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Specialist nurses in diabetes mellitus (Review)

Loveman E, Royle P, Waugh N

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Specialist nurses in diabetes mellitus (Review)
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TABLE OF CONTENTS

HEADER	1
ABSTRACT	1
PLAIN LANGUAGE SUMMARY	2
BACKGROUND	3
OBJECTIVES	4
METHODS	4
RESULTS	6
DISCUSSION	8
AUTHORS' CONCLUSIONS	8
ACKNOWLEDGEMENTS	9
REFERENCES	10
CHARACTERISTICS OF STUDIES	13
DATA AND ANALYSES	22
Analysis 1.1. Comparison 1 Results, Outcome 1 Results.	22
APPENDICES	22
WHAT'S NEW	23
CONTRIBUTIONS OF AUTHORS	23
DECLARATIONS OF INTEREST	23
SOURCES OF SUPPORT	23
INDEX TERMS	23

[Intervention Review]

Specialist nurses in diabetes mellitus

Emma Loveman¹, Pamela Royle², Norman Waugh³

¹Southampton Health Technology Assessments Centre, University of Southampton, Southampton, UK. ²Department of Public Health, University of Aberdeen, School of Medicine, Aberdeen, UK. ³Department of Public Health, University of Aberdeen, Aberdeen, UK

Contact address: Hubertus JM Vrijhoef, Health Care Studies, University Maastricht, Universiteitssingel 40, Maastricht, 6200 MD, Netherlands. b.vrijhoef@zw.unimaas.nl.

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ABSTRACT

Background

The patient with diabetes has many different learning needs relating to diet, monitoring, and treatments. In many health care systems specialist nurses provide much of these needs, usually aiming to empower patients to self-manage their diabetes. The present review aims to assess the effects of the involvement of specialist nurse care on outcomes for people with diabetes, compared to usual care in hospital clinics or primary care with no input from specialist nurses.

Objectives

To assess the effects of diabetes specialist nurses / nurse case manager in diabetes on the metabolic control of patients with type 1 and type 2 diabetes mellitus.

Search methods

We carried out a comprehensive search of databases including the Cochrane Library, MEDLINE and EMBASE to identify trials. Bibliographies of relevant papers were searched, and hand searching of relevant publications was undertaken to identify additional trials.

Selection criteria

Randomised controlled trials and controlled clinical trials of the effects of a specialist nurse practitioner on short and long term diabetic outcomes were included in the review.

Data collection and analysis

Three investigators performed data extraction and quality scoring independently; any discrepancies were resolved by consensus.

Main results

Six trials including 1382 participants followed for six to 12 months were included. Two trials were in adolescents. Due to substantial heterogeneity between trials a meta-analysis was not performed. Glycated haemoglobin (HbA1c) in the intervention groups was not found to be significantly different from the control groups over a 12 month follow up period. One study demonstrated a significant reduction in HbA1c in the presence of the diabetes specialist nurse/nurse case manager at 6 months. Significant differences in episodes of hypoglycaemia and hyperglycaemia between intervention and control groups were found in one trial. Where reported, emergency admissions and quality of life were not found to be significantly different between groups. No information was found regarding BMI, mortality, long term diabetic complications, adverse effects, or costs.

Authors' conclusions

The presence of a diabetes specialist nurse / nurse case manager may improve patients' diabetic control over short time periods, but from currently available trials the effects over longer periods of time are not evident. There were no significant differences overall in hypoglycaemic episodes, hyperglycaemic incidents, or hospital admissions. Quality of life was not shown to be affected by input from a diabetes specialist nurse/nurse case manager.

PLAIN LANGUAGE SUMMARY**Specialist nurses in diabetes mellitus**

Specialist diabetes nurses provide education and support services to people with diabetes in many health care systems. A key goal is helping enable people to self-manage their diabetes. However, this review of trials found no strong evidence of benefit of care from specialist diabetes nurses for adolescents and adults with diabetes. Although short-term benefits may be possible, this has not been shown to result in long-term improvements. People receiving care from diabetes nurses do not appear to have improved health when compared with usual care in hospital clinics or primary care with no specialist nursing input. No data were shown on quality of life measures.

BACKGROUND

Education of the patient with diabetes

Treatment goals of diabetes are avoidance of late diabetic complications, normalisation of blood glucose levels and to enable people with diabetes to achieve a good health related quality of life. The patient with diabetes has to cope with many issues regarding the chronic disease, its control and complications. Education is not only required in the first few months following diagnosis, but is also a necessary component of their care throughout, and should be adjusted to the patient's own individual needs. Therefore, behavioural modifications require long-term information, education and care.

The diabetes specialist nurse / nurse case manager

Specialist nurses are defined as 'a registered nurse, who, after a significant period of experience in a specialised field of nursing and with additional nursing education, is authorised to practice as a specialist with advanced expertise in a clinical specialty to involve in clinical practice, consultation, teaching and research' (Tang 1993). Specialist nurses may or may not have a formal qualification in diabetes care. In addition, the specialist diabetes nurse will also be defined as a nurse who works wholly in diabetes care, based in either the hospital or community, including domiciliary visits, and crossing the boundaries between the two.

Nurse case managers will be defined as registered nurses who are certified diabetes educators and trained to follow a set of detailed management algorithms specific to diabetes (Aubert 1998).

In many areas of Europe, Australia, New Zealand, and the USA, specialist nurses provide much of the education and support given to patients with diabetes in both community and acute hospital settings. However, variations in health care, both within and between countries (Felton 1997) mean that whilst some patients gain access to the specialist nurses, others do not. This variation largely depends upon the accessibility of funds and the preference of individual clinicians. The present review aims to assess the effects of specialist nurse care; which includes education of people with diabetes, the provision of ongoing advice on controlling diabetes, advice on dealing with intercurrent illnesses, advice/supervision of initiation of treatment(s), and advice about learning to live with the diagnosis of diabetes, in comparison to no intervention from a specialist nurse. The review recognises that nurses act within complex health care systems and are often part of a broader package of care. The review attempts to identify other possible influencing variables within each included trial, and in addition included studies in which the service of a specialist nurse is added to an existing diabetes service which otherwise did not change. Only nurse interventions at individual patient level were included. Education in groups were excluded.

The role of the diabetes specialist nurse

Diabetes is a complex condition, and has effects on many aspects of peoples lives. The specialist nurse is typically involved in co-ordinating the ongoing care of patients, educating and counselling, but also providing advice on medication and management of intercurrent illness.

Education

Education is probably the most important role of the specialist nurse, with a large amount of information regarding the disease, its control and life style changes, needing to be imparted over a prolonged period of time. Increasing the patient's understanding of the disease through education can prevent or delay the onset of complications and reduce the number of hospitalisations, and as such is the key to improving the quality of life (Diab education 1985).

Counselling

Alongside the role of educator, the specialist nurse also provides a counselling role (Brown 1988). In addition to learning new practical skills, the patients have to take on the implications of a life-long disease, and may need help in accepting the changes which are occurring in their lives. The specialist nurse is in a unique position in that a relationship between patient and nurse will be maintained over a long period of time, and can provide support and time for patients as part of their role.

Disease management

The specialist nurse may also make adjustments to a patient's treatment regimen, for example insulin dosage. Nurses may also advise patients on the management of intercurrent illnesses, in particular advising on diabetic treatments during other illnesses. This enables a broader approach to patient management.

The non-educational roles of the diabetes specialist nurse may increase the effectiveness of education.

Diabetes information given to patients at any time needs to be up-to-date and consistent to reduce possible confusion caused by conflicting advice. Throughout the course of the disease patients are likely to come into contact with a number of health professionals, such as dieticians, primary care physicians, nurses, chiropodists, and the specialist nurse has a role in maintaining the professional knowledge of these people. Similarly the specialist nurse has a responsibility to ensure that the position of other health care professionals are not undermined by the advent of specialist nurses. Other roles of the specialist nurse are in research, and advising on local policies (Grzebalski 1997).

The role of the nurse case manager

In the USA, diabetes self management education is performed by a range of health care professionals such as nurses, dieticians, pharmacists, exercise specialists, doctors and social workers who have become 'Certified Diabetes Educators', (Felton 1997). Their role in the care of patients with diabetes will reflect only some of those of the specialist nurse. In particular, they are much less likely to make adjustments to treatments regimens, or advise on intercurrent illnesses. Similarly, education of other health care professionals, and coordination of the patients care are not undertaken by the diabetes educator (AADE 2001). However, some nurse diabetes educators, have also been trained to be nurse case managers. Their role is similar to that of the specialist nurse, for example they can make adjustments to treatments following a set of management algorithms (Aubert 1998). Therefore, nurse case managers are included in this review.

