app they may use. Some of them use all the functions; some may use just a specific part of it. But only if it's working for them.' (Nurse 6)

'It's not for everybody. You've got to choose the right person that, it's the same with anything isn't it, with a treatment, the way you deliver it. That's just easy, yeah.' (Nurse 10)

7.10 Discussion

7.10.1 Summary of main findings

This interview study addressed how mobile apps can support DSNs in clinical practice, and intended to provide end-user needs and requirements, which were essential for the design and development of the app described in the next chapter. The interviews with nurses identified varying themes related to four main areas; prior experience, perceptions and views, challenges in diabetes management and willingness to use apps.

There were three key themes relating to the nurses prior experience of using apps; lack of experience in using apps, lack of knowledge and awareness of available clinical support apps, and the tendency towards recommending apps for patients. Nearly all nurses own personal smartphones and tablets, and some were provided with smart devices by their trusts. Nurses had prior experience in using apps for personal but not clinical purposes. There were no differences in the level of experience of using clinical support apps between nurses who were or were not provided with the devices by their trusts. Lack of experience was attributed to reasons including lack of resources, not being technology-minded or that apps did not meet their needs. Most nurses were only aware of the available apps that support patients in self-management, and some were not able to see how an app might fit within their work. Consequently, they suggested that there is a need to raise nurses' awareness of the available clinical apps. On the other hand, some nurses tended to recommend the use of trusted apps to their patients, whereas others were cautious in doing that.

The current study found that nurses have both positive and negative views around the use of apps in the clinical setting. Positively, nurses perceived many benefits, but most importantly, apps bring convenience, being described as straightforward, accessible, and time-saving. They appreciated the possibility that apps may improve patients' care particularly through standardisation of care. On the negative side, nurses also perceived some barriers and concerns associated with their use. The limitations described were largely caused by the lack of resources and funding, technical issues,

interest in technology and the limited time in the clinic setting. A particular concern was in the form of privacy and confidentiality, but this concern reduced when they realised that most clinical apps do not require any form of patients' identifiable data. Other concerns related to the source of the app, safety of the equipment, trust in technology, patient perception and overreliance on technology.

Nurses thought that apps may offer a solution to some difficulties that they are currently facing in the diabetes management. Two main areas identified where nurses believed that apps would mostly assist in were patient education and decision-support. Nurses suggested that decision-support apps would be of great benefit, in particular for professionals from other specialties and for nursing homes, allowing them to make rapid decisions with reduced errors, reducing the number of referrals and prompting nurses to ask the right questions. The information most demanded was related to dose adjustment, insulin titration and medication prescribing, specifically for patients with comorbidities. There were two key themes relating to this area, poor understanding of the concept of decision-support and basic requirements for clinical support apps.

Most nurses expressed strong willingness to use apps in clinical practice. Two factors were mostly emphasised by nurses that would impact their willingness: simplicity and usefulness of the app. Most nurses agreed that they would be more likely to use apps on mobile devices, particularly when they are in community or when ward computers were being used by other HCPs. There were two themes relating to the area of willingness, mobile apps are the future, and apps are self-explanatory. Nurses believed that it is only a matter of time before mobile apps are embraced and widely utilised in their clinical practice. They further explained that they had self-learning experience with apps and thus, the use of apps does not require any training.

An additional theme emerged but did not fit under any of the four areas; one app does not fit all. It was clearly shown in this study that nurses' needs and preferences varied according to their job role. Nurses considered the one-size-fits-all approach would not work with app design and development.

Themes appear to be interrelated and have overlapping elements. There was interconnection between the lack of experience and the perceived limitations of app use. Lack of resources was reported as a main reason for the lack of experience among nurses and as a major barrier for nurses' use of apps in clinical setting. Lack of knowledge and awareness could be linked with the poor understanding of decision-support; nurses who were mindful of the range of available clinical support apps were more familiar with this concept. Tendency towards recommending apps for patients was found to be associated with perceived concerns; nurses who expressed more concerns were less likely to recommend the use of apps. However, these perceived concerns were not enough to cease their willingness to use apps. Lastly, the perceived benefits of using apps were related to the theme apps are the future. The countless benefits they were anticipating from the use of apps have clearly influenced their willingness to use apps and their perception of apps as the future. All themes emerging in this study and their relationships are demonstrated in Figure 7.1.

In the context of using a new technology such as apps, nurses thought that they would never use their personal devices for work-related tasks. It is not only about the provision of devices; nurses were not willing to use their personal accounts for app stores to download work-related apps and emphasised the need to have a separate work account. It is clear that nurses' work and personal life are kept apart. This strongly emphasise the presence of work-personal life boundaries among nurses. Contrary to findings in the literature (Moyer, 2013), BYOD, short for "bring your own device", was not acceptable among DSNs. Nurses demonstrated that this violates their Trusts' regulations and policies, as they are not allowed to carry or use their own personal devices on the wards, for example, or during patient consultation. Besides, this may possibly violate professionalism. Moreover, nurses expressed a fear of possible disturbance to personal life when using personal devices for work related-purposes. They are not willing to receive calls or messages during non-working hours or holidays. They further explained that they would not use their own devices and charge themselves as long as their Trusts do not offer any compensation or overtime pay.

Overall, mobile apps seem to have a potential to facilitate and support DSNs' work whether in the community or in the hospital.

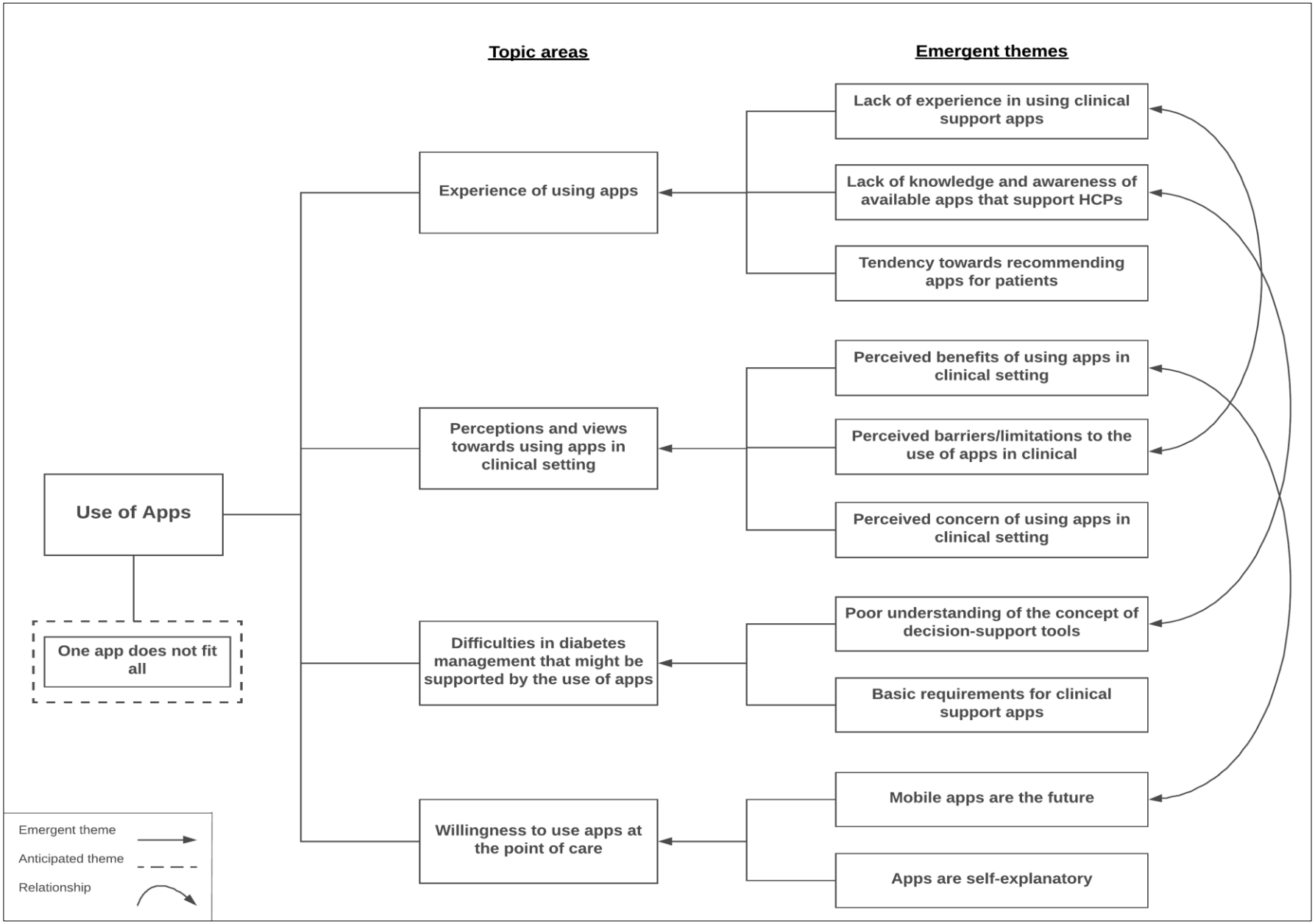


Figure 7.1 Themes identified in the study and their relationships

7.10.2 Comparison with other relevant studies

The qualitative review (Chapter 6) identified that qualitative research on the use of mobile apps among HCPs in clinical practice is limited.

Most studies in the area were experimental, assessing the effectiveness or feasibility of a study-specific app. Other related studies used quantitative instrument for data collection, most commonly a questionnaire. Most of these cross-sectional studies explored the prevalence of mobile devices and/or apps use among HCPs and their views and attitudes towards their use in clinical practice within a wide variety of clinical settings (Jamal *et al.*, 2016; Johansson *et al.*, 2014; Koehler *et al.*, 2013; Liu *et al.*, 2016; Moore & Jayewardene, 2014; Okazaki *et al.*, 2012). Broadly speaking, the findings of the current interview study are not comparable with these studies. This is because they have applied statistical descriptive analysis and did not go beyond this.

No qualitative exploration of HCPs' perceptions or experiences in using clinical support apps have specifically addressed diabetes care and management. One interview study examined the experiences and views of nurses, in an acute care setting, on the use of iPhone to improve communication and decision-making processes at the point of care (Farrell, 2016). Overall there was good coherence with the findings of this study but there were no consistent themes.

None of the previous offer congruence with the aim and objectives of the current study or the findings. Additionally, these studies were in different settings, and their sample consisted of HCPs with diverse specialties, not limited to those specialised in diabetes.

Some elements found in this interview study were identified in previous studies. One of the perceived concerns found in this study was patient perception; this finding was consistent with related previous studies where nurses and other HCPs reported being perceived as unprofessional when using the device with the patient (Farrell, 2016; Johansson *et al.*, 2014; Koehler *et al.*, 2013). In the present study, nurses were not willing to embrace change in work routine that requires much effort. This has been shown in other studies where HCPs were more likely to use mobile devices if it could

fit into their workflow without requiring extra effort (Guo *et al.*, 2015). Similar concerns around privacy and confidentiality during the use of apps have been documented in previous studies (Jamal *et al.*, 2016; Koehler *et al.*, 2013). Results from a number of studies were coherent with this study with respect to the benefits of using mobile devices and/or apps; most HCPs found them to be useful, accessible, time-saving and to improve patient safety and quality of care (Farrell, 2016; Guo *et al.*, 2015; Johansson *et al.*, 2014; Moore & Jayewardene, 2014). Nurses in another study had similar belief that this technology would evolve and be embraced by all nurses in the future (Farrell, 2016). A further study addressed the potential concern related to nurses' overreliance on decision-support apps and not using their critical thinking skills (Sedgwick *et al.*, 2016). Lastly, medical residents in another study reported self-learning experience with mobile devices which is similar to the finding of this study (Jamal *et al.*, 2016).

On the other hand, the theme 'one app does not fit all' identified in this interview study was indicated in a number of patient-directed studies. Two studies (Miele *et al.*, 2015; Nielsen, 2013) pointed to this theme in their findings with regard to apps' features and functions, summarising that patients have different preferences and needs.

7.10.3 Methodological strengths and weaknesses

To the best of the authors' knowledge, this study is the first to thoroughly examine the use of mobile apps by DSNs in clinical settings to support diabetes management, with particular focus on decision-support. This study focused on the qualitative aspect where the nurses' experiences and perspectives on apps use within this environment were explored. The study reached saturation and some of the findings were coherent with the wider literature.

Qualitative data analysis is best carried out at least by two authors separately rather than an individual analyst. However, coding and analyses in the current study were mostly undertaken by the primary researcher and checked by academic supervisors through regular supervisory contact. The codes and themes were discussed until

consensus was achieved, to establish credibility and avoid bias in the interpretation of the data.

The main weakness of this study was its use of convenience sampling which has many limitations. This includes the high potential of selection bias, and the lack of representation of the entire population. Though, it was deemed appropriate for exploratory studies, such as the current study, where little is known about the area of interest (Green & Thorogood, 2009). All participants were females, with four only were aged<39 years. Nonetheless, nursing is a profession that always perceived as a feminine one and thus, it does not have a balanced number of men and women; fewer men enter the profession. There were no male DSNs in all Trusts that were approached.

7.10.4 Implications of study results

This interview study intended to generate preliminary data to inform the next stage of this research; the development of an app, and any subsequent future works in this area.

Need for additional research

The present study contributes to the currently poor understanding of the role of mobile apps and experiences of using them in improving clinical practice among HCPs. The topic area is still under development, and there is a need for further qualitative research with robust design to fully realise the potential benefits of this technology. Future research should focus on both HCPs who specialise in diabetes and others from a wide range of clinical expertise.

Implications for app developers

This study provides a number of suggestions and end-user requirements for app developers interested in developing clinical apps supporting diabetes management. Apps will need to be simple, quick, assist with workflow and help save time compared with other traditional methods of support. In addition, app developers are

recommended to involve HCPs in app design and development in order for the app to meets their needs to increase the likelihood of being utilised.

Implications for policymakers

There is a lack of regulations around the use of *m*Health apps. Policymakers need to regulate the use of apps for clinical practice and establish appropriate standards and policies within healthcare institutions. There is a need for an initiative to review, validate and assess the risk of the available clinical apps, developed by trustworthy and quality-assured companies, and then advertise them and promote their use among HCPs, e.g. establishing a library of approved clinical apps similar to the library launched by the NHS for approved patient-directed apps.

Implications for practice

Nurses are willing to use apps and certain that they will facilitate their work. However, they are very concerned to download and use any random app. They demanded that apps must be approved and recommended by their Trust to be able to use them. Mobile apps can be valuable tools for clinical practice due to their high accessibility. The challenges now lie with leaders and managers in clinical sectors to ensure that approved clinical apps that created by reputable organisations are utilised. It would be wise to arrange workshops or seminars to help disseminate the knowledge and share experiences with apps among clinical teams to promote safe use of them. These findings further suggest that it is feasible to provide nurses with access to decision-support apps to promote best practice and improve quality and safety of patient care. Nevertheless, nurses should be warned of becoming over reliant on such apps and that they never be used as a substitute for clinical judgment.

Chapter 8 Design and development of a mobile-based clinical decision-support app

Chapter overview

This chapter describes the design and development process of the mobile app 'Diabetes & CKD' that supports HCPs in clinical decision-making, including the rationale for the app design; functional, technical and medical requirements; the development process including the decision algorithms; and illustrates the final implemented design of the app with screen shots.

8.1 Design rationale and requirements

As discussed in the methodology chapter (Chapter 3, section 3.1), the UCD approach guided the design and development of the mobile app. This chapter addresses the fourth objective of this thesis, relating to the 'design & development' stage. 'Diabetes & CKD', a simple mobile clinical decision-support app for the management of adult patients (≥18) with T2D and CKD was designed and built for the study. CKD was selected taking into consideration the patterns of comorbidity that are most common in this population (Deshpande *et al.*, 2008). As was pointed out in the introduction to this thesis (Chapter 1, section 1.1.3), multimorbidity significantly increases the use of health services, because people with multimorbidity are more likely to receive duplicated testing, contraindicated prescriptions or conflicting advice (Zulman *et al.*, 2014). Furthermore, as indicated in the findings of the systematic review (Chapter 5, section 5.1.3.5), only two studies were identified that reported development and evaluation of a decision-support app for diabetes management. This app aims to assist HCPs, e.g. diabetes specialist nursing staff, GPs, junior doctors, in decision-making process at the point of care, with key objectives of improving quality of care and safety of patients and better and timely management of diabetes. A more complex version of the app, incorporating all the common comorbidities of diabetes, is planned to be developed and tested in the future.

8.1.1 Source of requirements

At the stage of 'requirements gathering', qualitative research was carried out to get insight into end-users needs and requirements. Interviews conducted with DSNs (Chapter 7) provided the main source of requirements. Identifying challenges that DSNs face helped to guide the development of the app. From the nurses' feedback, it was found that they were interested in tools that support them in decision-making. Other requirements were gathered from the literature and from feedback and suggestions of two diabetes and endocrinology consultants.

8.1.2 Functional requirements

It is a single function app and hence, there is only one key requirement. The app needed to allow the user to enter patient's parameters and convert them into recommendations. In other words, the app generates patient-specific advice to help clinicians in making informed decisions.

8.1.3 Technical requirements

The main non-functional requirements are as follows:

- The app needed to work across all mobile platforms and with all smartphones and tablets running on all operating systems
- The app needed to be downloadable on devices
- The app needed to support offline mode; i.e. it does not require the use of WiFi or network connection, to suit the hospital environment in which some of the end-users are working which often have poor network coverage
- The app may run within any evergreen browser; i.e. modern browser. This includes Google Chrome, Mozilla Firefox, Apple Safari and Microsoft Internet Explorer. However, no app feature is expected to make the app unusable in older versions of these browsers
- No patient's identifiable data are needed in the app
- No user account or login data are needed to use the app
- The number of data entries into the app kept to the minimum, including only

the data elements that impact on the management plan

- Inputted data stored temporarily on the device's memory and then wiped at the end of a session or upon reloading or exiting the app; they are not kept for future sessions. The server simply delivers the files necessary to run the app.

8.1.4 Medical requirements

The app needed to incorporate clinical management guidelines followed in the UK and best practices based on clinical guidelines, and to be updated regularly to reflect any update on the guidelines. The content of the app further needed to be verified by a number of diabetes and endocrinology consultants in order to ensure the accuracy of the given advice.

8.2 Design considerations

Two main factors informed the design of the app: first the needs identified from the interviews carried out with DSNs (Chapter 7) and second the management pathways presented in the next section. An iterative process of app design based on the specified user's needs and requirements was undertaken. Several UCD development cycles are required, however, only the first iteration of an ongoing app design and development process was carried out. Further iterations of app design and development are planned in the near future. At this stage, the app was built for research purposes only, and was not released, as it requires obtaining a number of approvals before it becomes available for clinical use. An extended version of the app is also planned to be developed and evaluated in the future.

8.3 Development process

The app was built by a software developer (Medic Genie; https://medicgenie.com) - funded by the student's scholarship - using an iterative development approach that involved frequent testing and modification by the developer. This process also involved consultation of a junior doctor to provide well-defined guidance and final verification of the management pathways' correctness. Development process included two parts; design and coding part, and both parts were done by programming visually.

8.3.1 Prototype development

Preliminary app sketches were drawn using pen and paper and given to the developer. The logical flow of the interface was designed in the following sequence:

1. Collection of basic demographic and clinical parameters of patient;
2. Summary of patient details;
3. Treatment plan prompt.

8.3.2 Management pathways (decision algorithms)

The development of the app involved generating the management pathways using the National Institute for Health and Care Excellence (NICE) most recent guidelines on diabetes, CKD, and hypertension. This included developing algorithms for glycaemic control, management of hypertension, dose adjustments recommendations in CKD and monitoring and referral. Two diabetes and endocrinology consultants advised the selection of the NICE guidelines and technology appraisals. Text analysis of these guidelines was undertaken. Then, they were cross-referenced to bring together relevant recommendations for the multiple conditions and identify all relative synergies, cautions, and contradictions based on a few demographic and clinical details relevant to the patient. In addition, the clinical expertise of the consultants involved in this work, in areas where no or limited guidance has been found, was taken into account.

8.3.2.1 Guidelines used in the development of the management pathways

- NICE guidelines [NG28] Type 2 diabetes in adults: management, December 2015 (National Institute for Health and Clinical Excellence, 2015a)
- NICE guidelines [CG182] Chronic kidney disease in adults: assessment and management, July 2014 (National Institute for Health and Clinical Excellence, 2014c)
- NICE guidelines [CG127] Hypertension in adults: diagnosis and management, August 2011 (National Institute for Health and Clinical Excellence, 2011)
- NICE guidelines [CG181] Cardiovascular disease: risk assessment and reduction,

including lipid modification, July 2014 (National Institute for Health and Clinical Excellence, 2014b)

- NICE technology appraisal guidance [TA288] Dapagliflozin in combination therapy for treating type 2 diabetes, June 2013 (National Institute for Health and Clinical Excellence, 2013)
- NICE technology appraisal guidance [TA315] Canagliflozin in combination therapy for treating type 2 diabetes, June 2014 (National Institute for Health and Clinical Excellence, 2014a)
- NICE technology appraisal guidance [TA336] Empagliflozin in combination therapy for treating type 2 diabetes, March 2015 (National Institute for Health and Clinical Excellence, 2015b)
- Clinical Practice Guideline on management of patients with diabetes and chronic kidney disease stage 3b or higher (eGFR <45 mL/min) (Guideline Development Group, 2015).

The developed decision algorithms along with the table of dose adjustments in CKD are in Appendix 13.

8.3.3 Implementation

The app was built during the fall and early winter of 2016. The approached developer converted the algorithms into a simple decision-support app named as 'Diabetes & CKD'. The initial version of the prototype, which had few elements for data entries, was tested by the developers for errors in the developed software codes and logic. The tested beta version software was further tested by two clinicians for the accuracy of the generated treatment plan, using a possible number of case scenarios. Once the app was finalised, a few individuals, not those included in the trial, tested it and comments received were used to make further amendments to the app.

Of particular interest during the development stage was that the developer's work was stored in a web server and thus, the work was accessible through the web browser regardless of location. The app was hosted by Medic Genie where the files stored on a

secure web server, but was by intention publicly accessible. No restricted access was required at this stage as it was built for research purpose only.

The developer followed a process with various steps within the app development:

- Familiarising with medical requirements
- Investigating possible app structures that best meet the given pathways
- Collection and translation of data (used as secondary input; to be combined with user input and transformed into expected outputs)
- Automated tests to verify algorithmic correctness
- User Interface (UI) design and User Experience (UX) considerations
- Compilation, of the above, into a functional web app.

8.3.3.1 Programming language

There are various tools that can be used to develop a mobile app. Some mobile development tools are platform-specific, whereas others are cross-platforms. For purpose of deploying the app across multiple platforms, it was implemented using client-side web technologies; i.e. HyperText Markup Language (HTML), Cascading Style Sheets (CSS) and JavaScript.

The algorithms were converted into the app logic most often using IF-THEN statements. This approach is not recommended for developing guideline-based decision-support tools, however, it was used due to the developer's lack of skills and experience in other approaches and the limited time and resources of this research. An alternative method for developing computer-interpretable guideline is the knowledge-based approaches, such as PRO*forma*, PRODIGY, Prestige, etc., where the guidelines are coded as a set of rules. The use of such an approach will facilitate the validation process of the implemented guideline and speed up its update since clinical guidelines are continually updated.

8.4 Final implemented design

With the software developer, the app interface and layout were discussed and agreed. It was decided to be straightforward with an easy-to-follow look. The app was

implemented using a standard template with a plain white background and a header and navigation along the top of the screen and contained the app name on all pages. When possible, dropdown menus, predefined lists or checkboxes were considered in attempt to reduce the amount of typing required for data input. Error check for numerical variables was applied to ensure that the inputted value was in range. However, some features were not feasible to implement at this stage, such as integrating the app with electronic patient records, as this requires a significant time for development and involves complex technical and organisational solutions that were not practical to carry out in the timeframe for this thesis. When the final prototype design was implemented, the developer delivered compiled, bundled and minified files necessary to run the app. In addition, the source code was delivered to allow for future development.

As indicated above, the key functionality of the app is to work out a personalised treatment plan based on patient's parameters. Based on this, the app consisted of a number of integrated dynamic screens. They were classified into the following three main types of screens:

Home screen

Whenever the app launched or reloaded, it opens to the home screen. This page acts as a dashboard where the user can select one of the two management pathways: glycaemic control or BP management. The home screen is shown in Figure 8.1.

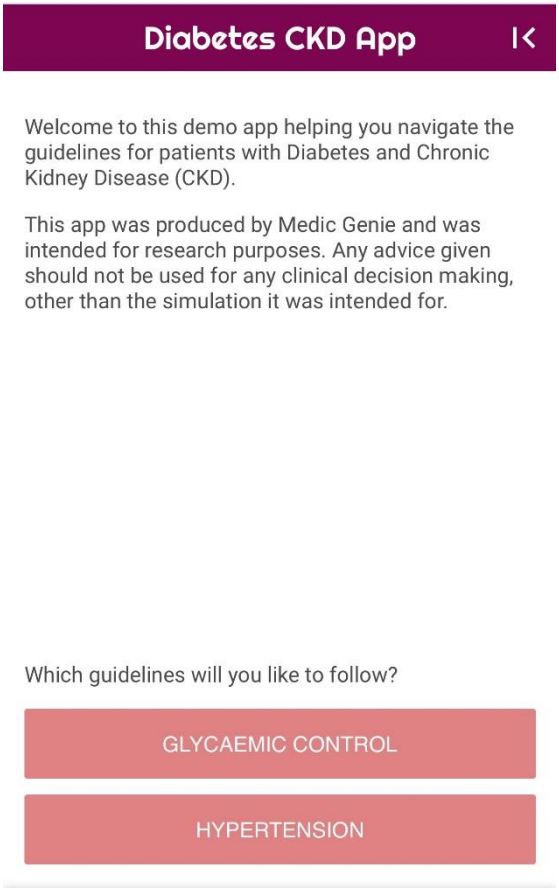


Figure 8.1 'Diabetes & CKD' home screen.

Data entry screens

Once a pathway was selected, and for the sake of simplicity, the user asked to enter one parameter at a time in individual screen, and click the Next button in order to move to the following data entry screen, answer a few related questions and follow on-screen instruction. Examples of screens that were implemented for data entry are demonstrated in Figure 8.2.

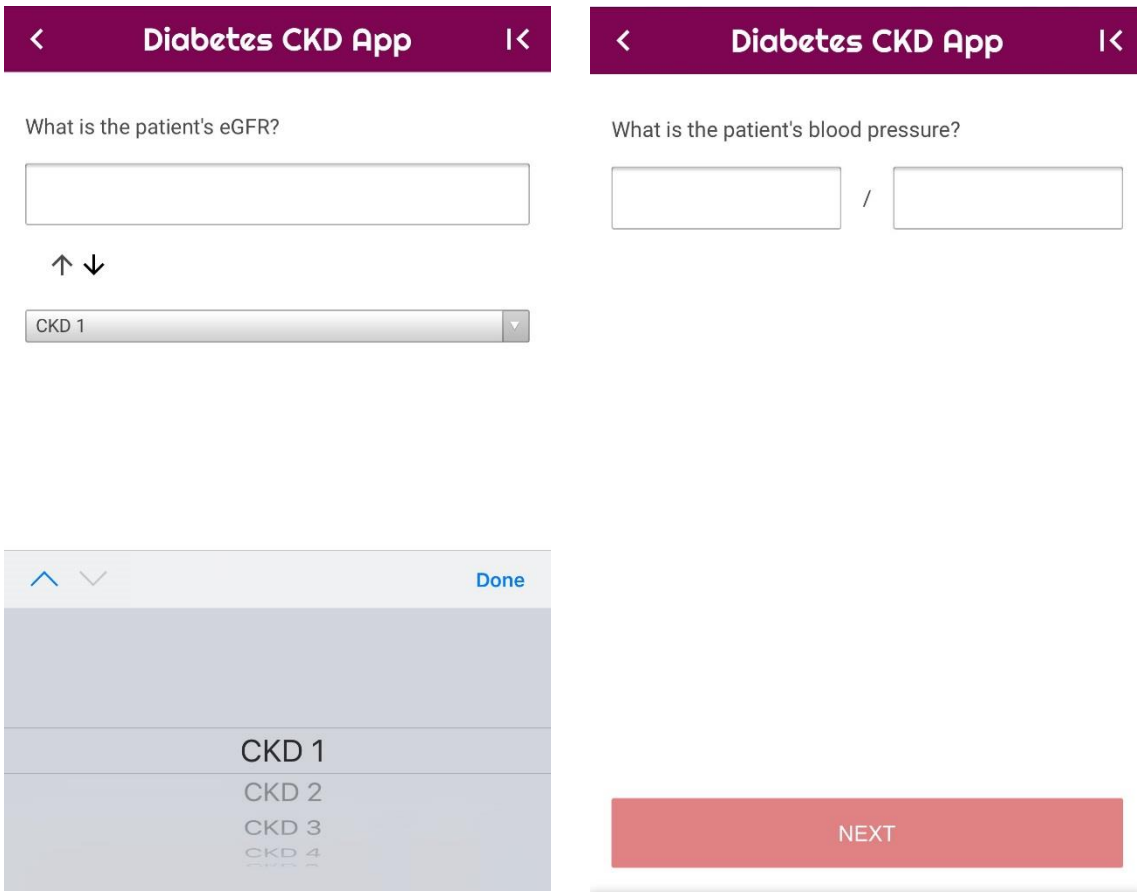


Figure 8.2 Examples of data entry screens.

Recommendation screens

When data entries have been completed, treatment recommendation is given, with attached link for referral and monitoring advices. Drug names were clickable for further details including the recommended dose or adjusted dose. Samples of the recommendation screens are illustrated in Figures 8.3 and 8.4.

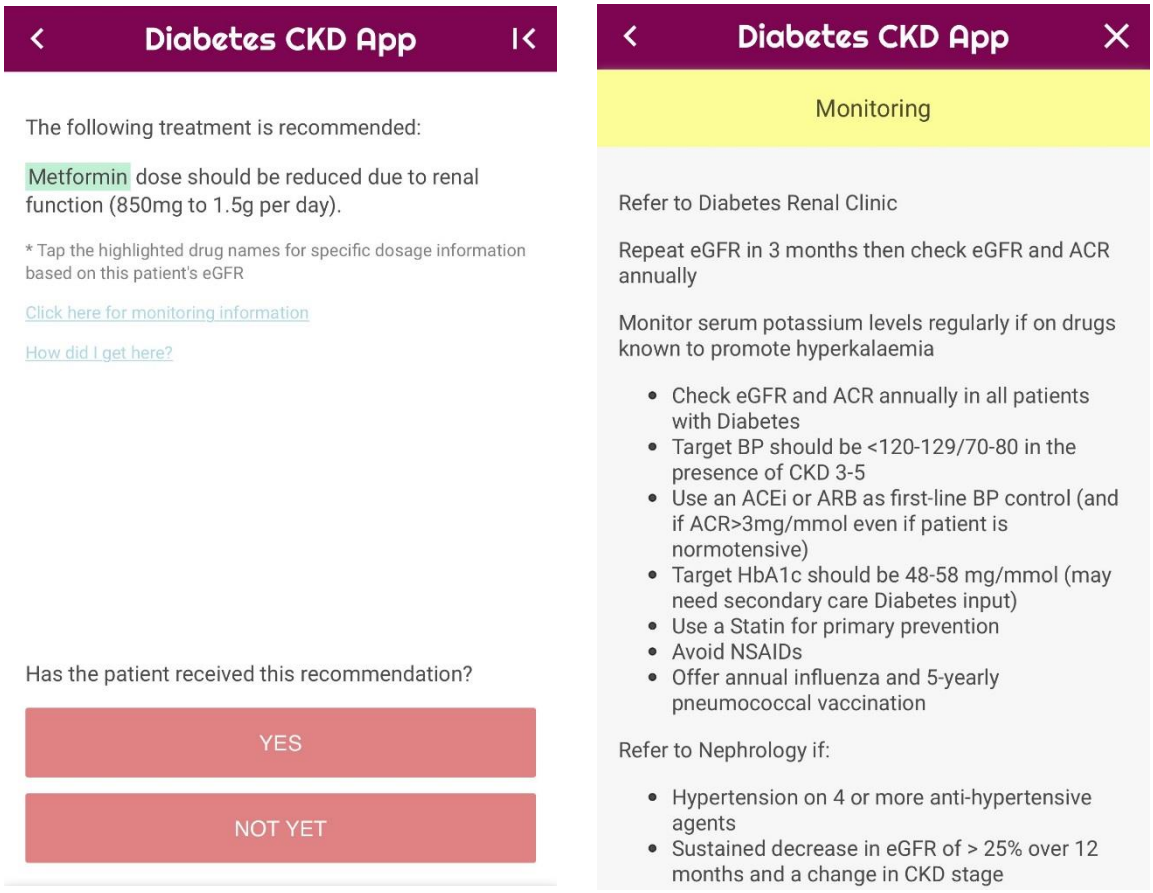
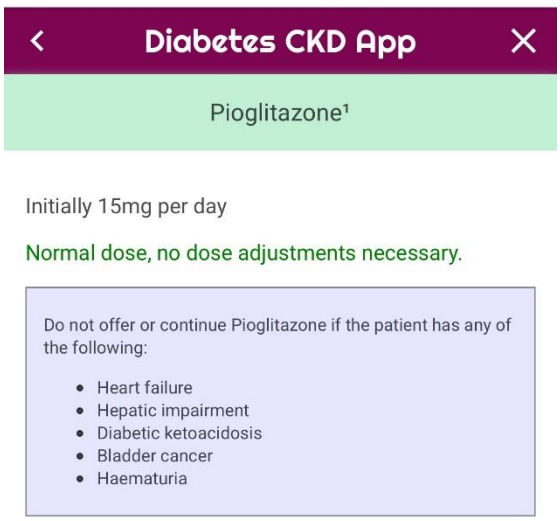


Figure 8.3 Examples of recommendation screens.



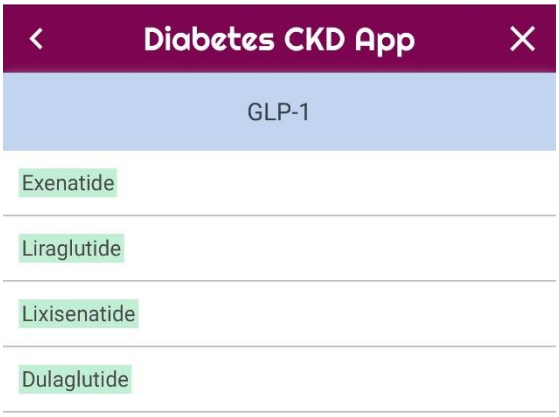


Figure 8.4 Additional examples of recommendation screens.

The final developed app was prepared for user trial and usability testing, and the results are reported in Chapter 9. The app will be further refined following the feedback collected from end-users.

Chapter 9 Evaluation of the developed mobile app

Chapter overview

This chapter presents methods and results for the evaluation of the developed mobile app 'Diabetes & CKD', including aim and objectives, research design and setting, ethical approval and considerations, recruitment of participants, sessions process, data analysis approaches, results (participant characteristics and findings) and discussion (strengths, weakness and implications).

9.1 Aim and objectives

This chapter addresses the fifth objective of this thesis, relating to the 'evaluation' stage of the applied UCD approach (Chapter 3, section 3.1). The aim is to test the developed mobile app 'Diabetes & CKD' as an intervention for supporting HCPs in managing patients with diabetes and CKD in a controlled environment.

Objectives are to:

- Assess the effect of using the app on workflow and adherence to clinical guidelines
- Explore how participants experienced the app and their suggestions for improvements
- Test usability of the app.

9.2 Research design and setting

This study adopted the mixed-methods quantitative and qualitative design. Three main methods were undertaken and discussed below. More details on each method and justification for their selection were provided previously (Chapter 3, sections 3.2.2.1 & 3.2.2.2).

9.2.1 Pilot randomised controlled experiment

A pilot randomised controlled experiment was carried out using case scenarios to investigate the feasibility and impact of introducing a clinical decision-support app.

Three case scenarios were prepared by a diabetes and endocrinology consultant from the University Hospitals Birmingham NHS Foundation Trust (see Appendix 14). Randomisation sequence was generated using the random number generator in Microsoft Excel Software.

The evaluation of the app first design was conducted to assess how the app could support HCPs in terms of (a) workflow efficiency (measured by time to complete the tasks), and (b) adherence to clinical guidelines (measured by accuracy of decision made, compared to the use of paper-based guideline algorithms) (see Appendix 13).

As indicated in Chapter 3 (sections 3.2.2.1), a controlled experiment tests a hypothesis about the effect of an intervention on some measurable outcomes in order to prove or disprove the null hypothesis which is an assumption that there is no difference between groups. The hypothesis here is that clinicians' work will be greatly aided - shorter time to make a decision and more accurate decision - by an app intervention that can provide decision-support on the care of patients with diabetes and CKD.

9.2.2 Satisfaction questionnaire

All participants in the intervention group were invited at the end of the piloting session to provide qualitative feedback, using a questionnaire (Appendix 14) to assess their subjective satisfaction from working with the app. The questionnaire had six open-ended questions relating to familiarity of respondents with the use of decision-support tools, overall satisfaction with the app, positive and negative aspects of the app, features to change/add, usability issues (if any), willingness to use the app in the future, and suggestions for improvements.

9.2.3 Usability testing

Usability testing session was undertaken to assess the app's interface and functionality and users' attitudes towards the app. Participants tested the app in controlled conditions, performing representative tasks using the case scenarios in Appendix 14. They were asked to follow the 'think-aloud' protocol which asks them to verbalise what they are doing while they are doing it, which slows participants down

considerably, therefore, measuring the time was considered not feasible in this session.

9.3 Ethics approval

Substantial amendments application for the previously granted ethical approval (see Chapter 7, section 7.3) was submitted to the University of Warwick's Biomedical and Scientific Research Ethics Sub-Committee in order to include this study, and changes have been approved with a reference number (REGO-2014-786 AMO1). In addition to the previously obtained Trusts' permissions (outlined in Chapter 7, section 7.3), the University Hospitals Birmingham NHS Foundation Trust was approached to obtain permission. However, they considered this study as service evaluation and did not require any permission. The amended ethical approval letter and access letter are in Appendix 11.

9.3.1 Ethical considerations

Participants were fully informed of the study by being given the 'participant information leaflet' and the 'participant consent form' (Appendix 14). Completed consent forms were collected from participants before the discussion started. Participants' contact information was not collected; participants were anonymised and are not identifiable. Participants had the right to withdraw from the study freely at any time, however, nobody did.

Collected study information (including recorded discussion and consent forms) was only accessed by the research team. Information was retained securely by the researcher; electronic copies of the discussion was stored on university-owned computers with access passwords, while paper records of consent forms were stored in a locked cabinet in the office at the University of Warwick. Data will be retained for a period of 10 years in line with the University of Warwick's policy on published data.

Participants were made aware that no major benefits or risks were anticipated as a result of participation in this study, since these were only simulation-based cases. All

case scenarios were prepared and tested by a diabetes and endocrinology consultant to ensure no incorrect information or decision is generated by the app.

9.4 Participants

Two types of end-users were considered as participants:

1. Junior doctors on the Foundation Program (FY1 or FY2)
2. DSNs from the interview study who expressed interest in taking part.

9.5 Recruitment of participants

Participants were recruited by two approaches:

1. Junior doctors were recruited for the controlled experiment at the University Hospitals Birmingham NHS Foundation Trust as part of a teaching session on diabetes and renal complications (see Appendix 14 for the session agenda). Thirty-nine junior doctors were recruited in total, with a 100% recruitment rate. As it was a pilot study, the power of statistical tests was not calculated to help in deciding how many participants to recruit.
2. Fifteen DSNs were invited to take part in the usability testing session, but only three were recruited at the Sandwell & West Birmingham Hospitals NHS Trust. Invitation emails were sent by the researcher to the mailing list of DSNs with two documents attached: the 'participant information leaflet' and the 'participant consent form'. Nurses interested in taking part were invited to contact the researcher by using the contact information given at the bottom of the information leaflet or by replying directly to the invitation email. DSNs who participated in the study were given a £20 Amazon.co.uk voucher as a reimbursement of their time, and were eligible to claim any travel expenses that they incurred through participating in this study.

9.6 Session process

The teaching session, where the pilot controlled experiment was undertaken, was carried out within the Hospital premises. During the piloting phase, junior doctors

were randomly divided into two groups using the software generated random numbers which were applied through a predefined sequence to alternating rows to ensure complete randomness of the assignment of a participant to each group. Those in the intervention group had access to the developed app 'Diabetes & CKD'. Those in the control group had access to paper-based guideline algorithms that informed the app development (Appendix 13). Only participants in the intervention group were given a link to the app by opening their browser to the specified web page. However, for practical reasons, it was not possible to demonstrate the app to them. At the beginning, an example simulation-based case scenario was explained by the consultant. Next, both groups were asked to deal with two simulation-based case scenarios that lasted around half an hour. It was intended to time participants in both groups to compare how long it take them to complete the tasks, which is a good measure of efficiency, however, due to practical reasons, time measurement was not feasible. Decisions made in each group were written down on the provided answer sheets (Appendix 14). At the end, intervention participants were asked to complete the satisfaction questionnaires in as detailed a way as possible.

For the usability testing, a seminar room at the hospital was booked for the session with a comfortable setting (i.e., seated around a table), to encourage maximum engagement from all participants. The session was run during informal time (dinner time) at the end of a working day. Group discussion lasted approximately one hour. The discussion was facilitated by the lead investigator of this research. The facilitator promoted turn-taking between participants to ensure that each participant contributed to all sections of the discussion. Also, participants were encouraged to talk to each other and not address themselves only to the facilitator. At the beginning of the session, a brief description of the app was provided, supplemented with a short demonstration. The researcher assisted nurses accessing the app on their own devices. During the testing phase, nurses were asked to perform tasks using the case scenarios and to verbalise what they are doing while they are doing it. Broad questions were asked to explore participants' views and opinions based on use during the session. At the end of the discussion, participants were given the opportunity to raise any relevant uncovered topics.

