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The competence of physiotherapists to deliver a cognitive behavioural approach for low back pain

by

Zara Hansen

A thesis submitted in partial fulfilment of the requirements for the degree of Doctor of Philosophy in Medical Sciences

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And to Patrick, who keeps me on my toes by always asking why.

"Stop learning and start thinking"

Jacob Barnett (Age 13) 2012

Declaration

The author declares that the work contained in this thesis is her own work and has not been used before.

The research was undertaken alongside a large randomised controlled trial conducted at The University of Warwick.

The author worked on this trial as Clinical Coordinator and was co-author on the protocol and main trial results paper which have already been published. Research presented in this thesis uses some data from the trial, but all analysis and interpretation of the data presented in this thesis was conducted by the author.

This thesis has not been submitted for a degree at any other university.

Publications and presentations

Hansen Z, Lamb SE. The design of a cognitive behavioural group intervention. Poster presented at the Low Back Pain Forum, Amsterdam, 2006.

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Lamb SE, Lall R, Hansen Z, Withers E, Griffiths F, Szczepura A, Barlow J, Underwood MR and On behalf of the Back Skills Training Trial (BeST) Team, Design considerations in a clinical trial of a cognitive behavioural intervention for the management of low back pain in primary care: Back Skills Training Trial, *BMC Musculoskeletal Disorders* (2007) 8:14

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Hansen Z, Kidd J, Lamb SE. Adaptation and psychometric testing of the CTS-R for use in chronic low back pain. Poster presented at the BABCP Annual Conference, Leeds 2012

Hansen Z, "It's not you it's me, assessing physiotherapists' competence to deliver a CB intervention in LBP" Invited lecture at Physiotherapy UK, Liverpool October 2012

Hansen Z, Kidd J, Lamb SE. How important is physiotherapist competence in the delivery of cognitive behavioural approaches for low back pain? Poster presented at the British Pain Society ASM, Manchester 2014

Abstract

Treatment guidelines for low back pain (LBP) advocate the use of cognitive behavioural approaches, typically delivered by physiotherapists. This thesis explores the role of physiotherapist competence in the delivery of these approaches. A systematic review of the literature found an absence of tools appropriate for the assessment of competence in delivering cognitive behavioural (CB) approaches in LBP. A consensus study was undertaken with experts and a new competency tool was developed with good psychometric properties. This competency tool was then used to explore the relationship between competency and clinical outcome in a cohort of LBP patients.

New insights into the role of experience on competence and patient outcome were found. Competence in delivering a CB intervention varied within the cohort. Specific previous experience of delivering similar interventions predicted competence score but not patient outcome. Years since qualification did not predict competence but negatively predicted patient outcome. Overall competence was not found to predict patient outcome in delivering a structured, manualised, cognitive behavioural approach for LBP and possible reasons for this finding are discussed.

Competence was further explored through a qualitative interview study which found interesting patterns in beliefs and behaviours of the physiotherapists. The most competent physiotherapists consistently discussed aspects of reflective learning on their practice. Physiotherapists reported most difficulty with switching from a didactic stance to one of a questioning approach. Overall physiotherapists valued the structure of the manualised CB approach they delivered in the study. Physiotherapists reported the CB approach was most difficult to apply to the patient group that the skills are advocated for, i.e. those with poor coping skills and high psychosocial risk factors. The thesis concludes with suggestions on how training in a CB approach may be enhanced for physiotherapists working with a LBP patient population.

Abbreviations

AERA American Educational Research Association

BeST Back Skills Training Trial

(C) Competent

CAT Competency Assessment Tool

CB Cognitive Behavioural CBT Cognitive Behavioural Therapy

CTS Cognitive Therapy Scale

CTS-R Cognitive Therapy Scale-Revised

CTS-R-Pain Cognitive Therapy Scale-Revised for Pain

FABQ Fear Avoidance Beliefs Questionnaire

GP General Practitioner

HC Higher competence level

ICC Intra-class correlation coefficient

IAPT Improving Access to Psychological Therapies

IRT Item Response Theory

LBP Low Back Pain

LC Lower competence level

MeSH Medical Subject Headings

MCQ Multiple Choice Questionnaire

MSK Musculoskeletal

MVK Modified Von Korff Scale

NICE National Institute for Clinical Excellence

NHS National Health Service

PABS-PT Pain Attitudes and Beliefs Scale - Physiotherapists

PCT Primary Care Trust

PMP Pain Management Programme

PPA Physiotherapy Pain Association

PSE Pain Self Efficacy

RCT Randomised Controlled Trial

RMQ Roland and Morris Questionnaire

SF-12 Short Form Health Survey – 12 item

UK United Kingdom

1 Chapter One – Introduction

1.1 Background

Low back pain (LBP) is a leading cause of morbidity in low, middle and high income countries (1). Despite worldwide research efforts, attempts to prevent and manage LBP have produced small to modest effects to date (2). Interventions that target relevant biological, psychological, and social factors, implicated in the development and maintenance of LBP, appear to offer the most promise (3). These 'biopsychosocial' approaches are typically delivered in healthcare settings by healthcare professionals, usually physiotherapists, and many are underpinned by a psychological model known as cognitive behavioural therapy (4).

Trials of biopsychosocial approaches in low back pain have yet to yield the patient outcomes that have been anticipated by some sections of the clinical and research community (5). Suggestions have been made to improve the targeting of these interventions to specific biopsychosocial factors within specific target populations, and research is underway in this area (3). Suggestions have also been made to improve the skills of physiotherapists delivering these interventions (6, 7). Whilst research has brought greater understanding of how physiotherapist's attitudes and beliefs impact on their behaviour (8), little research has been conducted to quantify their skill level both within clinical practice and as part of clinical trials investigating psychosocial interventions in LBP. This is the area of interest for this thesis.

I joined Warwick Clinical Trials Unit in 2004 as clinical lead for the Back Skills Training Trial (BeST). This was a large randomised controlled trial (RCT) investigating the clinical and cost effectiveness of a group based cognitive behavioural (CB) approach to LBP in primary care. The role of clinical lead involved: substantial contribution to the design of the intervention; responsibility for the recruitment, training and supervision of therapists; quality control of the intervention; data management relating to the CB intervention; and contribution to trial data analysis and reporting.