Integration into health care systems

In the UK, the British Diabetic Association report of 1985 recommended that each health district, serving 200,000 people, should have a minimum of two diabetes specialist nurses. This was increased to four per 250,000 people in 1991. Current practice levels have not always met this recommendation and an Audit Commission Study showed that only two of nine study sites audited met these recommended standards ([Audit Comm. 2000](#)). Recommendations from the Royal College of Nurses in the UK are that specialist nurses are paid at least at a level of a ward sister ([RCN 1991](#)), with many in more senior positions. Costs of these posts are potentially offset by savings made from reduced inpatient treatments for acute complications of diabetes, such as hypo- or hyperglycaemia, and treatment of chronic complications such as diabetic foot ulcers. Savings may also be made from increasing compliance in patients.

Effectiveness of specialist nurses

Evidence of the effectiveness of diabetes specialist nurses is at present unclear. Patients in contact with specialist nurses are generally satisfied with the level of care that they receive ([Gafvels 1996](#)) and it is thought that patients often contact the specialist nurses in preference to their general practices. The impression is that this is because the specialist nurses can provide better information and advice than general practice staff. However, measurement of outcomes of receiving care from a specialist nurse has not been reviewed in a systematic way. Thus a review of the evidence of the benefits and effectiveness of the nurse specialist is required.

The primary purpose of this review was to assess the evidence base for specialist nurses in general. However, in recent years there has been some sub-specialisation, particularly in the UK, with separation of nursing care for children and adults. This is not universally accepted, and a secondary aim was to see if there is any evidence to support the splitting of specialist nursing care into adult and paediatric groups.

Description of the condition

Diabetes mellitus is a metabolic disorder resulting from a defect in insulin secretion, insulin action, or both. Insulin deficiency leads to chronic hyperglycaemia (i.e. elevated levels of plasma glucose) with disturbances of carbohydrate, fat and protein metabolism. Long-term complications include retinopathy, nephropathy and neuropathy. The risk of cardiovascular disease is increased. There are various types of diabetes mellitus of differing etiology. The most common types are type 1 and type 2 diabetes. For a detailed overview of diabetes mellitus please see under 'Additional information' in the information on the Metabolic and Endocrine Disorders Group in *The Cochrane Library* (see 'About', 'Cochrane Review Groups (SRGs)'). For an explanation of methodological terms, see the main glossary in *The Cochrane Library*.

OBJECTIVES

To assess the effects of diabetes specialist nurses/nurse case managers on diabetes in patients with diabetes mellitus.

METHODS

Criteria for considering studies for this review

Types of studies

Studies were considered eligible if they were randomised controlled trials or controlled clinical trials fulfilling the inclusion criteria. The minimum trial duration was for a period of six months. This was based on experience with evidence of trials of other behavioural interventions.

Types of participants

Children and adults with type 1 or type 2 diabetes were included.

Diagnostic criteria

To be consistent with changes in classification and diagnostic criteria of diabetes through the years, the diagnosis was established using the standard criteria valid at the time of the beginning of the trial.

Types of interventions

- Specialist nurse intervention in addition to routine care versus routine care at individual patient level.
- Paediatric specialist nurse intervention versus routine care at individual patient level in the management of children with diabetes.

Types of outcome measures

Primary outcomes

Outcome measures reflected the different stages of the disease in which the specialist nurse was involved:

- glycosylated haemoglobin (HbA1c);
- short term diabetic complications (hypoglycaemic episodes, ketoacidotic incidents);
- long term diabetic complications (e.g. diabetic retinopathy, neuropathy, nephropathy).

Secondary outcomes

- mortality;
- emergency admissions;
- quality of life, ideally using a validated instrument;
- body mass index (BMI);
- costs;
- adverse effects.

Timing of outcome measurements

Medium (6-12 months) and long term (more than 12 months) outcome measurements were assessed.

Search methods for identification of studies

Electronic searches

We used the following sources for the identification of trials:

- The Cochrane Library (1981-2002);
- MEDLINE (1966-2002);
- EMBASE (1981-2002);

- CINAHL 1982-2002;
- British Nursing Index 1994-2002;
- Royal College of Nursing Journals Database 1985-1996;
- Health STAR 1981-2000/12;
- BIOSIS 1985-2002;
- PsycINFO 1977-2002;
- Science Citation Index 1981-2002;
- Social Sciences Citation Index 1981-2002.

We also searched databases of ongoing trials: Current Controlled Trials (www.controlled-trials.com - with links to other databases of ongoing trials).

The described search strategy (see under [Appendix 1](#)) was used for MEDLINE. For use with EMBASE, *The Cochrane Library* and the other databases this strategy was slightly adapted.

Handsearching

The journals *Diabetic Medicine*, *Diabetes Care*, *Diabetologia*, and *Diabetes* were hand searched for articles and proceedings of conferences abstracted in these journals from 1990 to 2001. Conference abstracts searched were: Abstracts of the Annual meetings of the European Association for the Study of Diabetes (EASD), and the Annual professional meetings of the British Diabetic Association.

We also searched reference lists of relevant trials and reviews.

Grey literature

Web of Science Proceedings 1990-2002, Conference Papers Index 1982-2002, HMIC (Health Management Information Consortium) databases, UK Theses, SIGLE.

It was anticipated that additional key words of relevance might have been identified during any of the electronic or other searches, and if this was the case, that the electronic search strategies would be modified to incorporate these terms. There were however, no additional key words added to the search strategy.

Data collection and analysis

Selection of studies

Two independent observers (EL, PR) reviewed titles, abstracts and keywords of all records retrieved. Full articles were retrieved for further assessment if the information given suggested that the study: 1. included patients with type 1 or type 2 diabetes mellitus, 2. compared specialist nurse intervention with no specialist nurse intervention, or paediatric nurse intervention to standard specialist nurse intervention, in which it was required that the intervention was evaluating the nurse alone (i.e. not a team approach), where education was individually based, and where nurses had responsibility for adjusting treatment regimens, 3. assessed one or more of the defined outcome measures. Full articles were also retrieved for clarification, when there was doubt about eligibility. Interrater agreement was assessed using Cohen's Kappa ([Fleiss 1981](#)). In cases of disagreement a judgement was made based upon discussion with a third independent reviewer (NW).

Data extraction and management

All three reviewers were involved in the data extraction process. Data concerning details of the study population, the intervention and outcomes were extracted independently by two of the three reviewers in each case using a data extraction form. This included the following information:

- (1) general information: title, authors, source, contact address, country, region (urban/rural), setting (hospital or community), language of publication, sponsoring, published/unpublished;
- (2) trial characteristics: design, randomisation (and method), allocation concealment, duration;
- (3) intervention(s): intervention, comparison intervention, (including length and nature of intervention), concurrent treatments;
- (4) participants: sampling, exclusion criteria, numbers, gender, age, baseline characteristics (for example glycated haemoglobin, BMI, ethnicity, sociodemographic details), duration of diabetes, intervention and control comparable at baseline, drop outs, withdrawals and losses to follow up, subgroups;
- (5) outcomes: as specified above, how outcomes were assessed, length of follow up, quality of reporting of outcomes;
- (6) results: for the outcomes as specified, intention-to-treat analysis.

Where necessary, authors were contacted about missing information in their trials.

Differences in data extraction were resolved by consensus.

Amendments to protocol

Two amendments have been made to the published research protocol: trials with a six month period of follow up were included and the quality assessment of controlled clinical trials followed the [CRD](#) criteria.

Assessment of risk of bias in included studies

Assessment of the quality of reporting of each trial was based largely on the quality criteria specified by Schulz and Jadad ([Jadad 1996](#); [Schulz 1995a](#); [Schulz 1995b](#)).

In particular the following factors were studied:

- (1) Minimisation of selection bias - a) was the randomisation procedure adequate? b) was the allocation concealment adequate?
- (2) Minimisation of attrition bias - a) were withdrawals properly described? b) was analysis by intention to treat?
- (3) Minimisation of detection bias - were outcome assessors blind to the intervention?

Based on these criteria, studies were broadly subdivided into the following three categories (see *Cochrane Handbook*):

A: All quality criteria met: low risk of bias.

B: One or more of the quality criteria only partly met: moderate risk of bias.

C: One or more criteria not met: high risk of bias.

Each trial was assessed independently by two assessors (EL, NW). Interrater agreement was assessed using Cohen's Kappa ([Fleiss 1981](#)). In cases of disagreement an assessment was made by a third independent assessor (PR) and then judgement was made based on consensus referring back to the original article.

As the number of trials identified was low, we included controlled clinical (non randomised) trials, and used the following quality criteria (CRD): Were the groups similar at baseline in terms of prognostic factors? Were the eligibility criteria specified? Were outcome assessors blinded to the treatment allocation? Were the point estimates and measure of variability presented for the primary outcome measure? Did the analyses include an intention to treat analysis? Were withdrawals and dropouts completely described? Were participants likely to be representative of the intended population?