9.7 Data analysis

The answer sheets for both groups were blinded and scored against a model answer prepared in advance by the consultant (Appendix 14). In the used scoring scale, minor and major decisions were not scored equally; they were given varied weight. The scoring was carried out by an independent clinician not directly involved in the preparations of the case scenarios. Scores were compared and analysed using independent samples *t*-test/Mann-Whitney U-test for hypothesis testing as appropriate. Outcome measure was the accuracy of decision (whether the decision matched that expected based on the guidelines). Statistical analysis was carried out using SPSS software (IBM Corp, 2015).

For the satisfaction questionnaire, basic analysis was undertaken. First, questionnaire responses were read carefully several times. Then, major patterns and trends were identified in the responses and were summarised for each question.

The usability testing session was audiotaped and transcribed verbatim by a professional transcription company and analysed using a narrative synthesis approach.

9.8 Results

9.8.1 Participant characteristics

Thirty-nine junior doctors were included in the controlled experiment (17 male, 22 female). Of them, 17 were allocated to the intervention group (5 male, 12 female) and 22 to the control group (12 male, 10 female). Minimal data were planned for collection at this stage, given that they all were junior doctors (FY1) and likely to be of similar ages.

Three DSNs were included in the usability testing session. All were females, aged 30–46 years. All were based in the hospital; however, all were also working in the community. Work experience with diabetes ranged from 6–16 years. Additionally, they all were provided with either a smartphone or tablet, or both, by their trust.

9.8.2 Findings

9.8.2.1 Pilot randomised controlled experiment

A Shapiro-Wilk's test (P>0.05) (Razali & Wah, 2011; Shaphiro & Wilk, 1965) and a visual inspection of their histograms, normal Q-Q plots and box plots showed that the participants' scores were approximately normally distributed for both intervention and control groups, with a skewness of -0.591 (SE=0.550) and a kurtosis of 0.419 (SE=1.063) for the intervention group and a skewness of -0.147 (SE=0.491) and a kurtosis of 0.785 (SE=0.953) for the control group (Cramer, 1998; Cramer & Howitt, 2004; Doane & Seward, 2011).

As the intervention and control distributions were sufficiently normal, an independent samples *t*-test was performed. There was no significant difference in the scores between intervention group (mean=7.235, SD=2.4630) and control group (mean=7.386, SD=2.5632); t (37) = -0.186, P=0.854 (maximum score is 13). The frequency distribution of the scores for both groups is presented in Figure 9.1. These results suggest that, for the given two case scenarios in this small cohort of participants, no difference was observed on the accuracy of decision made using the app compared to the use of paper-based guideline algorithms.

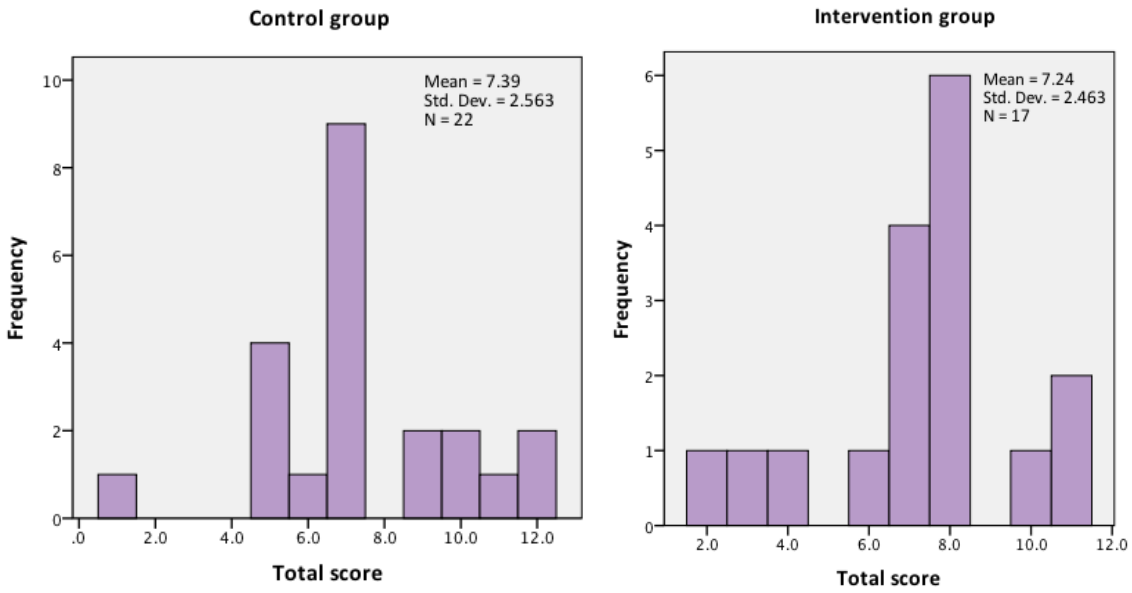


Figure 9.1 Frequency of scores for control and intervention groups.

A score of 8 was determined as the minimum standard of safe care for the given two case scenarios. Nine doctors (%53) in the intervention group got score 8 or above, whereas only 7 doctors (%32) in the control group scored 8 or above. Yet, when comparing their scores for each case individually, nearly %77 doctors in both groups scored the minimum of 3 in case one, while %41 and %50 doctors in the intervention and control groups respectively got the minimum score of 5 in case two.

9.8.2.2 Satisfaction questionnaire

Seventeen questionnaires were completed, with a 100% response rate (app arm), but with a considerable number of missing answers for sub-sections. Nearly half of the junior doctors indicated prior experience using decision-support apps such as the BNF app and Medscape calculators. With regard to their overall impression, most were satisfied or somewhat satisfied with the app; with very few participants feeling that it did not meet their expectations and stated that the app needed more work. Respondents generally had good experiences using the app, with more positivity reported than negativity. On the positive side, ease and simplicity of the app were the most emphasised features. Participants used the following words/sentences more frequently to describe the app: easy to use, user-friendly, straightforward, quick, simple flow, good presentation, intuitive user interface, clear design, easy to input information, gives a good recommendation based on results, not too wordy, good font size and much easier to use than the algorithm.

By contrast, the most common negative point was the ambiguity of the navigation between pages and/or recommendations, followed by the difficulty scrolling up and down. Regarding usability, some respondents reported that they encountered some problems during the session. The app crashed a few times with some participants, resulting in disappointment.

In terms of suggestions for improvement, participants expressed the need for: easy and clear navigation, information on doses supported with links to evidence, additional information on drug side effects, e.g. weight loss or gain, hypos, etc., the possibility to save previous searches to go back to them easily, the ability to enter patient's current

medications to help streamline the options at the end and more specific advice regarding which combinations of dual/triple therapy would be more appropriate.

All participants thought that the app seems useful and, hence, they are willing to use such apps in their clinical practice, specifically for more complex patients when they are uncertain. They indicated that they would use it if it would help them save time compared to manually searching through guidance. They thought it would help them in the clinic and in ward care, especially overnight, but it would not be appropriate to use during consultation. They further pointed out that it might be hard to get the time to use the app, in particular, with those patients needing immediate management.

9.8.2.3 Usability testing

Consensus clearly emerged between the results of this usability testing and the satisfaction questionnaires. DSNs faced several usability problems as well when using the app. Once again, the ambiguity of the navigation between pages and/or recommendations was described as the most frustrating part of the app. Nurses found it unclear how to go back to the home screen and, when they wanted to go back to the last page, it took them back more or less to the beginning, and so they had to input the information in again.

> *'I am a bit scared to touch anything now in case it cancels everything again.'* (Nurse 2)

> *'Oh no it took me right back to the start. That would be annoying. So it's asking me to put everything in again.'* (Nurse 3)

The app crashed once with a nurse as she became unable to move or type in any data, she said:

> *'Mines stuck a little bit I think, it won't let me answer questions.'* (Nurse 1)

Some buttons within the app will only appear once the user typed in the data and, thus, they found this to be unclear and some users might miss it.

> *'When you say yes, that changes and it's not clear. I didn't realise it had changed.'* (Nurse 2)

The fact that users cannot skip any part and have to fill each section before they can move onto the next stage was described as unpractical.

> *'Sometimes in real life you might not get all the right information and then you can't move onto the next stage, because obviously you need all the information to get it.'* (Nurse 1)

Nurses felt that some data items were irrelevant, for example, when the app asks for blood pressure while looking at glycaemic control. They thought it is not doing anything but adding more data to input. By contrast, they asked for adding some data item such as the BMI. They explained that the BMI is an important indicator which they use a lot in diabetes to make decisions. So patients with a higher BMI would go through a different pathway from the patients with a lower BMI.

Nurses stated that some given advice would need further clarification. For instance, when the app recommends monitoring the patient, nurses wondered what sort of monitoring to do, and asked for some more information about how to monitor. They suggested giving guidance as to how often a patient need to be seen to check if the treatment they are on is adequate. In contrast, they were not happy with some of the given advice such as the recommendation to refer a patient to a nephrology. One nurse stated:

> *'I wouldn't accept a referral for her.'* (Nurse 1)

Several suggestions were given by DSNs to improve the app. They indicated a preference to use other gestures when communicating with the app such as the swipe as opposed to just using the touch. Furthermore, nurses thought providing background information on the home page would be helpful. So giving links to basic guidelines on drugs, hypo or driving information to direct users for further education. Nurses explained that there are many different combinations of medications for diabetes, and there is not always a right or a wrong way. They have got to try one drug and see how it goes. Therefore, nurses asked for more information on their side effects, e.g. whether the drug is weight neutral or if the patient likely to gain weight – perhaps a shortened list of pros and cons for each drug – to help them make decisions quicker. Additionally, they asked for more details on drug doses, such as the starting dose and

maximum dose. Nurses further suggested that the app allow users to enter patient's current medication because this obviously will reduce the given options.

On the other hand, nurses indicated several positive aspects of the app. They liked having the button 'how did I get here' which allows them to check if they have inputted something incorrectly at any point. They also suggested having this screen compulsory in order to enable users to make sure their information was correct and that they have not omitted anything. Moreover, they found it very useful that they could click on the drug names to give them more information about them, because it saves them flicking through the system looking for this specific information.

'And obviously it gives you a caution box there. That's brilliant.' (Nurse 3)

DSNs stated that the app was a good idea, particularly from a practice point of view. Although usability issues were experienced with the app, they did not hinder the completion of tasks. The fact that the app was still under development will make it easy to overcome all the usability problems experienced by nurses in this study.

9.9 Discussion

9.9.1 Summary of main findings

This feasibility study provided initial insights on the impact, usability and acceptability of an app supporting decision-making which was developed specifically for this research. The study employed multiple methods appropriate to address its objectives.

A pilot randomised controlled experiment was undertaken in a controlled environment to assess whether the use of the app improved adherence to clinical guidelines. The experiment tested the difference in effect using the app and the paper-based version of the app's algorithm, however, there was no difference between intervention and control groups (P=0.854). The scores were generally poor in both groups, with a mean around 7 (maximum score is 13). However, the number of safe doctors who scored 8 or above was higher in the intervention group compared to the control group.

Junior doctors in the intervention arm did not make more accurate decisions, but since this was their first exposure to the app, the need to explore and learn to operate the app might explain these results. Another key point is that participants in the control group were given the paper algorithms that informed the app development as opposed to the lengthy guidelines, which enabled them to answer better. Significant efforts have been made, under a supervision of two diabetes consultants, to carefully build these algorithms as simply as possible. In real-life scenarios, no one will carry the paper algorithms with them but it could be made available electronically and, thus, results may become similar. A more comprehensive study would also compare how participants in both groups scored in regard to trivial and serious deviations from the care described in NICE guidance and the risk arising from scoring each one.

The results from the satisfaction questionnaires showed that despite the reported negativity, most participants were satisfied with the app. They understood that it was still under development and, thus, they indicated there is room for improvement. They believed that the app would be a useful addition to their clinical practice and expressed their willing to use it when appropriate.

The app is intended to provide a personalised recommendation tailored to the patient as a mean of support to HCPs' clinical skills and judgment. Therefore, it should meet the needs of the target users in order to deliver its potential. The purpose of conducting the usability testing with DSNs, in conjunction with the controlled experiment, was to further evaluate the app qualitatively with another group of potential users. One important factor for the success of the app is to have a usable user interface. A think-aloud analysis was performed with DSNs to explore and identify potential usability problems. Nurses have experienced several usability issues during the session, though; they found learning to use the app is easy and straightforward.

The findings suggest that the app was well-accepted by both DSNs and junior doctors. Clearly, encountering frequent crashes will certainly affect user's satisfaction. Notably, however, the reported negative points could be attributed to the fact that the app is still immature. This highlights the need to provide participants with a well-functioning tool to increase their satisfaction and willingness to use the app.

9.9.2 Comparison with other relevant studies

Research on mobile decision-support apps (*m*Health DSS) in diabetes management is limited (see Chapter 5, section 5.1.6.6), as studies conducted thus far (Neubauer *et al.*, 2015; Neubauer *et al.*, 2014b; Sarala, 2014) were neither randomised nor controlled. However, app piloting was carried out in a field setting in those studies. In addition, these studies mainly shed light on the impact of using the app on patient-related outcomes.

Regarding HCP-related outcomes, one study assessed the usability of a decision-support app using a quantitative questionnaire (Neubauer *et al.*, 2015; Neubauer *et al.*, 2014b). Generally, the app was highly acceptable by HCPs involved in the trial. HCPs' compliance with given recommendations from the decision-support apps was assessed in two studies (Neubauer *et al.*, 2015; Neubauer *et al.*, 2014b; Sarala, 2014). Adherence by physicians and nurses to the suggested advice was high in both studies. The study of Spat et al. (Spat *et al.*, 2013) investigated HCPs' errors and workflow anomalies retrospectively. They compared the results generated by the app with those generated in the clinical study using a paper-based algorithm. The number of errors made by the app was very much fewer than errors made by physicians and nurses in the paper-based study.

The findings of the current study are not comparable with these studies. None of the studies described above have the same aim and objectives as the current study and, thus, the findings as well. This is because they have different designs, settings and reported outcomes.

9.9.3 Methodological strengths and weaknesses

This study, being a pilot not considering the statistical power required to detect a difference between groups, is unlikely to be generalisable to the entire population. The app was tested in a controlled setting which did not take into consideration the location. This may not give the same result as an assessment undertaken in the field within the intended context of the app, i.e. in clinical practice. Another aspect to consider is that blinding of participants to the intervention is impossible to conduct in

mobile app intervention trials. Furthermore, this was first-time use of the app for all participants. Therefore, the learning effect should be taken into account when interpreting the results.

Some deviation from the protocol occurred. It was intended to demonstrate the use of the app for the example case scenario presented by the consultant. However, participants in the intervention arm did not receive any training or explanation prior to the piloting session. It was not possible to demonstrate the app due to Internet connectivity issue in the teaching room as the Trust had blocked the web page. This may have had a negative impact on completing the scenarios when using the app. Likewise, it was planned to assess and compare time to complete the tasks in both groups as a measure of workflow efficiency, but, due to practical reasons, time measurement was not feasible. Limitations also included difficulty of recruiting participants, specifically in group setting. This is because of the busy schedule of HCPs.

Despite these limitations, this study has a few notable strengths. First, this was a randomised controlled experiment with a 100% recruitment and completion rates. Second, the outcome assessor was blinded to group allocation. Moreover, it used multiple methods to investigate both quantitative and qualitative aspects of the app evaluation. Also, it was piloted with two different groups of targeted users. This pilot study was exploratory in nature which could be strength in generating future hypotheses.

9.9.4 Implications of study results

The results of the present study, although not conclusive, can be useful in providing initial insights into the situation and feed into future research. Previously, no decision-support app interventions have undergone a robust assessment in diabetes management. Robust evaluations are needed to investigate whether such apps will improve workflow efficiency and lead to better adherence to guidelines in clinical practice. A better study would examine over a longer duration a large, controlled and randomly selected sample of HCPs involved in diabetes care and management. Future research should focus more on carrying out field trials, with a near-fully designed app.

Field trials can give better insight compared to studies conducted in a controlled environment. However, setting up such studies may involve higher cost and practical difficulties. Additionally, there is a need for future efforts to replicate the current study in a robust and large-scale trial but with a control group unaided by either apps or algorithms to anchor the scale in current practice and better understand its impact.

It is crucial to develop an app that integrates end-users' suggestions for improvements. The results from both the controlled experiment and usability testing will help further development and evaluation of a more user-friendly app. The app will be updated using the feedback and additional comorbidities will be considered for integration into the app to expand its usefulness.

Chapter 10 Overall discussion and conclusion for the thesis

Chapter overview

This chapter outlines key findings drawn from the quantitative and qualitative systematic reviews, interview study and app evaluation; summarises the contributions made to the field; discusses the limitations and challenges of the thesis as a whole; makes suggestions for further research; and ends with future plans and the thesis' conclusions.

10.1 Summary of main findings of the thesis

This thesis had a primary aim of developing and evaluating a mobile app that supports in diabetes management, starting with reviewing quantitative and qualitative literature. Findings indicated the paucity of research around the use of apps by HCPs in clinical practice. So a qualitative study explored end-users' views and needs for apps to support their clinical work. Interviews were conducted with DSNs (key workers in diabetes care), and the need and interest for apps was ascertained. Hence, a decision-support app 'Diabetes & CKD' was developed based on clinical guidelines and input from diabetes consultants. Finally, the app was evaluated in a controlled environment with two of the main targeted users, junior doctors and DSNs.

The UCD process (Chapter 3, section 3.1) was employed for the design, development and evaluation of the app. It involves three stages that guided the development and structure of the thesis objectives. The first stage is 'requirements gathering' and involved undertaking two systematic reviews, quantitative and qualitative, and the interview study. These studies addressed the first three objectives of this thesis. The second stage is 'design & development' which involved developing the decision algorithms and using programming languages to build the app. This stage addressed the fourth objective of this thesis. The final stage 'evaluation' involved testing the developed app using multiple methods and it addressed the fifth objective of this thesis.

The quantitative review and meta-analysis (Chapter 5) suggested that mobile apps might have a positive impact on glycaemic control in patients with diabetes, although the identified studies had considerable heterogeneity and methodological weaknesses, and most were small. Limited evidence of the added benefits or mixed results were found for other outcomes. The apps examined were different in two main ways: the combination of functionalities and the involvement of HCPs. It was not feasible to distinguish between the different functionalities in the calculation of the overall effect size. Thus, it is still unclear which app functionalities are most effective.

In the qualitative review (Chapter 6), there was no general agreement about all topics. Participants were satisfied with some of the app's features and functionalities and also they pointed out a number of negative aspects associated with its use. Apps involving HCPs' feedback could be more effective in improving glycaemic control and adherence. Users also expressed a greater preference for apps that engage their HCPs in their diabetes management. The different points of view provide enriched feedback for better app designs.

The two systematic reviews enabled full exploration of both quantitative and qualitative evidence on the impact of using apps to support people with diabetes and their HCPs. However, it was not possible to draw conclusions on their results either for patients or HCPs. Both reviews highlighted the dearth of research involving the use of apps with HCPs and women with GDM.

DSNs (Chapter 7) were not currently using apps in their clinical practice, even though most of them were provided with work-related smart devices. Most nurses were not aware of the existing medical apps. Therefore, there is a need to advertise the available reliable clinical apps. They appreciated the potential benefits that apps may bring to their clinical practice. However, barriers and concerns about their use were expressed. The lack of official regulatory framework around apps that outlined in Chapter 2 (section 2.3) was also identified as a concern and barrier, prompting nurses to avoid their use. Despite this, nurses are strongly willing to use apps. They see app technology as an opportunity rather than a potential threat. There is a place for simple apps to support DSNs in clinical practice.

The qualitative review and the interview study were consistent in part of their conclusion. They showed that there is no 'one size fits all' app design. Participants' varied responses indicate that every user is unique. This makes designing an app accommodating the needs of all individuals challenging. This highlights the need to develop either customisable apps or apps that are tailored specifically to one user group.

Considerable effort has gone into developing the 'Diabetes & CKD' app (Chapter 8). The app was evaluated in a pilot randomised controlled experiment and usability testing session (Chapter 9). The pilot study showed feasibility but was not powered to demonstrate a difference in the accuracy of decision made between the intervention and control groups. Users, both junior doctors and DSNs, have mixed views toward app usability, but generally were positive. This was coherent with the findings regarding apps usability from the reviews undertaken in this thesis.

10.2 Contributions to the field

Petre and Rugg in 2010 (Petre & Rugg, 2010) state that:

"Making a significant contribution means adding to knowledge or contributing to the discourse – that is, providing evidence to substantiate a conclusion that's worth making."

Research on the use of mobile apps among HCPs in clinical practice is lacking. This thesis was driven by gaps in the existing knowledge relating to the impact of using apps in diabetes care and management and contributes to a better understanding of the role of apps in supporting HCPs in clinical practice.

The following subsections highlight what makes the work carried out in this thesis an original contribution.

10.2.1 Design contribution

A key contribution of this thesis is the design and development of an innovative fully working mobile decision-support app 'Diabetes & CKD'. It supports HCPs in decision-

making for patients with diabetes and comorbidities. The app design took into consideration the needs and preferences of end-users in order to increase its acceptability and utilisation. Iterative development and refinement of the app will further enhance its design. It is hoped that the outputs from this thesis can inspire further ideas for developers and researchers for the design, development and evaluation of future diabetes apps.

10.2.2 Methodological contribution

The main methodological novelty was the application of a software development framework (UCD) for the entire thesis work. The UCD methods involved both quantitative and qualitative methods for data collection during the different design, development and evaluation stages of the thesis. The methodology chosen ensured thorough exploration of complex intervention such as the mobile app, particularly since it is still not fully mature.

The pilot randomised experiment is the first attempt to test a mobile diabetes decision-support app for HCPs in a controlled environment using case scenarios. This is novel in the field of diabetes. The method may have been described before or possibly has been applied but in areas other than diabetes.

10.2.3 Practical contribution

A number of practical contributions were made. Firstly, the study has undertaken detailed quantitative and qualitative systematic reviews which appraised and summarised the key characteristics and findings of available studies. To the best of the authors' knowledge, the qualitative review is the first to consider qualitative research studies that have explored patients' and HCPs' use of, and perspectives on, mobile apps for diabetes care and management.

Secondly, the interview study contributes to scholarly *m*Health literature since the qualitative aspects of HCPs' use of clinical support apps in diabetes care and management is an under-studied area. This study is the only qualitative study of DSNs' experiences and perspectives on apps use within this environment of which the

authors are aware. The findings provided valuable insights into end-users' needs and requirements that can inform recommendations for the design and development of future diabetes apps, and future research in *m*Health.

Thirdly, through conducting the pilot controlled experiment and usability testing with junior doctors and DSNs, this study helped to develop a deeper understanding of HCPs and their views and attitudes towards decision-support apps. Therefore, the contributions of this research are the findings related to the feasibility, usability and acceptability of the app. This will further help to shape and guide the design of this and other chronic disease apps to facilitate and support decision-making among HCPs.

10.3 Limitations and challenges

This section discusses the limitations and challenges of the approach undertaken in the thesis as a whole (rather than those indicated in the individual chapters), which may affect the interpretations and application of the findings and, therefore, need be taken into consideration.

With regard to external validity, the transferability/generalisability of findings to the entire population of HCPs in the interview study and the controlled experiment are limited due to the sampling method used and the absence of statistical power, respectively. Other groups of HCPs, e.g. male nurses or GPs, or another setting, might yield a different result. It was not possible to interview and evaluate the app with a varied group of HCPs involved in diabetes care. If this doctoral research had longer timeframe, a variety of HCPs could have been recruited. Undertaking further interviews including, for example, GPs and practice nurses, who have a central role in the care of diabetes, would enrich the findings and increase its validity.

In terms of internal validity, conducting the interviews and analysis by the primary researcher only was a limitation. Bias may have occurred in interpretation of the results. Therefore, findings of the interview study may considered subjective and not definitive. However, working in a team was infeasible since doctoral research work needs to be undertaken independently. The iterative data collection in UCD process, and attempts to ensure neutral analysis through close monitoring by academic

supervisors and regular discussion of categories, codes and themes until consensus was achieved, hopefully enhanced credibility.

There are also limitations with usability testing with an app still under development. A fully-developed app might have provided different results; possibly with reduced usability issues. Limitations also included time, resources and workforce available for the doctoral research. If more time had been available for the app development, without doubt, improvements could have been made, but this was not possible in the scope of this thesis.

The main challenge of this research is the difficulty of recruiting HCP participants. Interviews and usability testing require a prolonged timeframe for recruitment. Another major challenge was developing the decision algorithms by the primary researcher, who does not have a clinical background. However, involvement of the two diabetes consultants into the iterative development process facilitated the work.

Some decision-support apps may be considered a medical device and, thus, need to go through a regulatory approval process before they can be evaluated in a real-world setting. In particular, those involving interpretation of data, or some sort of complex calculation (as in this type of app) may pose risks to patients if they were unreliable. Undertaking an evaluation of such apps in field settings would be a challenge that needs to be taken into consideration when planning evaluation studies.

10.4 Further research

The findings of this thesis in relation to the evidence base are inconclusive. The technology is new and, thus, well-conducted studies are lacking. Therefore, the opportunities for conducting further research are broad.

Results from the systematic reviews provide a baseline from which future research can move forward. These reviews indicated that patients experienced a variety of benefits from using diabetes apps. A logical next step would be to carry out high-quality research into apps' impact in diabetes self-management and remote monitoring. Future research needs to be methodologically rigorous and avoid the weaknesses

identified in the studies included in the systematic reviews to ensure their contribution to the evidence base. In particular, studies need to be large-scale with longer follow-up and standardised outcome measures. Future research would certainly be facilitated if diabetes apps' functionalities were standardised. This will help to discover what benefits can be gained and increase generalisability of findings to a wider variety of populations. Further research that is directed toward women with GDM, adolescents and older people, e.g. older than 65 years, is supported as these groups were barely considered in apps research.

There is much scope for further research on the impact of using apps on clinical practice, given the increasing use of smart devices among HCPs. The mobility and convenience of apps may deliver benefits to workflow and patient care. Research is needed with robust designs and representative samples to evaluate the effectiveness of clinical apps to enhance care efficiency and patient outcomes and to explore experiences of using apps in improving clinical practice among HCPs.

The findings of the interview study may provide a structure to guide future research in this area with a wider variety of HCPs. Opportunities are wide open for further research to extend the interview study with other group of HCPs such as GPs, practice nurses, district nurses and junior doctors, also using quantitative questionnaires, and covering other health conditions. This will help validate the findings of this study and explore broader perspectives which will increase transferability of findings to the wider population of HCPs and healthcare.

Another effort for future research could involve undertaking app usability testing in real life for prolonged period of time. At the end, participants would be invited to provide feedback on the usability, satisfaction and acceptance of the app, which would be richer than feedback received upon initial introduction and use of the app.

10.5 Future plans and prospects

Since the systematic review search ended in late 2015, and given this fast-growing area of *m*Health, an updated search was undertaken in MEDLINE in December 2017, covering studies published in 2016 and 2017. The search found 965 records screened

at title and abstract level. Next, 76 records are currently under assessment for eligibility at full-text level. The inclusion of these further studies is highly anticipated to change the findings from older literature. The result will be published in a journal article and the manuscript is currently in preparation (see Appendix 15).

This thesis presents the first iteration of an ongoing app development process. Future plans include another iteration of app design and development with the end-users as the focus. This also involves updating the app using the feedback collected from the evaluation study undertaken in this thesis. This iterative data collection will further enhance the credibility of this research. Furthermore, common comorbidities of diabetes are to be included in the app.

There is a great deal of room for improvements and research building on the findings of the thesis. The findings of the evaluation study need further validation in a randomised controlled trial applied in a real-world setting. The app will be evaluated for its impact on HCPs' outcomes next, after regulatory approval if required, and eventually tested in a field setting.

10.6 Conclusion

This thesis explored available evidence on diabetes mobile apps; established a better understanding of end-user needs and requirements; translated those requirements into an app, and evaluated the final implemented design, although further work is needed in larger and longer studies.

Previous research has explored extensively the use of mobile technology interventions, with limited consideration of apps according to the definition and criteria used in this thesis. Existing literature draws attention to the potential of apps for improving patients' outcome, achieving treatment goals and improving quality of care. However, they are limited in showing apps' effectiveness in diabetes self-management, remote monitoring and clinical practice due to concerns about their quality. Using apps for self-care is highly dependent on the individual's motivation; without the patient's willingness to be an active participant in their care, apps implementation will likely fail. A decision-support app, developed through an informative requirement gathering

process, was found to be acceptable. Such apps have a potential to enforce and encourage evidence-based practice.

Despite the widespread use of smart devices, use of diabetes apps is still tentative. Utilisation of mobile apps is facing a number of challenges. These include, but are not limited to, poor evidence of effectiveness, lack of validation of diabetes apps and lack of integration with the healthcare system. The quote by David Schlanger, provided at the beginning of this thesis (p. xiv), pointed out to the lack of adoption of digital tools that may facilitate the delivery of healthcare. This thesis developed and evaluated one of the latest technologies that has a great potential to support HCPs in clinical practice. Yet, there still remains a need to understand further the benefits and the drawbacks of including apps within the care pathways for people with diabetes.

References

Akter, S. & Ray, P. (2010) mHealth - an Ultimate Platform to Serve the Unserved. *IMIA Yearbook 2010: Biomedical Informatics: Building Capacity Worldwide*, 5(1): 94-100.

Alanzi, T. M., Istepanian, R. S. H. & Philip, N. (2014) Usability study of mobile social networking system among Saudi Type 2 diabetes patients (SANAD). In *Biomedical Engineering (MECBME), 2014 Middle East Conference on* (p. 297-300).

Ali, E. E., Chew, L. & Yap, K. Y.-L. (2016) Evolution and current status of mhealth research: a systematic review. *BMJ Innovations*.

Almarri, A. & Bhatti, T. (2015) Consumers Attitude towards the Use of Mobile Health Apps: An Empirical Review. In *The Second International Conference on Electrical and Electronics Engineering, Clean Energy and Green Computing (EEECEGC2015)* on (p. 56).

American Diabetes Association, (1998) Economic Consequences of Diabetes Mellitus in the U.S. in 1997. *Diabetes Care*, 21(2): 296-309.

Arnhold, M., Quade, M. & Kirch, W. (2014) Mobile applications for diabetics: a systematic review and expert-based usability evaluation considering the special requirements of diabetes patients age 50 years or older. *J Med Internet Res*, 16(4): e104.

Årsand, E. (2009). *The few touch digital diabetes diary: user-involved design of mobile self-help tools for people with diabetes.* Doctoral Dissertation. University of Tromsø.

Årsand, E., Frøisland, D. H., Skrovseth, S. O., Chomutare, T., Tatara, N., Hartvigsen, G. & Tufano, J. T. (2012) Mobile health applications to assist patients with diabetes: lessons learned and design implications. *J Diabetes Sci Technol*, 6(5): 1197-1206.

Årsand, E., Tatara, N., Ostengen, G. & Hartvigsen, G. (2010) Mobile phone-based self-management tools for type 2 diabetes: the few touch application. *J Diabetes Sci Technol*, 4(2): 328-336.

Årsand, E., Tufano, J. T., Ralston, J. D. & Hjortdahl, P. (2008) Designing mobile dietary management support technologies for people with diabetes. *J Telemed Telecare*, 14(7): 329-332.

Bangor, A., Kortum, P. & Miller, J. (2009) Determining what individual SUS scores mean: Adding an adjective rating scale. *Journal of usability studies*, 4(3): 114-123.

Barnett-Page, E. & Thomas, J. (2009) Methods for the synthesis of qualitative research: a critical review. *BMC Medical Research Methodology*, 9(1): 59.

Barnett, K., Mercer, S. W., Norbury, M., Watt, G., Wyke, S. & Guthrie, B. (2012) Epidemiology of multimorbidity and implications for health care, research, and medical education: a cross-sectional study. *The Lancet*, 380(9836): 37-43.

Baron, J., McBain, H. & Newman, S. (2012) The impact of mobile monitoring technologies on glycosylated hemoglobin in diabetes: a systematic review. *J Diabetes Sci Technol*, 6(5): 1185-1196.

Bellazzi, R. (2007) Information Technology Solutions for Diabetes management and prevention Current Challenges and Future Research directions. In: Jarm, T., Kramar, P. & Zupanic, A., eds. *11th Mediterranean Conference on Medical and Biomedical Engineering and Computing 2007*. Springer Berlin Heidelberg: 14-17.

Benhamou, P. Y., Bosson, J. L., Penfornis, A., Dardari, D., Franc, S., Schaepelynck, P., Catargi, B., Hanaire, H., Chaillous, L., Renard, E. M., Quesada, J. L., Halimi, S., Charpentier, G. & TeleDiab Study, G. (2010) Telemedicine support using the DIABEO software on a smartphone improves HbA(1c), in poorly controlled type 1 diabetic patients: the randomised, 6-month, multicenter TeleDiab-1 trial. *Diabetologia* (53): 233.

Bonoto, C. B. u., de Ara˙jo, E. V. n., GodÛi, P. I., de Lemos, P. L. L., Godman, B., Bennie, M., Diniz, M. L. & Junior, G. A. A. (2017) Efficacy of Mobile Apps to Support the Care of Patients With Diabetes Mellitus: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. *JMIR Mhealth Uhealth*, 5(3):e4.

Boren, S. A., Puchbauer, A. M. & Williams, F. (2009) Computerized prompting and feedback of diabetes care: a review of the literature. *J Diabetes Sci Technol*, 3(4): 944-950.

Boulos, M. N., Brewer, A. C., Karimkhani, C., Buller, D. B. & Dellavalle, R. P. (2014) Mobile medical and health apps: state of the art, concerns, regulatory control and certification. *Online J Public Health Inform*, 5(3): 229.

Bowen, G. A. (2008) Naturalistic inquiry and the saturation concept: a research note. *Qualitative Research*, 8(1): 137-152.

Brandell, B. & Ford, C. (2013) Diabetes professionals must seize the opportunity in mobile health. *J Diabetes Sci Technol*, 7(6): 1616-1620.

Breland, J., Yeh, V. & Yu, J. (2013) Adherence to evidence-based guidelines among diabetes self-management apps. *Translational Behavioral Medicine*, 3(3): 277-286.

Brzan, P. P., Rotman, E., Pajnkihar, M. & Klanjsek, P. (2016) Mobile Applications for Control and Self Management of Diabetes: A Systematic Review. *Journal of medical systems*, *40*(9): 210.

Buchholz, A., Perry, B., Weiss, L. B. & Cooley, D. (2016) Smartphone Use and Perceptions among Medical Students and Practicing Physicians. *Journal of mobile technology in medicine*, 5(1): 27-32.

Buijink, A. W., Visser, B. J. & Marshall, L. (2013) Medical apps for smartphones: lack of evidence undermines quality and safety. 18(3): 90 - 92.

Busey, J. C. & Michael, P. (2008) Telehealth—Opportunities and Pitfalls. *Journal of the American Dietetic Association*, 108(8): 1296-1301.

Caburnay, C. A., Graff, K., Harris, J. K., McQueen, A., Smith, M., Fairchild, M. & Kreuter, M. W. (2015) Evaluating Diabetes Mobile Applications for Health Literate Designs and Functionality. *Preventing Chronic Disease*, 12(61): e61.

Cafazzo, J. A., Casselman, M., Hamming, N., Katzman, D. K. & Palmert, M. R. (2012a) Design of an mHealth App for the Self-management of Adolescent Type 1 Diabetes: A Pilot Study. *J Med Internet Res*, 14(3): 171-183.

Cafazzo, J. A., Casselman, M., Katzman, D. K. & Palmert, M. R. (2012b) Bant: An mHealth App for Adolescent Type 1 Diabetes - A Pilot Study. *Journal of Adolescent Health*, *50*(2): S77-S78.

Cameron, R. (2009) A sequential mixed model research design: Design, analytical and display issues. *International Journal of Multiple Research Approaches*, 3(2): 140-152.

Cato, K., Hyun, S. & Bakken, S. (2014) Response to a mobile health decision-support system for screening and management of tobacco use. *Oncol Nurs Forum*, 41(2): 145-152.

Charpentier, G., Benhamou, P.-Y., Dardari, D., Clergeot, A., Franc, S., Schaepelynck-Belicar, P., Catargi, B., Melki, V., Chaillous, L., Farret, A., Bosson, J.-L., Penfornis, A. & TeleDiab Study, G. (2011) The Diabeo Software Enabling Individualized Insulin Dose Adjustments Combined With Telemedicine Support Improves HbA(1c) in Poorly Controlled Type 1 Diabetic Patients A 6-month, randomized, open-label, parallel-group, multicenter trial (TeleDiab 1 Study). *Diabetes Care*, 34(3): 533-539.

Childs, B. P. (2005) The Complexity of Diabetes Care. *Diabetes Spectrum*, 18(3): 130-131.

Chomutare, T., Fernandez-Luque, L., Årsand, E. & Hartvigsen, G. (2011) Features of mobile diabetes applications: review of the literature and analysis of current applications compared against evidence-based guidelines. *J Med Internet Res*, 13(3): e65.

Chomutare, T., Tatara, N., Årsand, E. & Hartvigsen, G. (2013) Designing a diabetes mobile application with social network support. *Studies in health technology and informatics*, (188): 58-64.

Cleveringa, F. G., Gorter, K. J., van den Donk, M., van Gijsel, J. & Rutten, G. E. (2013) Computerized decision support systems in primary care for type 2 diabetes patients only improve patients' outcomes when combined with feedback on performance and case management: a systematic review. *Diabetes Technol Ther*, 15(2): 180-192.

Conway, N., Campbell, I., Forbes, P., Cunningham, S. & Wake, D. (2015) mHealth applications for diabetes: User preference and implications for app development. 22(4): 1111-1120.

Cramer, D. (1998) *Fundamental statistics for social research. Step-by-step calculations and computer techniques using SPSS for Windows.* 1st ed. London and New York: Routledge.

Cramer, D. & Howitt, D. L. (2004) *The Sage dictionary of statistics: a practical resource for students in the social sciences*. 1st ed. London, Thousand Oaks and New Delhi: Sage publications.

Creswell, J. W. (2014) *Research design: Qualitative, quantitative, and mixed methods approaches*. 4th ed. London, Thousand Oaks and New Delhi: Sage publications.

Critical Appraisal Skills Programme (CASP). (2013). *Qualitative Checklist*. [Online] Available from: http://www.casp-uk.net/checklists (Accessed 22/5/2017).

Cui, M., Wu, X., Mao, J., Wang, X. & Nie, M. (2016) T2DM Self-Management via Smartphone Applications: A Systematic Review and Meta-Analysis. *Plos One*, 11(11): 1-15.

De Jongh, T., Gurol-Urganci, I., Vodopivec-Jamsek, V., Car, J. & Atun, R. (2012) Mobile phone messaging for facilitating self-management of long-term illnesses. *Cochrane Database Syst Rev*, 12.

Deacon, A. J. & Edirippulige, S. (2015) Using mobile technology to motivate adolescents with type 1 diabetes mellitus: A systematic review of recent literature. *J Telemed Telecare*, 21(8): 431-438.

Deloitte (2016) *There's no place like phone. Consumer usage patterns in the era of peak smartphone.* [Online] Available from: http://www.deloitte.co.uk/mobileuk2016/assets/pdf/Deloitte-Mobile-Consumer-2016-There-is-no-place-like-phone.pdf (Accessed 22/3/2017).

Demidowich, A. P., Lu, K., Tamler, R. & Bloomgarden, Z. (2012) An evaluation of diabetes self-management applications for Android smartphones. *J Telemed Telecare*, 18(4): 235-238.

DeShazo, J., Harris, L., Turner, A. & Prattt, W. (2010) Designing and remotely testing mobile diabetes video games. *J Telemed Telecare*, 16(7): 378-382.

Deshpande, A. D., Harris-Hayes, M. & Schootman, M. (2008) Epidemiology of Diabetes and Diabetes-Related Complications. *Physical Therapy*, 88 (11): 1254-1264.

Diabetes UK (2009) *Improving supported self-management for people with diabetes*. [Online] Available from: http://www.diabetes.org.uk/Documents/Reports/Supported_self-management.pdf (Accessed 16/3/2017).

Diabetes UK (2016a) *State of the Nation 2016 (England): time to take control of diabetes*. [Online] Available from: https://www.diabetes.org.uk/Professionals/Position-statements-reports/Statistics/State-of-the-Nation-2016-Time-to-take-control-of-diabetes/ (Accessed 18/3/2017).

Diabetes UK (2016b) *Diabetes: Facts and Stats*. [Online] Available from: https://www.diabetes.org.uk/Professionals/Position-statements-reports/Statistics/ (Accessed 18/3/2017).

Doane, D. P. & Seward, L. E. (2011) Measuring skewness: a forgotten statistic. *Journal of Statistics Education*, 19(2): 1-18.

Dobson, K. G. & Hall, P. (2015) A pilot study examining patient attitudes and intentions to adopt assistive technologies into type 2 diabetes self-management. 9(2): 309-315.

Downs, S. H. & Black, N. (1998) The feasibility of creating a checklist for the assessment of the methodological quality both of randomised and non-randomised studies of health care interventions. *Journal of Epidemiology and Community Health*, 52(6): 377.

Drion, I., Pameijer, L. R., van Dijk, P. R., Groenier, K. H., Kleefstra, N. & Bilo, H. J. G. (2015) The Effects of a Mobile Phone Application on Quality of Life in Patients With Type 1 Diabetes Mellitus. *J Diabetes Sci Technol*, 9(5): 1086-1091.

El-Gayar, O., Timsina, P., Nawar, N. & Eid, W. (2013a) Mobile applications for diabetes self-management: status and potential. *J Diabetes Sci Technol*, 7(1): 247-262.

El-Gayar, O., Timsina, P., Nawar, N. & Eid, W. (2013b) A systematic review of IT for diabetes self-management: are we there yet? *Int J Med Inform*, 82(8): 637-652.

Eng, D. S. & Lee, J. M. (2013) The Promise and Peril of Mobile Health Applications for Diabetes and Endocrinology. *Pediatric Diabetes*, 14(4): 231-238.