Prior to the BeST trial, as a trained physiotherapist, I worked with patients with a range of musculo-skeletal complaints. I developed a special interest in chronic LBP which led to formal training as a cognitive-behavioural therapist. During this training I experienced a paradigm shift in my clinical practice with LBP patients which stimulated an interest in issues around physiotherapists adopting psychological models into their practice. When the opportunity arose for me to undertake a PhD study alongside the BeST trial there were many research avenues of interest to me. The question of whether the therapists I trained would be 'good enough' to deliver the intervention seemed critical and this thesis aims to explore what 'good enough' is and how we can measure it.

1.2 Aims

This thesis aims to contribute to the wider evidence base of biopsychosocial approaches in the management of LBP by exploring the role of competence in the delivery of interventions. Primarily, the aim is to produce a valid and reliable assessment tool that could be used to assess competence of physiotherapists delivering cognitive behavioural approaches in low back pain. This thesis also aims to explore the relationship between competence and clinical outcome in patients with low

back pain, and furthermore to explore competence from the physiotherapist's perspective.

Specifically the studies contained within this thesis are;

- 1) A systematic review of competence tools
- 2) A consensus study to design a competency tool
- 3) A reliability study to test the competency tool
- 4) Analysis of patient outcome data in relation to therapist competence data
- A qualitative study with physiotherapists to explore issues of integrating CB skills into practice

These studies were conducted alongside the BeST trial and involved the BeST study participants/therapists in the following ways: the systematic review was independent of the BeST trial, the competence tool was designed independently over the duration of the BeST trial, the competence tool was tested for reliability using recordings of BeST trial sessions; 'competence' data from the reliability studies were analysed with patient data from the BeST trial; finally, it was the physiotherapists who took part in the BeST trial that were interviewed for the qualitative study whilst they were delivering the BeST trial groups.

This introduction will now provide a background on LBP, psychosocial approaches to LBP, research on physiotherapists delivering these approaches and an overview of competence and its assessment. The setting for this research will also be outlined with a summary of the BeST trial.

1.3 The problem of low back pain

Low back pain is a common problem with a lifetime prevalence reported as between 49% and 80% (9). On a year to year basis the prevalence of LBP lasting for more than one day in the United Kingdom is between 37-49.1% (10, 11). Most episodes of LBP are mild and rarely disabling (12). However, of the small proportion of people that present to their general practitioner, the majority (62%) will have pain one year later (13). This figure represents cohorts of different low back pain patients following modelled trajectories of; 1) recovering, 2) persistent mild symptoms, 3) constantly fluctuating problems and 4) severe chronic levels of pain (14).

Low back pain has a wide ranging impact on an individual's ability to participate in work and social activities (15, 16) and has an impact on an individual's relationships and general health (17). Specifically, LBP appears to increase the likelihood of developing a mental health problem. For example, approximately 46% of people with chronic LBP who entered a functional restoration programme met diagnostic criteria for depression and had not experienced depression prior to the onset of their LBP (18).

Although it is a small percentage of the overall number of cases of LBP that will develop chronic pain, the high prevalence means that LBP is a major cause of disability in high, middle and low income countries (1). In the UK, LBP is the leading cause of years lost to disability causing 2313 (95% CI 1574-3113) disability adjusted life years per 100,000 population (19). This level of disability has far reaching economic costs, in the UK alone the loss in productivity from days off work and the direct costs of managing LBP and providing benefits has been estimated to total £10.7 billion¹ each year (9).

-

¹ These figures were based on the costs as estimated for 1998

The population of LBP sufferers is highly diverse in its characteristics. Despite this, considerable advances have been made in identifying risk factors and understanding the processes involved in the development of chronic LBP (20). The rationale for this direction in research is that risk factors are clinical predictors of outcome and therefore efforts to identify and manage them may modify outcomes (21). The most consistent reported risk factors are higher levels of functional disability, sciatica, older age, poor general health, increased psychological or psychosocial stress, negative cognitive characteristics, poor relations with work colleagues, heavy physical work demands, and presence of compensation (22). Of these, the risk factors that appear modifiable within the context of a health-care intervention are psychosocial stress and negative cognitive characteristics, such as catastrophisation (23).

Current conservative health-care treatments for LBP include exercise, manipulation and acupuncture (2). However they have shown modest treatment benefits (2, 24) and so treatments that target the modifiable risk factors more directly have been investigated (3). These 'biopsychosocial' approaches holistically target biological, psychological and social factors implicated in the development and maintenance of chronic LBP (5). This is in contrast to a biomedical framework which conceptualises illness or disorder using biological factors alone (25).

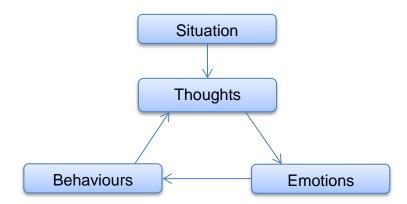
Several psychological models have been used in the design of biopsychosocial approaches including; graded exposure (26), mindfulness (27), acceptance and commitment therapy (28), psychologically informed practice (29), and cognitive behavioural therapy (CBT) (30). Of these approaches, CBT has the widest evidence base within mental and physical health problems (31, 32), which most likely accounts for

CBT becoming the psychological model most often applied in trials of LBP targeting psychological risk factors (4).

1.4 What is cognitive behavioural therapy?

Cognitive therapy was developed in the 1960s by Aaron T Beck (33). The therapy theorises that conscious thoughts or appraisals of situations or events are produced which trigger emotions, which in turn drive behaviour (34). The behaviours are often theorised to reinforce or maintain the thoughts. These conscious thoughts are usually linked to deeper rules or beliefs formed by experiences the individual has had. Figure 1 below shows the basic CBT model (33).

Figure 1 Basic cognitive behavioural therapy model linking thoughts, emotions and behaviour



According to the CBT paradigm, thoughts or beliefs can be accessed through specific questioning. Different techniques are then used to challenge any 'unhelpful' thoughts or beliefs (35).