RESULTS

Description of studies

Results of the search

6400 citations with their abstracts were obtained from electronic searches up to 2000, of which 53 were deemed relevant. No trials were identified from hand searching. A subsequent search in November 2001 identified 572 further citations, of which nine were deemed relevant. An updated search in February 2002 identified no further relevant trials. A further updated search in November 2002 identified 1 trial that was deemed relevant. In total 63 trials were deemed relevant from the abstracts for eligibility. Full papers were retrieved for all of these trials and independently assessed by two reviewers for inclusion.

Missing data

We contacted Drs Aubert, Davis and Wilson to clarify details of their trials. Dr Wilson supplied further information.

Assessment of publication bias inter-rater agreement

In general, agreement was high between the two reviewers, ($\kappa = 0.84$). Some cases were unclear and in these cases a third independent assessment was made and agreement was reached following discussion.

Included studies

Five trials initially met the inclusion criteria. Authors of additional three trials (Aubert 1998; Davies 2000; Wilson 2001) were contacted for further information to assess eligibility, only one reply (Wilson 2001) was received. This trial was presented as an abstract only and included on the basis of the information supplied from the author.

Study design

Included studies were randomised controlled trials in all cases with the exception of Couper 1999 which was a controlled clinical trial, where a geographical region was divided into two. The duration of included trials was 12 months in four trials (Marrero 1995; Piette 2000a; Piette 2001; Wilson 2001), 18 months in the Couper 1999 trial and six months in the Thompson 1999 trial.

Participants

A total of 1382 participants were included in the six trials. The individual study sample size ranged from 73 to 585. Participants gender was approximately distributed equally, except in the Piette 2001 study which was of a group of veterans, the majority of whom were male. Gender was not reported in one trial (Wilson 2001). Two trials (Marrero 1995; Couper 1999) were in adolescents, with mean ages of 13 and 14 years respectively. Mean ages in the adult trials

ranged from between 45 and 61 years. Participants of one trial were members of American Indian and Alaskan Native ethnic groups (Wilson 2001). The type of diabetes was noted in only one of the adult trials and was reported to be type 1 diabetes in approximately half of this population. Duration of diabetes was reported in only three trials, with the range of mean duration of diabetes in the adolescent trials being 4 - 8 years and in the adult trial from 14-19 years (Thompson 1999). Criteria for entry into the individual studies are outlined in the table [Characteristics of included studies](#) (characteristics of included studies).

Interventions

In only three trials (Couper 1999; Marrero 1995; Thompson 1999) was the diabetes specialist nurse / nurse case manager directly responsible for the alteration of treatment regimens, in others the nurse made a recommendation for treatment change. Whilst it cannot be clearly determined whether the physician has acted on these recommendations; this is often likely to be the case. For this reason these studies were included in the review.

In the two adolescent trials, a nurse case management approach was used, and in both cases some use was made of electronic communication such as telephone contact. In one of these trials nurses, together with the patients, set individual goals for frequency of blood glucose monitoring and insulin adjustment according to target blood glucose levels (Couper 1999). These participants also received weekly phone calls from the nurse. In the Marrero 1995 trial the adolescents used a glucometer with a modem which transmitted data from self monitoring of blood glucose to the hospital every two weeks. The nurse practitioners then suggested follow up care by telephone using an algorithm for regimen adjustments, referrals and advice.

In two of the adult trials a nurse case management approach was combined with automated telephone calls in which structured messages were relayed to patients, and where patients could report blood glucose levels, symptoms and self-care (Piette 2000a; Piette 2001). Telephone contact with the nurse was made following reports generated by the automated telephone calls, and nurses also made periodic calls. Patients in the intervention groups could also receive automated self-care calls. Nurses in these studies were unable to suggest alterations to treatments directly, rather recommended dosage adjustments to the primary care physician.

In the Thompson 1999 trial, the nurses also made use of telephone communication; patients were given individualised telephone contacts in which adjustments to treatments were recommended. The Wilson 2001 trial supplemented diabetes care with a nurse care coordinator who provided direct alterations in the patients care, and suggested alterations in medication to the primary care physician. In all trials the control interventions was 'usual care' which included contact with the physician and other members of the multidisciplinary team as necessary.

Duration of the intervention

With the exception of the study by Couper 1999 no trial reported the duration of the intervention and it is not clear whether the intervention continued for the same length of time as the length of follow up.

Outcomes

All included trials used glycated haemoglobin as an endpoint. Three trials also reported sub-group analyses of HbA1c. These were: those with a pre-defined normal HbA1c of less than 6.4% in the [Piette 2000a](#) trial, those with greater than 8% HbA1c and greater than 9% HbA1c in the [Piette 2001](#) trial, and the proportion of participants with at least a 10% drop in HbA1c in the [Thompson 1999](#) trial. Other primary outcomes included number of hypoglycaemic episodes, hyperglycaemic incidents ([Piette 2000a](#); [Piette 2001](#)), emergency room visits and hospitalisations ([Marrero 1995](#); [Piette 2000a](#)). Quality of life was used as an outcome in one trial, unfortunately no data were presented ([Marrero 1995](#)).

Excluded studies

Evaluation of the full papers of the 63 trials identified, led to exclusion of 55 trials. 2 further trials were excluded as no further information was received after contacting the relevant authors. Reasons for exclusions included not having any of the reviews prespecified outcomes, a too short period of follow-up, no control group, other members of team involved in patient care, education in groups, or nurses were unable to adjust treatments. In many cases more than one of the mentioned reasons were present. Reasons for excluding trials can be seen in the table [Characteristics of excluded studies](#).

Risk of bias in included studies

The five randomised controlled trials could be classified by their quality into three studies with moderate risk of bias ([Piette 2000a](#); [Piette 2001](#); [Thompson 1999](#)) and two studies with high risk of bias ([Marrero 1995](#); [Wilson 2001](#)). The controlled clinical trial was classified as having one or more quality criteria not met. Interrater agreement of trial quality was 0.33. Agreement was reached following discussion with a third reviewer.

Minimisation of selection bias

Of the five RCT's, the randomisation method was described and deemed to be adequate in three trials ([Piette 2000a](#); [Piette 2001](#); [Thompson 1999](#)). Of the remaining trials, a lottery was used in the [Wilson 2001](#) study, however, no further details of this are available, and the [Marrero 1995](#) trial does not report details of the method of randomisation. Evidence of adequate allocation concealment was noted in two trials only ([Piette 2001](#); [Thompson 1999](#)). No report of allocation concealment was made in the [Wilson 2001](#) trial or the [Marrero 1995](#) trial, and it is unclear whether allocation was concealed in the [Piette 2000a](#) study.

Minimisation of attrition bias

Numbers of study withdrawals were described in the four trials that had losses to follow up ([Couper 1999](#); [Piette 2000a](#); [Piette 2001](#); [Wilson 2001](#)). Analysis was reported to be by intention to treat in both [Piette 2000a](#) and [Piette 2001](#). No intention to treat analysis was undertaken in the [Wilson 2001](#) or [Couper 1999](#) trials. No losses to follow up were reported by [Marrero 1995](#) or [Thompson 1999](#).

Minimisation of detection bias

All trials evaluated diabetic control using HbA1c. Details of blinding of outcome assessors were not described in any of the trials.

Effects of interventions

Glycosylated haemoglobin A1c (HbA1c) - randomised controlled clinical trial in adults

Adjusting for differences in baseline insulin use, [Piette 2000a](#) found no significant difference in HbA1c between groups at 12 months (intervention 8.1%, control 8.4% [95% CI = -0.7 to 0.1%] P = 0.1). The intervention group had similar mean HbA1c levels to the control group at 12 months in the [Piette 2001](#) trial (intervention 8.1% [SD 0.1], control 8.2% [SD 0.1], P<0.3). In these two ([Piette 2000a](#); [Piette 2001](#)) studies, the nurse was not solely responsible for adjustments to treatments. In the [Thompson 1999](#) trial, a significant reduction in HbA1c was seen between the two groups at six months (Intervention 7.8% [SD 0.8], control 8.9% [SD 1.0], p<0.01). At baseline the intervention group and control group were not reported to be statistically different in any of these trials.

Results from [Wilson 2001](#) study (with up to 35% participants data missing) demonstrated a mean HbA1c of 8.8% [SD 2.1] in the intervention group versus 8.6% [SD 2.4] in the control group at baseline. Data at 12 month follow-up showed a mean HbA1c of 8.9% [SD 2.1] in the intervention versus 8.7% [SD 2.2] in the control group. These differences were not statistically significant.

HbA1c - randomised controlled clinical trial in adolescents

No significant differences in HbA1c were demonstrated in the [Marrero 1995](#) trial between the two groups (intervention 9.6% [SD1.9], control 9.7% [SD 1.5]) at six months. A similar finding was noted at 12 months (intervention 10.0% [SD1.6], control 10.3% [SD1.8]).