Ergotron Healthcare (2013) *Nursing Challenges and Changes Infographic*. [Online] Available from: http://www.ergotron.com/tabid/936/language/en-GB/Default.aspx (Accessed 29/4/2014).

Ericsson (2016). *Ericsson Mobility Report*. [Online] Available from: http://www.ericsson.com/ericsson-mobility report (Accessed 21/3/2017).

European Commission (2010) *Medical devices guidance documents*. [Online] Available from: http://ec.europa.eu/health/medical-devices/documents/guidelines/index_en.htm (Accessed 17/4/2017).

Farrell, M. (2016) Use of iPhones by nurses in an acute care setting to improve communication and decision-making processes: qualitative analysis of nurses' perspectives on iPhone use. *JMIR mHealth and uHealth*, *4*(2): e43.

Farrokhi, F. & Mahmoudi-Hamidabad, A. (2012) Rethinking convenience sampling: Defining quality criteria. *Theory and practice in language studies*, 2(4): 784.

Fatehi, F., Gray, L. C. & Russell, A. W. (2017) Mobile Health (mHealth) for Diabetes Care: Opportunities and Challenges. *Diabetes Technology & Therapeutics*, 19(1): 1-3.

Finkelstein, J. & Friedman, R. H. (2000) Potential Role of Telecommunication Technologies in the Management of Chronic Health Conditions. *Disease Management & Health Outcomes*, 8(2): 57-63.

Finn, R. (2013) *mHealth Report*. [Online] Available from: http://www.ruderfinn.com/pdf/Ruder%20Finn%20US%20mHealth%20report%20FINAL.pdf (Accessed 4/6/2014).

Follmann, D., Elliott, P., Suh, I. & Cutler, J. (1992) Variance imputation for overviews of clinical trials with continuous response. *J Clin Epidemiol*, 45(7): 769-773.

Franc, S., Borot, S., Ronsin, O., Dardari, D., Fagour, C., Renard, E., Marie Leguerrier, A., Vigeral, C., Moreau, F., Winiszewski, P., Vambergue, A., Mosnierpudar, H., Kessler, L., Reffet, S., Guerci, B., Millot, L., Halimi, S., Thivolet, C., Quesada, J. L., Clergeot, A., Schaepelynck-Belicar, P., Catargi, B., Melki, V., Chaillous, L., Farret, A., Penfornis, A., Charpentier, G., Benhamou, P. Y. & Hanaire, H. (2012a) Assessment of the relationship between the use of a telemedicine system and blood glucose control in patients with type 1 diabetes. In *Diabetes (*61): A599.

Franc, S., Borot, S., Ronsin, O., Quesada, J. L., Dardari, D., Fagour, C., Renard, E., Leguerrier, A. M., Vigeral, C., Moreau, F., Winiszewski, P., Vambergue, A., Mosnier-Pudar, H., Kessler, L., Reffet, S., Guerci, B., Millot, L., Halimi, S., Thivolet, C., Benhamou, P. Y., Penfornis, A., Charpentier, G. & Hanaires, H. (2014) Telemedicine and type 1 diabetes: Is technology per se sufficient to improve glycaemic control? *Diabetes & Metabolism*, 40(3): 235-235.

Franc, S. & Charpentier, G. (2015) Devices to Support Treatment Decisions in Type 1 Diabetes: The Diabeo System. In *Technological Advances in the Treatment of Type 1 Diabetes* (24): 210-225.

Franc, S., Dardari, D., Mounier, S., Boucherie, B., Laroye, H., Daoudi, A., Biedzinski, M., Peschard, C., Requeda, E., Pochat, A., Canipel, L. & Charpentier, G. (2012b) Telemedicine and type 1 diabetes: Results of the Telediab 1 study and future perspectives. *European Research in Telemedicine*, 1(1): 26-31.

Franceschi, R., Cauvin, V., Piras, E. M., Eccher, C., Di Palma, A. & Forti, S. (2014) Trec diabetes: A new telemedicine system. In *Diabetes technology & therapeutics* (16): A111.

Frazetta, D., Willet, K. & Fairchild, R. (2012) A systematic review of smartphone application use for type 2 diabetic patients. *Online Journal of Nursing Informatics (OJNI)*, 16(3): 2041.

Free, C., Phillips, G., Galli, L., Watson, L., Felix, L., Edwards, P., Patel, V. & Haines, A. (2013a) The effectiveness of mobile-health technology-based health behaviour change or disease management interventions for health care consumers: A systematic review. *PLoS Med*, 10(1): e1001362.

Free, C., Phillips, G., Watson, L., Galli, L., Felix, L., Edwards, P., Patel, V. & Haines, A. (2013b) The Effectiveness of Mobile-Health Technologies to Improve Health Care Service Delivery Processes: A Systematic Review and Meta-Analysis. *PLoS Med*, 10(1): e1001363.

Frøisland, D., Joergensen, K. D., Markestad, T., Årsand, E. & Skaarderud, F. (2011) Innovation in practice: Development of mobile phone applications, involving adolescents with type 1 diabetes. A pilot study. In *Pediatric Diabetes* (*12*): 85-86.

Frøisland, D. H. & Årsand, E. (2015) Integrating visual dietary documentation in mobile-phone-based self-management application for adolescents with type 1 diabetes. *J Diabetes Sci Technol*, 9(3): 541-548.

Frøisland, D. H., Årsand, E. & Skarderud, F. (2012) Improving Diabetes Care for Young People With Type 1 Diabetes Through Visual Learning on Mobile Phones: Mixed-Methods Study. *J Med Internet Res*, 14(4): 113-125.

Garabedian, L. F., Ross-Degnan, D. & Wharam, J. F. (2015) Mobile Phone and Smartphone Technologies for Diabetes Care and Self-Management. *Current Diabetes Reports*, 15(12): 109.

Garcia, E., Martin, C., Garcia, A., Harrison, R. & Flood, D. (2011) Systematic Analysis of Mobile Diabetes Management Applications on Different Platforms. In: Holzinger, A. & Simonic, K.-M., eds. *Information Quality in e-Health*. Springer Berlin Heidelberg: 379-396.

Garnweidner-Holme, M. L., Borgen, I., Garitano, I., Noll, J. & Lukasse, M. (2015) Designing and Developing a Mobile Smartphone Application for Women with Gestational Diabetes Mellitus Followed-Up at Diabetes Outpatient Clinics in Norway. *Healthcare*, 3(2): 310-323.

Gibson, O. J., Loerup, L., MacKillop, L., Farmer, A. J., Levy, J. C., Bartlett, K., Kenworthy, Y., Blincowe, J. & Tarassenko, L. (2013) GDm-health: Remote monitoring for gestational diabetes.

Glasgow, R., Strycker, L., Kurz, D., Faber, A., Bell, H., Dickman, J., Halterman, E., Estabrooks, P. & Osuna, D. (2010) Recruitment for an Internet-Based Diabetes Self-Management Program: Scientific and Ethical Implications. *Annals of Behavioral Medicine*, 40(1): 40-48.

Glasziou, P., Irwig, L., Bain, C. & Colditz, G. (2001) *Systematic reviews in health care: a practical guide*. Cambridge University Press.

Goyal, S. & Cafazzo, J. A. (2013) Mobile phone health apps for diabetes management: current evidence and future developments. *Qjm*, 106(12): 1067-1069.

Green, J. J. & Thorogood, N. (2009) *Qualitative methods for health research*. London, California, India: Sage Publications.

Greenwood, D. A., Gee, P. M., Fatkin, K. J. & Peeples, M. (2017) A Systematic Review of Reviews Evaluating Technology-Enabled Diabetes Self-Management Education and Support. *J Diabetes Sci Technol*.

Gröger, C., Silcher, S., Westkämper, E. & Mitschang, B. (2013) Leveraging Apps in Manufacturing. A Framework for App Technology in the Enterprise. *Procedia CIRP*, 7(0): 664-669.

Guideline Development Group, Bilo, H., Coentrão, L., Couchoud, C., Covic, A., De Sutter, J., Drechsler, C., Gnudi, L., Goldsmith, D., Heaf, J. and Heimburger, O., 2015. Clinical Practice Guideline on management of patients with diabetes and chronic kidney disease stage 3b or higher (eGFR< 45 mL/min). *Nephrology Dialysis Transplantation*, *30*(suppl_2), ii1-ii142.

Gulliksen, J., Göransson, B., Boivie, I., Blomkvist, S., Persson, J. & Cajander, Å. (2003) Key principles for user-centred systems design. *Behaviour & Information Technology*, 22(6): 397-409.

Guo, P., Watts, K. & Wharrad, H. (2015) An integrative review of the impact of mobile technologies used by healthcare professionals to support education and practice. *Nursing Open*, 3(2): 66-78.

Guthrie, B., Payne, K., Alderson, P., McMurdo, M. E. T. & Mercer, S. W. (2012) Adapting clinical guidelines to take account of multimorbidity. *BMJ*, 341-345.

Hadjipanayis, A., Klonis, A., Abdel-Mannan, O. A. & Sutcliffe, A. G. (2016) Smartphone use in Paediatric Practice: a national survey. *Journal of mobile technology in medicine*, 5(1): 3-8.

Haffey, F., Brady, R. & Maxwell, S. (2013) Smartphone apps to support hospital prescribing and pharmacology education: a review of current provision. *British journal of clinical pharmacology*, 77(1): 31–38.

Hale, K., Capra S. & Bauer, J. (2015) A Framework to Assist Health Professionals in Recommending High-Quality Apps for Supporting Chronic Disease Self-Management: Illustrative Assessment of Type 2 Diabetes Apps. *JMIR mHealth uHealth,* 3(3): e87.

Hamine, S., Gerth-Guyette, E., Faulx, D., Green, B. B. & Ginsburg, A. S. (2015) Impact of mHealth chronic disease management on treatment adherence and patient outcomes: a systematic review. *J Med Internet Res,* 17(2): e42.

Harris, L. T., Tufano, J., Le, T., Rees, C., Lewis, G. A., Evert, A. B., Flowers, J., Collins, C., Hoath, J., Hirsch, I. B., Goldberg, H. I. & Ralston, J. D. (2010) Designing mobile support for glycemic control in patients with diabetes. *J Biomed Inform*, 43(Suppl-5): S37-40.

Hendrich, A., Chow, M. P., Skierczynski, B. A. & Lu, Z. (2008) A 36-hospital time and motion study: how do medical-surgical nurses spend their time? *Perm J*, 12(3): 25-34.

Herbert, L., Owen, V., Pascarella, L. & Streisand, R. (2013) Text message interventions for children and adolescents with type 1 diabetes: a systematic review. *Diabetes Technol Ther*, 15(5): 362-370.

Hersh, W. (2009) A stimulus to define informatics and health information technology. *BMC Med Inform Decis Mak*, 9-24.

Higgins, J. P. T. & Green, S. (2011) *Cochrane Handbook for Systematic Reviews of Interventions*. The Cochrane Collaboration. Version 5.1.0 ed. West Sussex, England: A John Wiley & Sons, Ltd., Publication.

Higgins, J. P. T. & Thompson, S. G. (2002) Quantifying heterogeneity in a meta-analysis. *Statistics in Medicine.*, 21(11): 1539-1558.

Higgins, J. P. T., Thompson, S. G., Deeks, J. J. & Altman, D. G. (2003) Measuring inconsistency in meta-analyses. *BMJ*, 327(7414): 557-560.

Hill, J. & Masding, M. G. (2013) The development of an innovative mobile phone App for Type 1 diabetes alcohol education. *Diabetic Medicine*, 30(1):112.

Hirst, J. E., Loerup, L., Mackillop, L., Farmer, A., Kenworthy, Y., Bartlett, K., Velardo, C., Kevat, D. A., Tarassenko, L. & Levy, J. C. (2015a) Digital blood glucose monitoring could provide new objective assessments of blood glucose control in women with gestational diabetes. *Diabetic Medicine*, 33(11): 1598-1599.

Hirst, J. E., Mackillop, L., Loerup, L., Gibson, O. J., Farmer, A. J., Bartlett, K., Tarassenko, L., Kenworthy, Y., Kevat, D. A. & Levy, J. (2014) GDm-Health: A Pilot Study Examining Acceptability of Mobile Phone Assisted Remote Blood Glucose Monitoring for Women with Gestational Diabetes Mellitus. *Reproductive Sciences*, *21*(3): 252A-253A.

Hirst, J. E., Mackillop, L., Loerup, L., Kevat, D. A., Bartlett, K., Gibson, O., Kenworthy, Y., Levy, J. C., Tarassenko, L. & Farmer, A. (2015b) Acceptability and user satisfaction of a smartphone-based, interactive blood glucose management system in women with gestational diabetes mellitus. *Journal of diabetes science and technology*, *9*(1): 111-115.

Holl, B., Spat, S., Beck, P., Neubauer, K. M., Mader, J. K., Schaupp, L., Chiarugi, F. & Pieber, T. R. (2014) Glucotab - Automatic decision support for treatment of patients with diabetes type 2 in hospital. *Diabetes Technology & Therapeutics,* 16: A114.

Holmen, H., Torbjørnsen, A., Wahl, A. K., Jenum, A. K., Småstuen, M. C., Årsand, E. & Ribu, L. (2014) A mobile health intervention for self-management and lifestyle change for persons with type 2 diabetes, part 2: one-year results from the Norwegian randomized controlled trial RENEWING HEALTH. *JMIR mHealth and uHealth*, 2(4): e57.

Holtz, B. & Lauckner, C. (2012) Diabetes management via mobile phones: a systematic review. *Telemed J E Health*, 18(3): 175-184.

Hong, M. K., Cho, Y. Y., Rha, M. Y., Kim, J. H. & Lee, M.-K. (2015) Six-month Outcomes of Mobile Phone Application-based Self-management in a Patient with Type 2 Diabetes. *Clin Nutr Res*, 4(3): 201-207.

Hood, M., Wilson, R., Corsica, J., Bradley, L., Chirinos, D. & Vivo, A. (2016) What do we know about mobile applications for diabetes self-management? A review of reviews. *Journal of behavioral medicine*, *39*(6): 981-994.

Hou, C., Carter, B., Hewitt, J., Francisa, T. & Mayor, S. (2016) Do Mobile Phone Applications Improve Glycemic Control (HbA1c) in the Self-management of Diabetes? A Systematic Review, Meta-analysis, and GRADE of 14 Randomized Trials. *Diabetes Care*, 39(11): 2089- 2095.

Househ, M. S., Shubair, M. M., Yunus, F., Jamal, A. & Aldossari, B. (2015) The Use of an Adapted Health IT Usability Evaluation Model (Health-ITUEM) for Evaluating Consumer Reported Ratings of Diabetes mHealth Applications: Implications for Diabetes Care and Management. *Acta Informatica Medica*, 23(5): 290-295.

Hsu, W. C., Lau, K. H. K., Huang, R., Ghiloni, S., Le, H., Gilroy, S., Abrahamson, M. & Moore, J. (2015) Utilization of a Cloud-Based Diabetes Management Program for Insulin Initiation and Titration Enables Collaborative Decision Making Between Healthcare Providers and Patients. *Diabetes Technol Ther*, 18(2): 59-67.

Huckvale, K., Adomaviciute, S., Prieto, J.T., Leow, M.K.S. and Car, J., (2015). Smartphone apps for calculating insulin dose: a systematic assessment. *BMC medicine*, *13*(1): 106.

Huckvale, K., Velthoven, M. v., Cash-Gibson, L., Felix, L. & Car, J. (2011) Self-care using apps for smartphones and other mobile device software: a systematic review of the literature using the example of diabetes mellitus.

Humble, J., Debon, M., Krukowski, R., Womack, C. & Bailey, J. E. (2014) Interest in and use of smart phone technology for diabetes self-management in diverse populations. *Journal of Investigative Medicine,* 62(2): 584.

Humble, J. R., Tolley, E. A., Krukowski, R. A., Womack, C. R., Motley, T. S. & Bailey, J. E. (2015) Use of and interest in mobile health for diabetes self-care in vulnerable populations. 22(1): 32-38.

Hunt, C. W., Sanderson, B. K. & Ellison, K. J. (2014) Support for diabetes using technology: a pilot study to improve self-management. *Medsurg Nursing*, 23(4): 231.

Huntley, A. L., Johnson, R., Purdy, S., Valderas, J. M. & Salisbury, C. (2012) Measures of multimorbidity and morbidity burden for use in primary care and community settings: a systematic review and guide. *Ann Fam Med*, 10(2): 134-141.

Hyun, S., Hodorowski, J. K., Nirenberg, A., Perocchia, R. S., Staats, J. A., Velez, O. & Bakken, S. (2013) Mobile health-based approaches for smoking cessation resources. *Oncol Nurs Forum*, 40(4): e312-319.

IBM Corp. (2015) IBM SPSS Statistics [software program]. Version 20.0. Ny, USA.

IMS Institute for Healthcare Informatics (2013) *Patient Apps for Improved Healthcare From Novelty to Mainstream*. [Online] Available from: http://www.imshealth.com/portal/site/imshealth/menuitem.762a961826aad98f53c753c71ad8c22a/?vgnextoid=e0f913850c8b1410VgnVCM10000076192ca2RCRD (Accessed 10/12/2013).

International Diabetes Federation (2015) *IDF Diabetes Atlas*. [Online] Available from: www.idf.org/diabetesatlas (Accessed 17/3/2017).

Istepanian, R. S. H. (2015) Mobile applications for diabetes management: efficacy issues and regulatory challenges. *The Lancet Diabetes & Endocrinology*, 3(12): 921-923.

Istepanian, R. S. H., Mousa, A., Haddad, N., Sungoor, A., Hammadan, T., Soran, H. & Al-Anzi, T. (2014) The potential of m-health systems for diabetes management in post conflict regions a case study from Iraq. *Engineering in Medicine and Biology Society (EMBC), 36th Annual International Conference of the IEEE*, 3650-3653.

Jamal, A., Temsah, M.-H., Khan, S. A., Al-Eyadhy, A., Koppel, C. & Chiang, M. F. (2016) Mobile Phone Use Among Medical Residents: A Cross-Sectional Multicenter Survey in Saudi Arabia. *JMIR mHealth and uHealth*, 4(2): e61.

Jeffery, R., Iserman, E. & Haynes, R. B. (2013) Can computerized clinical decision support systems improve diabetes management? A systematic review and meta-analysis. *Diabet Med*, 30 (6): 739-745.

Johansson, P., Petersson, G., Saveman, B.-I. & Nilsson, G. (2014) Using advanced mobile devices in nursing practice – the views of nurses and nursing students. *Health Informatics Journal*, 20(3): 220-231.

Karat, J. (1996) User centered design: quality or quackery? *Interactions*, 3(4): 18-20.

Kaufman, N. (2010) Internet and information technology use in treatment of diabetes. *Int J Clin Pract Suppl*, 64(s166): 41-46.

Kim, H. S., Choi, W., Baek, E. K., Kim, Y. A., Yang, S. J., Choi, I. Y., Yoon, K. H. & Cho, J. H. (2014) Efficacy of the smartphone-based glucose management application stratified by user satisfaction. *Diabetes and Metabolism Journal*, 38(3): 204-210.

Kim, Y. J., Rhee, S. Y., Byun, J. K., Park, S. Y., Hong, S. M., Chin, S. O., Chon, S., Oh, S., Woo, J.-t. & Kim, S. W. (2015) A Smartphone Application Significantly Improved Diabetes Self-Care Activities with High User Satisfaction. *Diabetes & Metabolism Journal*, 39(3): 207-2014.

Kirwan, M., Vandelanotte, C., Fenning, A. & Duncan, J. M. (2013) Diabetes Self-Management Smartphone Application for Adults With Type 1 Diabetes: Randomized Controlled Trial. *J Med Internet Res*, 15(11): e235.

Kitsiou, S., Pare, G., Jaana, M. & Gerber, B. (2017) Effectiveness of mHealth interventions for patients with diabetes: An overview of systematic reviews. *PLoS ONE,* 12(3): e0173160.

Klasnja, P. & Pratt, W. (2012) Healthcare in the pocket: Mapping the space of mobile-phone health interventions. *J Biomed Inform*, 45(1): 184-198.

Klein, L. F., Rigo, S. J., Cazella, S. C. & Ben, Â. J. (2016) An Application for Mobile Devices Focused on Clinical Decision Support: Diabetes Mellitus Case. In: Lindgren, H., De Paz, J. F., Novais, P., Fernández-Caballero, A., Yoe, H., Jiménez Ramírez, A. & Villarrubia, G., eds. *Ambient Intelligence- Software and Applications – 7th International Symposium on Ambient Intelligence (ISAmI 2016)*. Springer International Publishing: 57-65.

Klonoff, D. C. & True, M. W. (2009) The missing element of telemedicine for diabetes: decision support software. *J Diabetes Sci Technol*, 3(5): 996-1001.

Knorr, K., Aspinall, D. & Wolters, M. (2015) On the Privacy, Security and Safety of Blood Pressure and Diabetes Apps. In: Federrath, H. & Gollmann, D., eds. *ICT Systems Security and Privacy Protection: 30th IFIP TC 11 International Conference.* Springer International Publishing (455): 571-584.

Koehler, N., Vujovic, O. & McMenamin, C. (2013) Healthcare professionals' use of mobile phones and the internet in clinical practice. *Journal of mobile technology in medicine*, 2(1S): 3-13.

Krishna, S. & Boren, S. A. (2008) Diabetes self-management care via cell phone: a systematic review. *Journal of Diabetes Science & Technology*, 2(3): 509-517.

Lau, J., Ioannidis, J. P. A., Terrin, N., Schmid, C. H. & Olkin, I. (2006) The case of the misleading funnel plot. *BMJ*, 333(7568): 597-600.

Lazar, J., Feng, J. H. & Hochheiser, H. (2010) *Research methods in human-computer interaction*. 1st Ed. John Wiley & Sons.

Le, T. X. (2008). *HealthReachMobile: A Prototype System for Mobile Diabetes Management.* Doctoral dissertation, University of Washington.

Lehocki, F., Balogh, S., Kovac, M., Zakovicova, E., de Witte, B. & Ieee (2012) Innovative Telemedicine Solutions for Diabetic Patients Best Practices for Telemedicine Service Implementation. In *2012 IEEE EMBS Conference on Biomedical Engineering and Sciences (IECBES),* 203-208.

Lewis, T. L. & Wyatt, J. C. (2014) mHealth and Mobile Medical Apps: A Framework to Assess Risk and Promote Safer Use. *J Med Internet Res*, 16(9): e210.

Li, K.-l. & 李潔寧. (2014). *m-Health smartphone applications on chronic disease monitoring: development and regulatory considerations.* Master Dissertation, University of Hong Kong.

Liang, X., Wang, Q., Yang, X., Cao, J., Chen, J., Mo, X., Huang, J., Wang, L. & Gu, D. (2011) Effect of mobile phone intervention for diabetes on glycaemic control: a meta-analysis. *Diabet Med*, 28(4): 455-463.

Liu, L. & Ogwu, S.-M. (2012) A Meta-Analysis of Mobile Health and Risk Reduction in Patients with Diabetes Mellitus: Challenge and Opportunity. *Journal of Mobile Technology in Medicine (JMTM)*, 1(3): 17-24.

Liu, Y., Ren, W., Qiu, Y., Liu, J., Yin, P. & Ren, J. (2016) The Use of Mobile Phone and Medical Apps among General Practitioners in Hangzhou City, Eastern China. *JMIR mHealth and uHealth*, 4(2): e94.

Loerup, L., Gibson, O. J., Hirst, J. E., Farmer, A. J., Bartlett, K., Blincowe, J. E., Kenworthy, Y. M., Kevat, D. A., MacKillop, L. H., Tarassenko, L. & Levy, J. C. (2013) GDm-Health: telehealth for remote monitoring and treatment of gestational diabetes.

Loerup, L., Gibson, O. J., Hirst, J. E., Farmer, A. J., Bartlett, K. J., Kenworthy, Y. M., Blincowe, J. E., Kevat, D. A., MacKillop, L. H., Tarassenko, L. & Levy, J. C. (2014a) GDm-Health: a pilot study demonstrating the feasibility of mobile phone assisted treatment advice and medication adjustment for women with gestational diabetes. *Diabetic Medicine*, *31*: 148-149.

Loerup, L., Hirst, J. E., MacKillop, L. H., Farmer, A., Kevat, D. A., Tarassenko, L., Gibson, O. J., Bartlett, K., Kenworthy, Y. M. & Levy, J. (2014b) GDm-Health: a pilot study examining acceptability of mobile phone assisted remote blood glucose monitoring for women with gestational diabetes. *Diabetic Medicine*, *31*: 147.

Logan, A. G., Irvine, M. J., McIsaac, W. J., Tisler, A., Rossos, P. G., Easty, A., Feig, D. S. & Cafazzo, J. A. (2012) Effect of Home Blood Pressure Telemonitoring With Self-Care Support on Uncontrolled Systolic Hypertension in Diabetics. *Hypertension*, 60(1): 51-57.

Luijks, H., Schermer, T., Bor, H., van Weel, C., Lagro-Janssen, T., Biermans, M. and de Grauw, W., (2012). Prevalence and incidence density rates of chronic comorbidity in type 2 diabetes patients: an exploratory cohort study. *BMC medicine*, *10*(1): 128.

Mackillop, L., Loerup, L., Bartlett, K., Farmer, A., Gibson, O. J., Hirst, J. E., Kenworthy, Y., Kevat, D. A., Levy, J. C. & Tarassenko, L. (2014) Development of a Real-Time Smartphone Solution for the Management of Women With or at High Risk of Gestational Diabetes. *J Diabetes Sci Technol*, *8*(6): 1105-1114.

Maguire, M. (2001) Methods to support human-centred design. *International journal of human-computer studies*, 55(4): 587-634.

Majeed-Ariss, R., Baildam, E., Campbell, M., Chieng, A., Fallon, D., Hall, A., McDonagh, E. J., Stones, R. S., Thomson, W. & Swallow, V. (2015) Apps and Adolescents: A Systematic Review of Adolescents? Use of Mobile Phone and Tablet Apps That Support Personal Management of Their Chronic or Long-Term Physical Conditions. *J Med Internet Res*, 17(12): e287.

Marengoni, A., Angleman, S., Melis, R., Mangialasche, F., Karp, A., Garmen, A., Meinow, B. & Fratiglioni, L. (2011) Aging with multimorbidity: a systematic review of the literature. *Ageing Res Rev*, 10(4): 430-439.

Martinez-Perez, B., de la Torre-Diez, I. & Lopez-Coronado, M. (2013) Mobile Health Applications for the Most Prevalent Conditions by the World Health Organization: Review and Analysis. *J Med Internet Res*, 15(6): e120.

MedData Group (2014) *Physician Percepons of Mobile & Connected Health: What Every Marketer Should Know*. [Online] Available from: http://www.meddatagroup.com/connected-health-report-w-landing-page/ (Accessed 28/4/2014).

Miele, F., Eccher, C. & Piras, E. M. (2015) Using a Mobile App to Manage Type 1 Diabetes: The Case of TreC Diabetes. In *Proceedings of the 5th International Conference on Digital Health.* ACM, 113-114.

Min, L. (2013). *Design and Evaluation of a Mobile Health Application for Adult Patients with Type 1 Diabetes Mellitus.* Doctoral Dissertation, University of Toronto.

MobiHealthNews (2010) *World of Health and Medical Apps Report*. [Online] Available from: http://mobihealthnews.com/research/the-world-of-health-and-medical-apps/ (Accessed 10/12/2013).

Moher, D., Liberati, A., Tetzlaff, J., Altman, D. G. & The, P. G. (2009) Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. *PLoS medicine*, 6(7): 399.

Moore, S. & Jayewardene, D. (2014) The use of smartphones in clinical practice: Sally Moore and Dharshana Jayewardene look at the rise in the use of mobile software at work. *Nursing Management*, 21(4): 18-22.

Mosa, A. S., Yoo, I. & Sheets, L. (2012) A systematic review of healthcare applications for smartphones. *BMC Med Inform Decis Mak*, 12(1): 67.

Moyer, J. E. (2013) Managing Mobile Devices in Hospitals: A Literature Review of BYOD Policies and Usage. *Journal of Hospital Librarianship*, 13(3): 197-208.

National Institute for Health and Clinical Excellence (2011) *Hypertension in adults: diagnosis and management*. [Online] Available from: https://www.nice.org.uk/guidance/cg127 (Accessed 16/3/2016).

National Institute for Health and Clinical Excellence (2013) *Dapagliflozin in combination therapy for treating type 2 diabetes*. [Online] Available from: https://www.nice.org.uk/guidance/ta288 (Accessed 16/3/2016).

National Institute for Health and Clinical Excellence (2014a) *Canagliflozin in combination therapy for treating type 2 diabetes*. [Online] Available from: https://www.nice.org.uk/guidance/ta315 (Accessed 16/3/2016).

National Institute for Health and Clinical Excellence (2014b) *Cardiovascular disease: risk assessment and reduction, including lipid modification*. [Online] Available from: https://www.nice.org.uk/guidance/cg181 (Accessed 16/3/2016).

National Institute for Health and Clinical Excellence (2014c) *Chronic kidney disease in adults: assessment and management*. [Online] Available from: https://www.nice.org.uk/guidance/cg182 (Accessed 16/3/2016).

National Institute for Health and Clinical Excellence (2015a) *Type 2 diabetes in adults: management*. [Online] Available from: https://www.nice.org.uk/guidance/ng28 (Accessed 16/3/2016).

National Institute for Health and Clinical Excellence (2015b) *Empagliflozin in combination therapy for treating type 2 diabetes*. [Online] Available from: https://www.nice.org.uk/guidance/ta336 (Accessed 16/3/2016).

Neubauer, K. M., Mader, J. K., Hoell, B., Schaupp, L., Beck, P., Spat, S., Augustin, T., Aberer, F., Plank, J. & Pieber, T. R. (2014a) Glucotab: A tablet-based workflow and decision support system to achieve safe glycemic control for basal-bolus insulin therapy in hospitalized patients with type 2 diabetes. *Diabetes*, 63: A603.

Neubauer, K. M., Mader, J. K., Höll, B., Aberer, F., Donsa, K., Augustin, T., Schaupp, L., Spat, S., Beck, P., Fruhwald, F. M., Schnedl, C., Rosenkranz, A. R., Lumenta, D. B., Kamolz, L.-P., Plank, J. & Pieber, T. R. (2015) Standardized Glycemic Management with a Computerized Workflow and Decision Support System for Hospitalized Patients with Type 2 Diabetes on Different Wards. *Diabetes Technol Ther*, 17(10): 685-692.

Neubauer, K. M., Mader, J. K., Schaupp, L., Holl, B., Spat, S., Augustin, T., Beck, P., Buttinger, M., Plank, J. & Pieber, T. R. (2014b) Tablet-based workflow and decision support of in-hospital glycaemic management-perceptions of nurses and physicians. *Diabetes Technology and Therapeutics*, 16: A140.

Nie, L., Xie, B., Yang, Y. & Shan, Y. M. (2016) Characteristics of Chinese m-Health Applications for Diabetes Self-Management. *Telemedicine and e-Health,* 22(7): 614-619.

Nielsen, R. P. D. P. (2013). *How are users applying smartphone apps for remote monitoring and self-management of diabetes in Denmark?* Master Dissertation, Aalborg University.

Norman, D. A. & Draper, S. W. (1986) *User Centered System Design; New Perspectives on Human-Computer Interaction*. Hillsdale, Earlbaum.

Noyes, J. & Baber, C. (1999) *User-centred design of systems*. London, Springer Science & Business Media.

O'Connor, P., Byrne, D., Butt, M., Offiah, G., Lydon, S., Mc Inerney, K., Stewart, B. & Kerin, M. J. (2014) Interns and their smartphones: use for clinical practice. *Postgrad Med J*, 90(1060): 75-79.

O'Reilly, M. K., Nason, G. J., Liddy, S., Fitzgerald, C. W., Kelly, M. E. & Shields, C. (2014) DOCSS: doctors on-call smartphone study. *Irish Journal of Medical Science,* 183(4): 573-577.

Okazaki, S., Alberto Castaneda, J., Sanz, S. & Henseler, J. (2012) Factors Affecting Mobile Diabetes Monitoring Adoption Among Physicians: Questionnaire Study and Path Model. *J Med Internet Res*, 14(6): 170-182.

Owen, T., Pearson, J., Thimbleby, H. & Buchanan, G. (2015) ConCap: Designing to Empower Individual Reflection on Chronic Conditions using Mobile Apps. In *Proceedings of the 17th International Conference on Human-Computer Interaction with Mobile Devices and Services.* ACM. 105-114.

Patterson, J. (2013). *Mobile Health, Self-Management, Diabetes & the Impact of Self-Efficacy: A Systematic Review of Literature.* Master Dissertation, University of Ottawa.

Pellegrini, C. A., Hoffman, S. A., Daly, E. R., Murillo, M., Iakovlev, G. & Spring, B. (2015) Acceptability of smartphone technology to interrupt sedentary time in adults with diabetes. *Translational Behavioral Medicine*, 5(3): 307-314.

Penfornis, A., Clergeot, A., Dardari, D., Benhamou, P., Schaepelynck, P., Hanaire, H., Catargi, B., Chaillous, L., Renard, E., Halimi, S., Bosson, J. & Charpentier, G. (2010) Improved glycemic control by the telemedicine system DIABEO patients with type 1 diabetes: results of the study Telediabl. In *DIABETES & METABOLISM* (36): A20-A21.

Petre, M. & Rugg, G. (2010) *The Unwritten Rules of PhD Research (Open Up Study Skills)*. Berkshire: Open University Press.

Pew Research Center (2016) *Smartphone Ownership and Internet Usage Continues to Climb in Emerging Economies*. [Online] Available from: www.pewresearch.org (Accessed 21/3/2017).

Pludwinski, S., Ahmad, F., Wayne, N. & Ritvo, P. (2015) Participant experiences in a smartphone-based health coaching intervention for type 2 diabetes: A qualitative inquiry. *J Telemed Telecare*, 22(3): 172-178.

Pope, C. & Mays, N. (2006) *Qualitative research in health care*. Third Edition. *Malden, MA: BMJ Books*. Blackwell Publishing.

Prgomet, M., Georgiou, A. & Westbrook, J. I. (2009) The impact of mobile handheld technology on hospital physicians' work practices and patient care: a systematic review. 16(6): 792– 801.

Public Health England (2016) *3.8 million people in England now have diabetes*. [Online] Available from: https://www.gov.uk/government/news/38-million-people-in-england-now-have-diabetes (Accessed 11/9/2017).

Pulman, A., Taylor, J., Galvin, K. & Masding, M. (2012) Designing Mobile Applications to Support Type 1 Diabetes Education. In *mLearn* Conference. Helsinki, Finland 54-61.

Pulman, A., Taylor, J., Galvin, K. & Masding, M. (2013a) Ideas and enhancements related to mobile applications to support type 1 diabetes. *JMIR mHealth and uHealth*, 1(2): e12.

Pulman, A. J., Hill, J. & Masding, M. G. (2013b) Reconsidering your perceptions: Exploring the lifeworld of a young person with Type 1 diabetes. *Diabetes UK Professional Conference 2013*, Manchester, England.

Pulman, A. J., Hill, J. & Masding, M. G. (2013c) Why haven't YOU thought of that? Over 15 great mobile App ideas for improving the quality of life of a young person with Type 1 diabetes. *Diabetes UK Professional Conference 2013*, Manchester, England.

QSR International. (2012) NVivo 10 [Software program]. Version 10. Doncaster, Australia.

Quinn, C. C., Shardell, M. D., Terrin, M. L., Barr, E. A., Ballew, S. H. & Gruber-Baldini, A. L. (2011) Cluster-randomized trial of a mobile phone personalized behavioral intervention for blood glucose control. *Diabetes Care*, 34(9): 1934-1942.

Rao, A., Hou, P., Golnik, T., Flaherty, J. & Vu, S. (2010) Evolution of data management tools for managing self-monitoring of blood glucose results: a survey of iPhone applications. *J Diabetes Sci Technol*, 4(4): 949-957.

Razali, N. M. & Wah, Y. B. (2011) Power comparisons of shapiro-wilk, kolmogorov-smirnov, lilliefors and anderson-darling tests. *Journal of statistical modeling and analytics*, 2(1): 21-33.

Research2Guidance (2013) *Mobile Health Market Report 2013-2017.* [Online] Available from: http://www.research2guidance.com/shop/index.php/mhealth-report-2 (Accessed 2/6/2014).

Research2Guidance (2014) *Diabetes App Market Report 2014.* [Online] Available from: http://www.research2guidance.com/shop/index.php/diabetes-app-market-report-2014 (Accessed 2/6/2014).

Research2guidance (2016) *mHealth App Developer Economics2016: the curent status and trends of the mHealth app market*. [Online] Available from: http://research2guidance.com/r2g/r2g-mHealth-App-Developer-Economics-2016.pdf (Accessed 21/4/2017).

Ribu, L., Holmen, H., Torbjørnsen, A., Wahl, A. K., Grottland, A., Smastuen, M. C., Elind, E., Bergmo, T. S., Breivik, E. & Årsand, E. (2013) Low-intensity self-management intervention for persons with type 2 diabetes using a mobile phone-based diabetes diary, with and without health counseling and motivational interviewing: protocol for a randomized controlled trial. *JMIR research protocols*, 2(2): e34-e34.

Robson, C. & McCartan, K. (2016) *Real world research*. 4th ed. John Wiley & Sons.

Rodgers, M., Sowden, A., Petticrew, M., Arai, L., Roberts, H., Britten, N. & Popay, J. (2009) Testing Methodological Guidance on the Conduct of Narrative Synthesis in Systematic Reviews: Effectiveness of Interventions to Promote Smoke Alarm Ownership and Function. *Evaluation*, 15(1): 49-73.

Roshanov, P. S., Misra, S., Gerstein, H. C., Garg, A. X., Sebaldt, R. J., Mackay, J. A., Weise-Kelly, L., Navarro, T., Wilczynski, N. L. & Haynes, R. B. (2011) Computerized clinical decision support systems for chronic disease management: a decision-maker-researcher partnership systematic review. *Implement Sci*, 6(1): 92.

Saffari, M., Ghanizadeh, G. & Koenig, H. G. (2014) Health education via mobile text messaging for glycemic control in adults with type 2 diabetes: A systematic review and meta-analysis. *Primary care diabetes*, 8(4): 275-285.

Saldaña, J. (2013) *The coding manual for qualitative researchers*. 2nd ed. London, Thousand Oaks and New Delhi: Sage publications

Salisbury, C., (2012). Multimorbidity: redesigning health care for people who use it. *The Lancet*, *380*(9836): 7-9.

Sarala, A. V. (2014). *Development of a Smartphone-enabled hypertension and diabetes management package to facilitate evidence-based care delivery in primary healthcare facilities in India: A formative research to inform intervention design.* Doctoral Dissertation, London School of Hygiene & Tropical Medicine.

Scheibe, M., Reichelt, J., Bellmann, M. & Kirch, W. (2015) Acceptance Factors of Mobile Apps for Diabetes by Patients Aged 50 or Older: A Qualitative Study. *Medicine 2.0*, 4(1): e1.

Sedgwick, M. G., Awosoga, O., Grigg, L. & Durnin, J.-M. (2016) A quantitative study exploring undergraduate nursing students' perception of their critical thinking and clinical decision making ability while using apps at the point of care. *Journal of Nursing Education and Practice*, 6(10): 1.

Shaphiro, S. S. & Wilk, M. B. (1965) An analysis of variance test for normality. *Biometrika*, 52(3): 591-611.

Silva, B. M., Rodrigues, J. J., de la Torre Diez, I., Lopez-Coronado, M. & Saleem, K. (2015) Mobile-health: A review of current state in 2015. *Journal of biomedical informatics*, 56: 265-272.

Siriwardena, L. S., Wickramasinghe, W. A., Perera, K. L., Marasinghe, R. B., Katulanda, P. & Hewapathirana, R. (2012) A review of telemedicine interventions in diabetes care. *J Telemed Telecare*, 18(3): 164-168.

Skinner, A. J. (2015). *Establishing the needs of Type 1 diabetes users for mobile application design.* Matser Dissertaion, Iowa State University.

Smith, S. M., Soubhi, H., Fortin, M., Hudon, C. & O'Dowd, T. (2012) Managing patients with multimorbidity: systematic review of interventions in primary care and community settings. *BMJ*, 345: E5205.

Spat, S., Höll, B., Petritsch, G., Schaupp, L., Beck, P. & Pieber, T. R. (2013) Automatic system testing of a decision support system for insulin dosing using Google Android. In *Stud. Health Technol. Inform. Conference* (186): 187-191.

Springer Publishing (2013) *2013 Nursing and Technology Survey*. [Online] Available from: http://www.springerpub.com/content/downloads/2013_Nursing-Technology-Survey_Springerpub.pdf (Accessed 29/4/2014).

SpyGlass Group (2014) *Healthcare without Bounds: Point of Care Communications for Nursing 2014*. [Online] Available from: www.spyglass-consulting.com (Accessed 29/4/2014).

Sterne, J. A. C., Egger, M. & Smith, G. D. (2001) Investigating and dealing with publication and other biases in meta-analysis. *BMJ*, 323(7304): 101-105.

Sterne, J. A. C., Sutton, A. J., Ioannidis, J. P. A., Terrin, N., Jones, D. R., Lau, J., Carpenter, J., Rücker, G., Harbord, R. M., Schmid, C. H., Tetzlaff, J., Deeks, J. J., Peters, J., Macaskill, P., Schwarzer, G., Duval, S., Altman, D. G., Moher, D. & Higgins, J. P. T. (2011) Recommendations for examining and interpreting funnel plot asymmetry in meta-analyses of randomised controlled trials. *BMJ*, 343: d4002.

Stoyanov, R. S., Hides, L., Kavanagh, J. D., Zelenko, O., Tjondronegoro, D. & Mani, M. (2015) Mobile App Rating Scale: A New Tool for Assessing the Quality of Health Mobile Apps. *JMIR Mhealth Uhealth*, 3(1): e27.

Strauss, A. L. & Corbin, J. (1990) *Basics of Qualitative Research: Grounded Theory Procedures and Techniques*. 1st ed. Newbury Park, CA: Sage Publishing.