It was recognised that due to the cyclical relationship in the model between thoughts and behaviours, that any techniques directly aimed at changing behaviour would also impact on thoughts and beliefs (36). Techniques that targeted behaviours were the basis of 'behaviourism', a psychological model based in learning theories that was in common use prior to the development of cognitive therapy (36). Cognitive and behavioural therapy merged and the current CBT 'umbrella' refers to any cognitive or behavioural intervention, or more commonly of recent, therapy that merges both (34). This has led to wide variation in the components of CBT interventions as described in RCTs and treatment manuals. This lack of universal agreement on the 'essential ingredients' of CBT is typical for many complex interventions (37) and whilst studies have been conducted to attempt to determine important components, there are no definitive answers as yet (38).

1.5 Cognitive behavioural approaches to low back pain

The lack of consensus on the components of a CB approach within mental health is also apparent within its application to LBP. This is highlighted in evidence reviews where the heterogeneity of treatment approaches causes problems in deciding which trials to include in the evidence synthesis. Henschke et al (39) conducted a Cochrane review on a range of psychological treatments for chronic LBP. They found 30 trials (3438 participants) to 2009 that met their inclusion criteria of trials of operant, cognitive, respondent and behavioural treatments. CBT was included in the behavioural category within the review. Henschke et al offer this definition of a CBT approach in the management of low back pain;

"Behavioural treatments are often applied together, as part of a combined treatment approach, commonly referred to as cognitive behavioural treatment. This combined behavioural treatment is based on a multidimensional model of pain that includes physical, affective, cognitive, and behavioural components. Treatment may therefore include education about a multidimensional view of pain, how to identify pain-eliciting and pain-aggravating situations, thoughts and behaviour, and use of coping strategies and applied relaxation. Goal setting and activity increase is encouraged, as the basis of

a combined treatment approach is to reduce feelings of helplessness and assist the patient to gain control over the pain experience" (39)p7

Whilst half of all the studies in the Henschke review were assessed to be at low risk of bias, the moderate or high risk of bias in the remaining studies meant that comparisons between treatments were difficult. Overall the authors concluded that there was low or very low quality evidence that combined behavioural therapy was better than wait list control for pain intensity, functional status and depression for short-term follow-up. Eccleston et al (32) conducted a systematic review on the efficacy of psychological treatments for all sites of chronic pain, not specifically LBP. Of the 42 studies meeting inclusion criteria, 35 were combined in a meta-analysis providing data from 4788 participants. Similar to the Henschke review, they found CBT was effective, albeit small effect sizes, for pain and disability levels short-term. More moderate effects were found on depression at 6 month follow-up and on the specific cognitive processes of catastrophisation.

The findings of these studies have been translated into clinical guidelines on the management of LBP. The National Institute for Clinical Excellence (NICE) produced guidelines on the management of LBP of less than one year duration (2). The guideline group reported a lack of conclusive evidence on low intensity combined physical and psychological interventions. Although the evidence was limited on longer programmes, the expert consensus was that referral to a high intensity programme (around 100 hours over a maximum of 8 weeks) could be beneficial for those patients that had received at least one less intensive treatment already and exhibited high disability and/or psychological distress. Since the original publication of this guideline, two large RCTs of interventions based on CB principles for LBP have published with positive results (29,

30). However, as they included patients with LBP duration of more than one year they were excluded in the guideline review process in 2012.

The European guidelines for the management of LBP (24) was stronger than the NICE guidelines in its recommendation of CBT approaches. This may in part be due to the focus on chronic LBP which meant that trials involving patients with LBP lasting longer than one year were included. They again highlighted the 'large variety of behavioural treatment modalities used for chronic LBP' and provided this understanding of CBT;

"Although they may vary in aims and methods, cognitive and behavioural treatments have in common 1) the assumption that the individual's feelings and behaviours are influenced by his/her thoughts; 2) the use of structured techniques to help patients identify, monitor and change maladaptive thoughts, feelings and behaviours; 3) an emphasis on teaching skills that patients can apply to a variety of problems" (24)p115

The European guidelines summarised available evidence and recommended cognitive behavioural treatment for patients with chronic LBP although there was no further guidance on how the treatment should be delivered. Also of note is that the authors recommend in their summary;

"The application of cognitive behavioural principles to physiotherapy in general needs to be evaluated."

1.6 Who will deliver the cognitive behavioural interventions for low back pain?

Increasingly trials are being conducted to investigate whether non-psychological specialist health professionals can deliver CB interventions within physical health problems such as LBP (6). One significant driver for this appears to be the UK national shortage of trained CB therapists (40). Within LBP trials, it has typically been physiotherapists delivering CB interventions (6). This is most likely due to

physiotherapists being the main healthcare provider of conservative treatments for LBP within the UK National Health Service (9).

Trials of physiotherapists delivering CB approaches in LBP have reported variable results (29, 30, 41-43). Comparisons across these trials are challenged because of differences in physiotherapist training, intervention design and trial methodology. However, attempts have been made to explore why some trials have been more successful than others (7). During a prominent LBP conference (Low Back Pain Forum, 2006) a workshop was conducted in which three groups debated possible explanations for the negative trials that had been published prior to the workshop. The groups focussed on 1) patient selection, 2) the intervention or 3) the assessment. The focus groups' main conclusions were: interventions should be targeted at those at high risk of chronic LBP by focussing on modifiable prognostic risk factors, the competencies of therapists delivering the interventions and adherence to treatment protocols should be investigated via a process evaluation, and finally that other outcome measurement tools should be explored in addition to the pain and disability outcome tools typically used in LBP trials.

Since this report there have been trials investigating targeting of psycho-social interventions in LBP (29, 44) and some studies investigating outcome measurement (45). However, there is limited research or commentary published exploring the competence of health care providers' ability to deliver psycho-social, or explicitly CBT, interventions in LBP. This literature will now be summarised.

1.6.1 Attempts to define competencies

In their comprehensive book on pain management, Main et al (4)p214 discuss the issue of competency in the delivery of CB interventions by physiotherapists. They comment that most trials either do not describe the training received by the physiotherapists or, where stated, it was minimal training. They also observe that there is normally no assessment of treatment fidelity or competence within trials. Main et al go on to suggest competencies shown below in Table 1, although there is no indication as to how they arrived at these items or how each would be assessed.