HbA1c - controlled clinical trial in adolescents

In the [Couper 1999](#) trial there were no statistically significant differences between the intervention and control groups at 6, 12 or 18 months (intervention 9.7% [SD 1.6], control 10.3% [SD 2.2] at six months, intervention 10.5% [SD 1.8], control 10.7% [SD 2.0] at 12 months, intervention 10.0% [SD 1.5], control 10.5% [SD 1.8] at 18 months).

Subgroup analyses

In a subgroup of patients who had HbA1c greater or equal to 8.0% at baseline in the [Piette 2001](#) study the intervention group had significantly lower HbA1c than controls at 12 months (8.7 ± 0.2% versus 9.2 ± 0.2%, p=0.04). Similarly, in patients who had HbA1c greater or equal to 9.0% at baseline the intervention group had significantly lower HbA1c than controls at 12 months (9.1± 0.3% versus 10.2 ± 0.3% p=0.04).

[Thompson 1999](#) observed the proportion of patients with greater or equal to 10% reduction in HbA1c at six months; the proportion of patients in the intervention group was statistically higher than the proportion in the control group (intervention 87% versus control 35%, p<0.001).

In the [Piette 2000a](#) trial the proportion of patients defined as having a normal HbA1c level of less than 6.4% was significantly greater in the intervention group at 12 months than the control group (intervention 17% versus control 8%, p=0.04).

Hypoglycaemic episodes

In adjusted outcomes for baseline differences in insulin use, hypoglycaemic episodes experienced throughout the intervention period of the [Piette 2000a](#) study were reported to be significantly different between the intervention group and control group (intervention 1.1, control 1.6 [95% CI -0.7 to -0.2] $p=0.001$). In the [Piette 2001](#) trial hypoglycaemic symptoms were not statistically different between the intervention and control group. No units of measurement used for these episodes in the two trials were provided.

Hyperglycaemic incidents

Hyperglycaemic incidents were reported in two trials ([Piette 2000a](#); [Piette 2001](#)). [Piette 2000a](#) reported a significantly lower number of events in the intervention group than the control group for the period of the trial (intervention 1.6, control 2.3 [95% CI -1.9 to -0.4] $p=0.0005$). Hyperglycaemic symptoms were not significantly different between the intervention and the control group in the [Piette 2001](#) trial. No units of measurement used for these incidents in the two trials were provided.

Emergency room visits

The Marrero trial reported no significant differences between emergency room visits in the intervention or control groups of their study of adolescents. [Piette 2000a](#) reported an increase in emergency room visits amongst the intervention group throughout the period of the study which was not statistically significant.

Hospitalisations

There were no statistical differences in hospital admissions between the intervention and control group in the [Marrero 1995](#) or the [Piette 2000a](#) trials.

Quality of life

[Marrero 1995](#) reported no between or within group differences on measures of quality of life, unfortunately no data were provided.

Diabetic complications

No diabetic complications were reported in the included trials.

Mortality

No included study reported mortality as an outcome.

Body mass index (BMI)

No included study reported BMI as an outcome.

Costs

No costs were reported in the included trials.

Adverse effects

No adverse effects were reported in the included trials.

Paediatric nurse specialists

We found no evidence for or against having the care of children with diabetes provided with nurses who only care for children, compared to those who look after adults and children.

DISCUSSION

Summary

This systematic review describes five randomised controlled trials and one controlled clinical trial studying the effects of a diabetes specialist nurse or nurse case manager on people with diabetes. All of the trials examined glycated haemoglobin, a measure of long term blood glucose control, as an endpoint. Despite there being an improvement in glycaemic control in the intervention groups of many of the trials reviewed, HbA1c in the intervention groups was not found to be significantly different from the control groups over a 12 month follow up period. One study demonstrated a reduction in HbA1c in the intervention group when compared to the control group at six months. In sub-groups of patients with higher baseline levels of HbA1c, a significant difference was observed between the intervention and control groups at 12 months, with the intervention groups having better metabolic control. Similarly, the proportion of participants with a greater than 10% drop in HbA1c was statistically significantly different between groups. Other outcomes such as hypoglycaemic or hyperglycaemic episodes were not found to be different as a result of the intervention and were generally poorly reported.

From currently available trials the effects of a diabetes specialist nurse / nurse case manager does not appear to be strong over longer periods of time. Unfortunately, it is difficult to establish from the reporting in many of the trials how long the interventions were undertaken for. In general the quality of the trials included in this review was not good. Only two of the included trials described their method of allocation concealment, and despite the proportion of drop outs ranging from 5 to 35% across the trials, only two trials carried out an intention to treat analysis.

Methodological considerations and limitations of the review

The diabetes specialist nurse / nurse case manager is an example of a complex intervention ([MRC 2000](#)) in that their role involves several components, which makes it difficult to establish with any precision which is their active ingredient. This has presented us with a number of difficulties in their evaluation. In all included trials it was important to establish that as far as possible it was only the presence of the nurse that was different between the two groups. Despite this, it is difficult to establish with any degree of certainty that any effects shown were attributable to that presence alone.

The eligibility criteria of the studies were diverse. For example, in the [Piette 2001](#) study all patients were on a hypoglycaemic agent whereas in the [Thompson 1999](#) study all were on insulin. Similarly, of the two studies of adolescents, one included only those with a mean glycated haemoglobin of more than 9% ([Couper 1999](#)). The entry levels of the outcomes were also different in all studies, with no trials reporting change scores, which leads to difficulties with standardisation. Pooling of data were therefore deemed to be inappropriate due to the profound heterogeneity between trials.

AUTHORS' CONCLUSIONS

Implications for practice

Of the six trials included, the interventions evaluated varied greatly, as can be seen in Table 1. Some evidence of an effect of the presence of a specialist nurse was evident at six months, but the findings

were greatly reduced beyond this time. This is somewhat similar to observations made in reviews of patient education in other chronic diseases and may be due to few trials assessing outcomes beyond the 6 month period (Cooper 2001). However, in all but one trial reported in this review, the follow up period was at least 12 months. The quality of the trials was generally low and this leads to difficulties in assessing the implications for practice. No implications for practice can be drawn from available data.

Implications for research

The present evidence base is unsatisfactory. Future research might firstly take the form of an observational study in several countries to identify the roles and time allocation of diabetes specialist nurses / nurse case managers, since roles vary even within countries. Secondly, qualitative research looking at the relative

educational impact of educators alone versus educators (such as the diabetes specialist nurse) who are also involved in clinical care would be useful, that is do diabetes specialist nurses / nurse case managers have greater educational effect because of their wider role? Thirdly, a randomised controlled trial of specialist nurse intervention should be performed. Because of the rising prevalence of diabetes, many health care systems are under considerable financial pressures. Future research should include an economic component, perhaps in the form of cost per quality adjusted life year.

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REFERENCES

References to studies included in this review

Couper 1999 {published data only}

Couper JJ, Taylor J. Failure to maintain the benefits of home-based intervention in adolescents with poorly controlled type 1 diabetes. *Diabetes Care* 1999;**22**(12):1933-7.

Marrero 1995 {published data only}

Marrero DG, Vandagriff JL, Kronz K, Fineberg NS, Golden MP, Gray D, et al. Using telecommunication technology to manage children with diabetes: the Computer-Linked Outpatient Clinic (CLOC) Study. *Diabetes Educator* 1995;**21**(4):313-9.

Piette 2000a {published data only}

Piette JD, Weinberger M, McPhee SJ, Mah CA, Kraemer FB, Crapo LM. Do automated calls with nurse follow-up improve self-care and glycemic control among vulnerable patients with diabetes?. *American Journal of Medicine* 2000;**108**(1):20-27.

Piette 2001 {published data only}

Piette JD, Weinberger M, Kraemer FB, McPhee SJ. Impact of automated calls with nurse follow-up on diabetes treatment outcomes in a Department of Veterans Affairs Health Care System: a randomized controlled trial. *Diabetes Care* 2001;**24**(2):202-8.

Thompson 1999 {published data only}

Thompson DM, Kozak SE, Sheps S. Insulin adjustment by a diabetes nurse educator improves glucose control in insulin-requiring diabetic patients: A randomized trial. *Canadian Medical Association Journal* 1999;**161**(8):959-62.

Wilson 2001 {published and unpublished data}

Wilson CA, Bochenski CL. The addition of a nurse care coordinator to a primary care system improves adherence with diabetes standards of care among American Indians and Alaskan Natives with diabetes. *Diabetes* 2001;**50**(Suppl.):A249.

References to studies excluded from this review

Ahern 2000 {published data only}

Ahern JA, Ramchandani N, Cooper J, Himmel A, Silver D, Tamborlane WV. Using a primary nurse manager to implement DCCT recommendations in a large pediatric program. *Diabetes Educator* 2000;**26**(6):990-4.