Subhi, Y., Bube, S. H., Rolskov Bojsen, S., Skou Thomsen, A. S. & Konge, L. (2015) Expert Involvement and Adherence to Medical Evidence in Medical Mobile Phone Apps: A Systematic Review. *JMIR mHealth uHealth,* 3(3): e79.

Sun, C., Wong, B., Malcolm, J. C. & Doyle, M.-A. (2016) Improving Glycemic Control in Type 1 Diabetes with the Use of Smart-Phone Based Mobile Applications: A Systematic Review.

Sutcliffe, P., Martin, S., Sturt, J., Powell, J., Griffiths, F., Adams, A. & Dale, J. (2011) Systematic review of communication technologies to promote access and engagement of young people with diabetes into healthcare. *BMC Endocrine Disorders*, 11(1): 1.

Tacconelli, E. (2010) Systematic reviews: CRD's guidance for undertaking reviews in health care. *The Lancet Infectious Diseases*, 10(4): 226.

Tamony, P., Holt, R. & Barnard, K. (2015) The Role of Mobile Applications in Improving Alcohol Health Literacy in Young Adults With Type 1 Diabetes: Help or Hindrance? 9(6): 1313–1320.

Tao, D. & Or, C. K. (2013) Effects of self-management health information technology on glycaemic control for patients with diabetes: a meta-analysis of randomized controlled trials. *J Telemed Telecare*, 19(3): 133-143.

Tatara, N. (2013). *Studying usage and experiences of mHealth technology for its improved usability-Mixed methods research for understanding users' long-term engagement with the Few Touch application for self-management of Type 2 diabetes mellitus.* Doctoral Dissertaion, UiT The Arctic University of Norges.

Tatara, N., Årsand, E., Bratteteig, T. & Hartvigsen, G. (2013a) Usage and perceptions of a mobile self-management application for people with type 2 diabetes: qualitative study of a five-month trial. *Studies in health technology and informatics*, 192 :127-131.

Tatara, N., Årsand, E., Nilsen, H. & Hartvigsen, G. (2009) A Review of Mobile Terminal-Based Applications for Self-Management of Patients with Diabetes. In *eHealth, Telemedicine, and Social Medicine (eTELEMED'09) International Conference* (pp. 166-175).

Tatara, N., Årsand, E., Skrøvseth, O. S. & Hartvigsen, G. (2013b) Long-Term Engagement With a Mobile Self-Management System for People With Type 2 Diabetes. *JMIR Mhealth Uhealth*, 1 (1): e1.

The Nordic Cochrane Centre. (2014) Review Manager (RevMan) [Software program]. Version 5.3. Copenhagen, Denmark.

Thomas, J. & Harden, A. (2008) Methods for the thematic synthesis of qualitative research in systematic reviews. *BMC Medical Research Methodology*, 8(1): 45.

Thomson Reuters Corporation. (2013) EndNote X7 [Software program]. Version X7.0.2. NY, USA.

Tiefengrabner, M., Domhardt, M., Oostingh, G. J., Schwenoha, K., Stutz, T., Weitgasser, R. & Ginzinger, S. W. (2014) Can smartphone-based logging support diabetologists in solving glycemic control problems? In *EHealth2014–Health Informatics Meets EHealth: Outcomes Research: The Benefit of Health-IT* (pp. *198*.188).

Tomky, D., Cypress, M., Dang, D., Maryniuk, M. & Peyrot, M. (2008) AADE Position Statement - AADE7™ Self-Care Behaviors. *The Diabetes Educator*, 34(3): 445-449.

Tong, A., Flemming, K., McInnes, E., Oliver, S. & Craig, J. (2012) Enhancing transparency in reporting the synthesis of qualitative research: ENTREQ. *BMC Medical Research Methodology*, 12(1): 181.

Torbjørnsen, A., Jenum, A. K., Småstuen, M. C., Årsand, E., Holmen, H., Wahl, A. K. & Ribu, L. (2014) A Low-Intensity Mobile Health Intervention With and Without Health Counseling for Persons With Type 2 Diabetes, Part 1: Baseline and Short-Term Results From a Randomized Controlled Trial in the Norwegian Part of RENEWING HEALTH. *JMIR mHealth and uHealth*, 2(4): e52.

Tran, J., Tran, R. & White, J. R. (2012) Smartphone-based glucose monitors and applications in the management of diabetes: an overview of 10 salient "apps" and a novel smartphone-connected blood glucose monitor. *Clinical Diabetes*, 30(4): 173-178.

Umpierrez, G. E., Smiley, D., Hermayer, K., Khan, A., Olson, D. E., Newton, C., Jacobs, S., Rizzo, M., Peng, L. & Reyes, D. (2013) Randomized study comparing a basal-bolus with a basal plus correction insulin regimen for the hospital management of medical and surgical patients with type 2 diabetes. *Diabetes Care*, 36(8): 2169-2174.

U.S. Food & Drug Administration (2013) *Mobile Medical Applications - Guidance for Industry and Food and Drug Administration Staff*. [Online] Available from: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ConnectedHealth/MobileMedicalApplications/default.htm?utm_source=twitterfeed&utm_medium=twitter (Accessed 10/12/2013).

Ventola, C. L. (2014) Mobile devices and apps for health care professionals: uses and benefits. *Pharmacy and Therapeutics,* 39(5): 356-364.

Waite, M., Martin, C., Curtis, S. & Nugrahani, Y. (2013) Mobile phone applications and type 1 diabetes: An approach to explore usability issues and the potential for enhanced self-management. *Diabetes & Primary Care*, 15(1): 38–49.

Waki, K., Aizawa, K., Kato, S., Fujita, H., Lee, H., Kobayashi, H., Ogawa, M., Mouri, K., Kadowaki, T. & Ohe, K. (2015) DialBetics With a Multimedia Food Recording Tool, FoodLog. *J Diabetes Sci Technol*, 9(3): 534-540.

Waki, K., Aramaki, E., Uchimura, Y., Okahata, S., Masukawa, S., Omae, K., Hayakawa, M., Fujita, H., Kadowaki, T. & Ohe, K. (2011) Dialbetics: A novel smartphone-based self-management support system for type 2 diabetic patients. *Journal of diabetes science and technology*, *8*(2): 209-215.

Waki, K., Fujita, H., Uchimura, Y., Aramaki, E., Omae, K., Kadowaki, T. & Ohe, K. (2012) DialBetics: smartphone-based self-management for type 2 diabetes patients. *J Diabetes Sci Technol*, 6(4): 983-985.

Waki, K., Fujita, H., Uchimura, Y., Hayashi, A., Aramaki, E., Omae, K., Kadowaki, T. & Ohe, K. (2013) Dialbetics: Smartphone-based selfmanagement for type 2 diabetes patients. *Diabetes Technology & Therapeutics,* 15: A116-A117.

Waki, K., Fujita, H., Uchimura, Y., Omae, K., Aramaki, E., Kato, S., Lee, H., Kobayashi, H., Kadowaki, T. & Ohe, K. (2014) DialBetics: A Novel Smartphone-based Self-management Support System for Type 2 Diabetes Patients. *J Diabetes Sci Technol*, 8(2): 209-215.

Wan, Q., Makeham, M., Zwar, N.A. and Petche, S., 2012. Qualitative evaluation of a diabetes electronic decision support tool: views of users. *BMC medical informatics and decision making*, *12*(1): 61.

Wang, J., Wang, Y., Wei, C., Yao, N., Yuan, A., Shan, Y. & Yuan, C. (2014) Smartphone Interventions for Long-Term Health Management of Chronic Diseases: An Integrative Review. *Telemedicine and E-Health*, 20(6): 570-583.

Wayne, N., Perez, D. F., Kaplan, D. M. & Ritvo, P. (2015) Health Coaching Reduces HbA1c in Type 2 Diabetic Patients From a Lower-Socioeconomic Status Community: A Randomized Controlled Trial. *J Med Internet Res*, 17(10): e224.

Wayne, N. & Ritvo, P. (2014) Smartphone-Enabled Health Coach Intervention for People With Diabetes From a Modest Socioeconomic Strata Community: Single-Arm Longitudinal Feasibility Study. *J Med Internet Res*, 16(6): e149.

Weber, S. (2010) Impacts of Clinical Decision Support Technology on Nursing and Medical Practice in U.S. Critical Care. *Canadian Journal of Nursing Informatics*, 5(4): 1094.

Whitehead, L. & Seaton, P. (2016) The Effectiveness of Self-Management Mobile Phone and Tablet Apps in Long-term Condition Management: A Systematic Review. *J Med Internet Res*, 18(5): e97.

Whiting, D. R., Guariguata, L., Weil, C. & Shaw, J. (2011) IDF Diabetes Atlas: Global estimates of the prevalence of diabetes for 2011 and 2030. *Diabetes Research and Clinical Practice*, 94(3): 311-321.

Williams, J. P. (2015). *A Review of Popular Glucose Tracking Apps and Use of mHealth by Latinos with Diabetes.* Master Dissertaion, Emory University.

Williams, J. P. & Schroeder, D. (2015) Popular Glucose Tracking Apps and Use of mHealth by Latinos With Diabetes. *JMIR mHealth and uHealth*, 3 (3): e84.

World Health Organization (2011) *mHealth New horizons for health through mobile technologies*. [Online] Available from: http://www.who.int/goe/publications/goe_mhealth_web.pdf (Accessed 10/12/2013).

World Health Organization (2016) *Global Report on Diabetes.* [Online] Available from: http://www.who.int/diabetes/global-report/en/ (Accessed 17/3/2017).

Wyatt, J. C. (2000) Decision support systems. *Journal of the Royal Society of Medicine*, 93(12): 629-633.

Zulman, D. M., Asch, S. M., Martins, S. B., Kerr, E. A., Hoffman, B. B. & Goldstein, M. K. (2014) Quality of Care for Patients with Multiple Chronic Conditions: The Role of Comorbidity Interrelatedness. *Journal of General Internal Medicine*, 29(3): 529-537.

Appendices

Appendix 1. Search strategy details and results for all electronic databases and journals and grey literature

Limit: 2008 - Present
No Limit for Language

Database	Link	Search	Date	Hits
Cochrane Central Register of Controlled Trials	http://www.thecochranelibrary.com/	#1 diabet* or "IDDM" or "NIDDM" or "MODY":ti,ab,kw or "hyperinsulin" or (insulin next sensitive*) or (insulin next resist*) or (insulin next depend*) or insulin?depend* or (non next insulin next depend*):ti,ab,kw or (noninsulin next depend*) or (non next insulin?depend*) or noninsulin?depend*:ti,ab,kw or (impaired next glucose next tolerance*) or (glucose next intoleran*):ti,ab,kw or (typ* next 1 next diabet*) or (typ* next 2 next diabet*) or (typ* next I next diabet*) or (typ* next II next diabet*) or (gestational next diabet*):ti,ab,kw #2 (telephon* or phon*) and (mobil* or cell*) #3 (smartphone? or smart?phone?) or (window? next phone?) or (window? next mobile?) or "nokia" or ("palm" next "OS") or ("palm" next computer?) or "Symbian" or iphone? or ipad? or (ipod? next "touch") or ("personal" next "digital" next assistant?) "PDA" or android? or blackberry* or "apps" or applet? or ("mobile" next app*) or ("software" next app*) or ("ehealth" or "e health" or "e-health" or e?health) or ("mhealth" or "m health" or "m-health" or m?health) or ("telehealth" or tele?health) or ("telemedicine" or tele?medicine) or (telemonitor* or tele?monitor*) or ("remote" next (consult* or diagnos* or monitor* or treat* or "care")) or "mobile health" #4 #2 or #3 #5 #1 and #4	27/8/2014	180
MEDLINE	OVID	1. diabet*.ab,ti. 2. IDDM.ab,ti. 3. NIDDM.ab,ti. 4. MODY.ab,ti. 5. exp Diabetes Mellitus/ 6. hyperinsulin.ab,ti. 7. insulin sensitive*.ab,ti. 8. insulin resist*.ab,ti. 9. insulin depend*.ab,ti. 10. insulin?depend*.ab,ti. 11. non insulin depend*.ab,ti. 12. noninsulin depend*.ab,ti. 13. non insulin?depend*.ab,ti. 14. noninsulin?depend*.ab,ti. 15. exp Insulin Resistance/ 16. impaired glucose tolerance*.ab,ti. 17. glucose intoleran*.ab,ti. 18. exp Glucose Intolerance/	28/8/2014	1335

Database	Link	Search	Date	Hits
		19. typ* 1 diabet*.ab,ti. 20. typ* 2 diabet*.ab,ti. 21. typ* I diabet*.ab,ti. 22. typ* II diabet*.ab,ti. 23. gestational diabet*.ab,ti. 24. or/1-23 25. telephon*.ab,ti. 26. phon*.ab,ti. 27. 25 or 26 28. mobil*.ab,ti. 29. cell*.ab,ti. 30. 28 or 29 31. 27 and 30 32. exp Cellular Phone/ 33. (smartphone? or smart?phone?).ab,ti. 34. (window? adj3 phone?).ab,ti. 35. (window? adj3 mobile?).ab,ti. 36. nokia.ab,ti. 37. palm OS.ab,ti. 38. (palm adj3 computer?).ab,ti. 39. symbian.ab,ti. 40. iphone?.ab,ti. 41. ipad?.ab,ti. 42. ipod? touch.ab,ti. 43. personal digital assistant?.ab,ti. 44. PDA.ab,ti. 45. android?.ab,ti. 46. blackberry*.ab,ti. 47. exp Computers, Handheld/ 48. apps.ab,ti. 49. exp Mobile Applications/ 50. applet?.ab,ti. 51. (mobile adj3 app*).ab,ti. 52. (software adj3 app*).ab,ti. 53. *Medical Informatics Applications/ 54. exp Decision Making, Computer-Assisted/ 55. (ehealth or "e health" or e-health or e?health).ab,ti. 56. (mhealth or "m health" or m-health or m?health).ab,ti. 57. (telehealth or tele?health).ab,ti. 58. (telemedicine or tele?medicine).ab,ti. 59. exp Telemedicine/ 60. (telemonitor* or tele?monitor*).ab,ti. 61. (remote adj2 (consult* or diagnos* or monitor* or treat* or care)).ab,ti. 62. "mobile health".ab,ti. 63. or/31-62 64. 24 and 63 65. limit 64 to yr="2008 - Current"		
EMBASE	OVID	1. diabet*.ab,ti. 2. IDDM.ab,ti. 3. NIDDM.ab,ti. 4. MODY.ab,ti. 5. exp Diabetes Mellitus/ 6. hyperinsulin.ab,ti. 7. insulin sensitive*.ab,ti. 8. insulin resist*.ab,ti. 9. insulin depend*.ab,ti. 10. insulin?depend*.ab,ti. 11. non insulin depend*.ab,ti. 12. noninsulin depend*.ab,ti. 13. non insulin?depend*.ab,ti.	28/8/2014	2479

Database	Link	Search	Date	Hits
		14. noninsulin?depend*.ab,ti. 15. exp Insulin Resistance/ 16. impaired glucose tolerance*.ab,ti. 17. glucose intoleran*.ab,ti. 18. exp Glucose Intolerance/ 19. typ* 1 diabet*.ab,ti. 20. typ* 2 diabet*.ab,ti. 21. typ* I diabet*.ab,ti. 22. typ* II diabet*.ab,ti. 23. gestational diabet*.ab,ti. 24. or/1-23 25. telephon*.ab,ti. 26. phon*.ab,ti. 27. 25 or 26 28. mobil*.ab,ti. 29. cell*.ab,ti. 30. 28 or 29 31. 27 and 30 32. exp Mobile Phone/ 33. (smartphone? or smart?phone?).ab,ti. 34. (window? adj3 phone?).ab,ti. 35. (window? adj3 mobile?).ab,ti. 36. nokia.ab,ti. 37. palm OS.ab,ti. 38. (palm adj3 computer?).ab,ti. 39. Symbian.ab,ti. 40. iphone?.ab,ti. 41. ipad?.ab,ti. 42. ipod? Touch.ab,ti. 43. personal digital assistant?.ab,ti. 44. PDA.ab,ti. 45. android?.ab,ti. 46. blackberry*.ab,ti. 47. exp Microcomputer/ 48. apps.ab,ti. 49. exp Mobile Applications/ 50. applet?.ab,ti. 51. (mobile adj3 app*).ab,ti. 52. (software adj3 app*).ab,ti. 53. *Medical Informatics Applications/ 54. exp Decision Support System/ 55. (ehealth or "e health" or e-health or e?health).ab,ti. 56. (mhealth or "m health" or m-health or m?health).ab,ti. 57. (telehealth or tele?health).ab,ti. 58. (telemedicine or tele?medicine).ab,ti. 59. exp Telemedicine/ 60. (telemonitor* or tele?monitor*).ab,ti. 61. (remote adj2 (consult* or diagnos* or monitor* or treat* or care)).ab,ti. 62. "mobile health".ab,ti. 63. or/31-62 64. 24 and 63 65. limit 64 to yr="2008 - Current"		
PsycINFO	http://search.proquest.com/psycinfo	#1 diabet* OR IDDM OR NIDDM OR MODY OR hyperinsulin OR insulin sensitive* OR insulin resist* OR insulin depend* OR insulin?depend* OR non insulin depend* OR noninsulin depend* OR non insulin?depend* OR noninsulin?depend* OR impaired glucose tolerance* OR glucose intoleran* OR typ* 1 diabet* OR typ* 2 diabet* OR typ* I diabet* OR typ* II diabet* OR gestational diabet*	2/9/2014	239

Database	Link	Search	Date	Hits
		#2 (telephon* OR phon*) AND (mobil* OR cell*) #3 smartphone? OR smart?phone? OR (window? PRE/3 phone?) OR (window? PRE/3 mobile?) OR nokia OR palm OS OR (palm PRE/3 computer?) OR Symbian OR iphone? OR ipad? OR ipod? touch OR personal digital assistant? OR PDA OR android? OR blackberry* OR apps OR applet? OR (mobile PRE/3 app*) OR (software PRE/3 app*) OR ehealth OR "e health" OR e-health OR e?health OR mhealth OR "m health" OR m-health OR m?health OR telehealth OR tele?health OR telemedicine OR tele?medicine OR telemonitor* OR tele?monitor* OR (remote PRE/2 (consult* OR diagnos* OR monitor* OR treat* OR care)) OR "mobile health" #4 1 AND (2 OR 3) #5 YR(2008-2014)		
IEEEXplore + IEEE Conference Publications	http://ieeexplore.ieee.org/Xplore/home.jsp	#1 diabet* OR "MeSH Terms":Diabetes Mellitus OR Type 1 Diabetes OR Type 2 Diabetes OR Gestational Diabetes OR Insulin OR Glucose #2 (telephone OR phone) AND (mobile OR cell*) #3 Smartphone OR iphone OR ipad OR ipod OR "PDA" OR android OR apps OR ehealth OR e-health OR mhealth OR m-health OR telehealth OR telemedicine OR telemonitoring OR (remote AND (diagnos* OR monitor* OR treat* OR care)) OR "MeSH Terms":Cellular Phone OR Computers, Handheld OR Mobile Applications OR Decision Support System OR Telemedicine OR Mobile Health #4 1 AND (2 OR 3) #5 YR(2008-2014)	3/9/2014	1615
Web of Science	https://apps.webofknowledge.com/	#1 diabet* OR IDDM OR NIDDM OR MODY OR hyperinsulin OR insulin sensitive* OR insulin resist* OR insulin depend* OR insulin?depend* OR non insulin depend* OR noninsulin depend* OR non insulin?depend* OR noninsulin?depend* OR impaired glucose tolerance* OR glucose intoleran* OR typ* 1 diabet* OR typ* 2 diabet* OR typ* I diabet* OR typ* II diabet* OR gestational diabet* #2 smartphone? OR smart?phone? OR iphone? OR ipad? OR ipod? touch OR personal digital assistant? OR PDA OR android? OR blackberry* OR apps OR applet? OR ehealth OR e-health OR e?health OR mhealth OR m-health OR m?health OR "mobile health" OR telehealth OR tele?health OR telemedicine OR tele?medicine OR telemonitor* OR tele?monitor* #3 (telephon* OR phon*) AND (mobil* OR cell*) #4 (remote NEAR/2 (consult* OR diagnos* OR monitor* OR treat* OR care)) #5 1 AND (2 OR 3 OR 4) #6 YR(2008-2014)	16/9/2014	1405

Database	Link	Search	Date	Hits
JMIR	http://www.jmir.org/	(diabetes or diabetic or diabetics or insulin or glucose or type 1 diabetes or type 2 diabetes or gestational diabetes) and (smartphone or mobile phone or cell phone or app or apps or mobile application or mhealth or m-health or mobile health)	4/9/2014	58
JMTM	http://www.journalmtm.com/	Searched across all issues	4/9/2014	9
Journal of Diabetes Science and Technology (DST)	http://jdst.org/	#1 smartphone or iphone in all fields or ipad or ipod in all fields or "PDA" or personal digital assistant in all fields or android or blackberry in all fields or pps or applet in all fields #2 mobile health or mhealth in all fields or ehealth or telehealth in all fields or telemedicine or telemonitoring in all fields #3 telephon* or phon* in all fields and mobil* or cell* in all fields #4 remote and diagnos* in all fields or remote and monitor* in all fields or remote and treat* in all fields or remote and care in all fields #5 decision support in all fields #6 1 or 2 or 3 or 4 or 5 #7 yr(2008-2014)	4/9/2014	369
Google Scholar	http://scholar.google.co.uk/	diabetes AND (smartphone OR apps OR mobile OR PDA OR iphone OR android OR mhealth OR ehealth OR telehealth OR telemedicine)	10/9/2014	361 50 pages
ProQuest Dissertations	http://search.proquest.com/	#1 ab(diabet* OR insulin OR glucose) OR ti(diabet* OR insulin OR glucose) #2 all(smartphone? OR smart?phone? OR iphone? OR ipad? OR ipod? touch OR personal digital assistant? OR PDA OR android? OR blackberry* OR apps OR applet? OR ehealth OR e-health OR e?health OR mhealth OR m-health OR m?health OR "mobile health" OR telehealth OR tele?health OR telemedicine OR tele?medicine OR telemonitor* OR tele?monitor*) #3 all((telephon* OR phon*)) AND all((mobil* OR cell*)) #4 all((remote PRE/2 (consult* OR diagnos* OR monitor* OR treat* OR care))) #4 1 AND (2 OR 3 OR 4) #5 YR(2008-2014)	9/9/2014	55
Other Conference Proceedings	--	Conference Papers Index (ProQuest), Papers First, Proceedings First, Web of Science Core Collection – Proceedings Paper, Zetoc.	15/9/2014	197
Other Theses & Dissertations	--	EThOS - Electronic Theses Online Delivery Service, DART-Europe Portal	16/9/2014	10
ClinicalTrials.gov	http://clinicaltrials.gov/	Condition: diabetes Intervention: smartphone application OR smartphone app OR	11/9/2014	30

Database	Link	Search	Date	Hits
		mobile application OR mobile app OR mHealth app Key words: cell phone OR PDA OR iphone OR android OR mhealth OR ehealth OR telehealth OR telemedicine OR telemonitoring		
Current Controlled Trials	http://controlled-trials.com/	diabetes AND (smartphone OR apps OR mobile application OR cell phone OR PDA OR iphone OR android OR mhealth OR ehealth OR telehealth OR telemedicine OR telemonitoring)	12/9/2014	0
WHO International Clinical Trials Registry Platform	http://www.who.int/ictrp/en	diabetes AND (smartphone OR apps OR mobile application OR cell phone OR PDA OR iphone OR android OR mhealth OR ehealth OR telehealth OR telemedicine OR telemonitoring)	12/9/2014	3

Appendix 2. Example of data extraction sheets for one RCT and one non-RCT

Name of the reviewer: Hala Alhodaib **Date of review:** 12/9/2015

Study Details
Study ID (EndNote): 12829
Study Title: Diabetes Self-Management Smartphone Application for Adults With Type 1 Diabetes: Randomized Controlled Trial
First author surname: Kirwan
Year of publication: 2013
Additional reference: No
Publication type: Peer-reviewed journal
Language: English
Country of origin: Australia
Study design: Parallel group, open-label RCT
Study setting: Secondary care
Method of recruitment: (1) An invitation letter sent to T1D patients registered with Diabetes Australia in New South Wales (n=3809) and Queensland (n=3207), (2) An advertisement in a T1D national newsletter (Yada Yada newsletter) emailed to more than 5000 recipients, and (3) Promotion in an online community forum (Reality Check Forum)
Dates of recruitment: Original data collected November 2010 to November 2011 and analysed in 2012
Duration of study: 9 months
Intervention period: 6 months
Follow up period: 3 months
Funding: Non-commercial (University) - Central Queensland University, Australia Registered trial: Yes - Australian New Zealand Clinical Trials Registry: https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=12612000132842
Aim of the study:
To examine the effectiveness of a freely-available smartphone application combined with text-message feedback from a certified diabetes educator to improve glycemic control and other diabetes-related outcomes in adult patients with T1D
Inclusion/Exclusion criteria
Inclusion criteria: (1) Aged 18-65 years, (2) Diagnosed with T1D >6 months, (3) HbA_{1c} >7.5%, (4) Treated with multiple daily injections or insulin pump, and (5) Own a smartphone (iPhone)
Exclusion criteria: (1) Pregnant, or (2) Patients already using a smartphone application to self-manage their diabetes, or (3) Early indicators of diabetes related complications: retinopathy, neuropathy, nephropathy and heart-disease
Ethical standards
Was ethical committee approval obtained? Yes, study approved by Central Queensland University

Human Research Ethics Board.
Informed consent obtained? Yes, written informed consent (via email) from the patient and their primary diabetes HCP (GP/endocrinologist)
Participants
Geographic location: Anywhere in Australia
Main receiver of intervention: Patient
Age group: 18 ≤ Adult ≤ 65
Type of diabetes: T1D
Treatment: Multiple daily injections or continuous subcutaneous insulin injections (Insulin Pump)
Severity of diabetes: NR
Comorbidities: None
Power calculation: Yes, calculated on the expected difference in mean (1.5%) in the primary outcome variable (HbA1c), and the logistically maximum available sample size was 36 patients per group based on part-time work status of the CDE. We allowed for a dropout of 11% (4 per group), consistent with dropout rates reported in recent reviews of similar studies, and variation in baseline (HbA1c=1.80) similar to previous studies. Based on these parameters, α=0.05 and 90% power, the estimated sample size was 68 in total and subsequently increased to 72 in line with the maximum caseload of the CDE
Incentives for participation: NR
Providers (Details of the healthcare worker(s) or systems responsible for providing or supporting the app)
Who delivers the intervention? Certified Diabetes Educator (CDE) - The information logged in the Glucose Buddy application was reviewed by a CDE via a Web interface on a weekly basis
Training offered in delivery of intervention? NR
Intervention
Name: Usual care plus a smartphone application named “Glucose Buddy”
Hardware (device): iPhone
Software (platform): iOS
Purpose: Self-care
Functions: (1) Manually enter BG levels, insulin dosages, other medications, diet (food item in grams), and physical activities (minutes), (2) View their data on a customizable graph and export this information via email
Application type: Freely available diabetes self-management app on iTunes (Apple online store) since October 2008
Any comparison (control): Usual care - a visit to their primary diabetes HCP (GP/endocrinologist) every 3 months
Any supporting intervention? Yes - Text-message feedback from a Credentialed Diabetes Educator on a weekly basis
Phone provided (phone ownership): No
Paid for mobile phone service? Yes - A text-messaging software program was used to text message patients
Method of data transmission: Sync logs to online account

Feedback provided: Yes			
Type and nature of feedback: Personalised text-message - The content of the text messages sent to and received from patients fell into four categories: feedback on logs, diabetes questions, educational tips, and positive reinforcement			
Frequency of feedback: Intervention patients were sent a minimum of 1 personalised text-message per week for the first 6 months of the study, then stopped.			
Mode of data entry: Manual			
Data inputted: BG readings, carbohydrate consumption (grams), insulin dosages, other medications, and physical activities (minutes)			
Frequency of data input: No minimum amount of logging required			
Training offered: No education or training on how to use the Glucose Buddy smartphone application or website			
Mode of interaction: Patients could utilize the accompanying Glucose Buddy website to log diabetes parameters at their discretion besides the text-message communication with the CDE			
Require Internet access? No – Internet access required only to sync logs to the online account			
Security arrangements: NR			
Number of participants	**Overall**	**Intervention**	**Control**
Screened	197		
Excluded	125		
Randomised	72	36	36
Lost to follow-up (LTFU) 3-months		4	0
LTFU 6-months		4	4
LTFU 9-months		3	4
Dropout, n (%)	19/72 (26%)	11/36	8/36
Included	53	25	28
Patient's baseline characteristics	**Overall**	**Intervention**	**Control**
Number of patients, n	72	36	36
Age (years), mean (SD)	35.20 (10.43)	35.97 (10.67)	34.42 (10.26)
Gender (Male/Female), n	28/44	19/17	9/27
Diabetes duration (years), mean (SD)	18.94 (9.66)	19.69 (9.64)	18.19 (9.77)
Insulin pump use, n	27/72	14/36	13/36
HbA_{1c}, mean (SD)	8.78 (1.07) Male 8.79 (1.31) Female 8.77 (0.90)	9.08 (1.18) Male 9.10 (1.45) Female 9.07 (0.84)	8.47 (0.86) Male 8.17 (0.65) Female 8.57 (0.91)
Healthy diet (days per week), mean (SD)		3.56 (1.70)	2.60 (1.98)
Outcomes			
Primary outcomes: Change in glycaemic control (HbA_{1c})			

Secondary outcomes: Diabetes-related self-efficacy, self-care activities, QoL, and engagement by intervention patients			
Timing of assessment (time points): Baseline, 3-month, 6-month, 9-month			
Technical issues: No privacy breaches or technical problems			
Method of assessing outcomes			
HbA_{1c} level: Blood test collected by a pathology lab			
Diabetes-related self-efficacy: Online questionnaire - DES-SF			
Diabetes self-care activities: Measured using online questionnaire (SDSCA). Four scales used in this study: (1) general dietary behavior, (2) specific dietary behavior, (3) glucose monitoring, (4) exercise			
QoL: Measured using online questionnaire (DQOL). Three aspects of QoL directly related to diabetes: diabetes satisfaction, impact, and worry			
Engagement by intervention patients: Measured using the number of text messages sent to patients and the number of text-message responses, and the number of logs (BG, insulin, physical activity, and diet) entered by patients in the Glucose Buddy application during the 6-month study period			
Results			
HbA_{1c} level, mean (SD)	**Overall**	**Intervention**	**Control**
Time Points: Baseline	8.78 (1.07)	9.08 (1.18)	8.47 (0.86)
Time Points: 3-month	8.27 (0.86)	8.32 (0.84)	8.23 (0.89)
Time Points: 6-month	8.22 (0.91)	7.97 (0.73)	8.43 (1.00)
Time Points: 9-month	8.21 (1.05)	7.80 (0.75)	8.58 (1.16)
Diabetes-related self-efficacy, mean (SD)	**Overall**	**Intervention**	**Control**
Time Points: Baseline	3.62 (0.77)	3.62 (0.89)	3.62 (0.65)
Time Points: 3-month	3.78 (0.64)	3.88 (0.61)	3.70 (0.65)
Time Points: 6-month	3.73 (0.77)	3.82 (0.73)	3.64 (0.81)
Time Points: 9-month	3.61 (0.72)	3.60 (0.71)	3.62 (0.74)
Diabetes self-care activities, mean (SD)	**Overall**	**Intervention**	**Control**
General Diet			
Time Points: Baseline	3.81 (2.06)	3.42 (2.19)	4.19 (1.88)
Time Points: 3-month	4.10 (2.00)	4.23 (1.86)	3.97 (2.13)
Time Points: 6-month	4.36 (1.86)	4.59 (1.73)	4.16 (1.98)
Time Points: 9-month	4.37 (1.83)	4.62 (1.80)	4.14 (1.85)
Specific Diet			
Time Points: Baseline	3.08 (1.89)	3.56 (1.70)	2.60 (1.98)
Time Points: 3-month	3.10 (1.63)	3.22 (1.48)	3.00 (1.76)
Time Points: 6-month	3.68 (1.63)	3.80 (1.60)	3.56 (1.66)
Time Points: 9-month	3.93 (1.61)	3.80 (1.82)	4.05 (1.43)
Exercise			

Time Points: Baseline	2.74 (2.09)	2.57 (2.08)	2.92 (2.12)
Time Points: 3-month	2.45 (2.12)	2.36 (1.91)	2.53 (2.31)
Time Points: 6-month	2.83 (1.95)	2.55 (1.92)	3.06 (1.97)
Time Points: 9-month	2.96 (1.79)	3.12 (1.86)	2.82 (1.75)
Glucose Testing			
Time Points: Baseline	5.46 (2.04)	5.40 (2.03)	5.51 (2.08)
Time Points: 3-month	5.88 (1.64)	6.02 (1.64)	5.75 (1.65)
Time Points: 6-month	6.10 (1.56)	6.20 (1.46)	6.02 (1.67)
Time Points: 9-month	5.92 (1.62)	6.28 (1.06)	5.61 (1.95)
QoL, mean (SD)	**Overall**	**Intervention**	**Control**
Satisfaction			
Time Points: Baseline	3.14 (0.61)	3.20 (0.66)	3.09 (0.55)
Time Points: 3-month	3.22 (0.61)	3.35 (0.67)	3.11 (0.54)
Time Points: 6-month	3.32 (0.60)	3.43 (0.58)	3.23 (0.62)
Time Points: 9-month	3.35 (0.66)	3.42 (0.68)	3.29 (0.65)
Impact			
Time Points: Baseline	3.70 (0.53)	3.75 (0.52)	3.66 (0.54)
Time Points: 3-month	3.81 (0.57)	3.89 (0.58)	3.75 (0.56)
Time Points: 6-month	3.83 (0.61)	3.94 (0.62)	3.74 (0.61)
Time Points: 9-month	3.85 (0.53)	3.93 (0.52)	3.77 (0.55)
Worry			
Time Points: Baseline	3.98 (0.66)	4.06 (0.52)	3.90 (0.78)
Time Points: 3-month	4.10 (0.70)	4.19 (0.61)	4.01 (0.77)
Time Points: 6-month	4.16 (0.70)	4.35 (0.46)	3.99 (0.82)
Time Points: 9-month	4.15 (0.63)	4.34 (0.36)	3.99 (0.76)

The intervention group significantly improved glycemic control (HbA1c) from baseline (mean 9.08%, SD 1.18) to 9-month follow-up (mean 7.80%, SD 0.75), versus the control group (baseline: mean 8.47%, SD 0.86, follow-up: mean 8.58%, SD 1.16). No significant change over time was found in either group in relation to self-efficacy, self-care activities, and QoL

Engagement by intervention patients	**Month 1**	**Month 2**	**Month 3**	**Month 4**	**Month 5**	**Month 6**
Average number of text messages sent to patients, mean (SD)	9.75 (1.96)	6.67 (1.47)	7.58 (2.12)	7.11 (1.91)	8.56 (2.26)	7.94 (2.52)
Median number of text messages sent to patients	9	7	7	7.5	8	8
Total number of text messages sent to patients	351	240	273	256	308	286
Average number of text messages received by CDE, mean (SD)	6.47 (3.92)	2.36 (2.82)	2.03 (2.52)	1.11 (1.30)	2.22 (2.84)	1.33 (2.46)

Median number of text messages received by CDE	6	2	1	1	1.5	0
Total number of text messages received by CDE	233	85	73	40	80	48
Glucose Buddy Logs, mean (SD)	187.53 (137.41)	137.22 (143.39)	92.03 (109.66)	96.02 (129.06)	89.03 (107.14)	84.83 (153.47)
Glucose Buddy Logs, total N	6751	4940	3313	3457	3205	3054
Number of logs related to BG levels, n/N (%)	13,349/24,720 (54.00%)					
Number of logs related to insulin, n/N (%)	8158/24,720 (33.00%)					
Number of logs related to diet, n/N (%)	2966/24,720 (12.00%)					
Number of logs related to exercise, n/N (%)	247/24,720 (1.00%)					
Other outcomes	**Intervention**					
Costs incurred	Text messages Cost: $290.93 AUD ($8.08 per patient (n=36)) CDE Cost: The CDE spent on average 3 hours per week: 5 minutes per patient (n=36) per week (72 hours in total over 6-month period). A CDE hourly rate is approximately $28.85; thus the total study cost was $2077.20 AUD					
Adverse events						
There were no unintended effects to the participants						
Author's conclusion						
In adjunct to usual care, the use of a smartphone application combined with weekly text-message feedback from a health care professional led to a significant decrease in HbA_{1c} compared to a control group receiving only usual care. Integrating a smartphone application into secondary care was effective in improving glycemic control in patients with T1D (a decrease of 1.1% in HbA_{1c} level). This findings can be applied to adults with poorly controlled T1D that own a smartphone, though larger studies over a longer duration need to be conducted to validate this findings. There were no significant change in self-efficacy, QoL, and self-care activities for either group over time						
Reviewer's conclusion						
This RCT assessed the effectiveness of using a smartphone app on BG control and a number of other outcomes at different time points. The drop-out percentage considered high specifically in the intervention group						

Name of the reviewer: Hala Alhodaib **Date of review:** 27/10/2015

Study Details
Study title: Smartphone enabled health coach intervention for people with diabetes from a modest socioeconomic strata community: Single-arm longitudinal feasibility study
First author surname: Wayne
Year of publication: 2014
Additional reference: No
Publication type: Peer-reviewed journal
Language: English
Country of origin: Canada
Study design: Single group pre-post test design
Study setting: Primary care - (community health)
Method of recruitment: Participants were recruited at the Black Creek Community Health Centre through health care provider referral and poster advertising
Duration of study: NR
Intervention period: 24 weeks
Follow up period: 24 weeks
Funding: Research funding was provided by Mitacs and Ministry for Research and Innovation (Province of Ontario)
Aim of the study:
To develop and test a smartphone-assisted intervention that improves behavioral management of T2D in an ethnically diverse, lower socioeconomic strata (SES) population within an urban community health setting
Inclusion/Exclusion criteria
Inclusion criteria: Patients over 18 years old, diagnosed with T2D, and able to read and speak English
Exclusion criteria: Participants were excluded if baseline HbA1c > 9.5%
Ethical standards
Was ethical committee approval obtained? All study procedures were approved by the York University Human Participants Research Committee
Informed consent obtained? Yes, participants signed an informed consent
Participants
Geographic location: Toronto, Ontario, Canada
Main receiver of intervention: Patient
Age group: Adult ≥ 18
Type of diabetes: T2D
Treatment: NR
Severity of diabetes: NR
Comorbidities: NR

Power calculation: NR
Incentives for participation: NR
Providers (Details of the healthcare worker(s) or systems responsible for providing or supporting the app)
Who delivers the intervention? A graduate student trained in behaviour change techniques. Wellness plans were collaboratively created in multiple interactions focused on exercise instruction and reviews of electronic monitoring entries, with diet and medication guidelines set by primary care physicians and dieticians
Training offered in delivery of intervention? NR
Intervention
Name: Health Coach app
Hardware (device): Blackberry Curve 8900
Software (platform): NR
Purpose: Self-care, and telemonitoring
Functions: Tracking health behaviours (exercise, diet), self-monitoring health data (BG, BP, weight, mood, pain), messaging, and reminders
Application type: Study-specific
Any comparison (control): No, single arm
Any supporting intervention? No
Phone provided (phone ownership): Yes, most participants (n=19) did not own a smartphone and were loaned a device for the trial duration, unless they possessed a smartphone (n=2)
Paid for mobile phone service? Yes, full data access for the duration of the trial
Method of data transmission: No transmission
Feedback provided: Yes
Type and nature of feedback: Messaging - two-way secure messaging between participant and health coach who can selectively promote healthy choices at pivotal times of client decision-making, providing support immediately after healthy behaviours have been logged, and/or addressing questions and/or sending relevant materials
Frequency of feedback: NR
Mode of data entry: Manual, except the photo capture of meals where the food tracker automatically triggers the smartphone's camera
Data inputted: Exercise, diet, BG, BP, weight, mood, and pain
Training offered: NR
Require Internet access? NR
Security arrangements: Provider-client communications require two-way, certificate-based authentication and passwords stored in encrypted columns, with entered data recalled by client and health coach through a secure online portal

Number of participants	Intervention
Screened	NR
Randomised/Included	21

Excluded	NR
Missing participants	2 - primary care physician failure to forward lab results
Withdrawals	NR
Patient's baseline characteristics	**n (%)**
Number of patients, n	21
Age (years), mean (SD)	55.6 (12.3)
Gender	Male 9 (43%) Female 12 (57%)
Marital status	Single 5 (24%) Married or common-law 14 (67%) Widowed 2 (10%)
Children	Yes 18 (86%) No 3 (14%)
Ethnicity	Hispanic 3 (14%) African 3 (14%) Caribbean 3 (14%) South Asian 3 (14%) Caucasian 9 (43%)
Educational background	Less than high school 3 (14%) Completed high school 4 (19%) Some college/university 7 (33%) College diploma 6 (29%) University degree 1 (5%)
Employment	Full-time 12 (57%) Part-time 2 (10%) Not presently employed 7 (33%)
Outcomes	
Primary outcomes: HbA1c	
Secondary outcomes: Weight, BMI, Waist circumference	
Timing of assessment (time points): Baseline, 24 weeks	
Technical issues: As the Health Coach app was version 1.0, periodic malfunctions hindered client communications during the trial. Due to the close relationship between the health coach and software production team, the feedback and user experience was communicated as received, resulting in upgrades installed on the server at frequent intervals. This feedback loop led to significant improvements in the software throughout the trial. Therefore, throughout the trial, the temporary software malfunctions and upgrades inevitably resulted in service disruptions	
Method of assessing outcomes	
HbA_{1c} level: A clinical indicator collected by a lab	
Results	