Table 1 Minimum competencies for a cognitive behavioural approach in physiotherapy defined by Main et al (4)

1) Psychosocial assessment and management

- -Demonstrates an understanding of the role of psychological factors in the management of chronic pain
- -Is able to conduct a simple psychosocial assessment
- -Is able to identify the key psychosocial obstacles to recovery from incapacity in a variety of patients
- -Uses elements of CBT to improve patient understanding of their condition and to enhance treatment outcome
- -Can explain physiological and medical information in terms appropriate to the patient's level of understanding
- -Integrates physical assessment, interview and questionnaire information into a management plan

2) Patient-centred treatment

- -Leaves responsibility for rehabilitation with the patient non-directional
- -Is able to help the patient define clear, measurable and achievable rehabilitation goals
- -Helps the patient to identify the potential risks and barriers
- -Integrates the patient's social circumstances into the management plan
- -Helps the patient make an informed decision about participation in treatment

3) Patient motivation

- -Helps the patient identify obstacles to recovery
- -Reflects inconsistencies between the patient's aims and behaviour
- -Helps the patient see an alternative scenario to incapacity future orientated
- -Reinforces positive behaviours and goal achievement
- -Facilitates acceptance of chronic pain

1.6.2 Are physiotherapists able to identify risk factors?

There is conflicting evidence as to whether physiotherapists are able to identify risk factors. Expert clinicians were asked to stratify patients into high, medium, or low risk based on a video recording of the patient's assessment session with a physiotherapist (46). The stratification was compared between experts and with a stratification questionnaire filled out by the patient on the same day as the physiotherapy assessment. There was poor agreement between experts (GPs, physiotherapists and pain management specialists), and poor agreement between experts and the stratification tool. Agreement between the physiotherapists was highest but still relatively low (Kappa 0.37).

In contrast, Bishop and Foster (47) found that physiotherapists were able to identify risk factors and appropriately classify high and low risk patients in case scenarios in a survey of UK physiotherapists. With only two categories in this study; high and low risk, it would be easier to reach agreement compared with three categories in the Hill study; high, medium and low risk. In addition, the written case scenario would have provided limited information compared to the videoed assessment and this may have made classification more difficult. However, the latter is more representative of the clinical condition under which the physiotherapist would need to assess risk.

Inappropriate risk classification was not the only problem identified. In the Bishop and Foster study, despite appropriately classifying patients as high or low risk, when asked for treatment recommendations 35% of the physiotherapists advised the high risk patient not to work with 86% recommending activity restriction in this group. This is contrary to guidelines based on biopsychosocial approaches. In some ways this is

unsurprising as physiotherapists in the UK have predominantly biomedical training at undergraduate level (6, 48), furthermore, the education on pain and pain management is limited to 12 hours on average during an undergraduate 3 year degree (49).

1.6.3 Physiotherapist beliefs predict behaviour

It has now been shown that healthcare professionals' beliefs predict behaviour in delivering biopsychosocial interventions in low back pain (8, 50). Those holding more biomedical beliefs are more likely to advise activity restriction and avoidance of work, contrary to current guidance (51, 52). Interventions to change beliefs have had surprising results. Physiotherapist beliefs can be changed by education sessions (53), but this does not appear to always change their behaviour. After a 5 hour training session on biopsychosocial techniques, physiotherapists did not change what they did in clinical scenarios as documented by discharge summary questionnaires (54). This is not unique to physiotherapists and is found consistently across trials in all healthcare professionals working with LBP (8). Interestingly, physiotherapist undergraduates given 6 hours of either biomedical or biopsychosocial education on LBP also then demonstrated significantly different beliefs (55). However, those that had undergone the biopsychosocial education subsequently made recommendations for work and activity levels in case scenarios that were in line with evidence based guidelines, whereas the biomedical group did not. It may be that behaviour can be influenced more readily earlier in a healthcare professional's career.

1.6.4 Evidence of physiotherapists delivering cognitive behavioural approaches

There have been some attempts to deconstruct which aspects of a CB approach might be suitably adopted within physiotherapy practice.

Theoretical integration of cognitive behavioural skills into physiotherapy practice
In a systematic review Brunner et al (56) attempted to determine which CB skills or
interventions were effective in LBP of duration less than three months that could
feasibly be implemented by physiotherapists. They found eight articles, of which four
had a low risk of bias. Only two of the trial interventions were delivered by
physiotherapists alone, the rest by a multi-disciplinary team. As to be expected there
was a wide range in the components of the interventions along with study
methodologies. The authors concluded that physiotherapists could embed graded
activity into practice for patients with LBP of less than three months duration, however,
no rationale was provided for why they felt graded activity, and not the other
interventions, were appropriate.

Self-report of integration of cognitive behavioural skills into physiotherapy practice

Beissner et al (57) attempted to identify which CB skills could be adopted by

physiotherapists by asking them about their current practice. In a survey of American

physiotherapists, Beissner attempted to establish current use of CB skills with older

adults with chronic pain. They selected physiotherapists at random from across

America and 88% of those meeting inclusion criteria consented to participate (n=152).

There was a mixed pattern in the reported use of different CB techniques;

Frequently or always: activity pacing (81%)

pleasurable activity scheduling (39%)

Rarely or never: cognitive restructuring (77%)

relaxation training (84%)

use of visual imagery or distraction (88%)

Frequently reported barriers to implementation were cited as: insufficient knowledge (59%), reimbursement issues (31%), time pressures (27%) and patients not open to CB techniques (21%). Despite these pressures, the physiotherapists in the study expressed interest in CB approaches. Interest was highest in those physiotherapists with advanced degrees and lower numbers of patients with chronic pain. However, the question regarding interest in CBT techniques was preceded by a statement about the positive evidence base of the techniques. As such, it may have biased responses in those who wished to appear interested in evidence based medicine, such as those with higher degrees.