Aubert 1998 {published data only}

Aubert RE, Herman WH, Waters J, Moore W, Sutton D, Peterson BL, et al. Nurse case management to improve glycemic control in diabetic patients in a health maintenance organization. A randomized, controlled trial. *Annals of Internal Medicine* 1998;**129**(8):605-12.

Barglow 1983 {published data only}

Barglow P, Edidin DV, Budlongspringer AS, Berndt D, Phillips R, Dubowe, E. Diabetic control in children and adolescents - psycho-social factors and therapeutic efficacy. *Journal of Youth and Adolescence* 1983;**12**(2):77-94.

Blonde 1999 {published data only}

Blonde L, Guthrie R, Testa M, O'Brien T, Zimmerman R, Sandberg M, et al. Diabetes management by a team of diabetes nurse educators, endocrinologists and primary care physicians in a managed care setting [abstract]. *Abstract Book of Associated Health Service Research* 1999;**16**:318-9.

Brown 1995 {published data only}

Brown SA, Hanis CL. A community-based, culturally sensitive education and group-support intervention for Mexican Americans with NIDDM: a pilot study of efficacy. *Diabetes Educator* 1995;**21**(3):203-10.

Brown 1998 {published data only}

Brown SA. Effects of educational interventions in diabetes care: a meta-analysis of findings. *Nursing Research* 1998;**37**(4):223-30.

Carvalho 2000 {published data only}

Carvalho JY, Saylor CR. Continuum of care. An evaluation of a nurse case-managed program for children with diabetes. *Pediatric Nursing* 2000;**26**(3):296-300.

Cavan 2001 {published data only}

Cavan D.A, Hamilton P, Everett J, Kerr D. Reducing hospital inpatient length of stay for patients with diabetes. *Diabetic Medicine* 2001;**18**(2):162-4.

Chan 2000 {published data only}

Chan WB, Chan JCN, Chow CC, Yeung VTF, So WY, Li JKY, et al. Glycaemic control in type 2 diabetes: The impact of body weight, beta-cell function and patient education. *Quarterly Journal Medicine* 2000;**93**(3):183-90.

Colagiuri 1995 {published data only}

Colagiuri R, Colagiuri S, Naidu V. Can patients set their own educational priorities?. *Diabetes Research and Clinical Practice* 1995;**30**(2):131-6.

Corkery 1997 {published data only}

Corkery E, Palmer C, Foley ME, Schechter CB, Frisher L, Roman SH. Effect of a bicultural community health worker on completion of diabetes education in a Hispanic population. *Diabetes Care* 1997;**20**(3):254-7.

Davies 2000 {published data only}

Davies M, Dixon S, Currie CJ, Davis E, Peters JR. Evaluation of a hospital diabetes specialist nursing service: a randomized controlled trial. *Diabetic Medicine* 2000;**18**:301-7.

de Sonnaville 1997 {published data only}

de Sonnaville JJ, Bouma M, Colly LP, Deville W, Wijkel D, Heine RJ. Sustained good glycaemic control in NIDDM patients by implementation of structured care in general practice: 2-year follow-up study. *Diabetologia* 1997;**40**(11):1334-40.

Dougherty 1998 {published data only}

Dougherty GE, Soderstrom L, Schiffrin A. An economic evaluation of home care for children with newly diagnosed

diabetes: results from a randomized controlled trial. *Medical Care* 1998;**36**(4):586-98.

Dougherty 1999 {published data only}

Dougherty G, Schiffrin A, White D, Soderstrom L, Sufrategui M. Home-based management can achieve intensification cost-effectively in type I diabetes. *Pediatrics* 1999;**103**(1):122-8.

Drozda 1993 {published data only}

Drozda DJ, Allen SR, Turner AM, Slusher JA, McCain GC. Adherence behaviors in research protocols: comparison of two interventions. *Diabetes Educator* 1993;**19**(5):393-5.

Estey 1990 {published data only}

Estey AL, Tan MH, Mann K. Follow-up intervention: its effect on compliance behavior to a diabetes regimen. *Diabetes Educator* 1990;**16**(4):291-5.

Everett 1995 {published data only}

Everett J, Miles P, Jenkins E, Kerr D. Does nurse-led care help newly diagnosed type 2 patients cope with the crisis of diagnosis?. *Diabet Medicine* 1995;**12**(10):Supplement 2, page S7.

Feddersen 1994 {published data only}

Feddersen E, Lockwood DH. An inpatient diabetes educator's impact on length of hospital stay. *Diabetes Educator* 1994;**20**(2):125-8.

Fosbury 1997 {published data only}

Fosbury JA, Bosley CM, Ryle A, Sonksen PH, Judd SL. A trial of cognitive analytic therapy in poorly controlled type I patients. *Diabetes Care* 1997;**20**(6):959-64.

Fukuda 1999 {published data only}

Fukuda H, Muto T, Kawamori R. Evaluation of a diabetes patient education program consisting of a three-day hospitalization and a six-month follow-up by telephone counseling for mild type 2 diabetes and IGT. *Environmental Health and Preventative Medicine* 1999;**4**(3):122-9.

Goddijn 1999 {published data only}

Goddijn PP, Bilo HJ, Feskens EJ, Groeniert KH, van der Zee KI, Meyboom dJ. Longitudinal study on glycaemic control and quality of life in patients with Type 2 diabetes mellitus referred for intensified control. *Diabetic Medicine* 1999;**16**(1):23-30.

Goudswaard 2002 {published and unpublished data}

Goudswaard A, Stolk RP, de Valk HW, Rutten GEH. A randomised controlled trial of an education program by a diabetes nurse in poorly controlled Type 2 diabetes patients. *Diabetologia* 2002;**45**(Supplement 2):A316.

Hanestad 1993 {published data only}

Hanestad BR, Albrektsen G. The effects of participation in a support group on self-assessed quality of life in people with insulin-dependent diabetes mellitus. *Diabetes Research Clinical Practice* 1993;**19**(2):163-73.

Heller 1988 {published data only}

Heller SR, Clarke P, Daly H, Davis I, McCulloch DK, Allison SP, et al. Group education for obese patients with type 2 diabetes: greater success at less cost. *Diabetic Medicine* 1988;**5**(6):552-6.

Hollander 2001 {published data only}

Hollander P, Couch C, Hill S, Sheffield P. An analysis of patient outcomes between geriatric and non-geriatric type 2 diabetic patients who utilized a diabetes resource nurse case manager (CDE) in a primary care practice setting. *Diabetes* 2001;**50**:A198.

Kirkman 1994 {published data only}

Kirkman M, Weinberger M, Simel DL. A telephone-delivered intervention for patients with NIDDM. *Diabetes Care* 1994;**17**(8):840-6.

Koproski 1997 {published data only}

Koproski J, Pretto Z, Poretsky L. Effects of an intervention by a diabetes team in hospitalized patients with diabetes. *Diabetes Care* 1997;**20**(10):1553-5.

Korhonen 1983 {published data only}

Korhonen T, Huttunen JK, Aro A, Hentinen M, Ihalainen O, Majander H, et al. A controlled trial on the effects of patient education in the treatment of insulin-dependent diabetes. *Diabetes Care* 1983;**6**(3):256-61.

Korhonen 1987 {published data only}

Korhonen T, Uusitupa M, Aro A, Kumpulainen T, Siitonen O, Voutilainen E, et al. Efficacy of dietary instructions in newly diagnosed non-insulin-dependent diabetic patients. Comparison of two different patient education regimens. *Acta Medica Scandinavica* 1987;**222**(4):323-31.

Legorreta 1996 {published data only}

Legorreta AP, Peters AL, Ossorio RC, Lopez RJ, Jatulis D, Davidson MB. Effect of a comprehensive nurse managed diabetes program: an HMO prospective study. *American Journal of Managed Care* 1996;**2**:1024-30.

Litzelman 1993 {published data only}

Litzelman DK, Slemenda CW, Langefeld CD, Hays LM, Welch MA, Bild DE, et al. Reduction of lower extremity clinical abnormalities in patients with non-insulin-dependent diabetes mellitus. A randomized, controlled trial. *Annals Internal Medicine* 1993;**119**(1):36-41.

Lo 1996 {published data only}

Lo R, Lo B, Wells E, Chard M, Hathaway J. The development and evaluation of a computer-aided diabetes education program. *Australian Journal of Advanced Nursing* 1996;**13**(4):19-27.

Mazzuca 1997 {published data only}

Mazzuca KB, Farris NA, Mendenhall J, Stoupa RA. Demonstrating the added value of community health nursing for clients with insulin-dependent diabetes. *Journal of Community Health Nursing* 1997;**14**(4):211-24.

Mundingier 2000 {published data only}

Mundingier MO, Kane RL, Lenz ER, Totten AM, Tsai W, Cleary PD, et al. Primary care outcomes in patients treated by nurse

practitioners or physicians: a randomized trial. *Academic Nurse* 2000;**17**(1):8-17.