Outcome	**n**	**Baseline,**	**Post, mean**	**Mean**	**P value**

		mean (SD)	(SD)	change, mean (SD)	
Entire sample					
HbA1c (%)	19	7.58 (1.13)	7.31 (0.95)	−0.28 (0.57)	.05
Weight (kg)	14	94.6 (16.8)	93.2 (15.8)	−1.3 (1.9)	.02
BMI	13	34.4 (5.5)	33.9 (5.3)	−0.4 (0.7)	.05
Waist circumference (cm)	11	109.4 (16.1)	112.1 (16.1)	2.7 (4.3)	.06
Baseline A1c≥7.0%					
HbA1c (%)	12	8.26 (0.80)	7.83 (0.78)	−0.43 (0.63)	.04
Weight (kg)	9	100.1 (18.0)	98.1 (17.1)	−1.9 (1.7)	.01
BMI	8	36.2(5.8)	35.6 (5.7)	−0.7 (0.7)	.37
Waist circumference (cm)	7	114.4 (17.1)	116.5(16.4)	2.1 (5.3)	.33
Baseline A1c<7.0%					
HbA1c (%)	7	6.43 (0.39)	6.41 (0.38)	−0.01 (0.32)	.91
Weight (kg)	5	84.6 (8.7)	84.4 (8.8)	−0.2 (1.8)	.81
BMI	5	31.4 (3.7)	31.3 (3.8)	−0.1 (0.7)	.80
Waist circumference (cm)	4	100.6 (11.0)	104.4 (10.0)	3.8 (1.6)	.02
Adverse events					
NR					
Author's conclusion					
As mobile technology becomes more accessible, electronically assisted health coaching may emerge as a viable and effective means of managing chronic conditions through improved health behaviours across all SES					
Reviewer's conclusion					
This pilot study supported the feasibility of smartphone-based health coaching for individuals from lower SES with minimal prior smartphone experience. It was intended to generate results guiding the eventual design of an RCT, which will assess the effectiveness of health coaching in T2D patients both with and without the use of smartphone technology at multiple sites with diverse populations The result of the RCT is reported in Wayne 2015, and a qualitative evaluation from subsample of the RCT is reported in Pludwinski 2015					

Appendix 3. Example of data extraction sheet for one qualitative study

Name of the reviewer: Hala Alhodaib **Date of review:** 5/6/2016

Study Details
Study title: Participant experiences in a smartphone based health coaching intervention for type 2 diabetes: A qualitative inquiry
First author surname: Pludwinski
Year of publication: 2015
Additional reference: No
Publication type: Peer-reviewed journal
Country of origin: Canada
Study design: Semi-structured interview
Study setting: Community health (primary care)
Method of recruitment: This qualitative evaluation was part of a larger T2DM self-management RCT undertaken at the Black Creek Community Health Centre (BCCHC) in Toronto, Canada. After completing the trial, individuals were invited by phone or in person to participate in qualitative face-to-face interviews. Efforts were made to reach n=26 intervention participants, and n=11 were contacted. All the participants who were reached were invited and they agreed to participate in the study
Intervention period: 6 months
Funding: Funding for this project was provided by the Public Health Agency of Canada and the Federal Development Agency of Southern Ontario
Aim of the study:
The objective was to compare the effectiveness of six months of smartphone use with health coaching vs. health coaching of equal intensity without smartphone support. Using in person, semi-structured interviews following study completion, participants reflected on their smartphone- based experiences in relation to the role of the health coach in the enhanced intervention arm. We investigated the experience of individuals diagnosed with T2D who participated in an intervention in which the key elements were the provision of a smartphone and self-monitoring software. The interviews focused on use of a smartphone and the effects on motivation for health behaviour change
Inclusion/Exclusion criteria
Inclusion criteria: Subsample of T2D patients who participated in a larger RCT
Exclusion criteria: N/A
Ethical standards
Was ethical committee approval obtained? This study received ethical approval from York University's Human Participants Review Subcommittee (HPRC)
Informed consent obtained? All participants provided informed consent
Participants
Total number of participants: 11
Sample attrition/drop out: N/A
Geographic location: Lower income neighbourhood of Toronto, Ontario, Canada

Main receiver of intervention: Patient
Age group: Males (mean age=63.5±4.9), females (mean age=55.8±8.8)
Gender: 2 males, 9 females
Ethnicity (ethnic groups): The catchment area of the health centre serves a high proportion of recent immigrants from ethnic minority backgrounds
Education: NR
Type of diabetes: T2D
Severity of diabetes: NR
Diabetes duration: NR
Treatment: NR
Comorbidities: NR
Incentives for participation: NR
Providers (Details of the healthcare worker(s) or systems responsible for providing or supporting the app)
Who delivers the intervention? Health coach
Training offered in delivery of intervention? Training and supervision were also more intense as health coaches received continuous supervision throughout the trial, totaling 100 hrs. per coach, delivered by a registered clinical psychologist
Intervention
Name: Health Coach app
Hardware (device): NR
Software (platform): NR
Purpose: Telemonitoring, self-care
Functions: Tracking health behaviours (exercise, diet), self-monitoring health data (BG, BP, weight, medication), messaging, and reminders
Application type: Study-specific
Phone provided (phone ownership): Yes
Paid for mobile phone service? NR
Method of data transmission: NR
Feedback provided: Yes
Type and nature of feedback: Counselling interactions using messages between participant and health coach
Frequency of feedback: Smartphone and health coach contacts summating to one hour of contact weekly per patient
Mode of data entry: Manual, except the photo capture of meals where the food tracker automatically triggers the smartphone's camera
Data inputted: Exercise, diet, BG, BP, and weight
Training offered: NR
Require Internet access? NR

Security arrangements: To maintain confidentiality, personal information was removed from transcripts and audio interview recordings were stored in a locked cabinet in locked offices. Transcripts were transferred between locked password protected computers, with encrypted USB Keys

Data collection and analysis

Method of data collection: In person, semi-structured interviews. Interviews were conducted by a trained interviewer, and reviewed by two additional members of the research team to ensure standardised technique. Interview questions were developed by the lead investigator from prior research and modified by other team members. Interviews were conducted, transcribed verbatim, and reviewed for accuracy by the entire investigative team. Saturation–the point where no new information is detected with additional interviews–was evaluated and agreed on by all research team members, in accord with study goals

Duration of data collection: Each interview lasted approx. 30–40 min

Method of data analysis: Coding and analyses were performed using NVivo employing a thematic analytic approach that thoroughly explored relevant themes surfacing during the interviews. Thematic analysis provides a systematic identification of emergent patterns, and logically organises qualitative data into broader common and representative themes. Our analytic strategy of constant comparison included code development as the basic analytic unit (capturing important aspects of data) and, based on codes, the derivation of broader themes (team discussions) illustrating a coherent view of collected data

Outcomes

Participant perspectives and T2DM self-management experiences were explored in the context of changes in HbA1c levels, a reliable index of long-term glucose control

Findings

Key themes (1st order interpretations)

Thematic analysis identified four major themes:

1. Smartphone and software: Pertained to phone utility and self- activation through awareness, feedback, self-management and monitoring
2. The health coach: Focused on participant experiences with smartphone interactions in relation to perceived health coach qualities, roles and influences on diet, BG monitoring and exercise
3. Overall experience
4. Frustrations managing chronic conditions

Data extracts related to the key themes

Theme 1: Smartphone and software

Smartphone utility:

'I liked sending all the information to my health coach. I didn't have to tell her' (Participant #11 – change in HbA1c: –2.0%)

'I could just take a picture . . . a visual record of what I have eaten' (Participant #1 – change in HbA1c: –0.6%)

'It was not hard to use, the health coach explained everything' (Participant #7 – change in HbA1c: –1.7%)

'It was a helpful reminder of keeping a check on my blood . . . what I eat . . . what I shouldn't' (Participant #4 change in HbA1c: –1.1%)

Self activation:

'I eat, I take the picture, and then . . . I poke myself . . . how high the sugar is . . .' (Participant #7 – change in HbA1c: –1.7%)

Theme 2: The health coach

Overall health coach qualities

'Very persistent (with) monitoring what I have been eating . . . as soon as I sent a picture they would call back immediately' (Participant #5 – change in HbA1c: 0.5%)

Health coach supportive role

'I think this study helped me emotionally a lot, more than physical, I feel emotionally happy. That is important to me' (Participant #9 – change in HbA1c: –0.4%)

Working together

'We talk about everything that is going on in my life. What happened? Why is (my sugar) . . . a little bit higher (or) lower' (Participant #11 – change in HbA1c: –2.0%)

'It was like the doctor looking at you. I have to do this, I have to test my blood sugar, I have to test my pressure, how much exercise. … Your meal, what you eat . . . you have this eye looking at you on the phone (Participant #6 – change in HbA1c: .0.1%)

'(Smartphone) was my watcher. Somebody is watching you through your eyes . . . it was so interesting' (Participant #9 – change in HbA1c: –0.4%)

Focal contact activities

'She teach me how to eat, what I had to eat' (Participant #3 – change in HbA1c: –7.1%)

'We never discussed medication, I let (the health coach) know what I was taking, and brought them in' (Participant #5 – change in HbA1c: 0.5%)

'(If) my sugar (is) high, (health coach) will explain . . . there can be things to eat or something to drink to make sure it's okay' (Participant #2 – change in HbA1c: –2.0%)

'The exercise was an important part of the treatment, so (the health coach) was very aware that I'm doing the right exercise, how many times, (Participant #10 – change in HbA1c: 0.2%)

Theme 3: Overall experience

'When I first came here . . . I was in really bad shape. [My] sugar was very high. The A1c was high . . .' (Participant #11 – change in HbA1c: – 2.0%)

'The program is a big motivation in my life . . . it's a positive thing for me . . . with all that's going on I need positive things' (Participant #6 – Change in HbA1c: 0.1%)

Theme 4: Frustrations in managing chronic conditions

Medication and glucose measurement

'I used to feel weak. [Medication] is helpful, but to be honest, I don't take it' (Participant #7 – change in HbA1c: –1.7%)

'My sugar was sky high . . . I would eat half a sandwich and my sugar would double to 22 [mmol/l]' (Participant #8 – change in HbA1c: –1.1%)

Diet/weight loss

'Doctor just wants you to eat leaves and egg whites; I couldn't handle it' (Participant #8 – change in HbA1c: –1.1%)

Comorbidities

'I have type 2 diabetes, high cholesterol, macular degeneration, and carpal tunnel. I have a lot on my plate' (Participant #6 – change in HbA1c: 0.1%)

Author's explanations of the key themes (2nd order interpretations)

Theme 1: Smartphone and software

Two sub-themes:

(a) Smartphone utility, or direct use in behavioral tracking with the smartphone

Participants discussed exercise tracking, food tracking (via photo journaling), health coach communication and self-generated/coach-generated reminders

Individuals emphasized the benefits of self-monitoring changes in BG, diet and exercise

Participants viewed meal photographing as conveying helpful dietary feedback. Co-monitoring with the health coach was helpful in modifying portions

Applications were viewed as user friendly, although most participants had never used a smartphone

that enabled behaviour tracking and feedback. Some participants described learning to use the system as a challenge, while others found it easy from the start

Reminder messages could be programmed to appear on the patient's smartphone at predetermined times, a function that was appreciated by several participants

(b) Self activation, or processes related to personal monitoring, feedback, awareness and self-management

Processes identified by participants and associated with self-activation were: self-awareness, feedback, and self-management

The smartphone increased self-awareness of habitual behaviours, especially dietary choices. Having pictures of their food increased awareness of portion size and carbohydrate intake. The application also helped them connect blood sugar levels to food choice

Participants identified the feedback as motivating. When participants shared meal photographs, they received immediate feedback from coaches on where improvements could be made

The smartphone supported self-management and monitoring, as individuals monitored patterns of behaviours, giving them a chance to 'think twice' about consumption

Theme 2: The health coach

All participants shared positive experiences about their smartphone interactions with health coaches, emphasising the understanding and encouragement received in the behaviour change process

Four sub-themes:

(a) Overall health coach qualities

Various descriptions of the health coach included: strong, meticulous, confident, responsible, respectful and hardworking, especially in terms of monitoring and providing feedback. Appreciation was expressed in multiple forms, with representative descriptors being: best, nice, positive, generous, supportive, helpful and dedicated

(b) Health coach supportive role

Individuals described health coach support as having someone 'always by their side'. This helped reduce feelings of isolation and being misunderstood. Trust was important in relationship strengthening as individuals discussed their diabetes management but also felt comfortable discussing personal struggles

(c) Working together

Good listening skills were mentioned by participants who felt 'being heard' by the health coach built trust and therapeutic alliance. Their logged behaviours on the smartphone provided the ability for participants and health coaches to communicate by phone and in person. This feedback was perceived valuable in meeting personal goals. For example, a photo-journalled meal allowed participants to pause, think, and communicate with the coach. On the health coach side, there could be reference to specific food pictures, specific BG readings and specific exercise sessions; a strong tie appeared to develop in relation to program specific activities (diet, exercise, glucose monitoring, medication)

Some participants became more critical of their own behaviours related to food and exercise in ways that served productive discussions. Participants were activated by the co-monitoring with health coaches who were perceived as always watching (despite not being physically present) which increased the client's feelings of accountability to follow through with change

A few participants felt uncomfortable at the start because someone was 'watching' their diet and BG levels via smartphone. With time they realised benefits and became comfortable with health coach observation

(d) Focal contact activities

All participants agreed that the health coach assisted with diet, glucose testing, medication, and exercise. Individuals also discussed more specific ways in which their coach helped improve their self-management

In terms of diet, individuals worked on portion control, monitoring carbohydrate intake and ethnic specific food choices. Participants described how health coaches addressed various domains of diet, such as amounts/ types of food consumed in routine and celebrative situations

On the issue of medication, few subjects spoke in detail, explaining that medications were mostly discussed with their health coach at the start and thereafter the main emphasis was on healthy behaviours

All participants discussed BG monitoring. Their conversations included daily glucose readings and insights on using food and exercise logs for interpretation

Exercise was also part of participant conversations with health coaches, who encouraged participants by teaching techniques tailored to individual preferences and needs

Theme 3: Overall experience

Overall experience highlights factors that influenced participants after intervention completion. This theme reflects what participants 'took away' from the program. They described increased control and confidence in dealing with their condition and a substantial gain of knowledge about diabetes management

When discussing the program, participants described it as helpful and were motivated to participate in other programs where financial costs and burdens were non-existent

Theme 4: Frustrations in managing chronic conditions

Three challenges: although they existed prior to joining the program

(a) Medication and glucose measurement

Both injection and oral medication were noted as a combined adherence challenge and the self-administration of multiple medications was deemed frustrating. There was a common pattern of aversion to medications, as well as honest disclosures of adherence lapses

Participants were further frustrated by having to check blood sugar levels in relation to medications and were not often confident their regulation was accurately reflected in readings

(b) Diet/weight loss

Participants struggled with modifications in diet and with weight loss goals, specifically mentioning cooking practices and diet restrictions, and their impact on family members

(c) Comorbidities

Individuals suffered comorbidities (e.g. chronic pain, mental health difficulties, hypertension) further hindering diabetes management

Participants in this subsample had a clinically significant mean HbA1c reduction (–1.38%, SD= 2.08). However, positive views of smartphone functionality were expressed by individuals who did not achieve significant benefits, either in terms of glucose regulation or personal support, and negative views were expressed by individuals who demonstrated considerable benefits. These findings provide some confirmation that participants were not biased by their overall glucose regulation

Recommendations made by authors

In this qualitative study, it is evident that the smartphone monitoring software substantially enhanced the therapeutic alliance with patients who held their intervening coaches in high regard. Future studies can address how smartphone use enhances relationships and how different intensities and approaches to health coaching integrate effectively with smartphone use

Reviewer's conclusion

This is a qualitative study, and so the outcome change in HbA1c is not extracted, as it's a subgroup of the result from the RCT. The result of the RCT is reported in Wayne 2015, and a pilot feasibility study conducted before the RCT is reported in Wayne 2014

Appendix 4. Example of the Risk of Bias assessment for one RCT

Name of the reviewer: Hala Alhodaib **Date of review:** 26/2/2015

First author surname year of publication: Kirwan 2013

Bias domain	Source of bias	Support for judgment*	Authors' judgment**
Selection bias	Random sequence generation	"The study coordinator randomized patients using a freely available online randomization program." (www.randomization.com).	Low risk
	Allocation concealment	"A permuted block randomization design method was used during the 3-month rolling recruitment to ensure roughly equal numbers of patients were allocated to each comparison group." In block randomisation, as long as the block size is not fixed and the order in which treatments were allocated in each block was random, and both the ordering of blocks and their respective size were blinded; this will ensure that the allocation process is not predictable	Low risk
Performance bias	Blinding of participants and personnel	There was no blinding of participants, they were told about the two groups – it was not possible to blind them, as one group got access to the smartphone app and the other group did not Insufficient information to to permit judgement of the blinding of personnel	High risk
Detection bias	Blinding of outcome assessors to intervention allocation	No blinding of outcome assessors, but HbA1c and its measurement is not likely to be influenced by the lack of assessors blinding "The primary outcome measure was change in glycemic control assessed by HbA_{1c} which was collected by a pathology lab at the request of the patients' general practitioner or endocrinologist as per usual care (every 3 months) and then forwarded to the research team." "The secondary outcome measures, being diabetes-related self-efficacy, self-care activities, and quality of life, were collected via a Web-based survey." Self-reported outcomes may introduce bias	HbA1c - Low risk Other outcomes – High risk
Attrition bias	Incomplete outcome data	The dropout rate is high and not even between groups, which may imply a problem with the intervention. "Dropout was 26% (11 males, 8 females,	High risk

Bias domain	Source of bias	Support for judgment*	Authors' judgment**
		19/72) with logistic regression analysis revealing no significant difference in age, gender, diabetes duration, insulin pump use, and baseline HbA1c among those that completed the study and those that were lost to follow up." "Due to the dropout of patients, the study may not have been powered sufficiently to detect differences between groups for the secondary outcome measures." Reasons for subject attrition could not be determined as "patients could not be re-contacted." Analysis of missing data (ITT): "Linear mixed model analysis allows for inclusion of cases with missing data, without replacement of missing values, and therefore includes all randomized patients." They reported using the ITT, however, the result was presented per-protocol	
Reporting bias	Selective reporting of the outcome, subgroups, or analysis	All primary and secondary outcome measures were pre-specified in the trial protocol; however, the protocol was r**etrospectively registered in 30/01/2012.**	Low risk
Other bias	Bias due to problems not covered elsewhere; such as funding source, adequacy of statistical methods used, type of analysis [ITT/PP], baseline imbalance in important characteristics	Imbalance in baseline characteristics: There were differences in glycemic control (HbA1c) and gender between groups at baseline - the intervention group had a significantly higher HbA_{1c} at baseline (P=0.02) and thus had a greater potential to improve their glycemic control, and reported a healthier diet (P=0.03) than the control group. There were significantly more females (P=0.02) in the control group. Possible contamination: "although patients in the control group were instructed not to use any mobile applications to self-manage their diabetes during the study period, it is possible they did."	High risk
ITT=intention-to-treat; PP=per protocol			

Appendix 5. Example of the Downs and Black quality assessment for one non-RCT

Name of the reviewer: Hala Alhodaib **Date of review:** 12/02/2016

First author surname year of publication: Wayne 2014 **Total score:** 16

No	Criteria	Answer	Second reviewer	After discussion	Score
1	Is the hypothesis/aim/objective of the study clearly described?	Yes, "The intent of the study was to develop and test a smartphone-assisted intervention that improves behavioral management of type 2 diabetes in an ethnically diverse, lower SES population within an urban community health setting."	Not clear, no clear definition of the population: Low SES or modest?	Yes, the ambiguous target population should be assessed in another question that related to the population	1
2	Are the main outcomes to be measured clearly described in the Introduction or Methods section?	Yes, in the method section. "The primary study outcome was glycosylated hemoglobin (HbA1c) assessed at baseline and 24 weeks. HbA1c is a clinical indicator of glucose regulation correlated with debilitating and costly diabetic complication."	Yes, though secondary outcome was not mentioned in the method section		1
3	Are the characteristics of the patients included in the study clearly described?	Yes, "Eligible participants were patients over 18 years old, diagnosed with type 2 diabetes, and able to read and speak English. Participants were excluded if their baseline HbA1c was greater than 9.5%."	Yes, participants were recruited at the Black Creek Community Health Centre in Toronto, Ontario, Canada. Recruitment was through health care provider referral and poster advertising. Inclusion/exclusion criteria were clear		1
4	Are the interventions of interest clearly described?	Yes	No, how could the coach make his decision? How could the patients receive the feedback - same device? What frequency? The decrease in HbA1c could be purely attributed to the coach feedback intervention rather than the mobile app	Yes, the end-user interface was displayed and how the data input system worked, But not clear about the frequency, and how the coach interacted with the users	1
5	Are the distributions of principal confounders in	Yes=age, gender, ethnicity, marital status, children, education,	Yes		2

No	Criteria	Answer	Second reviewer	After discussion	Score
	each group of subjects to be compared clearly described?	employment. There is single group of patients			
6	Are the main findings of the study clearly described?	Yes, "There was a mean reduction of 0.28% (SD 0.57) (P=.05) found over the entire sample…"	No, no description of BMI, weight, waist circumference	No, other outcomes of interest were not reported in the result section. Only mentioned a subgroup outcome with significantly favourable result (high risk of reporting bias)	0
7	Does the study provide estimates of the random variability in the data for the main outcomes?	Yes, SD was reported	No	Yes	1
8	Have all important adverse events that may be a consequence of the intervention been reported?	No adverse events reported	No		0
9	Have the characteristics of patients lost to follow-up been described?	2 participants were lost, "The primary reason for missing data was primary care physician failure to forward lab results (n=2)."	No, only the reason reported	Partial, did not provide details on their characteristics, such as "there were no significant difference between the drop-out and those remained in the trial"	0
10	Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?	Yes	Yes		1
External validity					
11	Were the subjects asked to participate in the study representative of the entire population from which they were recruited?	Yes	Not sure whether representative of the entire population	Not clear Due to the lack of definition and classification of SES. Plus, in the article title they said modest SES; but in the main body they targeted lower SES	0
12	Were those subjects who	Yes	Not clear, is it	Not clear	0

No	Criteria	Answer	Second reviewer	After discussion	Score
	were prepared to participate representative of the entire population from which they were recruited?		consistent with the demographic characteristics in that community?		
13	Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive?	Yes, "Participants were recruited at the Black Creek Community Health Centre in Toronto, Ontario, Canada."	No, "Most participants (n=19) did not own a smartphone and were loaned a device for the trial duration."" Nonetheless, as the costs of mobile technology decrease, mobile technology interventions will be increasingly feasible and useful at all SES levels."	Yes, the app considered as the intervention and the smartphone would not considered facility	1
Internal validity - bias					
14	Was an attempt made to blind study subjects to the intervention they have received?	No, blinding is not feasible, it is not possible to blind subjects as they got access to the smartphone app	No		0
15	Was an attempt made to blind those measuring the main outcomes of the intervention?	No blinding to the assessors was stated, however, the primary outcome HbA1c is a clinical indicator and the lab result was forwarded by their primary care physician, "Second, our experience with primary care providers involved their inconsistent provision of HbA1c tests."	No, but for Hb1Ac not necessary		0
16	If any of the results of the study were based on "data dredging", was this made clear?	Yes, there is no unplanned analysis indicated	Yes		1
17	In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case control studies, is the time period between the intervention and outcome the same for cases and controls?	Yes, the follow-up was the same for all study patients	Yes		1
18	Were the statistical tests used to assess the main outcomes appropriate?	Yes, "Differences in outcome variables (baseline to 24 weeks) were analyzed using a paired samples t test."	Yes, descriptive statistics are reported (means and standard deviations). Differences in		1

No	Criteria	Answer	Second reviewer	After discussion	Score
			outcome variables (baseline to 24 weeks) were analysed using a paired samples t test		
19	Was compliance with the intervention/s reliable?	Yes	No, not mentioned	Not clear	0
20	Were the main outcome measures used accurate (valid and reliable)?	Yes	No	Yes	1
	Internal validity - confounding (selection bias)				
21	Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population?	Single group	One group	N/A	1
22	Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same time?	Single group, but the study did not specify the time period over which patients were recruited	No, time was not specified	N/A	1
23	Were study subjects randomised to intervention groups?	No randomisation; single group	N/A	No	0
24	Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?	No	No		0
25	Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?	"Participants were split into groupings according to baseline assessments (HbA1c≥7.0% and HbA1c<7.0%)."	No, "A total of 21 subjects consented and 19 participants completed the 6-month trial; 12 had baseline glycosylated hemoglobin (HbA1c) levels >7.0% and these subjects demonstrated a mean reduction of 0.43% (SD 0.63) (P<.05) with minimal changes in medication."	No Possible confounders: Changes in medications as no further description about what level was the minimal changes in medication Possibly the cohort were very proactive in improving their health status and hence communicated	0

No	Criteria	Answer	Second reviewer	After discussion	Score
			Medications? The effect from the coach intervention?	with their GP to modify the medication. At least the study should have mentioned how they deal with this confounder before they put it in their final conclusion	
26	Were losses of patients to follow-up taken into account?	Yes, the number and reason was reported, but they're not included in the analysis	Yes		1
27	Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance <5%?	No, it is a pilot study, which was not powered to detect differences "This pilot study enrolled a small convenience sample with no control group, limiting the generalizability of intervention results."	No		0

Appendix 6. Example of the CASP methodological quality assessment for one qualitative study

Name of the reviewer: Hala Alhodaib **Date of review:** 4/6/2016

First author surname year of publication: Pludwinski 2015

No.	Screening question	Yes	Can't tell	No
1	Was there a clear statement of the aims of the research?	✓		
"The objective was to compare the effectiveness of six months of smartphone use with health coaching vs. health coaching of equal intensity without smartphone support. Using in person, semi-structured interviews following study completion, participants reflected on their smartphone- based experiences in relation to the role of the health coach in the enhanced intervention arm."				
2	Is a qualitative methodology appropriate?	✓		
The study investigates the experience of individuals "The most precise quantitative assessments of smartphone- based health coaching must be derived through randomized controlled trials (RCTs), but RCTs only produce modest levels of patient feedback. We recently completed an RCT and, to provide more in-depth feedback, undertook semi-structured interviews with n= 11 intervention participants."				
Is it worth continuing?				
3	Was the research design appropriate to address the aims of the research?		✓	
Face-to-face interview would be considered one of the best qualitative methods to explore individuals experience, but the author did not justify the choice of methodology Only justification for the choice of the qualitative approach "Nonetheless, the qualitative approach provides a detailed perspective on what some participants experienced during interventions."				
4	Was the recruitment strategy appropriate to the aims of the research?	✓		
Even though it's not very detailed, what they reported is sufficient as their target population is a subsample of patients who participated in the RCT "After completing the trial, individuals were invited by phone or in person to participate in qualitative face to face interviews. Efforts were made to reach n= 26 intervention participants, and n= 11 were contacted. All the participants who were reached were invited and they agreed to participate in the study."				
5	Was the data collected in a way that addressed the research issue?	✓		
They reported sufficient details about the data collection method, which is in person, semi-structured interview and the setting. Also they provided the interview guide and discussed saturation "Interviews were conducted by a trained interviewer, and reviewed by two additional members of the research team to ensure standardized technique… Interview questions were developed by the lead investigator from prior research and modified by other team members. Interviews were conducted, transcribed verbatim, and reviewed for accuracy by the entire investigative team. Saturation–the point where no new information is detected with additional interviews–was evaluated				

and agreed on by all research team members, in accord with study goals."		
6	Has the relationship between researcher and participants been adequately considered?	✓ partially
I think the relationship is not adequately considered; the only method I thought maybe helpful in reducing the bias brought by the interviewers is the trained interviewer, but no further details or discussion are given. "Interviews (approx. 30–40min.) were conducted by a trained interviewer, and reviewed by two additional members of the research team to ensure standardized technique."		
7	Have ethical issues been taken into consideration?	✓
"This study received ethical approval from York University's Human Participants Review Subcommittee (HPRC) and all participants provided informed consent. To maintain confidentiality, personal information was removed from transcripts and audio interview recordings were stored in a locked cabinet in locked offices. Transcripts were transferred between locked password protected computers, with encrypted USB Keys."		
8	Was the data analysis sufficiently rigorous?	✓
Sufficient details of the analysis process "Coding and analyses were performed using NVivo employing a thematic analytic approach that thoroughly explored relevant themes surfacing during the interviews. Thematic analysis provides a systematic identification of emergent patterns, and logically organizes qualitative data into broader common and representative themes. Our analytic strategy of constant comparison included code development as the basic analytic unit (capturing important aspects of data) and, based on codes, the derivation of broader themes (team discussions) illustrating a coherent view of collected data."		
9	Is there a clear statement of findings?	✓
The findings were explicit and easy to follow and supported with evidences from the original sample		
10	How valuable is the research?	✓
They discussed some limitations of their research, compared it to other relevant research, recommended some future research But the sample size is small, and might not be representative of the whole population Other potential bias that were discussed are: "These findings provide some confirmation that participants were not biased by their overall glucose regulation." "These participants are, of course, were willing to participate in two studies (the RCT and this interview study), which may differentiate them from other participants whose blood sugars were significantly dysregulated. In future studies, it may be possible to identify and recruit additional groups of patients and in doing so, derive results more representative of the general population of diagnosed patients."		

Appendix 7. Ongoing and completed trials identified from the online trials registers

Study Title	Condition	Intervention	Primary Outcome	Sponsor	Study Start	Study Completion	Status	Contact
A Smartphone Application to Improve Medication Adherence Among People With Type 2 Diabetes Mellitus in Singapore: A Randomized Controlled Trial	Diabetes Mellitus	Mobile application	Medication adherence	Singapore General Hospital, National University, Singapore	August 2014	March 2015	Recruiting	Hua Heng McVin Cheen +6563214110 mcvin.cheen.h.h@sgh.com.sg
Audio Health Engagement Analysis in Diabetes: The AHEAD Study	T1D	CareCoach mobile application	Diabetes management	University of California, San Francisco	October 2013	June 2015	Not yet recruiting	Korey Hood hoodk@peds.ucsf.edu
Clinical Trial of Mobile Application to Enhance Diabetic Health Care	Diabetes Mellitus	Diabetes mobile application	Change of diabetic retinopathy risk factors	University of California, Los Angeles	September 2012	December 2014	Recruiting	Elaine Ngo Ngo@jsei.ucla.edu Marianne Bernardo Esguerra@jsei.ucla.edu
Effect of Mobile Phone Telemedicine on Diabetes Care	Diabetes Mellitus	Diabetes Doctor	Evidence for improved diabetic care with mobile phone application use	University of Nebraska	December 2012	June 2013	Unknown	Jay Patel 402-559-9013 jay.patel@unmc.edu
Influence of a Mobile Phone Application on Quality of Life of Patients With Type 1 Diabetes Mellitus: a	T1D	Dbees; diabetes mobile application	QoL	Medical Research Foundation, The Netherlands	September 2011	April 2012	Completed	Henk J. Bilo Isala clinics

Study Title	Condition	Intervention	Primary Outcome	Sponsor	Study Start	Study Completion	Status	Contact
Randomized Controlled Trial								
Changing the Healthcare Delivery Model: A Community Health Worker/Mobile Chronic Care Team Strategy	T2D	Mobile health care application	Goals/ behaviours met	George Washington University	April 2014	April 2016	Not yet recruiting	Linda Witkin 202-741-3047 lwitkin@mfa.gwu.edu Carine Nassar 202-877-0351 carine.m.nassar@medstar.net
Assessment of the Clinical Efficacy and Acceptability of the Think Positive (T+) Diabetes Management System in Insulin Requiring Diabetes	Diabetes Mellitus (Insulin-requiring, T1D or T2D)	Mobile phone telehealth application: Think Positive (T+)	Blood sugar levels (HbA_{1c})	University College London Hospitals	June 2010	November 2011	Completed	Justine Baron
Data Driven Feedback as a Method to Improve Glycaemic Control in Type 1 Diabetes	T1D	Few Touch application; Diastat	Change in the frequency of hyper- and hypo-glycemic events	University Hospital of North Norway; University of Tromso; The Research Council of Norway	March 2013	August 2013	Completed	Stein Olav Skrøvseth
STEP AND GO: A Study of Technology-based Exercise Promotion and Gaming Outcomes	Cardiovascular Disease; Obesity; Cancer; Diabetes	Game application loaded onto smartphone	Change in physical activity	The University of Texas, Galveston; American Heart Association	September 2014	December 2014	Not yet recruiting	Elizabeth J Lyons 409-772-1917 ellyons@utmb.edu Eloisa Martinez 409-266-9643 esmartin@utmb.

Study Title	Condition	Intervention	Primary Outcome	Sponsor	Study Start	Study Completion	Status	Contact
								edu
A Randomized Controlled Study on the Use of Self-management Tools to Improve Chronic Care	T2D; Hypertension	Mobile phone, software application, and assessment devices	Change in HbA_{1c}	VTT Technical Research Centre of Finland	May 2011	June 2012	Completed	Sipoo Health Care Centre
Motivation Psychology-based Smart Engagement System for Improved Older Adult Chronic Disease Management	Diabetes Mellitus	Software application on a digital tablet device	Improvement in HbA_{1c}	Baltimore Research & Education Foundation, Inc.	June 2014	March 2015	Not yet recruiting	Nanette Steinle 410-605-7432 Nanette.Steinle@va.gov Tammy Bremer 410-605-7188 Tammy.Bremer@va.gov
Interactive Tool to Support Self-management Through Lifestyle Feedback, Aimed at Physical Activity of COPD/DM Patients (RCTIt'sLiFe!)	COPD; T2D	Accelerometer, app on a smartphone; a server and a website	Physical activity	Maastricht University Medical Center; ZonMw: The Netherlands Organisation for Health Research and Development	April 2013	October 2014	Active, not recruiting	Luc de Witte
Self-Management Using Smartphone Application for Type2 DM in Real siTuation (SMART-DM)	T2D	Smartphone application	Fasting serum glucose and HbA_{1c}	Inje University, Korea	November 2012	October 2013	Completed	Jongha Park
Self-management in Type 2 Diabetes Patients Using the Few Touch Application	T2D	Few Touch application (FTA)	Improved glycemic control	University Hospital of North Norway; Oslo University C ollege; European Commission; The	March 2011	September 2013	Unknown	Astrid Grøttland +47 976 95 111 astrid.grottland@telemed.no Gerd Ersdal

Study Title	Condition	Intervention	Primary Outcome	Sponsor	Study Start	Study Completion	Status	Contact
				Research Council of Norway				+47 915 71 915 gerd.ersdal@telemed.no Lis Ribu +4792206229 Lis.Ribu@su.hio.no
Feasibility of Using a Smart Phone Application for Self-titration of Insulin on Glycemic Control in Patients With Type 2 Diabetes	Diabetes Mellitus	Smart phone application	Change in glycemic control (HbA_{1c})	National University, Singapore; Duke-NUS Graduate Medical School; Singapore General Hospital	March 2013	March 2015	Recruiting	Yong Mong Bee bee.yong.mong@sgh.com.sg David Matchar (65) 6516 2584 david.matchar@duke-nus.edu.sg
Assessment of an Electronic Self-Management Tool on Glycemic Control in Teens With Type 1 Diabetes	T1D	Bant iPhone application	Changes in HbA_{1c}	The Hospital for Sick Children; Thrasher Research Fund; University Health Network, Toronto; York University	July 2013	February 2016	Recruiting	Mark R Palmert 416-813-6217 ext 206217 mark.palmert@sickkids.ca Caitlin A Nunn 416-813-7654 ext 328158 caitlin.nunn@sickkids.ca Stephanie So 416-340-4800 ext 6843 Stephanie.So@uhn.ca

Study Title	Condition	Intervention	Primary Outcome	Sponsor	Study Start	Study Completion	Status	Contact
A Randomised Pilot Trial to Compare Remote Blood Glucose Monitoring With Standard Clinical Care in the Gestational Diabetic Population	GDM; Pregnancy	Blue tooth enabled glucose meter with smart phone application	HbA_{1c}	University of Oxford	September 2013	March 2015	Recruiting	Lucy Mackillop +441865861165 Lucy.Mackillop@ouh.nhs.uk Jane E Hirst +441865221008 jane.hirst@obs-gyn.ox.ac.uk
NEAT! Technology to Increase Breaks in Sedentary Behavior in Adults With Diabetes	Diabetes Mellitus	Accelerometer and NEAT app	Evaluation of NEAT	Northwestern University	February 2013	October 2013	Completed	Christine Pellegrini
Is a Smartphone Application Effective as an Oral Medication Adherence Aid	Hypertension; Diabetes; Dyslipidemia	Medication adherence smartphone app	Medication adherence	University of Arkansas	October 2013	October 2014	Recruiting	Paul H Anderson 5018128561 panderson3@uams.edu
Prospective Study, Insulin Pump-RT Advisor (IPRA©): A Decision Support Software for Diabetic Patients Treated by Insulin Pump and Using Continuous Glucose Monitoring. Experimental Study. Evaluation by an Expert Patient Panel	T1D	Decision support smartphone application IPRA©	Patient agreement with the IPRA© advices	Rennes University Hospital	June 2013	September 2013	Completed	Isabelle Guilhem
The Smart-phone as a Physical Fitness Monitor on a Population Level -	T2D	InterWalk smartphone app	Amount of time during interval walking	University of Copenhagen; Denmark	March 2014	October 2014	Recruiting	Laura Staun Valentiner +45 51173649 lauravalentiner@

Study Title	Condition	Intervention	Primary Outcome	Sponsor	Study Start	Study Completion	Status	Contact
Validity and Sensitivity and Improtance of Individual Motivation for Doing Interval Walking With the InterWalk Application								gmail.com Mathias Ried-Larsen +45 21782087 mathias.ried-larsen@regionh.dk
Comparative Efficacy of iBGStar Glucose Meter vs. Traditional Glucose Monitoring in Improving Metabolic Control and Compliance Towards Self-Monitoring of Blood Glucose in Young Patients With Type 1 Diabetes	Diabetes Mellitus	iBGStar Diabetes Manager app uploaded on iPhone	Change in HbA_{1c} levels	Sanofi, Italy	June 2012	April 2014	Active, not recruiting	Clinical Sciences & Operations
Role of Mobile Technology to Improve Diabetes Care in Adults With Type 1 Diabetes: the REMOTE-T1D Study, a Pilot Study	T1D	iBGStar meter	Hypoglycaemia fear and QoL	University of Colorado Denver School of Medicine Barbara Davis Center; Sanofi; Colorado Prevention Center	December 2012	November 2013	Completed	Satish K Garg
mHealth Skill Enhancement Plus Phone CBT for Type 2 Diabetes Distress Medication	T2D	Phone CBT approach supported by a mobile phone CBT skills practice	Acceptability questionnaire	University of Pittsburgh; National Institutes of Health (NIH)	May 2013	August 2014	Recruiting	Judith A. Callan 412-383-5321 callanja@pitt.edu

Study Title	Condition	Intervention	Primary Outcome	Sponsor	Study Start	Study Completion	Status	Contact
Nonadherence: Pilot Study		app						Lisa Tamres 412-624-1213 ltamres@pitt.edu
Brief CBT Interventions Delivered by Nurse Care Managers to Improve Type 2 Diabetes Outcomes: Pilot Study	T2D	CBT phone app	Acceptability questionnaire	University of Pittsburgh	January 2013	July 2014	Recruiting	Judith A. Callan 412-383-5321 callanja@pitt.edu Lisa Tamres 412-624-1213 ltamres@pitt.edu
A Mobile Personal Health Record for Behavioral Health Homes (mPHR)	Hypertension; Hyperlipidemia; Diabetes	Mobile personal health record app	Quality of general medical care	Emory University; National Institute of Mental Health (NIMH)	July 2014	June 2018	Not yet recruiting	Gretl Glick 404-712-8529 gglick@emory.edu Silke von Esenwein 404-712-8525 svonese@emory.edu Deborah Strotz 770-499-2422
The Mobile Health Platform - Development and Feasibility Evaluation	Obesity; Hypertension; Diabetes	The mobile health platform	Change in the acceptance and use of technology survey	Duke University, USA	March 2014	July 2014	Recruiting	Ryan J. Shaw 919-684-9434 Ryan.Shaw@duke.edu Markedia Y. Mason

Study Title	Condition	Intervention	Primary Outcome	Sponsor	Study Start	Study Completion	Status	Contact
								919-660-0357 markedia.mason@gmail.com
Webdia Study: Use of Smartphones to Improve Diabetes Control and Quality of Life in Children With Type 1 Diabetes - Randomized Crossover Study to Test the Impact of Using a Software for Smartphones and Tablets in Treating Type 1 Diabetes	T1D	Webdia smartphone software	Effect of Webdia use on HbA_{1c}	University Hospital, Geneva; Philippe Klee	May 2014	December 2015	Recruiting	Philippe Klee +41 79 55 33 476 philippe.klee@hcuge.ch Valérie M Schwitzgebel +41 22 372 45 92 valerie.schwitzgebel@hcuge.ch
Electronically Connected Health Coaching in Improving Type 2 Diabetes Self-Management - Phase III Trial	T2D	Lifestyle counselling with smartphone	HbA_{1c}	York University; Public Health Agency of Canada (PHAC)	February 2012	June 2014	Recruiting	Paul Ritvo 4165808021 pritvo@yorku.ca Noah Wayne 4168897289 noahwayne@gmail.com
Edmonton Automated Sugar Intelligence - Intelligent Diabetes Management, EASI-IDM, App Program to Assist Diabetes Care	T1D	Edmonton Automated Sugar Intelligence (EASI) app	Glucose control - HbA_{1c}	University of Alberta	August 2014	December 2016	Recruiting	Edmond Ryan idmuofa@ualberta.ca
Randomised Controlled Trial of the Diabetes Self-Management	T1D	Glucose Buddy iPhone app	improvement in glycaemic control	Central Queensland	January 2012	February 2013	Completed	Morwenna Kirwan +61749232546

Study Title	Condition	Intervention	Primary Outcome	Sponsor	Study Start	Study Completion	Status	Contact
'Glucose Buddy' Smartphone Applicatio				University, Australia				m.kirwan@cqu.edu.au
Surveys for determining the clinical usefulness and user satisfaction of diabetes self-management system using a smartphone	Diabetes Mellitus	Diabetes self-management smartphone app	User satisfaction of diabetes self-management smartphone app	KyungHee University Hospital, Seoul, Korea	April 2013	--	Recruiting	Sang Youl Rhee
The effect of Mobile Program on Quality of life and Blood Glucose control in Patient With Type II Diabetes	T2D	Educational software installed on mobile phone	QoL	Kerman University of Medical Sciences, Iran	December 2012	--	Completed	Fariba Borhani 00983413205220 faribaborhani@msn.com Hadi Ranjbar 00983413205219 hadiranjbar@kmu.ac.ir