Assessment of integration of cognitive behavioural skills into physiotherapy practice

Some attempts have been made to measure skills consistent with a CB approach in

LBP. As part of an RCT investigating a CB approach in LBP (41), physiotherapists were
videoed as part of the treatment fidelity checks (58). The intention was to validate the
treatment logs by videoing the treatment session and then cross checking what was
done in the session with how it was recorded in the treatment log. The checklist used in
the treatment log contained 12 items, four specific to pain management techniques (the
CB component) such as 'modifying patient behaviour', three items specific to spinal
therapy such as 'manual therapy techniques' and five generic items that could be seen
in either treatment arm such as 'advice regarding activities'. Three raters assessed 12
video recordings and reliability of ratings varied with the lowest reliability found in the
CB component category (Kappa of 0.45 for CB pain management, 0.68 for manual
therapy, and 0.61 for generic skills). The authors acknowledged that they did not
examine the competency in delivering the interventions; just skills consistent with the

intervention arm. However, this study demonstrated that physiotherapists could demonstrate some skills that were perceived as cognitive behavioural by the raters, albeit with a modest agreement between raters.

1.6.5 Challenges facing physiotherapists integrating psychosocial approaches into practice

Foster and Delitto (6) wrote an overview of the challenges facing physiotherapists in integrating psychosocial approaches into physiotherapist practice for patients with low back pain. In addition to the biomedical paradigm that persists throughout undergraduate and postgraduate training, there are few opportunities for physiotherapists to attend training courses on biopsychosocial training. As a consequence, physiotherapists report feeling ill equipped to manage psychosocial issues in LBP patients (59). Foster and Delitto argue that external pressures such as patient expectations and time pressures may also contribute to physiotherapists continuing within a biomedical framework. They conclude that more research needs to be conducted on integrating psychosocial perspectives into physiotherapy practice and make the following suggestions for research into;

- better identification of appropriate patients
- better design of intervention 'dose' level
- incentives for physiotherapists to change behaviour
- facilitating undergraduate training programmes to adopt evidence based biopsychosocial approaches over less evidence based biomedical approaches

The Foster and Delitto article focusses on achieving behaviour change in physiotherapists towards a biopsychosocial approach. It does not ask the next logical questions: which behaviours need to be demonstrated, how much behaviour change is enough, and how can we determine/measure this. Or rephrased; 'which competencies?' and 'what level of competence?'

1.7 Competence and the assessment of competence

1.7.1 What is competence?

There are many theories and models of competence (60)p163-182. Conceptualisations of professional competence can range from simply meaning 'properly qualified' to making statements about someone's expertise within a specific framework (60)p163-165. This can be in contrast to the everyday usage of the term 'competent' which is often in reference to the performance of someone and as such tends to describe a characteristic (60)p164.

A recent systematic review of conceptions of competence in health sciences (61) found agreement that competence is made up of knowledge and skills. However there were many more components cited as integral to competence such as attitudes and ability but without overall agreement. Fernandez et al (61) note that this lack of consensus reflects the fact that the components of competence are comparatively difficult to observe and assess.

A definition of competence was selected for this thesis appropriate for the primary aim of exploring the influence of physiotherapist competence on patient outcome;

'The extent to which a therapist has the knowledge and skill required to deliver a treatment to the standard needed for it to achieve its expected effects'

Fairburn and Cooper (62)p374

1.7.2 How can competence be developed and assessed?

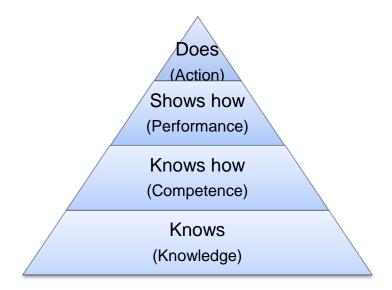
Assessment of competence is also an area with diverse theories and methods (63).

Four models popular within medical/health professions education are Miller's pyramid,

Dreyfus model of skill acquisition, reflective practice, and deliberate practice.

Miller's pyramid provides a systematic approach to the development and assessment of competence (64) shown below in Figure 2.

Figure 2 Miller's framework for clinical assessment (64)



The model proposes how each ascending skill/knowledge level relies on acquisition of the previous level. In this way the model affords a rationale for performance assessment tools as providing a way in which several aspects of competence can be assessed directly and indirectly. Miller (64) comments that most assessments of professional competence over-emphasise the 'knows' and 'knows how' categories when these may be very different from what the professional is able to demonstrate in a performance test; 'shows how'. This in turn may differ to what they actually do when not

under assessment; 'does'. In support of this observation, no relationship was found between increased CBT knowledge and increased clinical skill in a meta-analysis of CB treatments for substance abuse (65).

Dreyfus (66) provides a further popular model of competence which deconstructs the stages of competence in relation to increasing levels of knowledge and behaviours rather than seeing these aspects as distinct. The Dreyfus model proposes five stages of skill acquisition; novice, advanced beginner, competent, proficient and expert (66). These stages were deconstructed and applied to nursing in an articulate article by Benner (67). The model focuses on learning from experience and emphasises the transition from rigid adherence to the rules to a more flexible approach to problems in an increasingly demanding environment (60)p125. The Dreyfus model is useful to characterise behaviours consistent with each stage of competence and has been used in the development of the main competence tool used in CBT, the Cognitive Therapy Scale discussed further in Chapter three, section 3.1.1 (68).

Theories relating to reflective practice are diverse. Mann et al (69) summarised the evidence as part of a systematic review of reflective practice in health professionals' education. They state that there appears to be agreement that in order to learn from experience, a professional needs to be able to;

- critically evaluate their own experience and practice to identify learning needs
- understand their own attitudes/beliefs in the context of the professional culture
- link new and existing knowledge
- engage in self-monitoring and self-regulation through the above points

Reflective practice has been linked to greater levels of understanding/knowledge although there is currently a lack of research linking reflective practice to changes in clinical practice (69).

Deliberate practice is the engagement in activities directly related to the task that the performer wants to improve in (70). It is different from general experience and is associated with the acquisition of expert levels of performance across many professions (71). Ericsson (70) has found that several features of deliberate practice can further improve competence level; if the practice is goal orientated, if the professional is motivated to improve, if they are provided with feedback and if the professional is provided with ample opportunities for repetition and refinement of the skills.