Peters 1995 {published data only}

Peters AL, Davidson MB. Management of patients with diabetes by nurses with support of subspecialists. *Health Maintenance Organisation Practice* 1995;**9**:8-14.

Peters 1998 {published data only}

Peters AL, Davidson MB. Application of a diabetes managed care program. The feasibility of using nurses and a computer system to provide effective care. *Diabetes Care* 1998;**21**(7):1037-43.

Philis-Tsimikas 2000 {published data only}

Philis-Tsimikas A, Rivard L, Walker C, Talavera G, Grunkemeier D, Vallejo C, et al. Nurse management of diabetes mellitus in low income Latino populations (Project Dulce) improves care, clinical outcomes and culture bound beliefs. *Circulation* 2000;**102**(18):4110.

Piette 2000b {published data only}

Piette JD, Weinberger M, McPhee SJ. The effect of automated calls with telephone nurse follow-up on patient-centered outcomes of diabetes care - A randomized, controlled trial. *Medical Care* 2000;**38**(2):218-30.

Pouwer 2001 {published data only}

Pouwer F, Snoek FJ, Der Ploeg HM, Ader HJ, Heine RJ. Monitoring of psychological well-being in outpatients with diabetes: effects on mood, HbA(1c), and the patient's evaluation of the quality of diabetes care: a randomized controlled trial. *Diabetes Care* 2001;**24**(11):1929-35.

Raz 1988 {published data only}

Raz I, Soskolne V, Stein P. Influence of small-group education sessions on glucose homeostasis in NIDDM. *Diabetes Care* 1988;**11**(1):67-71.

Rettig 1986 {published data only}

Rettig BA, Shrauger DG, Recker RR, Gallagher TF, Wiltse H. A randomized study of the effects of a home diabetes education program. *Diabetes Care* 1986;**9**(2):173-8.

Ridgeway 1999 {published data only}

Ridgeway NA, Harvill DR, Harvill LM, Falin TM, Forester GM, Gose OD. Improved control of type 2 diabetes mellitus: a practical education/behavior modification program in a primary care clinic. *Southern Medical Journal* 1999;**92**(7):667-72.

Ryle 1993 {published data only}

Ryle A, Boa C, Fosbury J. Identifying the causes of poor self-management in insulin dependent diabetics: The use of cognitive-analytic therapy techniques. In: Hodes, M, Moorey, S editor(s). England UK: Gaskell/Royal College of Psychiatrists: London, 1993.

Sadur 1999 {published data only}

Sadur CN, Moline N, Costa M, Michalik D, Mendlowitz D, Roller S, et al. Diabetes management in a health maintenance organization - Efficacy of care management using cluster visits. *Diabetes Care* 1999;**22**(12):2011-7.

Scott 1999 {published data only}

Scott TL, Aubert RE. The effect of nurse case management on diabetes self-management among HMO patients in a randomized trial. *Diabetes* 1999;**48**(Suppl. 1):A38.

Shamoon 1995 {published data only}

Shamoon H, Duffy H, Fleisher N, Engel S, Saenger P, Strelyzn M, et al. Implementation of treatment protocols in the diabetes control and complications trial. *Diabetes Care* 1995;**18**(3):361-76.

Sikka 1999 {published data only}

Sikka R, Waters J, Moore W, Sutton DR, Herman WH, Aubert RE. Renal assessment practices and the effect of nurse case management of health maintenance organization patients with diabetes. *Diabetes Care* 1999;**22**(1):1-6.

Sturmberg 1999 {published data only}

Sturmberg JP, Overend D. General practice based diabetes clinics. An integration model. *Australian Family Physician* 1999;**28**(3):240-5.

Tu 1993 {published data only}

Tu KS, McDaniel G, Gay JT. Diabetes self-care knowledge, behaviors, and metabolic control of older adults--the effect of a posteducational follow-up program. *Diabetes Educator* 1993;**19**(1):25-30.

Vrijhoef {published data only}

* Vrijhoef HJM, Diederiks JPM, Spreeuwenberg C, Wolffenbuttel BHR. [Substitution model with central role for nurse specialist is justified in the care for stable Type 2 diabetic outpatients]. *Journal of Advanced Nursing* 2001;**36**(4):546-55.

Ward 1999 {published data only}

Ward A, Metz L, Oddone EZ, Edelman D. Foot education improves knowledge and satisfaction among patients at high risk for diabetic foot ulcer. *Diabetes Educator* 1999;**25**(4):560-7.

Weinberger 1995 {published data only}

Weinberger M, Kirkman MS, Samsa GP, Shortliffe EA, Landsman PB, Cowper PA, et al. A nurse-coordinated intervention for primary care patients with non-insulin-dependent diabetes mellitus: impact on glycemic control and health-related quality of life. *Journal of General Internal Medicine* 1995;**10**(2):59-66.

Whitlock 2000 {published data only}

Whitlock WL, Brown A, Moore K, Pavlisacsak H, Dingbaum A, Lacefield D, et al. Telemedicine improved diabetic management. *Military Medicine* 2000;**165**(8):579-84.

Young 1997 {published data only}

Young A, Power E, Lowe D, Gill GV. Effect of diabetes specialist nurse input on HbA1c levels in poorly controlled insulin treated patients. *Diabet Medicine* 1997;**14**(supplement 1):S41.

Additional references

AADE 2001

American Association of Diabetes Educators. Website: www.diabetesnet.com/aade.html last accessed December 2001.

Audit Comm. 2000

Audit Commission Publications. Testing times: a review of diabetes services in England and Wales. 2000.

Brown 1988

Brown F. The role of counselling in diabetes care. *Practical Diabetes* 1988;**5**:174-5.

Cochrane MDSG 2000

Cochrane Menstrual Disorders and Subfertility Group. Statistical guidelines for reviewers. *The Cochrane Collaboration. Database on disk and CD-Rom* 2000, Issue 2.

Cooper 2001

Cooper H, Booth K, Fear S, Gill G. Chronic disease patient education: lessons from meta-analyses. *Patient Education and Counselling* 2001;**44**:107-17.

CRD

Centre for reviews and dissemination. CRD report 4; Undertaking systematic reviews of research on effectiveness. <http://www.york.ac.uk/inst/crd/report4.htm> last accessed June 2002.

Diab education 1985

Diabetes Education Study Group of the European Association for the Study of Diabetes. Teaching Letters 1985; Vol. 1.

Diabetes UK 2000

Diabetes UK. Web page: <http://www.diabetes.org.uk> last accessed June 2002.

Felton 1997

Felton A. The diabetes specialist nurse: a global view. In: JC Pickup, G Williams editor(s). Textbook of diabetes. 2nd Edition. Oxford: Blackwell Science, 1997:81.9-81.10.

Fleiss 1981

Fleiss JL. Statistical Methods of Rates and Proportions. 2nd Edition. New York: Wiley, 1981:217-34.

Gafvels 1996

Gafvels CM, Lither FG. Insulin treated diabetic patients: use of, experience of and attitudes to diabetes care. *European Journal of Public Health* 1996;**6**(4):262-9.

Grzebalski 1997

Grzebalski DK. The role of the diabetes specialist nurse. In: JC Pickup, G Williams editor(s). Textbook of diabetes. 2nd Edition. Oxford: Blackwell Science, 1997:81.0-81.8.

Jadad 1996

Jadad AR, Moore RA, Carroll D, Jenkinson C, Reynolds JM, Gavaghan DJ, et al. Assessing the Quality of Reports and Randomized Clinical Trials: Is Blinding necessary?. *Controlled Clinical Trials* 1996;**17**:1-12.

MRC 2000

Medical Research Council. [A framework for development and evaluation of RCTs for complex interventions to improve health]. <http://www.mrc.ac.uk/> last accessed June 2000.

RCN 1991

Royal College of Nursing. The Role of the Diabetes Specialist Nurse: A working party report. 1991.

Schulz 1995a

Schulz KF, Chalmers I, Hayes RJ, Altman DG. Empirical Evidence of bias: dimensions of methodological quality associated with estimates of treatment effects in controlled trials. *Journal of the American Medical Association* 1995;**273**:408-12.

Schulz 1995b

Schulz KF. The methodological quality of randomization as assessed from reports of trials in specialist and general medical journals. *Online Journal of Current Clinical Trials* 1995;**197**.

Tang 1993

Tang P. Evaluation of nurse specialist pilot scheme: draft report. Hospital Authority Head Office, Nursing Section 1993.

* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Couper 1999

Methods	DESIGN: non-randomised controlled trial SETTING: hospital and community COUNTRY: Australia DURATION OF INTERVENTION: 6 months LENGTH OF ALLOCATION TO GROUPS: geographical region divided into two groups of equal socio-economic status ANALYSIS BY INTENTION TO TREAT: no
Participants	INCLUSION CRITERIA: Adolescents with mean HbA1c >9.0% over preceding 12 months, age 12-17 years

Specialist nurses in diabetes mellitus (Review)

Couper 1999 (Continued)

EXCLUSION CRITERIA:
not defined
NUMBERS:
intervention: 37
control: 32
GENDER (male/female):
intervention: 18/19
control: 10/22
ETHNIC GROUPS:
not described
MEAN AGE:
intervention: 14.2 (SD 1.7)
control: 14.3 (SD 1.9)
BASELINE MEASUREMENTS:
HbA1c:
intervention: 11.1% (SD 1.3)
control: 10.5% (SD 1.6)
TYPE OF DIABETES:
all type 1
DURATION OF DIABETES (YEARS):
intervention: 7.1 (SD 3.6)
control: 5.8 (SD 3.0)
NUMBERS ON INSULIN : all
LOSSES TO FOLLOW-UP:
4 out of 73

Interventions

INTERVENTION:
Diabetes nurse educator gave:
- Monthly home visits of 45-60 minutes. Patients set their own goals for frequency of blood glucose monitoring and insulin adjustment according to target blood glucose levels. Aimed to reach their individually chosen target blood glucose and HbA1c levels at 3 and 6 months respectively. Plus received structured education on long-term significance of metabolic control, nutrition, exercise, sick day management, hyperglycaemic events and hypoglycaemic events and insulin adjustment.
- Weekly phone contact of 5-10 minutes.
- Routine care
CONTROL:
Routine Care. Hospital visits at 3 month intervals for review of diabetes by a paediatric endocrinologist, dietician and diabetes educator and availability of 24 hour phone access for acute problems. Insulin dose and frequency adjusted according to standard clinical management independent of group to which patient assigned.
LENGTH OF FOLLOW-UP: After the 6 month intervention, there was a 12 month follow-up period when both groups received routine care.

Outcomes

PRIMARY:
-HbA1c

Notes

QUALITY ASSESSMENT: one or more criteria not met

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	High risk	C - Inadequate

Marrero 1995

Methods

DESIGN: Randomised controlled trial

Specialist nurses in diabetes mellitus (Review)

Marrero 1995 (Continued)

SETTING: Paediatric outpatient clinic
 COUNTRY: USA
 DURATION OF INTERVENTION: unsure, possible 12 months
 ALLOCATION TO GROUPS: Not described
 ANALYSIS BY INTENTION TO TREAT: not applicable - no losses to follow-up

Participants	<p> INCLUSION CRITERIA: members of a paediatric diabetes clinic, at least 5 years old, diagnosed with type 1 diabetes for at least 6 months, telephone at home. EXCLUSION CRITERIA: not stated NUMBERS: Intervention: 52 Control: 54 GENDER (male/female): Intervention: 31/21 Control: 32/22 ETHNIC GROUPS: Intervention: 51 white, 1 black; Control 51: white, 3 black. MEAN AGE: Intervention: 13.3 (SD 4.5); Control: 13.3 (SD 4.9) BASELINE MEASUREMENTS: HbA1c: Intervention: 9.4% (SD 1.9); Control: 9.9% (SD 1.6) TYPE OF DIABETES: all type 1 DURATION OF DIABETES (YEARS): Intervention: 4.3 (SD 3.4); Control: 8.0 (SD 4.7) NUMBERS ON INSULIN: All LOSSES TO FOLLOW-UP: Not described </p>
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Interventions	<p> INTERVENTION: Glucometer with memory and modem used. All self monitoring of blood glucose data transmitted every data from home to hospital every 2 weeks. Data reviewed by paediatric nurse practitioners. Frequency of follow-up used an age-appropriate algorithm based on data. If mean blood glucose within normal range, a postcard sent. If not, then telephone contact made - discussed possible regimen adjustments, need for a clinic visit or referral to dietitian, social worker or physical therapist. All insulin adjustments made by nurse practitioners using dose-adjusted algorithms, designed to achieve mean weekly blood glucose levels <141mg/dL and no more than 2 asymptomatic hypoglycemic episodes per week. Also attended the clinic for routine care every 3 months. CONTROL: Standard Care. Clinic visits every 3 months. Used the same monitoring but without modem. Regimen adjustments made by the endocrinologist over this time using the same algorithm. If HbA1c at clinic was raised the nurse phoned patients. LENGTH OF FOLLOW-UP: 12 months. </p>
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Outcomes	<p> PRIMARY: - HbA1c - Hospitalisations - Emergency room visits. SECONDARY: - Quality of life </p>
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Notes	<p> QUALITY ASSESSMENT: one or more criteria not met COMMENTS: unsure whether care programmes were identical. </p>
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Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Piette 2000a

Methods	<p>DESIGN: Randomised controlled trial SETTING: Community outpatients of a general medicine clinic in a county health system COUNTRY: USA DURATION OF INTERVENTION: unclear, possible 12 months ALLOCATION TO GROUPS: random number tables ANALYSIS BY INTENTION TO TREAT: yes</p>
Participants	<p>INCLUSION CRITERIA: adults with a diagnosis of diabetes mellitus or an active prescription for a hypoglycaemic agent identified from medical records EXCLUSION CRITERIA: age . >75 years, psychotic disorder, disabling sensory impairment, life expectancy <12 months, primary language not English or Spanish, newly diagnosed (<6 months), planned to discontinue services of clinic in 12 months, no touch telephone NUMBERS: Intervention: 140 Control: 140 GENDER (male/female): Intervention: 48/76 Control: 54/70 ETHNIC GROUPS: Intervention: 36 white, 59 Hispanic, 29 Other Control: 36 white, 64 Hispanic, 24 Other. MEAN AGE: Intervention: 56 (SD 10) Control: 53 (SD 10) BASELINE MEASUREMENTS: HbA1c: Intervention: 8.8% (SD 1.8) Control: 8.6% (SD 1.8) Hyperglycaemic symptoms (median and IQR): Intervention: 2 (1-4) Control: 2 (1-4) Hypoglycaemic symptoms (median and IQR): Intervention: 1 (0-3) Control: 2 (0-3) TYPE OF DIABETES: not given DURATION OF DIABETES (YEARS): not given NUMBERS ON INSULIN: Intervention: 54 Control: 38 LOSSES TO FOLLOW-UP: 32/280 (16 in each group)</p>
Interventions	<p>INTERVENTION: Automated telephone system : Structured messages of recorded statements and queries bi-weekly to determine patients health, with a 5-8 min. assessment. Patients reported self monitoring of blood glucose readings, self-care, perceived glycemic control and symptoms of poor glycemic control. Interacted with system using touch-tone keypad. Also given option to participate in interactive self-education. After several months offered additional automated self-care education calls. A Spanish language version of the automated calls provided. - Telephone nurse follow-up: each week nurse used reports generated by automated telephone system to prioritise patient contacts with follow-up calls - nurse addressed problems reported during assessments and provided more self-care education. Nurse also made periodic calls to follow-up on issues discussed in a prior week, or check on those who rarely responded to calls. Depending on problem, nurse contacted the primary care physician. Nurse did not have ability to authorise medication changes, but recommended dosage adjustment to primary care physician. CONTROL: Usual care: Patients had no systematic monitoring between clinic visits or reminders of upcoming clinic appointments. Follow-up visits at providers discretion. Additional visits at patients initiative. Nurse contact over the telephone, diabetes education clinic and interpreter service available. LENGTH OF FOLLOW-UP: 12 months</p>
Outcomes	<p>PRIMARY: -HbA1c -Hypoglycemic symptoms -Hyperglycemic symptoms -Emergency admissions -Hospitalisations</p>

Piette 2001 (Continued)

COMMENTS: Far more diabetic outpatient visits in intervention group.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Thompson 1999

Methods	DESIGN: Randomised controlled trial SETTING: Hospital diabetes clinic COUNTRY: Canada DURATION OF INTERVENTION: 6 months ALLOCATION TO GROUPS: random number table ANALYSIS BY INTENTION TO TREAT: not applicable - no losses to follow-up
Participants	INCLUSION CRITERIA: receiving insulin, have undergone standard diabetes education, able to self-monitor, under care of one of the centre's endocrinologists, poorly controlled (most recent HbA1c greater or equal to 8.5%). EXCLUSION CRITERIA: inability to communicate by phone, any contraindication to tight glucose control, any other serious illness, use of insulin pump. NUMBERS: Intervention: 23 Control: 23 GENDER (male/female): Intervention: 10/13 Control: 12/11 ETHNIC GOUPS: not described MEAN AGE: Intervention: 47.5 (SD 11.8) Control: 50 (SD 14.8) BASELINE MEASUREMENTS: HbA1c: Intervention: 9.4% (SD 0.8) Control: 9.6% (SD 1.0) TYPE OF DIABETES: type 1: Intervention: 14 Control: 12 DURATION OF DIABETES (YEARS): Intervention: 14.7 (SD 9.2) Control: 19.2 (SD 7.9) NUMBERS ON INSULIN: all patients LOSSES TO FOLLOW-UP: none reported
Interventions	INTERVENTION: Individualised telephone contact by diabetes nurse educator. Calls averaged 3 per week, lasting 15 minutes over 6 months. Insulin adjustments recommended during most calls. Reviewed patients records with physician as needed - typically about once every 2 weeks CONTROL: Given supplies as needed and continued usual contact with physicians and clinic, including HbA1c measurement every 3 months. LENGTH OF FOLLOW-UP: 6 months
Outcomes	PRIMARY: - HbA1c - proportion patients experienced 10% drop in HbA1c SECONDARY: diabetes complications - not defined.
Notes	QUALITY ASSESSMENT: one or more criteria met COMMENTS: unsure whether intervention group also had contact with physicians.