Appendix 8. Characteristics of included studies tables

Table 1. Included RCTs

Study	Country	Design	Intervention purpose & functionality	Comparator	Number of subjects	Age (yrs)	Duration	Outcomes
Type 1 diabetes								
Charpentier 2011, Franc 2012, Franc 2014, Franc 2015 **Franc 2012, Benhamou 2010, Penfornis 2010 (abstracts)**	France	3-armed, multicentre RCT	Self-care **Diabeo software:** Insulin management, Diabetes-related data collection (BG level, medication, diet)	**Control group (G1):** Kept their paper logbook with two follow-up visits at the hospital, after 3 and 6 months **Intervention group (G2):** Received a smartphone loaded with the Diabeo software with face-to-face follow-up visits on month 3 and month 6	**G1:** n=61 **G2:** n=60	**G1:** 36.8±14.1 **G2:** 32.9±11.7	6 months	HbA_{1c} level Proportion of patients reaching the HbA_{1c} target of<7.5% Frequency of self-monitoring BG Frequency of hypoglycaemia episodes Insulin dose QoL and satisfaction measured using Diabetes QOL questionnaire & DHP Time spent on consultation Satisfaction with app App utilisation
Kirwan 2013	Australia	RCT	Self-care, but with weekly feedback from diabetes educator **Glucose Buddy app:** Diabetes-related data collection (BG	**Control group:** Received usual care; a visit to their primary diabetes health care practitioner (general practitioner or endocrinologist)	**Intervention:** n=36 **Control:** n=36	**Intervention:** 35.97±10.67 **Control:** 34.42±10.26	9 months	HbA_{1c} level Diabetes-related self-efficacy (DES-SF) Self-management behaviours (SDSCA) QoL (DQOL) scale App utilisation

Study	Country	Design	Intervention purpose & functionality	Comparator	Number of subjects	Age (yrs)	Duration	Outcomes
			level, diet, medication, physical activity)	every 3 months				
Drion 2015	Netherlands	RCT	Self-care **DBEES app:** Diabetes-related data collection (BG level, diet, medication, physical activity)	**Control group:** Used standard paper diary	**Intervention:** n=31 **Control:** n=32	**Intervention:** 33 [23] **Control:** 35 [18]	3 months	HbA_{1c} level QoL measured using RAND-36 health survey Diabetes-related distress PAID Frequency of self-monitoring BG Usability of the app SUS
Type 2 diabetes								
Holmen 2014, Torbjørnsen 2014, Ribu 2013	Norway	3-armed RCT	Self-care **Few Touch App (FTA):** Diabetes-related data collection (BG level, diet, physical activity), Diet evaluation and management, Education	**Control group (G1):** Received usual care by their GP **Intervention group (G2):** Received the FTA diary in addition to the usual care	**G1:** n=50 **G2:** n=51	**G1:** 55.9±12.2 **G2:** 58.6±11.8	1 year	HbA_{1c} level QoL (SF-36) Depressive Symptoms (CES-D) Self-management behaviours (HeiQ) Lifestyle Change (Physical activity, Dietary habits) measured using Physical activity (from HUNT) and motivation (transtheoretical model) Weight App utilisation
Istepanian 2014	Iraq	Pilot RCT	Self-care and telemonitoring **DIAR app:** Diabetes-related data collection (BG level), Communication	**Control group:** Followed their usual diabetes care pathway plan and follow-up visits	**Intervention:** n=6 **Control:** n=6	**Intervention:** 54.8±12.7 **Control:** 55.2±10.1	6 months	HbA_{1c} level Diabetic knowledge measured using Questionnaire adapted and translated into Arabic from The Diabetic Knowledge Test [Michigan Diabetes Research and Training Center] Cholesterol levels

Study	Country	Design	Intervention purpose & functionality	Comparator	Number of subjects	Age (yrs)	Duration	Outcomes
			and remote monitoring, Reminders					
Waki 2014 **Waki 2013 (abstract)**	Japan	RCT	Self-care and telemonitoring **DialBetics app:** Diabetes-related data collection (BG level, medication, diet, physical activity, BP, weight), Communication and remote monitoring, Diet evaluation and management, Reminders	**Control group:** Would continue their self-care regimen, but they did not receive or use any devices to monitor their health data; they did not record their diet and exercise	**Intervention:** n=27 **Control:** n=27	**Intervention:** 57.1±10.2 **Control:** 57.4±9.4	3 months	HbA_{1c} level Fasting blood sugar (FBS) BP BMI Cholesterol levels Change in medication Self-management behaviours (in terms of diet and exercise) measured using the Japanese version of the questionnaire Summary of Diabetes Self-care Activities Usability of the app and user's satisfaction measured using custom questionnaires Compliance with app use
Wayne 2015	Canada	RCT	Self-care and telemonitoring **Health Coach app:** Diabetes-related data collection (BG level, diet, medication, physical activity, BP, weight, mood), Coaching, Diet evaluation and	**Control group:** Received Health Coach support in selecting and progressing toward goals without access to a smartphone	**Intervention:** n=48 **Control:** n=49	**Intervention:** 53±10.9 **Control:** 53.3±11.9	6 months	HbA_{1c} level Weight BMI Waist circumference Satisfaction with life measured using Satisfaction with Life Scale Depression and anxiety (HADS) Positive and negative affect measured using Positive and Negative Affect Schedule (PANAS) QoL SF-12

Study	Country	Design	Intervention purpose & functionality	Comparator	Number of subjects	Age (yrs)	Duration	Outcomes
			management, Reminders					Compliance with app use
Hsu 2015	USA	RCT	Self-care, telemonitoring **Cloud-based diabetes management app:** Insulin management, Diabetes-related data collection (BG level, medication), Communication and remote monitoring	**Control group:** Received high standards of care from diabetes specialists and certified diabetes educators in a tertiary center specializing in diabetes care in initiating and titrating insulin, with interim face-to-face visits, as well as telephone/fax communication with educators and physicians as dictated by their HCPs	**Intervention:** n=20 **Control:** n=20	**Intervention:** 53.3 **Control:** 53.8	12 weeks	HbA_{1c} level Average BG level Proportion of patients reaching the HbA_{1c} target of<7% Frequency of hypoglycaemia episodes Weight Insulin dose Patient satisfaction measured using Diabetes Treatment Satisfaction Questionnaire (DTSQ) Time HCPs and patients spent on managing the insulin titration
Type 1 & 2 diabetes								
Logan 2012	Canada	RCT	Self-care and telemonitoring **A custom app running on a**	**Control group:** Subjects were issued with an identical-appearing home	**Intervention:** n=55 **Control:** n=55	**Intervention:** 63.1±9.0 **Control:** 62.7±7.8	1 year	Change in mean daytime ambulatory systolic BP Changes in 7 days of home BP readings Psychological questionnaire (ASI,

Study	Country	Design	Intervention purpose & functionality	Comparator	Number of subjects	Age (yrs)	Duration	Outcomes
			BlackBerry smartphone: BP monitoring, Communication and remote monitoring	BP device without built-in Bluetooth capability for Home BP monitoring during the study without self-care support				HADS) and Comfort with self-measurement of BP questionnaires Change in number of antihypertensive drugs Number of GP visits App utilisation

Table 2. Included non-RCTs

Study	Country	Design	Intervention purpose & functionality	Comparator	Number of participants	Mean age (yrs)	Duration of intervention	Key outcomes
Type 1 diabetes								
Cafazzo 2012 **Cafazzo 2012 (abstract)**	Canada	Pre-post design with no control (Clinical pilot phase)	Self-care **Bant app:** Diabetes-related data collection (BG), Insulin management, Social support	--	20	14.9±1.3	3 months	HbA_{1c} level Frequency of self-monitoring BG Diabetes-related self-efficacy measured using Diabetes Family Responsibility Questionnaire Self-management behaviours measured using 14-item Self-Care Inventory QoL (DQOLY) App utilisation Satisfaction with app
Frøisland 2012, Frøisland 2015 **Frøisland 2011 (abstract)**	Norway	Pre-post design with no control	Self-care **DiaMob app:** Diabetes-related data collection (BG level, medication, diet, physical activity), Reminders, Education	--	12	16.2±1.7	3 months	HbA_{1c} level Diabetic knowledge measured using 27-item questionnaire based on the Norwegian National Health Informatics' diabetes quiz Usability of the app SUS
Min 2013	Canada	Post-only design (Usability testing phase)	Self-care **Bant app:** Diabetes-related data collection (BG level, insulin, diet, physical activity,	--	7	--	--	Usability of the app and willingness to use it in the future SUS followed by a general post-session questionnaire

Study	Country	Design	Intervention purpose & functionality	Comparator	Number of participants	Mean age (yrs)	Duration of intervention	Key outcomes
			emotion)					
Miele 2015 **Franceschi 2014 (abstract)**	Italy	Post-only design	Telemonitoring **TreC Diabetes app:** Diabetes-related data collection (BG level, medication, diet, physical activity), Insulin management, Communication and remote monitoring, Reminders	--	15	4 to 12	3 months	User's usage trends and patterns
Type 2 diabetes								
Årsand 2009, Årsand 2010	Norway	Post-only design	Self-care **Few Touch App (FTA):** Diabetes-related data collection (BG, physical activity), Diet evaluation and management, Education	--	12	56.2	6 months	HbA_{1c} level Number of steps Usability of the app SUS
Tatara 2013, Tatara 2013, Tatara 2013	Norway	Post-only design (2-phases)	Self-care **Few Touch App (FTA):** Diabetes-related data collection (BG,	--	**Phase 1:** n= 12 **Phase 2:** n= 11	**Phase 1:** 55.1±9.6 **Phase 2:** 57.2±8.6	**Phase 1:** 1 year **Phase 2:** 5 months	User's usage trends and patterns Usability of the app SUS questionnaire

Study	Country	Design	Intervention purpose & functionality	Comparator	Number of participants	Mean age (yrs)	Duration of intervention	Key outcomes
			physical activity), Diet evaluation and management, Education					
Chomutare 2013	Norway	Pre-post design with no control	Self-care **Few Touch App (FTA) with extension:** Diabetes-related data collection (BG, physical activity), Diet evaluation and management, Education, Social support	--	7	62.7±9.0	12 weeks	HbA_{1c} level Usability of the app SUS Diabetes-related self-efficacy measured (HeiQ) and the DES-SF App utilisation
Sarala 2014	India	Pre-post design with no control (Pilot phase)	Clinical practice **mPower Heart DSS:** Clinical decision-support in computation of personalised patient's management plan based on logged clinical parameters	--	19 HCPs	--	8 months	Compliance with the DSS-based clinical management plan
Wayne 2014	Canada	Pre-post design with no control	Self-care and telemonitoring **Health Coach app:**	--	21	55.6±12.3	6 months	HbA_{1c} level Weight BMI Waist circumference

Study	Country	Design	Intervention purpose & functionality	Comparator	Number of participants	Mean age (yrs)	Duration of intervention	Key outcomes
			Diabetes-related data collection (BG level, diet, medication, physical activity, BP, weight, mood), Coaching, Reminders					
Kim 2014	Korea	Pre-post design with control	Self-care and telemonitoring **Mobile Smartcare app:** Diabetes-related data collection (BG, BP), Communication and remote monitoring	**Control group:** Received usual care with no smartphone app	**Intervention:** n=38 **Control:** n=35	**Intervention:** 51.8±10.3 **Control:** 53.8±9.0	3 months	HbA_{1c} level BP Cholesterol levels BMI Satisfaction with the app measured using a questionnaire survey on the smartphone app and number of complaints
Hunt 2014	USA	Crossover, repeated-measures design	Self-care **Diabetes Buddy app:** Diabetes-related data collection (BG level, diet, medication, physical activity)	**Control group:** Were given a paper journal to log diabetes self-management activities	**G1:** n=6 **G2:** n=8	Adult ≥ 19	3 months	Diabetes-related self-efficacy DMSES Self-management behaviours measured using SDSCA-Revised questionnaire Logging behaviour
Alanzi 2014	Saudi Arabia	Post-only design (Usability testing)	Self-care **SANAD system:** Diabetes-related	--	33	18 to 65	--	Users' satisfaction with the app' s usability measured using the questionnaire for user interaction satisfaction (QUIS)

Study	Country	Design	Intervention purpose & functionality	Comparator	Number of participants	Mean age (yrs)	Duration of intervention	Key outcomes
			data collection (BG), Social support, Cognitive behavioural therapy					
Hong 2015	Korea	Case report	Self-care **Diabetes & Nutrition app:** Diabetes-related data collection (BG), Diet evaluation and management	--	1	46	6 months	HbA_{1c} level FBS BP Cholesterol levels Weight BMI Waist circumference Change in medication Usability of the app SUS
Pellegrini 2015	USA	Pre-post design with no control	Self-care **NEAT! App:** Tracking physical activity, Reminders	--	9	53.1±10.7	1 month	App utilisation Changes in sedentary behaviour and physical activity
Waki 2015 **Waki 2011 (abstract)**	Japan	Post-only design	Self-care and telemonitoring **DialBetics app:** Diabetes-related data collection (BG level, medication, diet, physical activity, BP, weight), Communication	--	5	58.6±4.1	1 week	Compliance with app use

Study	Country	Design	Intervention purpose & functionality	Comparator	Number of participants	Mean age (yrs)	Duration of intervention	Key outcomes
			and remote monitoring, Diet evaluation and management, Reminders					
Neubauer 2015, Spat 2013 **Neubauer 2014, Neubauer 2014, Holl 2014 (abstracts)**	Austria	Post-only design	Clinical practice **GlucoTab app:** Clinical decision-support for standardised glycaemic management and insulin titration	--	99 patients 65 HCPs 18 HCPs	67±11 36±11 32 ±11	7.8±4.5 days	Proportion of BG measurements in the target range of 70–140 mg/dL Average BG level Compliance with given recommendation Usability of the app measured using a questionnaire User errors
Type 1 & 2 diabetes								
Rao 2010	USA	Post-only design (Task analysis)	Self-care **3 top-rated apps - Diamedic Diabetes Logbook Blood Sugar Diabetes Control WaveSense Diabetes Manager:** Diabetes-related data collection (BG), Diet evaluation and management, Insulin management	--	23	43.7	--	Usability of the apps (time taken per task, number of requests for help, and perceived ease of use for performing the tasks) Importance and desirability of app features

Study	Country	Design	Intervention purpose & functionality	Comparator	Number of participants	Mean age (yrs)	Duration of intervention	Key outcomes
Tiefengrabner 2014	Austria	Post-only design	Self-care and telemonitoring **Diabetes diary:** Diabetes-related data collection (BG level, medication, diet, physical activity), Communication and remote monitoring	--	9	25 to 65	2 weeks	Logging behaviour
Gestational diabetes								
Mackillop 2014, Hirst 2015, Hirst 2015 **Loerup 2015, Hirst 2015, Loerup 2014, Loerup 2014, Hirst 2014, Loerup 2013, Gibson 2012 (abstracts)**	UK	Post-only design (2-phases)	Telemonitoring **GDm-health:** Diabetes-related data collection (BG, medication), Communication and remote monitoring, Reminders	GDM	**Phase 1:** n=7 **Phase 2:** n=52	--	Average 13.1 weeks	Average BG level App utilisation Satisfaction (OMDTSQ)

Table 3. Included cross-sectional studies

Study	Country	Design	Diabetes type	Number of participants	Mean age (yrs)	Key outcomes
Type 2 diabetes						
Dobson 2015	Canada	Cross-sectional survey	Type 2	44	58.7±11.02	Users' current use of technology in their self-management Patient's attitudes toward using mobile apps in self-management Users' confidence and intention to use technological diabetes applications
Type 1 & 2 diabetes						
Humble 2015 **Humble 2014 (abstract)**	USA	Cross-sectional survey	Type 1 & 2	**Practice 1:** n=29 **Practice 2:** n=31	**Practice 1:** 63.1±2.4 **Practice 2:** 61.9±2.2	Users' current use of smartphones and apps Users' interest in mHealth support services for diabetes self-care
Williams 2015, William 2015	USA	Cross-sectional survey	Type 1 & 2	588	NR	Latinos' use of mobile phones and glucose tracking apps
Conway 2015	UK	Cross-sectional survey	Type 1 & 2	234	46 to 65	Users' current use of technology in diabetes self-care Users' preference for mHealth Preferred features/functionality of mHealth apps
Kim 2015	Korea	Cross-sectional survey	NR	90	43.5±10.5	Satisfaction Diabetes related self-care activities after the use of the app (SDSCA)
Nielsen 2013	Denmark	Cross-sectional survey	NR	42	18 to 60	Users' perceptions and preferences of smartphone apps for remote monitoring and self-management of diabetes

Table 4. Included qualitative studies

Study, Year	Country	Data collection method	Intervention purpose & functionality	Number of participants	Study aims/objectives	Analysis method
Type 1 diabetes						
Frøisland 2015	Norway	Semi-structured interview, field notes	Self-care **DiaMob app:** Diabetes-related data collection (BG level, medication, diet, physical activity), Reminders, Education	12	To evaluate adolescent patients' experiences with two different mobile phone applications for diabetes care; adolescents to use their experiences to guide product developers by advising on further improvements Focuses on the user experiences related to patient empowerment (self-efficacy and self-treatment), and prospective nutrition-based mobile systems easing daily self-care	Qualitative description, influenced by phenomenology and hermeneutics
Cafazzo 2012	Canada	Ethnographic interview (User-centered design phase)	Self-care **Bant app:** Diabetes-related data collection (BG), Insulin management, Social support	6 adolescents (with 1 parent for each)	Engaging adolescents with T1D, their families, and care providers in the design, development, and pilot evaluation of a home- and community-based diabetes telemanagement system	Thematic analysis
Lehocki 2012	Slovak Republic	Usability testing (field testing and user feedback)	Telemonitoring **Mobile app for assisted diabetes management:** Diabetes-related data collection (BG), Communication and remote monitoring, Insulin management, Diet evaluation module, Reminders, Foot care, Information export	15	To highlight best practices in development of telemedicine services for self-management of patients with diabetes; to describe key characteristics and functionalities of the telemedicine system	NR
Pulman 2013	UK	Semi-structured interview	Self-care --	9	Explore what young people aged 18–21 with T1D feel about their use of mobile and web-based technology and whether it might enable them to	Thematic analysis

Study, Year	Country	Data collection method	Intervention purpose & functionality	Number of participants	Study aims/objectives	Analysis method
					engage better with the NHS and their own health to enhance health-related QoL. To build a few prototype mobile phone applications	
Min 2013	Canada	Interview (Requirements gathering phase)	Self-care **Bant app:** Diabetes-related data collection (BG level, insulin, diet, physical activity, emotion)	8	To design and develop a mobile application (bant for adults) that can help adult T1DM patients better manage their disease. UCD process emphasising data visualization, social communities, and (gamification)	An affinity diagram
Miele 2015	Italy	Semi-structured interview generally with the parents	Telemonitoring **TreC Diabetes app:** Diabetes-related data collection (BG level, medication, diet, physical activity), Insulin management, Communication and remote monitoring, Reminders	15	An observational study to assess user acceptance of the system	The analysis was quantitatively driven
Owen 2015	UK	Entry and exit interviews	Self-care **ConCap:** Diabetes-related data collection (BG level, insulin/ medication)	12	To understand how mobile interventions can support management of health information; to discover user behaviours and needs	NR
Skinner 2015	USA	Interview	Self-care --	6 families (11 participants)	To understand users' needs to offer appropriate design guidelines for a mobile application to help daily management and adherence of children with T1D	A critical ethnography epistemology approach
Årsand 2010	Norway	Focus groups, semi-structured interviews, tailor-made questionnaires	Self-care **Few Touch App (FTA):** Diabetes-related data collection (BG, physical activity), Diet evaluation and management, Education	12	How tools can be designed for supporting lifestyle changes among people with T2D and how these were perceived by users	NR
Tatara 2013	Norway	Questionnaires,	Self-care	**Phase 1:**	Trial 1: to understand how a design solution	Thematic analysis

Study, Year	Country	Data collection method	Intervention purpose & functionality	Number of participants	Study aims/objectives	Analysis method
		semi-structured interviews, and focus groups	**Few Touch App (FTA):** Diabetes-related data collection (BG, physical activity), Diet evaluation and management, Education	n=12 **Phase 2:** n=11	developed in a UCD was experienced by users Trial 2: to understand how the Few Touch application is used, experienced and perceived by target users	
Sarala 2014	India	In-depth interview (Design phase)	Clinical practice **mPower Heart DSS:** Clinical decision-support	19 HCPs 33 Patients	To pilot the smartphone-enabled hypertension and diabetes intervention package at primary healthcare facilities in India to identify barriers, synergies and health system strengthening requirements for feasibility and scalability of such an intervention	Thematic analysis - the themes were based on the objectives of the evaluation
Pellegrini 2015	USA	Questionnaire, and interview	Self-care **NEAT! App:** Tracking physical activity, Reminders	9	Feasibility study to examine the acceptability of using NEAT! (a technology to interrupt prolonged sedentary time among adults with T2D	Inductive thematic analysis
Waki 2015	Japan	Interview	Self-care and telemonitoring **DialBetics app:** Diabetes-related data collection (BG level, medication, diet, physical activity, BP, weight), Communication and remote monitoring, Diet evaluation and management, Reminders	5	To test a more patient-friendly version of DialBetics; to determine if usability and compliance improved with the new, FoodLog-assisted meal-input function	NR
Pludwinski 2015	Canada	Semi-structured interview	Self-care and telemonitoring **Health Coach app:** Diabetes-related data collection (BG level, diet, medication, physical activity, BP, weight, mood), Personal goal setting, Communication and remote monitoring, Reminders	11	To investigate the experience of individuals with T2D using a smartphone and self-monitoring software; interviews focused on use of a smartphone and the effects on motivation for health behaviour change	Thematic analysis
Hsu 2015	USA	Exit interview	Self-care, telemonitoring **Cloud-based diabetes**	20	To explore users' experience with the diabetes management system and interaction with their	NR

Study, Year	Country	Data collection method	Intervention purpose & functionality	Number of participants	Study aims/objectives	Analysis method
			management app: Insulin management, Diabetes-related data collection (BG level, medication), Communication and remote monitoring		HCPs	
Type 1 & 2 diabetes						
Harris 2010	USA	2-phase UCD: Design evaluation (modified think-aloud), and Usability testing (interview)	Self-care **HealthReachMobile:** Diabetes-related data collection (BG), Diet evaluation and management, Education	**Phase 1:** n=6 **Phase 2:** n=8	To assess the feasibility and acceptability of using mobile phones as part of an existing Web-based system for collaboration between patients with diabetes and a primary care team; usability and workflow impediments	Thematic analysis
Deshazo 2010	USA	2-phase UCD: Focus groups, and Usability testing (questionnaire)	Self-care **3 mini-games Hangman QuizShow, and Countdown:** Nutrition education	**Phase 1:** n=11 **Phase 2:** n=10	To investigate game design (refined by focus groups) and usability for three mobile phone video games for diabetes education.	NR
Nielsen 2013	Denmark	Questionnaire, and structured written interview	Self-care and telemonitoring --	42 patients 1 HCP	To study users' perceptions and preferences of apps for diabetes for adherence to remote monitoring and self-management; HCPs' perspectives	**Survey:** MAST (Model for Assessment of Telemedicine Applications) framework model was applied **Interview:** Analysed using SCOT (Social Construction of Technology) theoretical analysis

Study, Year	Country	Data collection method	Intervention purpose & functionality	Number of participants	Study aims/objectives	Analysis method
Scheibe 2015	Germany	Guided interview	Self-care **On Track Diabetes, and Glukose Monitor:** Diabetes-related data collection, Reminders, Information export	32	To investigate factors influencing the acceptance of diabetes apps among patients aged 50 or older; current usage of mobile devices and apps, acceptance-promoting/-inhibiting factors, features of a helpful diabetes app, and contact persons for technical questions	Structured content analysis by Mayring, which allows for an association between the deductive and inductive creation of categories
Gestational diabetes						
Garnweidner-Holme 2015	Norway	2-phase UCD: Interview, and Usability testing (think-aloud)	Self-care **Pregnant+ app:** Diabetes-related data collection (BG), Diet evaluation and management, Education	**Phase 1:** 10 **Phase 2:** 11	To document the process of designing and developing the smartphone Pregnant+ app that automatically transfers blood sugar levels from the glucometer and has information about healthy eating and physical activity	A quotation count report was performed to analyze the interviews

Appendix 9. Summary of findings tables

Table 1. Outcome Matrix: Narrative synthesis results indicating the number of supporting trials for the effects

Outcome	Number of trials that examined the outcome	Significant positive effect[1]	Positive effect[2]	No effect[3]	Negative effect[4]
Clinical outcomes					
Glycaemic control	8 RCTs 9 non-RCTs	Kirwan 2013, Charpentier 2011, Hsu 2015, Waki 2014, Wayne 2014, Hong 2015	Wayne 2015, Årsand 2009 Kim 2014, Chomutare 2013, Mackillop 2014, Neubauer 2015	Drion 2015, Holmen 2014, Istepanian 2014, Cafazzo 2012, Frøisland 2012	
Percentage of subjects reaching the HbA_{1c} target	2 RCTs 1 non-RCT		Neubauer 2015	Charpentier 2011, Hsu 2015	
Frequency of hypoglycaemia episodes	2 RCTs			Charpentier 2011, Hsu 2015	
BP	2 RCTs 1 non-RCT	Logan 2012		Waki 2014, Kim 2014	
Cholesterol levels (LDL-C, HDL-C, TG)	2 RCTs 1 non-RCT			Waki 2014, Istepanian 2014, Kim 2014	
Body composition (weight, BMI, waist circumference)	4 RCTs 3 non-RCTs	Wayne 2015, Wayne 2014, Hong 2015	Waki 2014	Holmen 2014, Hsu 2015, Kim 2014	
Change in medication	4 RCTs 1 non-RCT	Hong 2015		Charpentier 2011, Waki 2014, Logan 2012, Hsu 2015	
Psychosocial outcomes					
QoL	5 RCTs 1 non-RCT		Wayne 2015	Kirwan 2013, Charpentier 2011, Drion 2015, Holmen 2014, Cafazzo 2012	
Depression and anxiety	3 RCTs		Wayne 2015	Holmen 2014	Logan 2012
Diabetes-related distress	1 RCT			Drion 2015	
Diabetes-related self-efficacy	1 RCT 3 non-RCTs		Cafazzo 2012	Kirwan 2013, Hunt 2014, Chomutare 2013	

Outcome	Number of trials that examined the outcome	Significant positive effect[1]	Positive effect[2]	No effect[3]	Negative effect[4]
Positive and negative affect	1 RCT	Wayne 2015			
Satisfaction with Life	1 RCT		Wayne 2015		
Satisfaction with diabetes treatment	1 RCT	Hsu 2015	Hirst 2015		
Comfort with BP self-monitoring	1 RCT				Logan 2012
Behavioural outcomes					
Diabetes self-management behaviours	3 RCTs 3 non-RCTs	Holmen 2014, Kim 2015	Cafazzo 2012	Kirwan 2013, Waki 2014, Hunt 2014	
Frequency of self-monitoring	2 RCTs 1 non-RCT	Cafazzo 2012		Charpentier 2011, Drion 2015	
Logging behaviour	2 non-RCTs		Tiefengrabner 2014	Hunt 2014	
Lifestyle change (physical activity, dietary habits)	1 RCT			Holmen 2014	
Performance of physical activity	2 non-RCTs	Pellegrin 2015	Årsand 2010		
Knowledge outcome					
Knowledge about diabetes and diabetes management	1 RCT 1 non-RCT	Istepanian 2014		Frøisland 2012	

[1] Significant between-groups improvement or significant pre/post improvement; at least in one measure or subscale
[2] Non-significant improvement or pre/post improvement but not significant; at least in one measure or subscale
[3] No difference between-groups or no change in single group
[4] Any negative impact between-groups or pre/post; either significant or not

Table 2. Outcome Matrix: Narrative synthesis results indicating the number of supporting trials for each outcome

Patient-reported outcomes		
Satisfaction with app	1 RCT 4 non-RCTs	Charpentier 2011, Cafazzo 2012, Kim 2014, Kim 2015, Hirst 2015
Usability of app	2 RCTs 8 non-RCTs	Drion 2015, Waki 2014, Frøisland 2012, Hong 2015, Chomutare 2013, Alanzi 2014, Rao 2010, Min 2013, Årsand 2009, Tatara 2013
Current use of apps, preferences, attitudes, or intention to use apps	6 non-RCTs	Dobson 2015, Williams 2015, Humble 2015, Conway 2015, Rao 2010, Nielsen 2013
HCP-related outcomes		
Usability of app	1 non-RCT	Neubauer 2015/ 2014[1]
Compliance with given recommendation	2 non-RCTs	Sarala 2014, Neubauer 2015/ 2014[1]
User errors and workflow anomalies	1 non-RCT	Spat 2013
Miscellaneous outcomes		
Number of GP visits	1 RCT	Logan 2012[2]
Time spent on consultation visit	2 RCTs	Charpentier 2011, Hsu 2015
Utilisation and compliance with app use	4 RCTs 8 non-RCTs	Kirwan 2013, Holmen 2014, Wayne 2015, Franc 2014, Chomutare 2013, Miele 2015, Tatara 2013, Pellegrin 2015, Mackillop 2014, Cafazzo 2012, Waki 2014, Waki 2015

[1] Two-parts study; first part was published as a conference abstract, and the second was published as journal article
[2] No significant difference between-groups

Table 3. Mobile apps interventions and impact on HbA1c from non-RCTs only

Study	Study design	Number of subjects	Mean change, mean±SD	P value
Type 1 diabetes				
Cafazzo 2012	Pre-post design with no control	20	- 0.4±1.27	0.11
Frøisland 2012	Pre-post design with no control	12	- 0.2±1.27	0.38
Type 2 diabetes				
Wayne 2014	Pre-post design with no control	21	- 0.28±0.57	0.05
Kim 2014	Pre-post design with control	Intervention: 38 Control: 35	- 0.2	--
Chomutare 2013	Pre-post design with no control	7	- 0.18±0.97	--
Årsand 2010	Post-only design with no control	12	- 0.1	--
Hong 2015	Case report	1	- 1.8	--

Table 4. Mobile apps interventions and impact on QoL

Study	Study design	Number of subjects	Impact on QoL	Measurement tool
Type 1 diabetes				
Kirwan 2013	RCT	Intervention: 36 Control: 36	No difference	DQOL
Charpentier 2011	3-armed, multicentre RCT	Intervention: 61 Control: 60	No difference	DQOL and DHP
Drion 2015	RCT	Intervention: 31 Control: 32	No difference	SF-36
Cafazzo 2012	Pre-post design with no control	20	No difference	DQOLY
Type 2 diabetes				
Holmen 2014	3-armed RCT	Intervention: 50 Control: 51	No difference	SF-36
Wayne 2015	RCT	Intervention: 48 Control: 49	Positive[1]	SF-12

[1] Within-groups significant improvement in one subscale

Table 5. Mobile apps interventions and impact on depression and anxiety

Study	Study design	Number of subjects	Impact on depression	Measurement tool
Type 2 diabetes				
Holmen 2014	3-armed RCT	Intervention: 50 Control: 51	No difference	CES-D
Wayne 2015	RCT	Intervention: 48 Control: 49	Positive[1]	HADS
Type 1 & 2 diabetes				
Logan 2012	RCT	Intervention: 55 Control: 55	Negative[2]	ASI, HADS

[1] Within-groups significant improvement in one subscale
[2] Significant negative result in one subscale only

Table 6. Mobile apps interventions and impact on diabetes-related self-efficacy

Study	Study design	Number of subjects	Impact on self-efficacy	Measurement tool
Type 1 diabetes				
Kirwan 2013	RCT	Intervention: 36 Control: 36	No difference	DES-SF
Cafazzo 2012	Pre-post design with no control	20	Positive[1]	Diabetes Family Responsibility Questionnaire
Type 2 diabetes				
Hunt 2014	Crossover, repeated measure design	Group 1: 6 Group 2: 8	No difference	DMSES
Chomutare 2013	Pre-post design with no control	7	No difference	HeiQ, DES-SF

[1] Slight improvement but not significant

Table 7. Mobile apps interventions and impact on self-management activities

Study	Study design	Number of subjects	Impact on self-management	Measurement tool
Type 1 diabetes				
Kirwan 2013	RCT	Intervention: 36 Control: 36	No difference	SDSCA
Cafazzo 2012	Pre-post design with no control	20	Positive[2]	14-item Self-Care Inventory
Type 2 diabetes				
Holmen 2014	3-armed RCT	Intervention: 50 Control: 51	Significant positive[1]	HeiQ
Waki 2014	RCT	Intervention: 27 Control: 27	No difference	Japanese version of SDSCA
Hunt 2014	Crossover, repeated-measure design	Group 1: 6 Group 2: 8	No difference	SDSCA
Type 1 & 2 diabetes				
Kim 2015	Cross-sectional survey	90	Significant positive[1]	SDSCA

[1] Significant improvement at least for one item

[2] Slight improvement but not significant in one item

Table 8. Mobile apps interventions usability results

Study	Study design	Duration	Usability score, mean±SD	Measurement tool
Type 1 diabetes				
Drion 2015	RCT	3 months	72±20	SUS*
Frøisland 2012	Pre-post design with no control	3 months	73.0±22.1	SUS*
Min 2013	Post-only design with no control	--	80 or higher	SUS*
Type 2 diabetes				
Waki 2014	RCT	3 months	Reported as the frequency of participants in agreement with given statements	Waki 2014
Hong 2015	Case report	6 months	92.5	SUS*
Chomutare 2013	Pre-post design with no control	3 months	84.6±13.2	SUS*
Alanazi 2014	Post-only design with no control	--	Reported as mean ratings of each individual item in all five parts	Questionnaire for User Interaction and Satisfaction (QUIS)
Årsand 2009	Post-only design with no control	6 months	84.0±13.7	SUS*
Tatara 2013	Post-only design with no control	Halfway trial 1: 6 months End of trial 1: 1 year End of trial 2: 5 months	84.0±13.55 86.0±10.08 74.1±16.95	SUS*
Type 1 & 2 diabetes				
Rao 2010	Post-only design with no control	--	Reported as time taken per task, number of requests for help, and composite ease of use score across eight parameters	Custom-built questionnaire

* SUS scores are ranged from 0 to 100; a score of 70 or greater considered acceptable, while a score less than 70 is below average

Appendix 10. Summary of methodological quality of included qualitative studies using CASP assessment tool

Study	Aims and methods	Research design	Sampling	Data Collection	Reflexivity	Ethical issues	Data Analysis	Discussion of findings	Value
Frøisland 2012, Frøisland 2015	Aims stated and qualitative methods appropriate	Researchers justified their choice of mixed-method design and the use of triangulation. Data collection method not explicitly justified	Convenience sample No description of recruitment or selection of	Semi-structured interviews. No justification of data collection method. A topic guide was used. Interviews audio recorded and transcribed. Field notes taken during interviews as an additional data source. Data saturation not discussed	Potential bias in the formulation of research questions, data collection and analysis were not discussed	No details on how study explained to participants. Confidentiality not discussed. Ethical approval was obtained from regional committee. All participants gave written consent. Lacking details on how researchers handled issues raised by the study	Inductive analytic approach based on qualitative description, influenced by phenomenology and hermeneutics. Deductive approach based on empowerment theory. Notes from interviews were used in identifying themes. Two researchers coded interview transcripts independently; discrepancies	Findings explicit and clearly discussed in relation to other published research and research question. Discussion of credibility and validity of the research through researcher triangulation	Briefly considered the contribution to existing knowledge and practice with some attempt to describe the findings in relation to relevant research-based literature. Provided recommendations for practice and education. Acknowledged limitations in transferability to other populations, and suggested areas for future research

							resolved through consensus. Sufficient data presented to support findings but did not provide contradictory data		
Cafazzo 2012	Aims clearly stated and qualitative methods appropriate	Researchers justified their choice of mixed-method user-centered design Data collection method not explicitly justified	No description of how recruitment was undertaken or about selection of those who volunteered. No discussion about the reasons why some chose not to participate	Ethnographic semi-structured interview; each participant and parent interviewed individually, then together. Each interview conducted by research coordinator using an interview guide based on study objectives and a priori knowledge of diabetes management, behaviour change theory, and health care software design. Sessions recorded and transcribed verbatim. Data saturation discussed	Potential bias in the formulation of research questions, data collection and analysis were not discussed	Ethical approval sought, and informed consent obtained. No details on how study explained to participants. Confidentiality not discussed. Lacking details on how researchers handled issues raised by the study	Data analysed thematically; general inductive method used. Transcripts read repeatedly and text segments coded for potential themes. As the coding framework developed, transcripts were reanalysed in light of new themes. One reviewer	Findings were explicit and clearly discussed in relation to research question. No discussion of the credibility of findings	Considered the contribution of the study to existing knowledge with some attempt to describe the findings in relation to relevant research-based literature. Acknowledged limitations in transferability to other populations, and suggested areas for future research

							analysed the coding, which was validated through member checking of adolescent health and endocrinology specialists. No data presented to support findings		
Miele 2015	Aims clearly stated and qualitative methods appropriate	Research design and data collection method was not justified	15 young patients aged 4 - 12 years were recruited. No further details about the recruitment and selection process	Semi-structured interviews were conducted generally with the parents. No details about how and where the interviews were conducted. Data saturation was not discussed	Potential bias in the formulation of research questions, data collection and analysis was not discussed	Ethical approval and informed written consent not reported. No details on how the study was explained to participants. Confidentiality not discussed. Lacking details on how researchers handled issues raised by the	Exact method used for analysis not specified. The analysis was quantitatively driven. No data presented to support findings. Did not consider researcher bias on analysis or selection of data	Only a summary of findings was presented. No discussion of the credibility of findings	Briefly considered the contribution of the study to existing knowledge. Did not make suggestions for future research. Transferability not discussed

						study		
Owen 2015	Aims clearly stated and research importance and relevance articulated. Qualitative methods appropriate	Research design and data collection method was not explicitly justified	Only experienced users of mobile phones were recruited. Choice of purposive sampling method was justified to avoid learning effects and general unfamiliarity with devices. 12 participants with T1D were recruited through an email call to local Diabetes Support groups and sessions were organized either through similar correspondence, or through telephone conversations. Participants	Entry and exit interviews conducted with all participants. The entry session elicited each individual's existing attitudes and management practices of diabetes. The exit session was used to query participants regarding their usage of the app during the study period. No justification of why this data collection method. No details about how and where the interviews were conducted. Interviews audio recorded and field notes were taken during the interviews. Exact quotations transcribed from the relevant audio recordings. Data saturation not discussed	Potential bias in the formulation of research questions, data collection and analysis were not discussed	Brief discussion on confidentiality and how study explained to participants. Ethical approval and informed written consent were not reported. Lacking details on how researchers handled issues raised by the study	Exact method used for the analysis is not specified. Notes from interviews taken into account in analysis. Sufficient data presented to support findings, but did not provide a description of how data presented was selected. No indication of involvement of multiple researchers in analysis. Did not consider researcher bias on analysis or selection of data	Findings explicit and clearly discussed in relation to other research and original research question. No discussion of the credibility of findings except the use of logged information into the app during the study to verify participant's reports	Considered the contribution of the study to existing knowledge with some attempt to describe the findings in relation to relevant research-based literature. Provided a number of key design considerations. Did not make suggestions for future research. Transferability not discussed

			received sum of £114 as an incentive for completing the study. No discussion about whether some people chose not to participate and their reasons					
Lehocki 2012	Aims clearly stated and qualitative methods appropriate	Research design and data collection method was not justified	15 patients with T1D age 27-38 were recruited. Physicians selected motivated patients to achieve maximum adherence. The goal was to obtain the quality feedback on usability and acceptability of the system. 14 patients completed the study, one cancelled	Field testing and user feedback, evaluated in free comments and discussions with patients either by authors or feedback received through physicians. Data collection method not explicitly described. Data saturation not discussed	Authors are aware that patient selection might introduce potential selection bias in evaluation. Potential bias in the formulation of research questions, data collection and analysis not discussed	No details on how the study was explained to participants. Confidentiality was not discussed. Ethical approval and informed written consent not reported. Lacking details on how researchers handled issues raised by the study	No details about analysis methodology or process. No indication of involvement of multiple researchers in analysis. No data presented to support the findings. Contradictory data not presented. No examination of researcher's role, potential bias and influence	The findings were not explicit and poorly presented. Did not discuss credibility of findings	Did not consider the contribution of the study to existing knowledge and practice. Limited attempt to describe the findings in relation to relevant research-based literature. Provided a number of design charecteristics. Identifies the need for research. No explicit discussion of transferability to

			attendance due to purchase of new mobile phone running on different OS			during analysis and in presentation of data		other populations
Pulman 2013, Pulman 2012	Aims clearly stated and research importance and relevance articulated. Qualitative methods appropriate	Use of qualitative design justified to allow for the development of a breadth and depth of understanding of the studied experience. Data collection method was explicitly justified	Convenience sample of young people with T1D aged between 18 and 21 years. Recruitment was conducted at a district hospital located in south west England (SWDC) and a local university, but unclear how many were approached and how many declined. 9 participants were interviewed. Lacking details about how participants invited to participate	4 semi-structured, in-depth interviews and 5 unstructured interviews were conducted. Choice of data collection methods explicitly justified. A semistructured interview guide was used. Data saturation not discussed	Potential bias in the formulation of research questions, data collection and analysis were not discussed	No details on how study explained to participants. Confidentiality not discussed. Ethical approval and informed written consent not reported. Lacking details on how researchers handled issues raised by the study	No details about analysis methodology or process. Interviews transcribed and loaded onto NVivo for theme identification. Does not state who conducted the analysis or if multiple authors involved. Sufficient data presented to support findings but did not provide contradictory data	No discussion around identified themes. Many of the findings presented in terms of the proposed ideas, and clearly discussed in relation to other research and original research question. Some discussion of the credibility and validity of the research	Considered the contribution of the study to existing knowledge with some attempt to describe the findings in relation to relevant research-based literature. Provided a number of suggestions for mobile apps design and development. Identified further research areas. No explicit discussion of transferability to other populations