Each of the four models of competence presented in this section varies in their focus on cognitive and behavioural elements. They each provide insights into the training and assessment of competence and will be re-visited as appropriate throughout this thesis. There has been wide research into many aspects of skill acquisition, and the development of competence and expertise. It is beyond the scope of this thesis to further review this literature beyond the four popular models presented above. However, the reader is directed towards *K. Anders Ericsson's Development of professional expertise (72)* for further reading on the subject.

1.7.3 Competence assessment within physiotherapy

In a similar path to most of the professions allied to medicine (60), physiotherapy has slowly increased the level of qualification required to become a member of its professional organisation, the Chartered Society of Physiotherapy. Within the last 20 years, physiotherapy training programmes have been affiliated with, and subsequently fully integrated into, universities (73). The current UK Bachelor of Science honours degree in physiotherapy is normally completed within three years and most programmes consist of a mixture of time spent within the university and time spent on

clinical placement (74). Competence is assessed via several methods during this degree including essays, written, and practical exams, with performance assessed by a clinical educator whilst the student is on clinical placement via the use of a checklist of various attributes and skills (75). Whilst there have been attempts to gain national consensus on the performance checklists and validation of these tools, there still exists much local variation (76, 77).

Qualified physiotherapists have to undertake mandatory continuing professional development (CPD) activities to maintain their professional status (78). However, there is a wide range of informal and formal CPD opportunities with little research into their effect on performance (79). Formal CPD activities can range from short courses through to courses affiliated with universities that lead to a qualification commensurate with specialisation in that given field of study. Even within the most popular postgraduate study; a master's degree that allows membership to the Musculoskeletal Association of Chartered Physiotherapists, there has been no formal assessment of change in practice after the post-graduate qualification, although change in practice has been implied in self-report interview studies (80).

Around 2005 a competence framework entitled the 'Knowledge and Skills Framework' was launched as part of a review of the National Health Service pay structure: Agenda for Change. This framework has been widely implemented as a structure in which to standardise progression of skills linked with incremental pay awards (81). However, the framework includes general competencies and does not allow for the assessment of discrete situation specific skills. In order to address this lack of guidance on skill development/competence for specific skills within physiotherapy, the Chartered Society of Physiotherapists have engaged with special interest groups within the society to

attempt to operationalise the specialist skills and form a competency framework (82). This work is in the initial stages and is expected to produce frameworks for consultation in 2014 which will then lead onto work to develop a competency document (83). In summary, there are currently no specific tools within undergraduate or postgraduate physiotherapy practice with which to assess skill/competency delivering CB approaches.

1.7.4 Competence assessment within cognitive behavioural therapy

The title of cognitive behaviour therapist is not a protected title. However, to be employed within the NHS as a CB therapist the current qualifying criterion is to have gained a post graduate certificate, diploma, or masters in CBT (34). These courses are only accessible to those with a graduate qualification in the healthcare professions. Competency is assessed during these programmes typically through the use of essays, submission of case studies, and submission of recordings of therapy sessions which are then evaluated, usually using a performance tool (84). Several tools for the assessment of performance in CBT have been developed (85). The Cognitive Therapy Scale (CTS) has remained the most widely used and researched tool (86, 87) and is discussed further in Chapter three, section 3.1.1. These tools have been developed to assess CBT students and practitioners applying skills within mental health. It appears that no specific tools have been developed to assess CBT competence within pain/chronic low back pain.

This chapter has outlined relevant background information for investigating the role of competency in the efficacy of cognitive behavioural approaches in LBP. The Back Skills Training Trial (BeST) provided an opportunity to investigate this area and provided the

setting for several of the studies contained within this thesis. The BeST trial will now be outlined to provide context.

1.8 The setting for this research; The Back Skills Training trial

The Back Skills Training Trial (BeST) was a large multi-centre randomised controlled trial investigating the effectiveness of a group cognitive behavioural approach (CBA) for low back pain (88). From April 2005 to April 2007, 701 patients with moderate to severely troublesome LBP lasting longer than six weeks were recruited from primary care. All patients received a single session of advice based on the active management strategy (89) with two thirds (n=468) randomised to receive the trial intervention. The active management strategy encourages patients to return to normal activities as quickly as possible, return to work with adaptations as necessary, and use pain medications (89). In the BeST trial this advice was delivered by the research nurse during the randomisation appointment and was supported by a booklet called The Back Book (90). The CBA intervention was delivered by a single health professional in healthcare or community settings. Health professionals, predominantly physiotherapists, were recruited and trained over two days in CB principles and the specifics of the intervention. Therapists were provided with a variety of supporting information/resources; a comprehensive manual, session crib sheets, video demonstration of two sessions and a website with supporting documents and discussion forum (91). In addition therapists were supported by informal supervision either face-to-face or via the telephone on average for 1.5 hours whilst delivering a group in the BeST trial. The intervention consisted of a one-to-one assessment session and six subsequent group sessions lasting 90 minutes once per week. A summary of the session content is shown in Table 2 below adapted from Hansen et al (91).

Patients were followed up at 3, 6 and 12 months by postal questionnaire. The primary end point of the trial was self-rated disability measured by the Roland Morris Questionnaire (RMQ) and the Von Korff Scale (MVK) which consists of disability and pain sub-scales. Two primary outcomes were used due to concerns over scaling of the RMQ (88). Secondary outcome measures included mental and physical health-related quality of life (12-item short form health survey: SF-12), fear avoidance beliefs questionnaire (FABQ), pain-self efficacy scale (PSE), and self-rated benefit from and satisfaction with treatment. In addition data were collected on health care resource use for economic analysis. Two-thirds of patients randomised to the CB intervention attended the assessment and at least three of the six group sessions. The follow-up rate was 85% at 12 months and found significant benefit for the CBA intervention over the single session of advice: RMQ between group difference 1.3 points, 0.56–2.06; p=0.0008, MVK Disability between group difference 8.4%, 4.47–12.32; p<0.0001), MVK Pain between group difference 7.0%, 3.12–10.81; p<0.0001. All but one secondary outcome measure also showed clinical and statistical significance and the intervention was highly cost-effective (88).