Thompson 1999 (Continued)

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Wilson 2001

Methods	DESIGN: Randomised controlled trial SETTING: Primary care system COUNTRY: USA DURATION OF INTERVENTION: unclear, possible 12 months ALLOCATION TO GROUPS: By lottery ANALYSIS BY INTENTION TO TREAT: used last value carried forward for available clinical data *data provided from author
Participants	INCLUSION CRITERIA: not reported EXCLUSION CRITERIA: not reported NUMBERS: Intervention: 295 Control: 290 GENDER: not reported ETHNIC GROUPS: American Indian and Alaskan Natives MEAN AGES: Intervention: 48 (SD 13) Control: 45 (SD 14) BASELINE MEASUREMENT: HbA1c: Intervention: 8.8% (SD 2.4) Control: 8.6% (SD 2.3) TYPE OF DIABETES: not reported DURATION OF DIABETES (YEARS): Intervention: 4.3 (SD 4.7) Control: 4.1 (SD 4.9) NUMBERS ON INSULIN: not reported LOSSES TO FOLLOW-UP: 150 lost (Intervention 48; Control 102)
Interventions	INTERVENTION: Addition of a nurse care coordinator (*registered nurse and a certified diabetes educator) to primary care system. *Provided direct alterations in the patients care using standards or care and standing orders. *Suggested changes in medication in concert with the primary care physician. CONTROL: usual care without a care coordinator. LENGTH OF FOLLOW-UP: 12 months
Outcomes	PRIMARY: - HbA1c
Notes	QUALITY ASSESSMENT: one or more criteria not met COMMENTS: unsure whether care programmes were identical.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

SD Standard deviation

IQR Interquartile range

Specialist nurses in diabetes mellitus (Review)

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Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Ahern 2000	Before and after study
Aubert 1998	Participants may have concurrently received formal diabetes education
Barglow 1983	Trial length four months
Blonde 1999	Team approach
Brown 1995	Trial length eight weeks
Brown 1998	Trial length eight weeks
Carvalho 2000	Before and after study
Cavan 2001	Before and after study
Chan 2000	No control group
Colagiuri 1995	No control group
Corkery 1997	No nurse intervention
Davies 2000	Unclear if participants were inpatients due to diabetes or due to other conditions
de Sonnaville 1997	Team approach to education
Dougherty 1998	Compared conventional hospital and clinic management versus substantial home care with a diabetes specialist nurse in collaboration with the attending diabetologist for both groups. Trial is about treatment at diagnosis. Same study as Dougherty 1999
Dougherty 1999	Compared conventional hospital and clinic management versus substantial home care with a diabetes specialist nurse in collaboration with the attending diabetologist for both groups. Trial is about treatment at diagnosis. Same study as Dougherty 1998
Drozda 1993	Nurse involved was not a diabetes specialist nurse
Estey 1990	Trial length three months
Everett 1995	Before and after study
Feddersen 1994	Educational programme to staff
Fosbury 1997	No alterations to treatment regimens (diabetes specialist nurse was control group)
Fukuda 1999	No alterations to treatment regimens
Goddijn 1999	Before and after study
Goudswaard 2002	Individual education programme, no adjustment to treatment regimens as per protocol

Study	Reason for exclusion
Hanestad 1993	Team approach, no adjustment to treatment regimens
Heller 1988	Team approach, no adjustment to treatment regimens
Hollander 2001	No control group
Kirkman 1994	No adjustments to treatment regimens
Koproski 1997	Diabetes team intervention
Korhonen 1983	Team approach
Korhonen 1987	Team approach. No adjustment to treatment regimen
Legorreta 1996	Team approach
Litzelman 1993	No adjustment to treatment regimens
Lo 1996	Before and after study
Mazzuca 1997	Team approach
Mundinger 2000	Team approach
Peters 1995	No control group
Peters 1998	Group educational program
Philis-Tsimikas 2000	No control group
Piette 2000b	No adjustment to treatment regimens
Pouwer 2001	No adjustments to treatment regimens
Raz 1988	Group education
Rettig 1986	No alteration to treatment regimens
Ridgeway 1999	Nurse and dietitian, no adjustment to treatments
Ryle 1993	No routine care
Sadur 1999	Group intervention
Scott 1999	Behavioural outcomes only
Shamoon 1995	Team approach
Sikka 1999	No alteration to treatments
Sturmberg 1999	No control group
Tu 1993	Team approach
Vrijhoef	No adjustments to treatment regimens

Study	Reason for exclusion
Ward 1999	No comparison group, educational group sessions
Weinberger 1995	No adjustment to treatment regimens
Whitlock 2000	No adjustment to treatment regimens
Young 1997	Retrospective study

DATA AND ANALYSES

Comparison 1. Results

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Results			Other data	No numeric data

Analysis 1.1. Comparison 1 Results, Outcome 1 Results.

Study	Results
Couper 1999	HbA1c (%): 9.7 (SD1.6)/10.3 (SD2.2) at 6 months 10.5 (SD1.8)/10.7 (SD2.0) at 12 months 10.0 (SD1.5)/10.5 (SD1.8) at 18 months.
Marrero 1995	HbA1c (%): 9.6 (SD1.9)/9.7 (SD1.5) at 6 months 10.0 (SD1.6)/10.3 (SD1.8) at 12 months. hospitalisation: no data emergency room: no data QOL: no data
Piette 2000a	HbA1c (%): 8.3 (SD1.9)/8.3 (SD1.9), hypoglycaemia: 1 (0-2)/2 (1-3), hyperglycaemia: 1 (0-2)/2 (1-3), emergency room visits: 48%/20%, hospitalisation: 25%/23%
Piette 2001	HbA1c (%): 8.1 (SD0.1)/8.2 (SD0.1) hypoglycaemia: 1.1 (SD0.1)/1.4 (SD0.1) hyperglycaemia: 1.4 (SD0.1)/1.6 (SD0.1)
Thompson 1999	HbA1c (%): 7.8 (SD0.8) / 8.9 (1.0) proportion with 10% HbA1c: 87%/35% (change scores)
Wilson 2001	HbA1c (%): 8.9 (SD2.1)/8.7 (SD2.2) DATA FROM ABSTRACT AND * AUTHOR CORRESPONDENCE

APPENDICES

Appendix 1. Search strategy

Search terms

Specialist nurses in diabetes mellitus (Review)

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(Continued)

Unless otherwise stated, search terms are free text terms; MeSH = Medical subject heading (Medline medical index term); exp = exploded MeSH; the dollar sign (\$) stands for any character(s); the question mark (?) = to substitute for one or no characters; tw = text word; pt = publication type; sh = MeSH; adj = adjacent.

DIABETES

- #1 explode 'Diabetes-Mellitus' / MeSH, all subheadings
- #2 iddm or niddm
- #3 #1 or #2

NURSES

- #4 explode 'Nurses-' / MeSH, all subheadings
- #5 explode 'Nursing-' / MeSH, all subheadings
- #6 #4 or #5

DIABETES AND NURSES

- #7 #3 and #6
- #8 diabet* with nurs*
- #9 diabet* near educator*
- #10 (nurs* near case* near manage*) and diabet*
- #11 #7 or #8 or #9 or #10

WHAT'S NEW

Date	Event	Description
1 November 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

EMMA LOVEMAN: Protocol development, searching for trials, quality assessment of trials, data extraction, and development of final review.

PAMELA ROYLE: Searching for trials, quality assessment of trials, data extraction, development of final review.

NORMAN WAUGH: Protocol development, quality assessment of trials, data extraction, development of final review.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- National Coordinating Centre for Health Technology Assessment, UK.

External sources

- No sources of support supplied

INDEX TERMS

Medical Subject Headings (MeSH)

*Specialties, Nursing; Case Management; Diabetes Mellitus [*nursing]; Quality of Life; Randomized Controlled Trials as Topic

MeSH check words

Humans