Skinner 2015	Aims clearly stated and qualitative methods appropriate	Researcher justified the choice of qualitative design as the interpersonal aspect of previous research is notably lacking. Data collection method was explicitly justified	6 families living with T1D recruited using a personal letter to the director of a camp aimed at children living with T1D and their families, plus personal contacts made by the researcher at a diabetes clinic. A randomised sampling method was used to select the interested recruits and the order in which participants contacted, since it was not feasible to interview all interested volunteers. Did not report the number of volunteers, but	General interview guide approach was conducted whether in person or via video/phone call. Interviews were recorded and transcribed. Data collection method was explicitly described. Data saturation was discussed	Potential influence and bias of the interviewer's status as having a brother with T1D has been critically examined	Sufficient details on how the study was explained to participants. Ethical approval sought, informed consent obtained. Confidentiality not discussed. Lacking details on how researchers handled issues raised by the study	Qualitative analysis following a critical ethnography epistemology approach within the cognitive ethnography frame. Each interview had been read enough times, and all ideas had been extracted and highlighted by color coding. Coded categories that emerged clustered together to form themes. Analysis method justified. No indication of involvement of multiple	Findings were explicit and clearly discussed in relation to the original research question. No discussion of the credibility of findings	Briefly considered the contribution of the study to existing knowledge and practice. Provided a number of design requirements for practice. Acknowledged the limitations in transferability to other populations, and suggested areas for future research

			reported some reasons why some were removed from the list of potential participants			researchers in analysis. Sufficient data presented to support findings but did not provide contradictory data		
Min 2013	Aims clearly stated and qualitative methods appropriate	Researcher justified the choice of qualitative design as to understand adults with T1D culture and to generate a theory about what their needs would be for a mobile self-management support app. Data collection methods explicitly justified	8 participants with T1D were recruited for the interview from Toronto General Hospital Diabetes Clinic. No description of how recruitment was undertaken for the interview or selection of those who volunteered. 6 participants were recruited for usability testing initially by an RN in their circle of care either in person	Semi-structured interviews at the Centre for Global eHealth Innovation; interview guide used. Interviews recorded and transcribed. Usability testing at The Centre for Global eHealth Innovation in the usability laboratories. Participants asked to complete a total of eight scenarios by interacting with a paper prototype of the mobile app. Data collection methods explicitly described. Data saturation not discussed	Considered potential bias in data collection and analysis	Ethical approval sought, informed consent obtained for both study phases. Confidentiality not discussed. Lacking details on how research explained to participants, but considered how researchers dealt with some issues raised by the study	An affinity diagram was used to analyse data collected from the interviews. Members of the Interactive Media Lab were recruited to group related statement cards together to avoid potential bias. After data organised into category and sub-category, the groupings were	Findings explicit and clearly discussed in relation to original research question. No discussion of credibility of findings except the use of more than one analyst for the interview	Considered the contribution of the study to existing knowledge and understanding. Provided a number of design principles that must be included in the app. Discussed the transferability of the findings and highlighted the limitations of the study. Further research areas suggested

			or via a recruitment letter sent through email, but no details on how participants selected. No discussion about reasons why some chose not to participate				translated into user requirements. In-depth description of the analysis process for interview and usability testing, but no data presented to support findings. Contradictory data was taken into account		
Pludwinski 2015	Aims clearly stated and qualitative methods appropriate	Researcher justified choice of qualitative design to provide a detailed perspective on what participants experienced during interventions. Data collection method not explicitly justified	After completing the trial, individuals with T2D at the Black Creek Community Health Centre in Toronto were invited by phone or in person to participate in interviews. Efforts were made to reach 26 intervention	Face-to-face semi-structured interviews conducted by trained interviewer, and reviewed by two additional members of the research team to ensure standardized technique; interview guide used. Interviews recorded and transcribed verbatim. Data saturation discussed	Potential bias in formulation of research questions, data collection and analysis not discussed	No details on how study explained to participants. Confidentiality discussed. Ethical approval sought, informed written consent obtained.	Data analysed using thematic analytic approach. Coding and analyses using NVivo. Analysis method justified. Sufficient data presented to support findings. Contradictory data not taken	Findings explicit and clearly discussed in relation to original research question. No discussion of the credibility of findings except the use of more than one	Briefly considered contribution of study to existing knowledge. No explicit discussion of transferability to other populations. Highlighted some limitations of the study, and suggested few areas for future research

			participants; 11 contacted. All participants who were reached were invited and agreed to participate				into account	analyst for the interview	
Årsand 2009, Årsand 2010	Aims clearly stated and qualitative methods appropriate	Researcher justified choice of qualitative design to provide rich insights into design concepts. Data collection methods explicitly justified	15 people with T2D recruited through letters to all members of the Norwegian Diabetes Association aged 40–70 years. A few of these were also recruited at a members' meeting. No details on how participants selected. No discussion about reasons why some chose not to participate	Focus group meetings and semi-structured interviews. The focus groups were arranged in the NST's assembly rooms; topic guide used. Focus groups/ interviews audio- and/or video-taped and transcribed. Field notes taken and used as additional data source. During most of the meetings, three project members have participated, where two have mainly been responsible for asking questions, initiating discussions and managing the themes of the meeting, while the third participant has taken notes during	Potential influence and bias of the researchers' status as two of the members of the project group have T1D themselves. Using interviewers with in-depth knowledge of the subject may bias the questions and thus the results. Potential selection bias was also considered. The self-selected cohorts were heavily involved in the design of the tested app. Additionally,	Ethical approval sought, informed written consent obtained. Confidentiality not discussed. Lacking details on how research explained to participants	No details about analysis methodology or process. The analysis of user data done by one person only. The dataset and aggregated result files were made available internally and colleagues were encouraged to comment on them, and they did. Sufficient data presented to support findings. Contradictory	Findings explicit and clearly discussed in relation to original research question. There was a discussion of the credibility and validity of the research through use of a set of methods to achieve triangulation. Also, because time did not allow a full process	Considered contribution of study to existing knowledge and practice. Discussed transferability of findings and highlighted limitations of the study. Further research areas suggested

				the discussions. Data saturation not discussed	recruitment of the informants was addressed to members of the Norwegian Diabetes Association resulting in a more motivated cohort than the general population with T2D		data not taken into account	where two or more investigators analysed the data and transcripts, sharing both raw and aggregated results considered as a quality assurance mechanism to prevent wrong interpretation of the data	
Tatara 2013, Tatara 2013, Tatara 2013	Aims clearly stated and qualitative methods appropriate	Researchers justified their choice of mixed-methods design and the use of triangulation. Data collection methods were explicitly justified	12 participants with T2D recruited in Trial 1, but no details on how participants were recruited and selected. 11 recruited in Trial 2 from the Motivation Group (a patient-oriented	Questionnaires, semi-structured interviews, and focus groups; topic guide used. All interviews and focus groups audio recorded. Data saturation not discussed	Potential selection bias discussed; participants recruited from the Motivation Group considered highly motivated for self-management	Ethical approval sought, informed written consent was obtained. Confidentiality discussed. Lacking details on how research explained to	Data analysed using thematic analysis following the framework suggested by Braun and Clarke in which codes and themes identified at semantic level using a	Findings explicit and clearly discussed in relation to other published research and original research question. Discussion of credibility	Considered contribution of study to existing knowledge and practice with some attempt to describe findings in relation to relevant research-based literature. Acknowledged limitations in transferability to

	learning course), but no details on how selected. Limited discussion about reasons why some chose not to participate; "due to both small population in towns of North Norway and inconvenience in transportation due to geography."		participants	theoretical approach. Findings from thematic analysis investigated by collating results of questionnaires and analyses of usage data. Results used to explain mechanisms of participants' engagement with the app over time and factors associated with usability. The researcher examined their own role during analysis process. Sufficient data presented to support the findings. Contradictory	and validity of the research through researcher triangulation and having more than one analyst	other populations, and suggested areas for future research

							data not taken into account		
Sarala 2014	Aims clearly stated and qualitative methods appropriate	Researchers justified their choice of mixed-methods design for evaluation of intervention design and implementation. Data collection methods explicitly justified	33 patients with T2D recruited from 8 outpatient departments in India for the interview. Posters and badges were used to inform patients about the project, but no details on how the participants were selected. 18 healthcare professionals recruited during the design phase using purposive sampling to ensure that perspectives of individuals with	In-depth interviews conducted in Hindi or English, in settings ensuring sufficient privacy and confidentiality, and digitally recorded. Topic guide was used. Interviews with patients conducted by a research staff member, trained using the interview guide and mock interviews. Interviews with healthcare team were conducted by Project Coordinator. Data saturation discussed	Potential bias during data collection and analysis discussed. The principal investigator conducted most of the interviews, which could have brought bias in the interpretation of the results. However, close monitoring by the PhD supervisors helped minimise the bias in the interpretation	No explicit discussion about ethical approval. Informed written consent obtained. Confidentiality discussed. Briefly considered how study was explained to participants	Thematic content analysis approach used to explore the data. Themes for the interviews based on the objectives of evaluation. Interview notes and recordings reviewed on the same day, and themes and questions further developed using an inductive approach to condense raw information into a	Findings explicit and clearly discussed in relation to original research question. There was a discussion of the credibility and validity of the research through having more than one analyst	Considered the contribution of study to existing knowledge and implications for practice with some attempt to describe findings in relation to relevant research-based literature. Acknowledged limitations in transferability to other populations, and suggested areas for future research

			varied roles in the healthcare organisation were assessed. On the pilot phase, the healthcare team who were assigned to implementing the intervention were all included. No discussion about reasons why some chose not to participate				summary and to establish clear links between the research objectives and findings. Researchers have examined their own role during analysis process. Sufficient data presented to support the findings. Contradictory data not taken into account		
Pellegrini 2015	Aims clearly stated and qualitative methods appropriate	Research design and data collection methods were not justified	9 participants with T2D recruited via flyers posted in the Chicago land community and online postings (e.g., Craigslist). 1 did not complete the one-month intervention and	Questionnaire and a brief 14-question interview with a staff member were conducted. Data collection methods not explicitly described. Data saturation not discussed	Potential bias in the formulation of research questions, data collection and analysis not discussed	Ethical approval sought, informed written consent obtained. Confidentiality not discussed. Eligible participants attended a	An inductive thematic analysis used to determine the pattern of responses to the interview on evaluation of app. Categories and themes derived	Findings explicit and clearly discussed in relation to the original research question, but limited discussion around identified	Considered contribution of study to existing knowledge and implications for practice with some attempt to describe findings in relation to relevant research-based literature. Acknowledged

			was unable to contact. Reported numbers who were screened and excluded, and reasons why			baseline orientation session, in which they were given complete details about the study and learned about the technology used	according to different questions from questionnaire and interview. The frequency of responses obtained from the questionnaire were examined. Limited data presented to support the findings. Contradictory data not taken into account	themes. No discussion of credibility of findings	limitations in transferability to other populations, and suggested areas for future research
Waki 2015	Aims clearly stated and qualitative methods appropriate	Research design and data collection methods not justified	5 participants diagnosed with T2D recruited; all had participated in previous 3-month trial. No details on how participants recruited and selected. No discussion about	Face-to face interview. Data collection method not described or justified. Data saturation not discussed	Potential bias in formulation of research questions, data collection and analysis not discussed	Ethical approval sought, informed written consent obtained. Confidentiality not discussed. Lacking details on how research was	No details about analysis methodology or process. No examination of researcher's role, potential bias and influence during analysis and presentation of	Findings explicit and clearly discussed in relation to original research question. No discussion of credibility of findings	Considered the contribution of study to existing knowledge. No explicit discussion of transferability to other populations. Did not make suggestions for future research

			reasons why some chose not to participate			explained to participants	data. Limited data presented to support the findings. Contradictory data considered briefly	
Hsu 2016	Aims clearly stated and qualitative methods appropriate	Research design and data collection methods not justified	Staggered recruitment in a tertiary diabetes centre. 20 patients with T2D (+18 years of age) being started on basal insulin therapy were recruited, all trained by a diabetes educator before commencing therapy. A member of the study staff assessed patient interest in study after this diabetes educator meeting. No	Intervention group underwent an exit interview. Data collection method not described or justified. Data saturation not discussed	Potential bias in formulation of research questions, data collection and analysis not discussed	Ethical approval sought, informed written consent obtained. Confidentiality not discussed. Lacking details on how research was explained to participants	No details about analysis methodology or process. No examination of researcher's role, potential bias and influence during analysis and in presentation of data. Limited data presented to support the findings	Summary of findings presented, and clearly discussed in relation to original research question. No discussion of credibility of findings	Considered the contribution of study to existing knowledge. No explicit discussion of transferability to other populations. Did not make suggestions for future research

			details on how participants recruited and selected. No discussion about reasons why some chose not to participate						
Harris 2010, Le 2008	Aims clearly stated and qualitative methods appropriate	Researcher did not justify choice of qualitative design. Data collection methods partially justified	6 participants with diabetes in phase 1 recruited by email from patients enrolled in a past diabetes management pilot study at University of Washington. 8 participants with T2D in phase 2 recruited by phone. No details on how participants selected. No discussion about reasons why some chose not	A modified think-aloud method used in phase 1 for usability testing, and post-trial interview used in phase 2. Think-aloud sessions and interviews were video and/or audio-recorded, and audio recordings transcribed using a commercial transcription service. All sessions were located at the UW Laboratory for Usability Testing and Evaluation (LUTE); which has equipment specifically designed to test and record user interaction with computers and personal devices. Data saturation not	Potential selection bias in the recruitment strategy was discussed. It is considered that the sample was more highly motivated to manage their health and had higher levels of technical literacy than the general population of patients with diabetes	No details on how ethical standards maintained. No explicit discussion about ethical approval. Briefly reported in one table that they presented consent forms and explained voluntary study withdrawal. Confidentiality not discussed	No sufficient details about the analysis methodology or process. The transcripts of audio recordings were open coded by three researchers separately to identify salient themes using Weft QDA, an open sourced qualitative analysis tool. The sessions' documents analysed in sequential order with	Findings explicit and clearly discussed in relation to original research question. No discussion of credibility of findings except use of more than one analyst	Considered the contribution of study to existing knowledge and practice. Provided several key design recommendations . Acknowledged limitations in transferability to other populations. Did not make suggestions for future research

			to participate	discussed			respect to the session timeline, because some usability changes were introduced to hypoglycaemia messages after the 3rd session and analysing in order made it easier to differentiate the effect of those changes. Limited data presented to support findings. Contradictory data not taken into account		
Deshazo 2010	Aims clearly stated and qualitative methods appropriate	Researcher did not justify the choice of qualitative design. Data collection methods explicitly justified	6 participants with diabetes recruited for focus groups from a college campus and a local diabetes clinic.	Two focus groups and a remote usability testing. Focus groups audio was recorded and professionally transcribed. A moderator facilitated	Potential bias in formulation of research questions, data collection and analysis not discussed	Ethical approval sought for usability testing, but no details for focus groups. No explicit	No details about analysis methodology or process. Researchers examined their own role during analysis	The findings were poorly presented, but were discussed in relation to the original research	Considered the contribution of study to existing knowledge. Acknowledged limitations in transferability to other populations.

			10 participants with diabetes recruited for remote usability testing via advertisements on online message boards specific to diabetes and local classified advertisements. 8 websites used, and followed up with updated postings several days per week for two weeks. No details on how participants selected. No discussion about reasons why some chose not to participate	each focus group with help of an assistant. Field notes taken and used as an additional data source. All aspects of usability testing were accomplished online. Participants were instructed to play the games as much or as little as they chose for one week, and then complete an 11-item online questionnaire with categorical and unstructured (narrative) responses. Open-ended narrative responses were obtained for favourite and least favourite aspects of games, as well as suggestions for improving the games. Data saturation not discussed		discussion about informed written consent. No details on how ethical standards maintained. Confidentiality not discussed	process. No data presented to support the findings. Contradictory data not taken into account	question. Did not discuss credibility of findings	Did not make suggestions for future research
Scheibe 2015	Aims clearly stated and qualitative methods	Researchers justified their choice of qualitative	32 participants with diabetes recruited from diabetics' self-	Guided interview conducted in open setting. It adopts a theory-	Briefly considered bias in data collection, but not in	Ethical approval sought. No explicit	Researchers started analysis in accordance with the	Findings explicit and clearly discussed in	Considered strengths and contribution of study to existing

	appropriate	design to have an open approach toward this field of research, and to focus on relevant subjective aspects of participants. Data collection method explicitly justified	help groups, diabetics' associations, and specialty shops for diabetics, general medical practices, diabetologists' practices, and pharmacies. No details on how participants selected. No discussion about reasons why some chose not to participate	based and uniform interview guideline with open-ended questions. Interviews transcribed verbatim, and individual steps were processed with qualitative data analysis (QDA) software MAXQDA. Data collection method justified. Data saturation not discussed	formulation of research questions and data analysis	discussion about informed written consent. No details on how ethical standards maintained. Confidentiality not discussed	structure of the guideline. They used the structured content analysis by Mayring, which allows for an association between the deductive and inductive creation of categories. The analytical focus was on designing a system of categories and subcategories, as well as their characteristics, which in turn served as a structural dimension. Researchers did not examine their own role during analysis	relation to original research question. No discussion of credibility of findings	knowledge. Acknowledged few limitations of study. No discussion of transferability to other populations. Did not make suggestions for future research

							process. Sufficient data presented to support the findings. Contradictory data not taken into account		
Nielsen 2013	Aims clearly stated and qualitative methods appropriate	Researchers justified choice of qualitative design to understand human experiences and describe them. Data collection method explicitly justified	The target group for the e-survey is social networks of diabetes patients on Facebook. Systematic selection strategy used to ensure representative sample of target group. There were 71 views to the survey, but the total respondents are 42, of which 24 are full answers and 18 incomplete answers.	Online survey and structured written interview. The survey was a combination of open and closed questions, constructed in English and translated to Danish. The sequence of questions was controlled, so that respondents could not jump to the next without answering the current question. A written interview was used as it was not possible to interview the HCP personally. The interview guide became the interview itself. Data saturation not discussed	Briefly considered bias in data collection and analysis, but not in formulation of research questions	No explicit discussion about ethical approval and informed written consent. No details on how ethical standards maintained. Confidentiality not discussed	Topics (i.e. themes) were pre-defined in the context of the problem. MAST framework model was applied to present the survey result. Interview result analysed using SCOT theoretical analysis. In order to confirm or discard any similarities, researcher crossed the results of the	Findings explicit and clearly discussed in relation to original research question Discussion of credibility and validity of findings through triangulation of methods	Considered the contribution of study to existing knowledge. Acknowledged limitations in transferability to other populations. Did not make suggestions for future research

	One HCP interviewed. No sufficient details about selection process		survey and interview worked through the MAST model in the SCOT analysis. Sufficient data presented to support the findings. Researchers examined their own role during analysis process. Contradictory data not taken into account

Garnweidner-Holme 2015	Aims clearly stated and qualitative methods appropriate	Researchers justified their choice of qualitative design to give useful insights in the first phase of designing and developing the app. Data collection methods not justified	Participants purposively recruited at three outpatient clinics in the area of Oslo, Norway. 10 women with GDM recruited for the interview, and 11 for usability testing. Very limited details about recruitment and selection process. No discussion about why some chose not to participate	Interview and think-aloud method were conducted. The interviews were carried out at the outpatient clinics by the first author, a public health nutritionist, and occasionally accompanied by other project members. For usability testing, users were asked to speak aloud while performing six tasks on the second prototype. All interviews were audio taped and transcribed verbatim. Limited details on the data collection methods and settings. Data saturation not discussed	Potential bias in formulation of research questions, data collection and analysis not discussed	Ethical approval sought, informed written consent obtained. Confidentiality not discussed. Lacking details on how research was explained to participants	A quotation count report was performed to analyse the interviews. No further details about analysis methodology or process. No sufficient data presented to support the findings. Researchers did not examine their own role during analysis process	Findings explicit and clearly discussed in relation to original research question. No discussion of credibility of findings	Considered the contribution of study to existing knowledge and practice. Acknowledged few limitations of study. No discussion of transferability to other populations. Did not make suggestions for future research

4th June 2014

Warwick
Medical School

PRIVATE
Mrs Hala Alhodaib
26 Rodyard Way
Coventry
CV1 2UD

Dear Hala

Study Title and BSREC Reference: Diabetes Specialist Nurses' Perceptions, Views, Experiences and Preferences of Using Mobile Applications in a Clinical Setting **REGO-2014-786**

Thank you for submitting the above-named project to the University of Warwick Biomedical and Scientific Research Ethics Committee for research ethical review.

I am pleased to advise that research ethical approval is granted.

May I take this opportunity to wish you success with the study, and to remind you that any substantial amendments require approval from the Committee before they can be implemented. Please keep a copy of the original signed version of this letter with your study documentation.

Yours sincerely

pp

Dr David Davies
Chair
Biomedical and Scientific
Research Ethics Sub-Committee

Biomedical and Scientific
Research Ethics Sub-Committee
A010 Medical School Building
Warwick Medical School,
Coventry, CV4 7AL.
Tel: 02476-151875
Email: BSREC@Warwick.ac.uk

Medical School Building
The University of Warwick
Coventry CV4 7AL United Kingdom
Tel: +44 (0)24 7657 4880
Fax: +44 (0)24 7652 8375

THE UNIVERSITY OF
WARWICK

WARWICK

MEDICAL SCHOOL

PRIVATE
Mrs Hala Alhodaib
Health Sciences
Warwick Medical School
University of Warwick
Coventry
CV4 7AL

22nd March 2016

Dear Mrs Alhodaib

Study Title and BSREC Reference: *Design, Development and Evaluation of a Mobile-based Clinical Decision Support Application for the Management of Patients with Diabetes and Kidney Disease to Facilitate Evidence-based Care Delivery* RFGO-2014-786 AMO1

Thank you for submitting a substantial amendment application for the above-named project to the University of Warwick's Biomedical and Scientific Research Ethics Sub-Committee.

I am pleased to confirm that the changes that you wish to make to this study have been approved.

Please keep a copy of the signed version of this letter with your study documentation.

Yours sincerely

Professor Scott Weich
Chair
Biomedical and Scientific
Research Ethics Sub-Committee

Biomedical and Scientific Research Ethics Sub-Committee
A010 Medical School Building
Warwick Medical School,
Coventry, CV4 7AL.
T: 02476-528207
E: BSREC@Warwick.ac.uk

http://www2.warwick.ac.uk/services/ris/research_integrity/researchethicscommittees/biomed

The Dudley Group NHS
NHS Foundation Trust

RESEARCH & DEVELOPMENT DIRECTORATE
CLINICAL RESEARCH UNIT, 1st FLOOR, NORTH WING
Tel/Fax: 01384 321024/ 01384 456111 Ext 1024

Russells Hall Hospital
Dudley
West Midlands
DY1 2HQ

08 January 2015

Hala Alhodaib
PhD Student
Populations, Evidence and Technologies
Division of Health Sciences
Warwick Medical School
University of Warwick
Coventry
CV4 7AL

Dear Ms Alhodaib

ID 1244: Re: Study of Diabetes Specialist Nurses' Perceptions, Views, Experiences and Preferences of Using Mobile Applications in a Clinical Setting
Sponsor: University of Warwick; Ref Number: REGO2014-786
Date of NHS Permission: 08 January 2015

NHS permission for the above research has been granted on the basis described in the protocol and supporting documentation. The documents reviewed for this purpose are:

Document	Version
Letter from University of Warwick Biomedical Science Research Ethics Committee	Dated 04/06/2014
Protocol	V1.0 dated 04/06/2014
Interview Guide	V1.0 dated 04/06/2014
Interview Information Sheet	V1.0 dated 04/06/2014
Interview Consent Form	V1.0 dated 04/06/2014
FG Information Sheet	V1.0 dated 04/06/2014
FG Consent Form	V1.0 dated 04/06/2014

The Trust has no concerns regarding the potential risks of this study which involves members of staff in non clinical research.

Permission has been granted on the understanding that the study is conducted in accordance with the Research Governance Framework, Trust policies and procedures. Permission is only granted for the activities for which a favourable opinion has been given by the REC.

Enclosed with this letter you will find copies of policies relevant to undertaking this piece of research in the Trust:

(a) The Trust's policy for taking and documenting informed consent for research studies;
(b) The Trust's Policy for addressing fraud and misconduct in research
(c) PI Checklist

Sandwell & West Birmingham Hospitals NHS Trust

RESEARCH AND DEVELOPMENT

K Raza, PhD, FRCP — Director of R&D
J Bell, BSc, MSc, PhD — Head of R&D — (0121) 507 4811
S Collinge, BSc (Hons) — RM&G Manager — (0121) 507 4092
B Baines BA (Hons) — R&D Administrator — (0121) 507 4091

D46, Second Floor
Sheldon Block
City Hospital
Dudley Road
Birmingham
B18 7QH

Date: 10 February 2015

Researcher: Mrs Hala Alhodaib

Address: 26 Radyard Way
Coventry
CV1 2UD

Dear Mrs Alhodaib

Letter of access for research

This letter should be presented to each participating organisation before you commence your research at that site. The participating organisation is Sandwell & West Birmingham Hospitals NHS Trust.

In accepting this letter, each participating organisation confirms your right of access to conduct research through their organisation for the purpose and on the terms and conditions set out below. This right of access commences on 10 February 2015 and ends on 01 September 2017 unless terminated earlier in accordance with the clauses below.

Research Project:	Protocol for a Study of Diabetes Specialist Nurses' Perceptions, Views, Experiences and Preferences of Using Mobile Applications in a Clinical Setting
NHS Trust:	Sandwell and West Birmingham Hospitals NHS Trust
Trust Ref:	14EDUC43
Researchers Name:	Hala Alhodaib
Local Research Manager:	Dr Peter Davies
Research End Date:	01 September 2017
Research Activity:	Staff recruitment and consent Interviews Focus Groups

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from Sandwell & West Birmingham Hospitals NHS Trust. Please note that you cannot start the research until the Principal Investigator

Sandwell & West Birmingham Hospitals NHS Trust

RESEARCH AND DEVELOPMENT

K Raza, PhD, FRCP	R&D Director		D46 Sheldon Block
J Bell, BSc, MSc, PhD	Head of R&D	(0121) 507 4811	City Hospital
F Lloyd BSc (Hons)	Trust Lead Research Nurse	(0121) 507 5421	Dudley Road
S Collinge, BSc (Hons)	RM&G Manager	(0121) 507 4969	Birmingham
B Baines BA (Hons)	Research Governance Co-ordinator	(0121) 507 4091	B18 7QH
Z Khalil BArch	Research Governance Co-ordinator	(0121) 507 4092	
		Email: swbh.randd@nhs.net	

JB/ZK/R&D Ref: 14EDUC43

10 February 2015

Mrs Hala Alhodaib
PhD Student
Populations, Evidence and Technologies
Division of Health Sciences
Warwick Medical School
University of Warwick
Coventry
CV4 7AL

Dear Mrs Alhodaib

Study Title:	**Protocol for a Study of Diabetes Specialist Nurses' Perceptions, Views, Experiences and Preferences of Using Mobile Applications in a Clinical Setting**
University REC Ref:	**REGO-2014-786**

Thank you for submitting your request to conduct this research in the Trust.

Conditions of Approval

I am pleased to inform you that the request is approved for the project you describe, and that your research can proceed subject to the following conditions:

1. That you keep an up to date and accurate record of your research in a study file, and that you make this file and other records available for audit by the Research and Development Office when requested.

2. That you inform the R&D office of any changes to the study, related documentation or study personnel.*

3. That you notify the R&D office of any serious adverse events arising from this research in accordance with Trust Procedure for safety reporting in research.*

4. That where the research continues for more that 1 year, you provide the R&D office with an annual report of your research progress, when approval will be reviewed.*

***Please send updates and documents to swbh.randd@nhs.net**

Invitation email

Dear (diabetes specialist nurse),

This letter is an invitation to consider participating in a study I am conducting as part of my Doctoral degree at Warwick Medical School at the University of Warwick under the supervision of Dr Paul Sutcliffe, Dr Krishnarajah Nirantharakumar, and Dr Sailesh Sankar. I am conducting interviews as part of the research study and I hope to interview at least 10 diabetes specialist nurses, in order to increase our understanding of how mobile applications (apps) is perceived and experienced by those in the field of diabetes care. As a diabetes specialist nurse who's actively involved in the management of patients with diabetes, you are in an ideal position to give us valuable first-hand information from your own perspective.

Participation in this research is completely voluntary. It will involve an interview which may take up to 45 minutes (but this depends on how much you have to say) and will take place in a mutually agreed location. However, the interview could be conducted online using Skype or telephone. If you decide to participate, the interview would be arranged at a convenient time. During the interview, you will be asked questions to capture your thoughts and perspectives on using mobile apps at the point of care. There are no right or wrong answers. What is important are your opinions. Your responses to the questions will be kept private and confidential. You may decline to answer any of the interview questions. Further, you may decide to withdraw from this study at any time. With your permission, the interview will be audio recorded, and later transcribed for analysis. The audio recordings will only be reviewed by members of the research team. This study has been reviewed and received ethics clearance through the Biomedical and Scientific Research Ethics Committee (BSREC) at the University of Warwick.

Your participation will be a valuable addition to the broader research community, and findings could lead to developing a mobile app that support you in clinical work. You will receive a £20 Amazon.co.uk voucher as a thank you for taking part in this study. Additionally, we will cover any travel expenses you may incur through participating in this study. The result of the study may be published or presented at professional meetings, but your name will not appear in any thesis or report resulting from this study, however, with your permission anonymous quotations may be used.

The participant information sheet and consent form have been attached to provide you with more information about this study and what your involvement would entail if you decide to take part. If you are interested in participating, please suggest a day and time that suits you and I will do my best to be available. If you have any further questions about the research, please feel free to contact me at the email or number listed below.

I very much look forward to speaking with you and thank you in advance for your assistance in this research.

Thank you,
Hala Alhodaib
Principal Investigator
Doctoral Student
University of Warwick

THE UNIVERSITY OF WARWICK

Appendix 12. Interview study materials

Study Title: Perceptions, Perspectives and Experiences of Diabetes Specialist Nurses in Using Mobile Applications in a Clinical Setting: A Semi-Structured Interview

Researcher: Hala Alhodaib

Introduction

You are invited to take part in an interview to help explore your perceptions, perspectives and experiences of using mobile applications (sometimes referred to as "apps") at the point of care. My name is Hala Alhodaib, and I am a PhD student from the University of Warwick working on the use of mobile applications in diabetes management. Before you decide, you need to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully.

Please ask the researcher if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the study about?

The purpose of the current study is to explore and understand diabetes specialist nurses' views and experiences of using mobile applications in a clinical setting, and to find out the clinical areas of diabetes management that might be supported with mobile applications.

This will help a further research to design and develop a mobile application that will provide tools to support diabetes specialist nurses in managing their patients.

Why have I been invited?

You have been invited to take part in an interview because you are a diabetes specialist nurse.

Do I have to take part?

It is entirely up to you to decide. We will describe the study and go through this information sheet, which we will give you to keep. If you choose to participate, we will ask you to sign a consent form to confirm that you have agreed to take part. You will be free to withdraw at any time, without giving a reason and this will not affect you or your circumstances in any way.

What will happen to me if I take part?

If you decide to participate, you can contact the researcher using the contact information at the bottom of the leaflet to make an interview date/time at your preference. The interview will be face-to-face at a mutually agreed upon time and place. During the interview, you will be asked to complete a consent form (after reading this information sheet), and then you will be asked about your view and experience of using mobile applications in clinical work. The conversation will be audio recorded but your identity will be kept anonymised.

Benefits and risks

No major benefits or risks are anticipated, but you will have to give up 30–45 minutes of your time. You will receive a £20 Amazon.co.uk voucher as a thank you for taking part in this study. Additionally, any travel expenses you may incur through participating in this study will be covered. The research result will benefit in developing a mobile application to support you in clinical work.

Will my taking part in the study be kept confidential?

Yes. We will follow strict ethical and legal practice and all information about you will be handled in confidence. All information which is collected about you during the course of the research will be kept strictly confidential. Our procedures for data handling, processing, storing and destruction comply with the United Kingdom (UK) Data Protection Act 1998.

You will only be asked to provide basic information (age and gender) and your name will not be taken. During the study, data will be stored within a locked filing cabinet in the office at the Warwick Medical School and on university owned computers which require a user name and password by Hala Alhodaib. This data will be accessed only by Hala Alhodaib and the research team from the University of Warwick. After the study, the data will be kept for a period of 10 years in line with the University of Warwick's policy on published data.

It will not be possible to identify you from any published material arising from the study as anonymity will be ensured as all participants will be given a participant identification number.

What if there is a problem and who should I contact if I wish to make a complaint?

This study is covered by the University of Warwick's insurance and indemnity cover.

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a Senior University of Warwick official entirely independent of this study:

Jo Horsburgh
Deputy Registrar
Deputy Registrar's Office
University of Warwick

Coventry, UK, CV4 8UW.
T: +00 44 (0) 2476 522 713 E: J.Horsburgh@warwick.ac.uk

What will happen if I don't want to carry on with this research?

You may decide to stop being a part of the research study at any time without explanation. You have the right to ask that any data you have supplied to that point be withdrawn/destroyed. You have the right to omit or refuse to answer or respond to any question that is asked of you and there will be no consequences of withdrawal or changing your mind part way through.

You have the right to have your questions about the study answered (unless answering these questions would interfere with the study's outcome). If you have any questions as a result of reading this information sheet, you should ask the researcher before the study begins.

What will happen to the results of the research study?

All the information collected from the study will be examined and analysed. The study results will help to develop a mobile application, and will be submitted to a scientific journal for publication or conference presentation. The results will be used within the final PhD thesis. All data collected will be anonymous so no one can identify you as an individual.

Who is organising and funding the research?

The researcher who is a PhD student at the University of Warwick is organising the study. There is no external funding for the study.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by the University of Warwick's Biomedical and Scientific Research Ethics Committee (BSREC): **REGO-2014-786**, 4th June 2014.

What if I want more information about the study?

I will be glad to answer your questions about this study at any time. You may contact me at:

h.alhodaib@warwick.ac.uk

Thank you for taking the time to read this participant information leaflet.

THE UNIVERSITY OF WARWICK

Consent Form

Title of Study: **Perceptions, Perspectives and Experiences of Diabetes Specialist Nurses in Using Mobile Applications in a Clinical Setting: A Semi-Structured Interview**

Name of Researcher(s): Hala Alhodaib

Please initial the boxes

1. I confirm that I have read and understand the information sheet dated 4th June 2014, for the above study. I have had the opportunity to consider the information and ask questions which have been answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected. ☐

3. I understand that my conversation with the researcher will be recorded, and data collected during the study may be looked at by individuals from The University of Warwick, where it is relevant to my taking part in this research. I give permission for these individuals to have access to data collected during the study. ☐

4. I agree to take part in the above study. ☐

Your name (printed)	Date	Your signature

Witness name (printed)	Date	Signature

If you would like to take part in the second phase of the study which involves a one hour focus group, please enter your contact details below (e.g. work or home telephone number, email)

Interview Guide

Research Questions

- *How do DSNs currently use mobile applications?*
- *What are the DSNs' perceptions and views towards the use of mobile applications in a clinical setting?*
- *What are the challenges facing DSNs in diabetes management that might be supported by the use of mobile applications?*
- *Are DSNs willing to use mobile applications at the point of care?*
- *What are the potential benefits and concerns of using mobile applications in a clinical setting?*

Participant Details

1. Age:
2. Gender:
3. Profession:
4. Experience Level in Years:
5. Mobile Phone/Smartphone/Tablet Ownership (Yes/No):
    a. *If yes, for how long have you owned the Smartphone/Tablet?*
    b. *What is your Smartphone/Tablet brand?*

(Black- Questions to be ask participant, Red- possible probes, and my ideas that may be explored further)

Discussion Questions

1. Can you please tell me about your experience of using mobile applications (these are sometimes referred to as "mobile apps" or "apps")?
- *Have you ever used an app for any purpose? For clinical purpose? Provide details.*
- *What were the reasons for using the app that you mentioned?*
- *Could you describe in as much detail as possible how satisfied you were with the app used? Why?*

2. In your opinion, how might mobile apps help diabetes professionals during clinical work?
- *E.g., access guidelines, treatment/diagnosis information, calculators, drug information, access to HER, and secure texting.*

3. What are the potential benefits of using mobile apps at the point of care?
- *E.g., time spent with patient, workflow, patient's safety, and quality of care.*

- *Can you give examples of how mobile apps might benefit/facilitate your work?*

4. What are the potential limitations of using mobile apps at the point of care?

- *E.g. technological limitations, time limitations.*
- *What if you were provided with the smartphone/tablet instead of using your own device?*
- *What are the barriers of using mobile apps during a patient visit?*
- *Can you tell me about any concerns you may have about the use of mobile apps (in your work)?*

  E.g., confidentiality, patient perception.
- *How important is it for you to check the credibility of information source (content source, who created it) into a mobile app?*

5. Could you describe any challenges/difficulty you are facing in managing your patients where mobile apps may support you?

- *Examples may include, managing diabetes in a setting like nursing homes, diabetes with comorbidities, decision making.*
- *Do you have further examples of this?*
- *How do you feel about having a mobile app to support you in those areas?*
- *Do you think there is a place for such a mobile app in clinical work?*

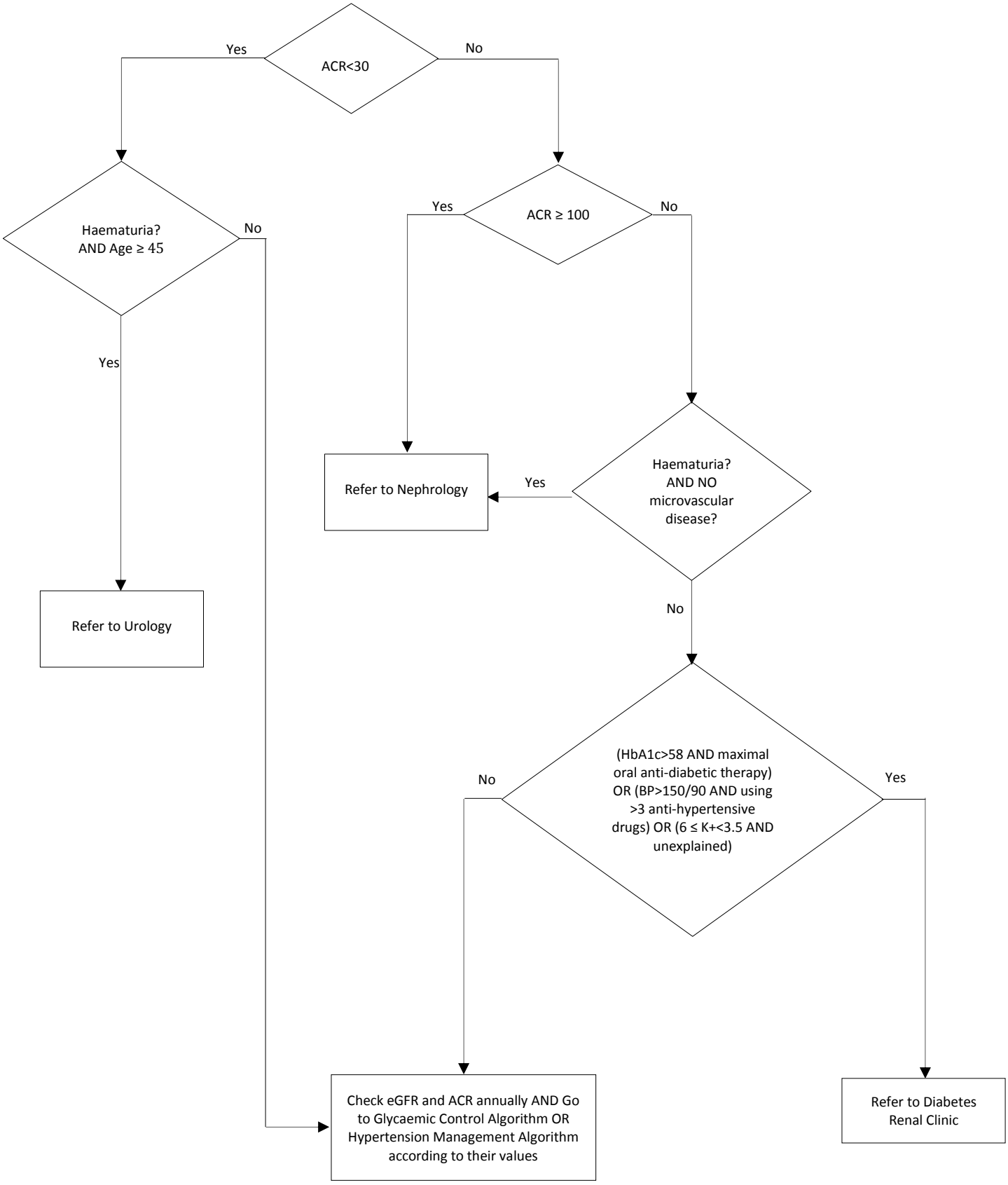
6. How likely would you be to use a mobile app? Why, why not?