Assessment

- History taking including current problems and eliciting beliefs on LBP and activity
- Collaborative goal setting with plan to start activity goal
- Exercises chosen collaboratively from options with level negotiated
- Exercises practised and progression discussed

Session 1; Understanding pain

- Group activity to demonstrate hurt ≠ harm
- Current thinking on causes of long-term pain explained
- Discussion on groups experience of alternative treatments for LBP with reference to research evidence and need to self-manage

Benefits of exercise

- Discussion of physical impact of inactivity or altered activity and how changes impact on pain (disuse syndrome)
- Discussion on effects of activity / exercise
- Introduction to LBP model

Session 2; Pain fluctuations

- Over / underactivity cycle explained
- Use of pacing
- Group problem solving for a specific task that tends to be 'overdone' e.g. gardening

Working out starting point for exercises or activities

How to use baseline setting

How to set goals

- SMART system used to break down an example goal
- Feedback from group on how progressing with goals from assessment
- Group problem solving problems with goals

Session 3: Unhelpful thoughts and feelings

- Styles of unhelpful thinking discussed including catastrophising
- Link with unhelpful behaviours
- Identifying unhelpful thoughts
- Group problem solving for challenging unhelpful thoughts

Relaxation (cont'd in session 4)

- Discussion on ways of relaxing and benefits
- Four styles practised in session; relaxed breathing, tense/relax, autogenic and imagery

Session 4; Restarting activities or hobbies

- Discussion on activities commonly avoided in LBP
- Fear avoidance cycle
- Group problem solving out of cycle
- Development of specific goals relating to restarting activities

Session 5; When pain worries us

- Effect of attention to pain explored through group activity
- Hypervigilance cycle used to link unhelpful thoughts and behaviours
- Group problem solving out of cycle
- Discussion on the use of medication / distraction / alternating activities

Session 6; Coping with flare-ups

- Discussion on causes of flare-ups
- Plan of what to do in and out of flare-ups
- Revision of topics over previous sessions and questions

1.9 Chapter Summary

This chapter has shown that LBP is a significant problem worldwide causing morbidity, disability and considerable economic consequences. Cognitive behavioural approaches to prevent or reduce pain and disability are being investigated, including methods to improve their effectiveness. One area with limited research to date surrounds the effective delivery of interventions, specifically the competence of therapists in their delivery, which is the focus of this thesis. Models of competence and assessment of competence within physiotherapy and CBT have been discussed, and the setting for this research, the Back Skills Training Trial, has been outlined.

2 Chapter Two - Suitable tools to assess competency

2.1 Background

This chapter describes a systematic review to search for tools to assess competence in physiotherapists delivering a cognitive behavioural (CB) approach in low back pain (LBP), and to assess the quality of the tools. The scope was to find tools that could be used to assess competency of physiotherapists delivering a CB approach in low back pain, and to assess the validity of the tools using the structure of the American Educational Research Association (AERA) *Standards* of validity assessment (92) and judgements on whether the tool was broadly fit for our purpose.

Whilst there have been studies that had evaluated physiotherapists delivering CB approaches in LBP populations (for example; (29, 41-43)), none have attempted to measure the skill/competence level in the intervention delivery. A few authors have raised this as an issue of importance in understanding the treatment outcomes of these studies (3, 6, 7). However, the extensive literature published debating the issue of small effect sizes in LBP research is notable by the limited discourse on the importance of how well treatments are delivered.

Systematic reviews represent a comprehensive and transparent approach to reviewing the literature. Narrative literature reviews can be open to criticism as the results can be biased by the search process (93)p4.

Within a systematic review, articles that meet inclusion criteria are assessed for quality/risk of bias. In this way confidence in the results of the review can be judged based on an assessment of the quality of the research from which the conclusions were drawn. Various methods and tools have been developed for rating the quality/risk of bias within interventional trials and in general there is a move away from objective scoring tools to more domain-based narrative summaries of the quality of the research (94).

2.1.1 Assessment of tool quality

Attempts have been made to evaluate the quality of competency assessment tools (CAT) although no explicit tools have emerged (77). The quality, or validity, of the CAT encompasses design and psychometric properties. A discussion on the concept of validity and its assessment now follows.

Validity has long been defined as the degree to which a result reflects the construct it purports to measure (95). Historically, validity was divided into several categories including content, criterion and construct validity (96). A lack of distinction between the categories has led to a more recent unifying conceptualisation of validity under the term construct validity (97). There has been a shift in focus away from using theories and models to validate any tool towards describing the range and quality of evidence that can be presented to support the output from the assessment i.e. what evidence is there that the assessment result can be trusted? (95). The evidence presented should reflect all the different areas in which the assessment process could be biased enabling readers to assess the validity of the results.

The Standards for educational and psychological testing are guidelines for use in the development and evaluation of educational assessment tools (92). These guidelines have been produced since 1966 through a collaboration of three associations: AERA, the American Psychological Association, and the National Council on Measurement in Education and were developed to "promote the sound and ethical use of tests and to provide a basis for evaluating the quality of testing practices". The Standards are widely used and contain detailed guidance on acceptable methods for the development and assessment of tests within education, psychology and employment. The Standards present a useful framework with which to evaluate tools and the following definition of validity;

Validity refers to the degree to which evidence and theory support the interpretations of test scores entailed by proposed uses of tests. Validity is therefore the most fundamental consideration in developing and evaluating tests. The process of validation involves accumulating evidence to provide a sound scientific basis for the proposed score interpretations. It is the interpretations of test scores required by proposed uses that are evaluated, not the test itself (92)p9

The *Standards* advocate a move towards presenting evidence to support validity across a series of domains of assessment: test content, response processes, internal structure, relationship to other variables, and consequences of testing, as follows:

Evidence based on test content

This domain relates to evidence that the contents of the CAT, including the items and format, map or correlate with the domains they are attempting to assess. This item also encompasses assessment of bias within the measure, i.e. whether

different sub-groups will benefit or be penalised on the basis of the items. For example, a measure of CB competency that appears to over-emphasise certain skills, where there is no evidence that these skills are more or less important.