- *What might be the challenges to adopting mobile apps?*
- *Would you be more likely/less likely to use the application if this was on a mobile device or on a traditional computer?*
- *Do you think you may need a training to use such a mobile app? If so, what in?*
- *Are there any other features that you think should be considered to increase your willingness to use a mobile app?*

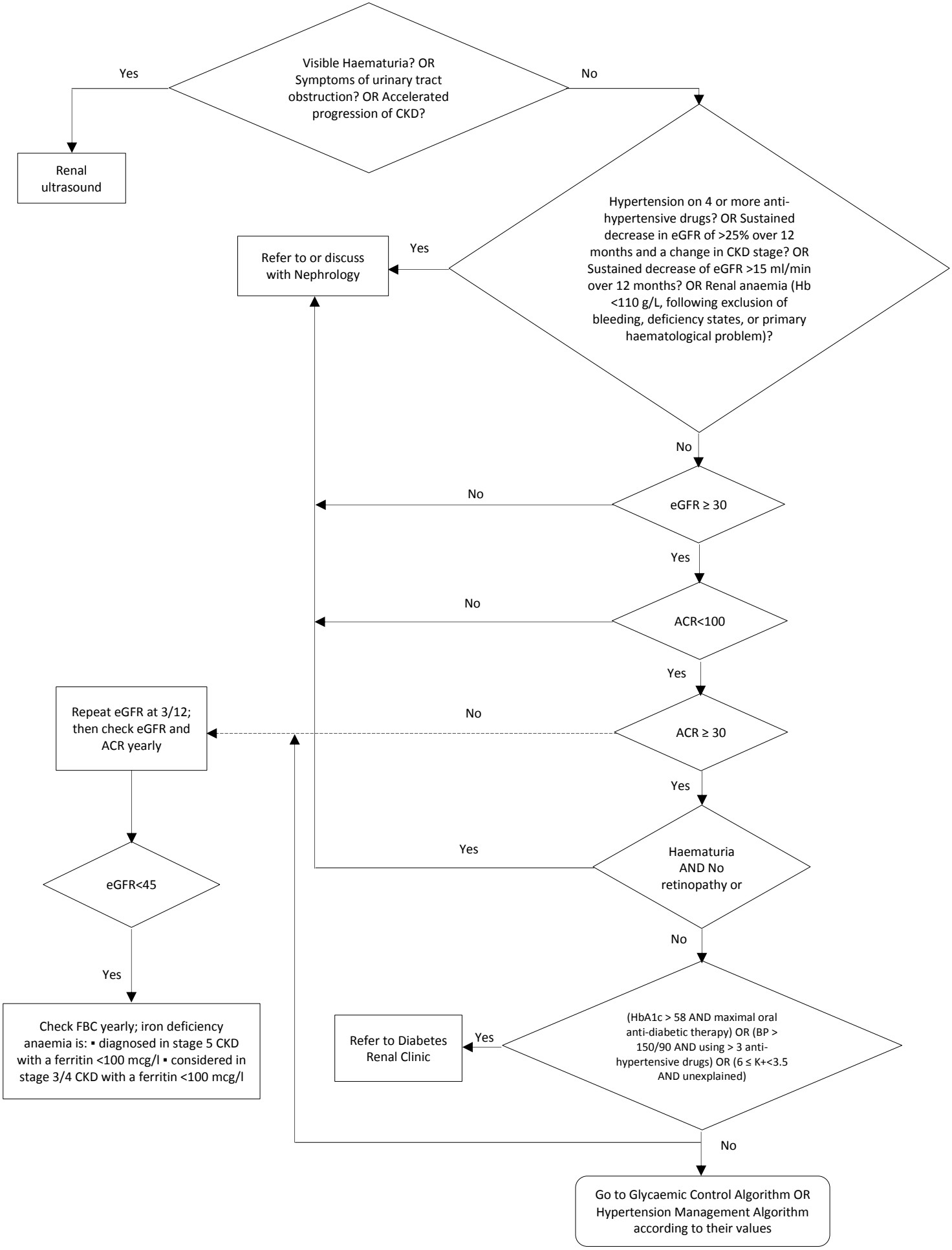
7. Thank you for all the information you have provided, is there anything else you'd like to add before we end?

Appendix 13. Decision algorithms and table

Algorithm for diabetes and CKD stage 1 – 2 (60 ≤ eGFR ≤ 90)

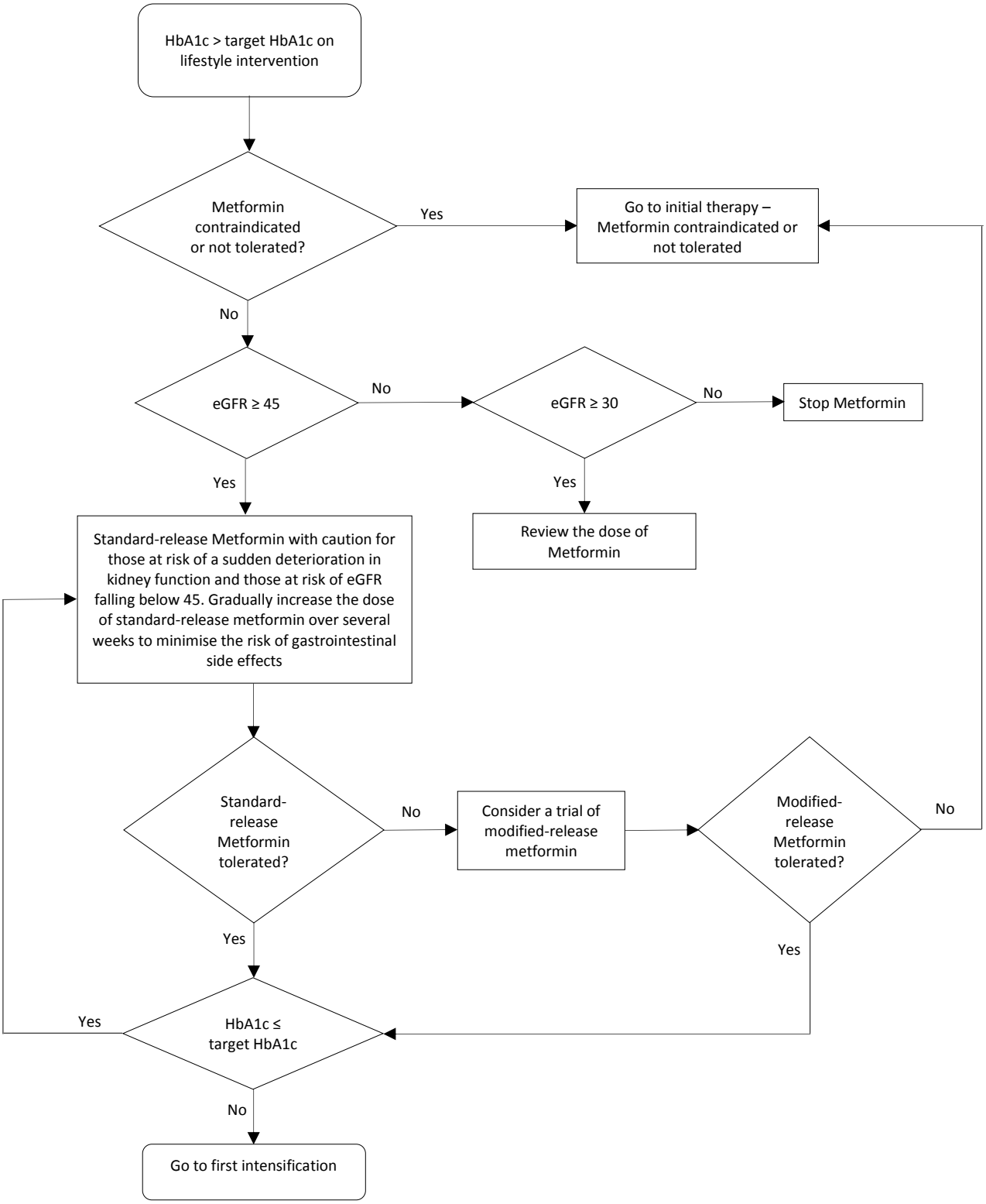


Algorithm for diabetes and CKD stage 3 – 5 (eGFR<60)

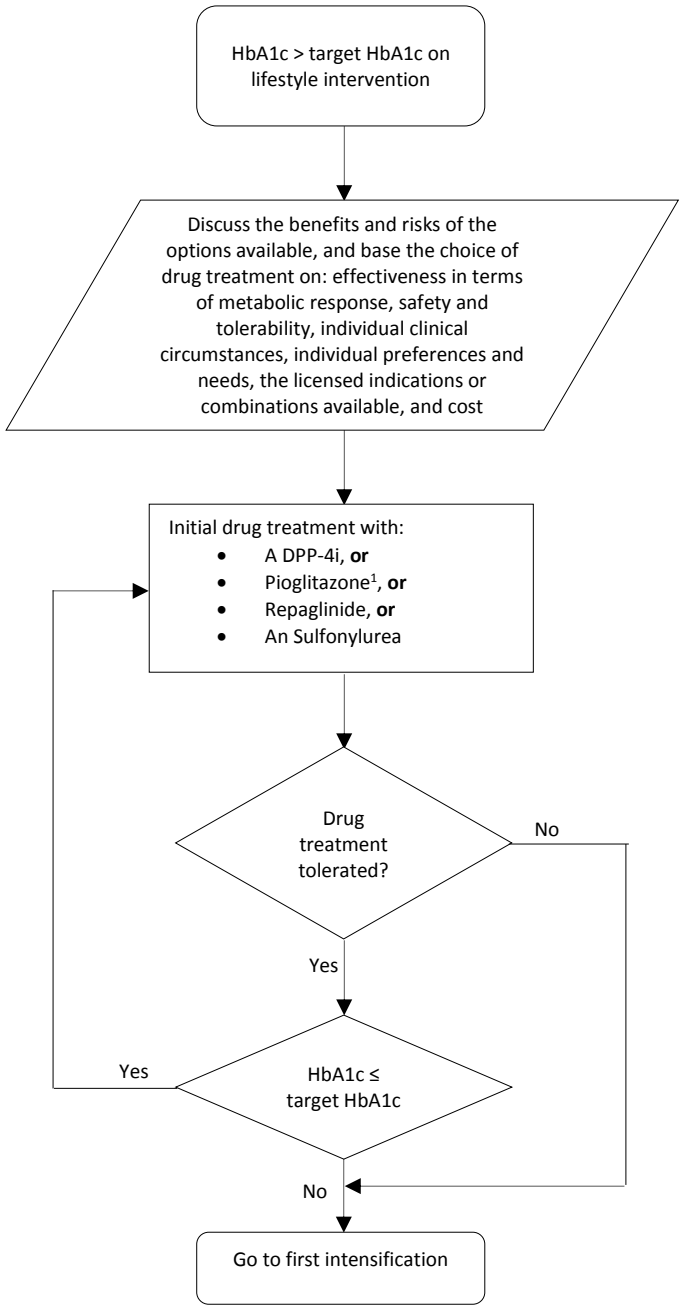


Algorithm for glycaemic control

Initial therapy:



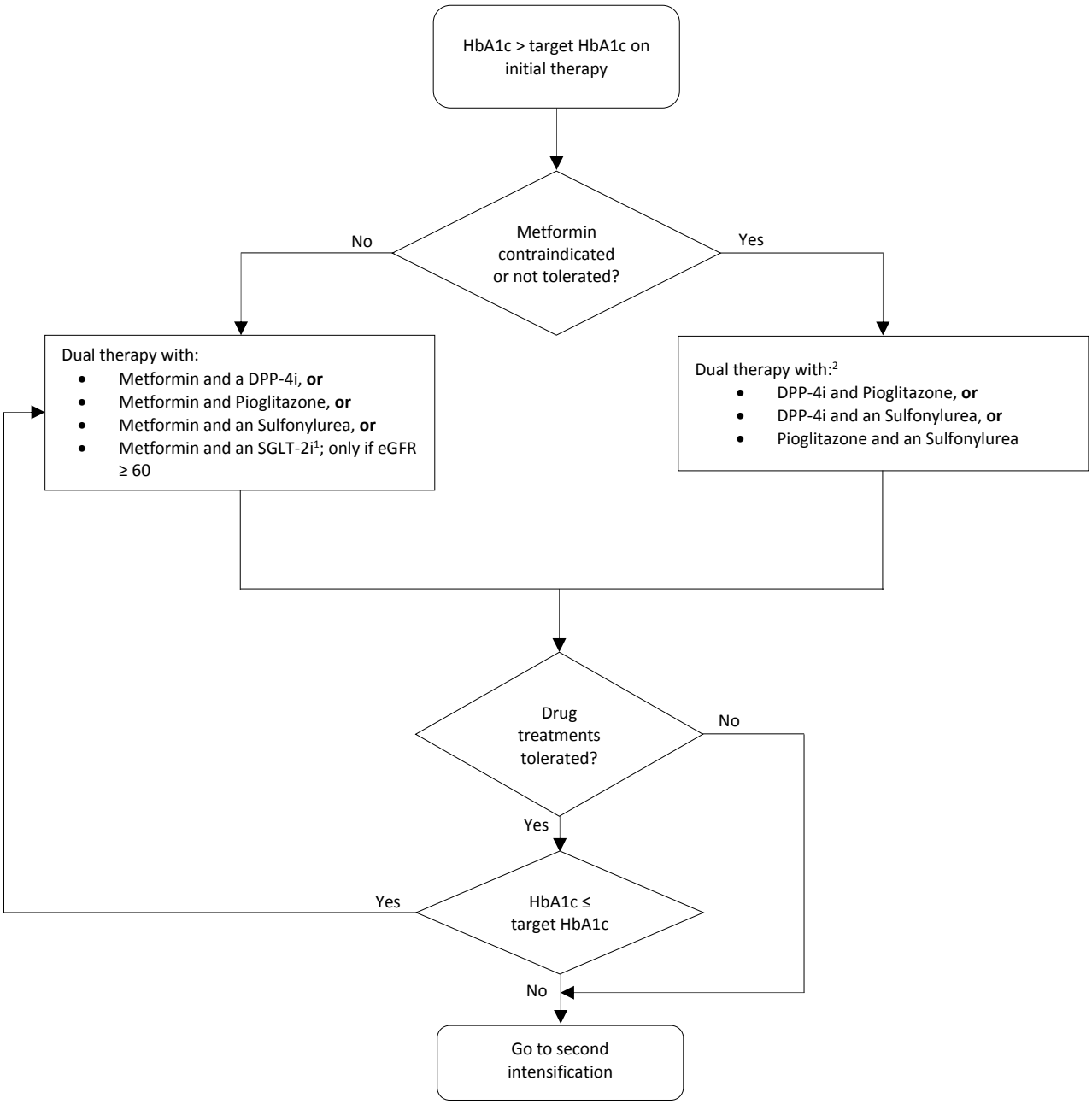
Initial therapy – Metformin contraindicated or not tolerated:



[1] Do not offer or continue **Pioglitazone** if the patient has any of the following:

- heart failure or history of heart failure
- hepatic impairment
- diabetic ketoacidosis
- current, or a history of bladder cancer
- uninvestigated macroscopic haematuria.

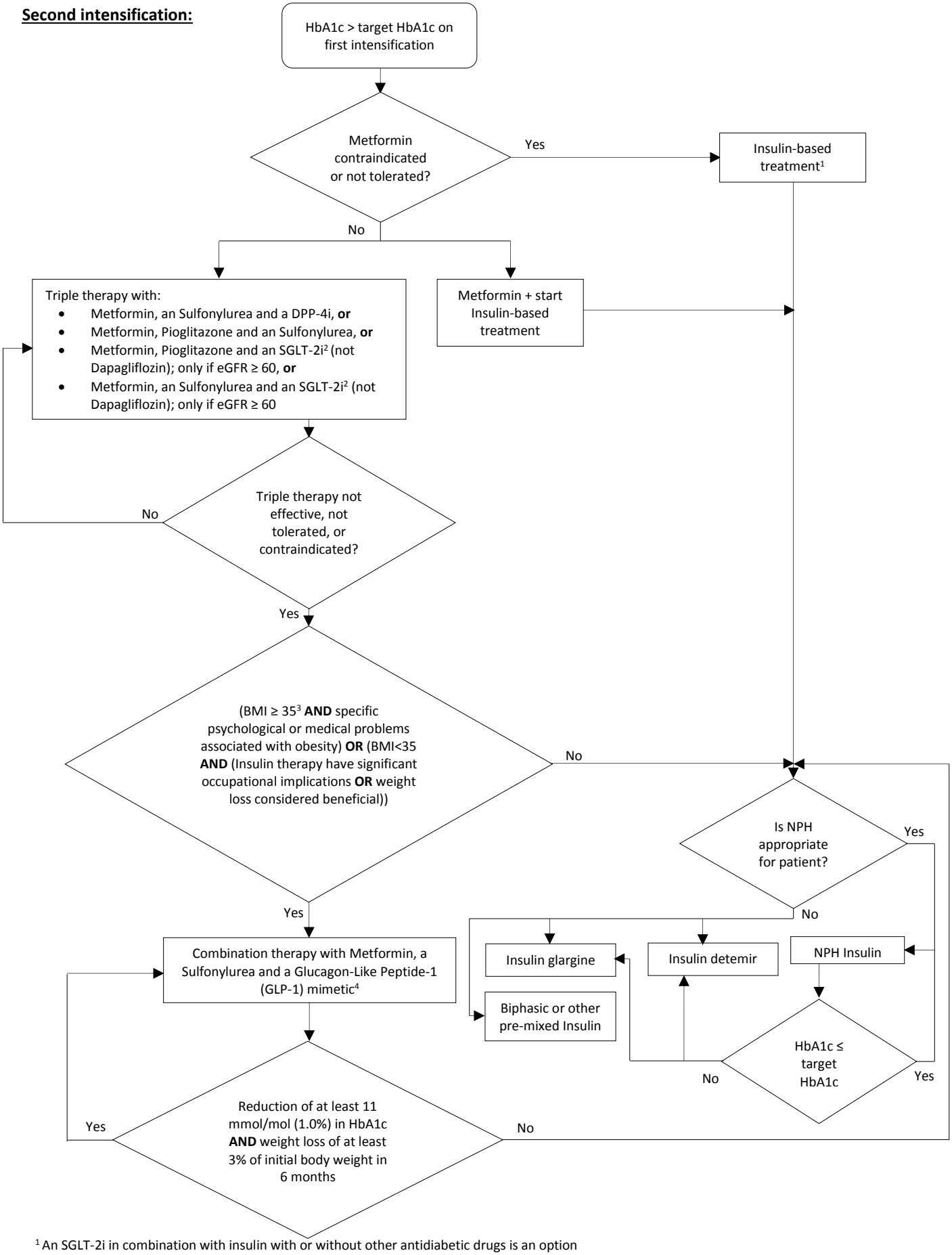
First intensification:



[1] Interrupt treatment with the SGLT-2i in patients who are hospitalised for major surgery or acute serious illnesses, and treatment may be restarted once the patient's condition has stabilised

[2] No licensed combination containing Repaglinide that can be offered at first intensification

Second intensification:



[1] An SGLT-2i in combination with insulin with or without other antidiabetic drugs is an option

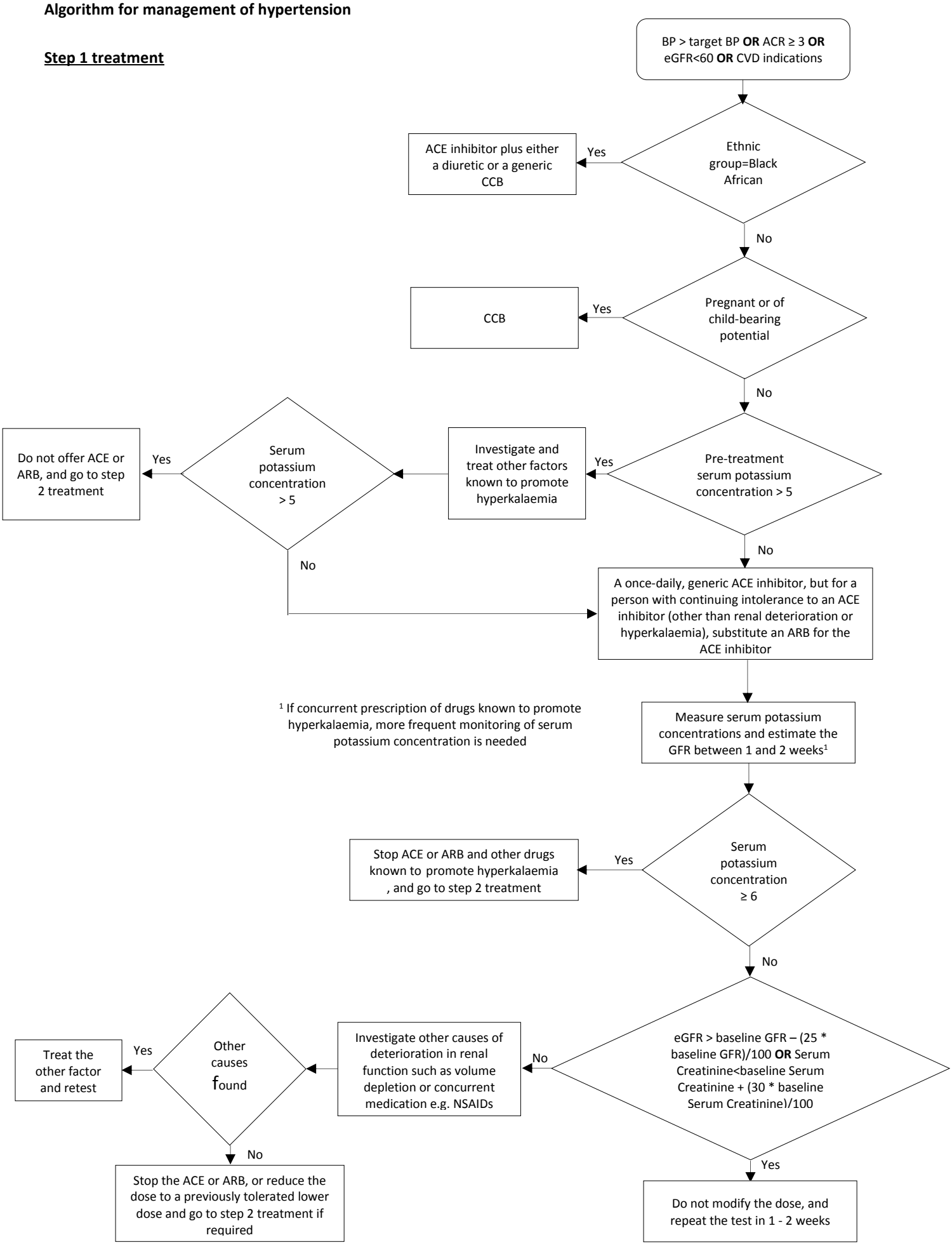
[2] Interrupt treatment with the SGLT-2i in patients who are hospitalised for major surgery or acute serious illnesses, and treatment may be restarted once the patient's condition has stabilised

[3] Adjust accordingly for people from black, Asian and other minority ethnic groups

[4] Liraglutide and Dulaglutide are licensed to be used only if eGFR ≥ 30, and all GLP-1 mimetic should be stopped if eGFR<30

Algorithm for management of hypertension

Step 1 treatment



Step 2 & 3 & 4 treatment

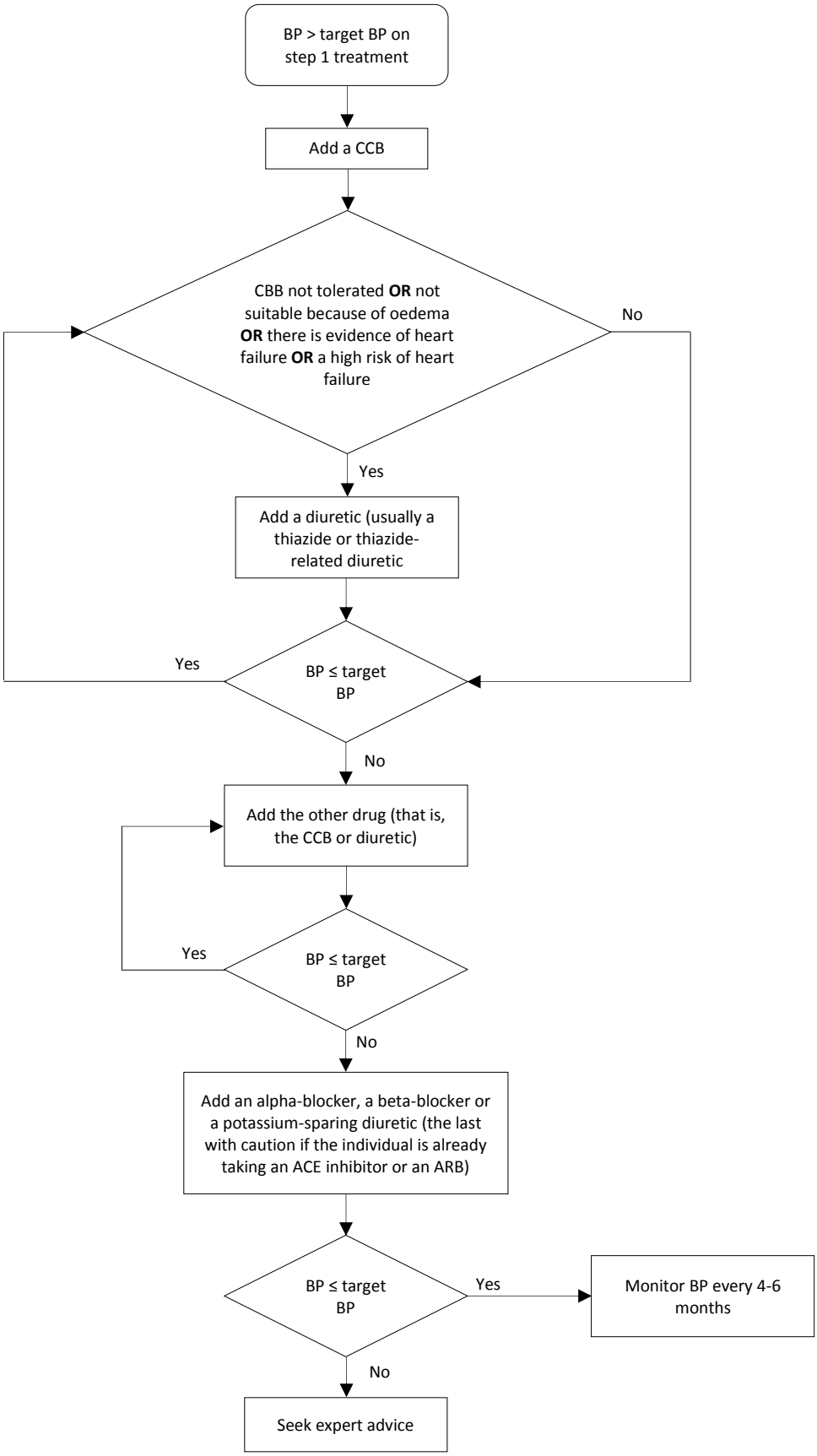


Table 1. Dose adjustment recommendations in CKD (reproduced from Clinical Practice Guideline on management of patients with diabetes and chronic kidney disease stage 3b or higher)

	Drug	CKD-1 (GFR≥90)	CKD-2 (60≤GFR≤89)	CKD- 3a (45≤GFR≤59)	CKD- 3b (30≤GFR≤44)	CKD-4 (15≤GFR≤29)	CKD-5ND (GFR<15)	CKD-5D (GFR<15)
Biguanides	**Metformin**	No adjustments		1.5g-850 mg/day; do not initiate if eGFR <45		To be avoided		
Sulfonylureas	**Glicazide**	Start at low doses and dose titration every 1-4 weeks (High risk of hypoglycemia)						
	Glimepiride	Reduce dosage to 1 mg/day (High risk of hypoglycemia)						
Meglitinides	**Repaglinide**	No adjustments					Limited experience available	
	Nateglinide	No adjustments					Start at 60 mg/day	To be avoided
TZD's	**Pioglitazone**	No adjustments						
DPP-4 inhibitors	**Sitagliptin**	No adjustments		Reduce to 50 mg/once daily if eGFR 30-50		Reduce to 25 mg/once daily		
	Vildagliptin	No adjustments		Reduce to 50 mg/once daily if eGFR <50				
	Saxagliptin	No adjustments		Reduce to 2.5 mg/once daily				
	Linagliptin	No adjustments						
	Alogliptin	No adjustments		Reduce to 12.5 mg/once daily		Reduce to 6.5 mg/once daily; and use with caution		
Incretin mimitics (GLP-1)	**Exenatide**	No adjustments		Careful use if eGFR 30-50		To be avoided		
	Liraglutide	No adjustments				To be avoided		
	Lixisenatide	No adjustments		Careful use if eGFR 30-50		To be avoided – no information available		
	Dulaglutide	No adjustments				To be avoided		
SGLT-2 inhibitors	**Dapagliflozin**	No adjustments		To be avoided - ineffective				
	Canagliflozin	No adjustments		Reduce to 100 mg/once daily	To be avoided			
	Empagliflozin	No adjustments		Reduce to 10 mg/once daily	To be avoided			

Appendix 14. App evaluation study materials

Example Case Scenario:

Mr. Patel

Is an Indian male, 57 years of age, with Type 2 Diabetes first diagnosed 4 years ago, which had been uncontrolled with Metformin 1 g BD plus Gliclazide 80 mg BD. Basal NPH Insulin was initiated replacing Gliclazde and titrated over the last 3 months (the patient continued on Metformin). This resulted in a few mild hypoglycemia episodes not requiring assistance. As Insulin titration progressed, hypoglycemic episodes were more frequent but not severe. He has Stage 3 Chronic Kidney Disease (CKD) i.e. "moderate" renal impairment. He presents now for routine follow-up and is noted to have gained 3 kg weight over the past month. There is no retinopathy and no clinical evidence of congestive heart failure or peripheral vascular disease. Laboratory evaluation reveals trace protein on urinalysis, with albumin-to-creatinine ratio indicating a moderately increased albuminuria. He is also treated with an Angiotensin-Converting Enzyme (ACE) Inhibitor for the past 2 years.

Task 1: How will you manage his glycaemic control?

Task 2: How will you manage his blood pressure?

Measure	Result	Measure	Result
HbA_{1c}	8.6% or 70 mmol/mol	**Serum potassium**	5 mmol/litre
Blood pressure (measured twice)	160/100 mmHg	**Weight**	110 kg
eGFR	47 mL/min/1.73 m2	**Height**	177 cm
ACR	250 mg/mmol	**BMI**	35.1 kg/m2

Case Scenario 1:

Mrs. Smith

A white female, 65 years of age, who has had Type 2 Diabetes for approximately 8 years and Hypertension for 5 years. She also has Stage 2 Chronic Kidney Disease (CKD). She presents after a recent ophthalmic examination that showed diabetic retinopathy with poor glycemic control despite receiving Metformin (2000 mg/d) plus a SGLT-2 Inhibitor (Dapagliflozin 10 mg OD) for the last 12 months. On review of systems, she indicates no weight change. She has mild Dyslipidemia controlled with a Statin and Hypertension treated with an Angiotensin II Receptor Blocker (ARB).

How will you approach managing her glycaemic control?

Measure	Result	Measure	Result
HbA_{1c}	9% or 75mmol/mol	**ACR**	110 mg/mmol
Blood pressure	120/70 mmHg	**Serum potassium**	3 mmol/litre
eGFR	64 mL/min/1.73 m2	**BMI**	29 kg/m2

Case Scenario 2:

Mr. John

A white male, 46 years of age, who is registered as a new patient at the GP practice. His medical history included Type 2 Diabetes and Hypertension for the past 11 years. Previously he had been told that he had protein in his urine. He now presents at the clinic with peripheral neuropathy. The patient had evidence of both microvascular and macrovascular disease. He also had microscopic haematuria. His GFR had deteriorated by 10ml/min (26%) over the past year from G3b to G4. Renal ultrasound shows normal-size kidneys. He was referred for smoking cessation counselling and given advice on weight reduction. His current medications include Metformin 1 g BD, Gliclazide 160 mg BD and Sitagliptin 100 mg OD, a Thiazide plus an Angiotensin-Converting Enzyme (ACE) Inhibitor. His blood lipids are well controlled on Atorvastatin 10 mg daily.

Task: How will you approach his glycaemic control management?

Measure	Result	Measure	Result
HbA_{1c}	76 mmol/mol (9.1%)	**ACR**	200 mg/mmol
Blood pressure	140/80 mmHg	**Serum potassium**	3.5 mmol/litre
eGFR	28 mL/min/1.73 m2	**BMI**	28 kg/m2

Feedback Sheet

1. Do you have any prior experience of using a mobile-based platform as a decision-support tool?

2. Your overall satisfaction with the app.

3. Positive and negative things about the app.

4. Usability issues if any was encountered during the session.

5. Features to change/add.

6. Your willingness to use the app in the future and why.

    - When appropriate to use the app?

    - When and why not appropriate to use the app?

    - Wishes/ suggestions for improvements.

7. Any other thoughts about the app.

Study Title: **Design, Development and Evaluation of a Mobile-based Clinical Decision Support Application for the Management of Patients with Diabetes and Kidney Disease to Facilitate Evidence-based Care Delivery**

Investigator: Hala Alhodaib

Introduction

You are invited to take part in a session to test a study-specific mobile application (hereafter referred to as "app") that assist in decision-making process. My name is Hala Alhodaib, and I am a PhD student from the University of Warwick working on the use of mobile apps in diabetes management. Before you decide, you need to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully.

Please ask the researcher if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the study about?

The purpose of the current study is to test a mobile app as an intervention for supporting clinicians in decision-making in patients with diabetes and chronic kidney disease, and to explore how the app was experienced and any suggestions for improvements.

This will help to further refine the developed app, and to plan and develop a more complex version of the app that includes all the common comorbidities of diabetes in the future.

Why have I been invited?

You have been invited to take part in this session because of your professional role.

Do I have to take part?

It is entirely up to you to decide. We will describe the study and go through this information sheet, which we will give you to keep. If you choose to participate, we will ask you to sign a consent form to confirm that you have agreed to take part. You will be free to withdraw at any time, without giving a reason and this will not affect you or your circumstances in any way.

What will happen to me if I take part?

If you decide to participate, you can contact the researcher using the contact information at the bottom of the leaflet. The session will be held at a mutually agreed upon time and place. During the session, you will be asked to complete a consent form (after reading this information sheet). After that, you will be asked to deal with a number of simulation-based case scenarios, and then you will be given the option to join a group discussion around the overall satisfaction with the app to help identify positive and negative aspects of the app, features to change/add. The session will be audio recorded but your identity will be kept anonymised.

What are the possible benefits and risks of taking part in this study?

No major benefits or risks are anticipated, but you will have to give up 60 – 90 minutes of your time. You will receive a £20 Amazon.co.uk voucher as a thank you for taking part in this study. Additionally, any travel expenses you may incur through participating in this study will be covered. The research result

Will my taking part in the study be kept confidential?

Yes. We will follow strict ethical and legal practice and all information about you will be handled in confidence. All information which is collected about you during the course of the research will be kept strictly confidential. Our procedures for data handling, processing, storing and destruction comply with the United Kingdom (UK) Data Protection Act 1998.

You will only be asked to provide basic information (age and gender) and your name will not be taken. During the study, data will be stored within a locked filing cabinet in the office at the Warwick Medical School and on University owned computers which require a user name and password by Hala Alhodaib. This data will be accessed only by Hala Alhodaib and the research team from the University of Warwick and the University of Birmingham. After the study, the data will be kept for a period of 10 years in line with the University of Warwick's policy on published data.

It will not be possible to identify you from any published material arising from the study as anonymity will be ensured as all participants will be given a participant identification number.

What if there is a problem?

This study is covered by the University of Warwick's insurance and indemnity cover. If you have an issue, please contact the Chief Investigator of the study:

Hala Alhodaib
E: h.alhodaib@warwick.ac.uk

Who should I contact if I wish to make a complaint?

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a Senior University of Warwick official entirely independent of this study:

Director of Delivery Assurance
Registrar's Office
University House
University of Warwick
Coventry, CV4 8UW
T: 024 7657 4774 E: Complaints@Warwick.ac.uk

What will happen if I don't want to carry on being part of the study?

You may decide to stop being a part of the research study at any time without explanation. You have the right to ask that any data you have supplied to that point be withdrawn/destroyed. You have the right to omit or refuse to answer or respond to any question that is asked of you and there will be no consequences of withdrawal or changing your mind part way through.

You have the right to have your questions about the study answered (unless answering these questions would interfere with the study's outcome). If you have any questions as a result of reading this information sheet, you should ask the researcher before the study begins.

What will happen to the results of the research study?

All the information collected from the study will be examined and analysed. The study results will help to develop a mobile app, and will be submitted to a scientific journal for publication or conference presentation. The results will be used within the final PhD thesis. All data collected will be anonymous so no one can identify you as an individual.

Who is organising and funding the research?

The principal investigator who is a PhD student at the University of Warwick is organising the study, and she has received a scholarship, which covers the studentship and the research consumables.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by the University of Warwick's Biomedical and Scientific Research Ethics Committee (BSREC): **REGO-2014-786 AMO1**, 22nd March 2016.

What if I want more information about the study?

I will be glad to answer your questions about this study at any time. You may contact me at:

E: h.alhodaib@warwick.ac.uk

Or you may contact my academic supervisor, Dr Paul Sutcliffe at:

T: 02476574505 E: P.A.Sutcliffe@warwick.ac.uk

Thank you for taking the time to read this participant information leaflet.

Consent Form

Study Title: **Design, Development and Evaluation of a Mobile-based Clinical Decision Support Application for the Management of Patients with Diabetes and Kidney Disease to Facilitate Evidence-based Care Delivery**

Name of Researcher(s): Hala Alhodaib, Dr Paul Sutcliffe, and Dr Krishnarajah Nirantharakumar

	Please initial The boxes
1. I confirm that I have read and understand the information sheet dated 22nd March 2016, for the above study. I have had the opportunity to consider the information and ask questions which have been answered satisfactorily.	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected.	☐
3. I understand that my conversation with the researcher will be recorded, and data collected during the study may be looked at by individuals from The University of Warwick, where it is relevant to my taking part in this research. I give permission for these individuals to have access to data collected during the study.	☐
4. I agree to take part in the above study.	☐

Name of participant	**Date**	**Signature**
Name of person taking consent	**Date**	**Signature**

If you would like to take part in the second phase of the study which involves a one hour focus group, please enter your contact details below (e.g. work/ mobile/ home telephone number, email)

Diabetes and Renal Complications Workshop
Agenda

Thursday 23rd February 2017
Lecture Theatre 2 & 3
14.00 – 16.00 pm

14.00 – 14.10	Introduction by Dr. Krishnarajah Nirantharakumar
14.10 – 14.40	Diabetes and Renal Complications lecture by Professor Wasim Hanif
14.40 – 14.50	Example simulation-based case scenario explained by Professor Wasim Hanif
14.50 – 15.00	Preparation for a mobile app testing session: You will be randomly divided into two groups (control & intervention). Participants in the control group will have access to a paper-based guidelines algorithm and Internet. Those in the intervention group in addition to this will have access to the developed mobile app. We will assist participants in the intervention group in accessing the app and train them on how to use it
15.00 – 15.10	Demonstration of using the app for the case scenario presented by Professor Wasim Hanif
15.10 – 15.30	Mobile app testing session: Both groups will be asked to deal with two simulation-based case scenarios. Decisions made in each group will be written down on the provided answer sheet. Outcome measure: Accuracy of decision (whether the recommendation match what is expected based on the guidelines)
15.30 – 15.40	Participants in the intervention group will be invited to fill in a short questionnaire to provide their feedback around positive and negative aspects of the app, features to change/add, and their overall satisfaction with the app
15.40 – 16.00	Discussion around the provided simulation-based case scenarios with Professor Wasim Hanif

Answer Sheet

To access the mobile app: https://diabetes.medicgenie.com

Case	Decision	Time taken
Case 1		
Case 2		

Model Answer

Case	Answer	Score
Case 1	Add-on Sulfonylurea or Pioglitazone or DPP-4i, or switch the patient to another dual therapy combination	+ 3
	Switch Dapagliflozin to another SGLT-2i (according to NICE guidelines, only Canaglifozin and Empagliflozin are recommended as options in triple therapy regimens)	+ 2
	Start Insulin	- 1
	No change	- 1
Case 2	Because the patient is currently CKD stage G4A3, Metformin should be stopped	+ 3
	Reduce Sitagliptin dose (Pioglitazone should not be offered because the patient had microscopic haematuria)	+ 1
	Start Insulin	+ 2
	Refer the patient to a Nephrologist in view of the rapid decline in renal function, and to an Urologist to investigate the haematuria, given his age and smoking history	+ 2

Appendix 15. Contributions to science and outputs from this thesis

- **Diapedia: The living textbook of diabetes**

Alhodaib, Hala. Information technology in DM [internet]. 2014 Aug 13; Diapedia 81040851628 rev. no. 7. Available from: https://doi.org/10.14496/dia.81040851628.7

Presentations

- Presentation at the Cochrane UK & Ireland Annual Symposium 2014, University of Manchester titled: Mobile phone messaging for facilitating self-management for long-term illnesses. Awarded the 3rd prize in the student competition, and the entry is published on the Students 4 Best Evidence website. Available from: http://www.students4bestevidence.net/cochrane-evidence-useful-usable-used-mobile-phone-messaging-for-facilitating-self-management-of-long-term-illnesses/
- Poster session at WMG Doctoral Research and Innovation Conference 2014, University of Warwick titled: Telehealth for diabetes mellitus: Smartphone applications as a management tool.
- Poster session at the 8th Saudi Student Conference 2015, Queen Elizabeth II Centre, London titled: Exploring the Potential of Using Mobile Applications in Diabetes Management: A systematic review. Available from: Proceedings of the Eighth Saudi Students Conference in the UK

Manuscripts in preparation

The following manuscripts are in preparation and will be submitted for publication within the next couple of months:

1. Alhodaib, H. I., Gao, X., Nirantharakumar, K., Chen, Y-F., Fang, Q., Sutcliffe, P. Mobile Applications for the Management of Diabetes Mellitus: A Systematic Review and Meta-analysis, (in preparation).
2. Alhodaib, H. I., Nirantharakumar, K., Sutcliffe, P., Lindenmeyer, A. Perceptions, Perspectives and Experiences of Diabetes Specialist Nurses in Using Mobile

Applications in a Clinical Setting: An Interview Study, (in preparation).

3. Alhodaib, H. I., Sutcliffe, P., Hanif, W., Sankar, S., Nirantharakumar, K. Design, Development and Evaluation of a Mobile-based Clinical Decision Support Application for the Management of Patients with Diabetes and Kidney Disease to Facilitate Evidence-based Care Delivery, (in preparation).