Evidence based on response processes

This domain is looking for evidence that the CAT is being used and interpreted in the way it was intended. This also implies that the CAT is relatively easy to use and consistent in its scoring approach. If it is not easy to use and consistent then this provides a source of error and this domain seeks to eliminate or control any source of error associated with test administration. For example, in the assessment of CB competence an item may have been designed to measure the construct of empathy, however, examiners and students may have different views on how empathy is demonstrated leading to inconsistency in its application. This could be addressed explicitly through interviews of examinees/examiners or could be implied through a training programme or a manual written for the CAT.

Dalton (77) argued that an additional area of validity evidence should include acceptability, such as time to complete and costs of administering. These aspects are noteworthy when considering generalisability of the CAT but appear to be contained within the response processes domain when considering ease of use.

Evidence based on internal structure

This domain relates to the psychometric properties of the CAT including individual items or constructs. Several analyses can be conducted; analyses to see how well items relate to each other i.e. whether they are measuring the same overall construct known as internal consistency such as Cronbach's Alpha, Item

Response Theory and Rasch Analysis (77, 98). Items can also be assessed to see if membership of a sub-group means the measure becomes unstable; known as differential item function techniques (77). Factor analysis can also been used to support the existence of differing constructs within the tool (99)p667. All of these techniques can provide statistical evidence of validity related to internal structure. Reliability testing also falls into this domain which refers to the consistency of assessment outcomes (100).

Evidence based on relationship to other variables

This domain relates to how well a CAT correlates with other measures or scores that it might be expected to correlate with, including any 'gold standard' (101).

Other validity evidence that can be presented includes the ability of the tool to predict an outcome of relevance, sometimes referred to as predictive validity (95).

Evidence based on the consequences of testing

This area of validity evidence is more subjective and as a result more controversial (95). It refers to the impact of the assessment on those undergoing the assessment. This ranges from evidence that shows that any cut off score for passing/failing has been appropriately selected, or that the tool has been useful in the learning process.

AERA acknowledge that each domain does not "represent distinct types of validity" and as such, it is the overall validity evidence that needs to be considered in context with the assessment tool being evaluated (92)p11.

2.2 Methods

The Cochrane Collaboration is a highly recognised international independent body that was established in 1993 to bring together research findings through systematic reviews (102). They have produced guidelines on best practice for systematic review methodology which were used in the design and development of this study (94). The review is reported using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses; PRISMA statement (103). As this statement is primarily for the reporting of interventional trials, only items appropriate to the current review have been used.

2.2.1 Information sources / Search

Studies were identified by searching ten health related bibliographic databases shown in Table 3 below, from inception to July 2013. These databases were selected to provide optimal coverage of trials within medicine, psychology and pedagogy. Studies were also identified by screening reference lists of retrieved papers and by conducting searches on key authors of retrieved papers.

Grey literature

Within the clinical trials literature it is well documented that negative trials are less likely to be published than positive ones, and that this can lead to publication bias in systematic reviews (104). Including into reviews the unpublished, so called grey literature, can potentially avoid this bias but the process is not without its own difficulties. Unpublished trials have been found to have less methodological rigour (105) although any quality assessment done as part of a systematic review would identify any issues and be able to account for them in the reviews conclusions.

Grey literature includes many sources of unpublished literature from dissertations to reports. Abstracts presented at conferences are seen to be a significant source of grey literature (106) although not all bibliographic databases index them, for example MEDLINE. Most of the databases searched for this review included conference proceedings: AMED, CINAHL, PsycINFO, PsycARTICLES, ERIC, Web of Science, EMBASE, and Scopus. No conference abstracts of studies meeting inclusion criteria were found in the searches detailed in Table 3. A decision was made not to extend the search of grey literature using other databases such as OpenSIGLE, as it was felt unlikely to yield studies of validated tools within the time and resource constraints of the study. However, it is acknowledged that this strategy may have excluded potential CATs.

The search terms shown in Table 3 were selected to be as broad as possible. Key words were truncated, 'exploded' or mapped onto medical subject headings (MeSH) where appropriate to increase article returns. Search results were entered into an online bibliographic management software programme (EndNote basic²) and duplicate records were removed.

² EndNote basic, Thomson Reuters, www.thomsonreuters.com

Table 3 Search strategy by bibliographic source

		T		
Database (number of articles found)	Host	Search Strategy		
MEDLINE (638)	OVID	For databases using MeSH (MEDLINE, Embase,		
		AMED)		
Embase (870)	OVID	1. Cognitive therapy (MeSH major topic, exploded)		
, ,		OR Behaviour therapy (MeSH major topic,		
AMED (Allied and	Connect	exploded) OR Cognitive behavio* (keyword)		
complementary medicine)		Clinical competence (MeSH major topic, exploded)		
(29)		OR competenc* (keyword)		
()		3. assess* OR intervention* OR therap* OR clinical		
		(keyword)		
		4. 2 AND 3		
		5. 1 AND 4 limited to English		
()				
Web of Science (395)	Connect	For Web of Science, SCOPUS, CINHAHL, PsycINFO,		
Scopus (773)	Connect	PsycARTICLE, ERIC		
000000000000000000000000000000000000000	Connect	1. Cbt OR cognitive therap* OR cognitive behavio*		
CINAHL (Cumulative	Oomicot	Therap* OR behavio* therap* OR cognitive		
Index to Nursing and Allied		behavio*		
Health Literature) (233)		2. Clinical competenc* OR competenc*		
PsycINFO (237)	ProQuest	3. assess* OR intervention* OR therap* OR clinical		
PsycARTICLES (52)	ProQuest	4. 2 AND 3		
, ,		5. 1 AND 4 limited to English		
ERIC (214)	ProQuest			
		N.B. All search terms in 'topic' for Web of Science,		
		'article title, abstract, keywords for SCOPUS, 'all text' in		
		CINAHL, 'keyword' in PsycINFO, and 'anywhere except		
		full text' in PsycARTICLES and ERIC		
PEDRO (21)	CEBP	For PEDRO;		
		Cbt OR cognitive OR behav* (abstract and title)		
		2. Competenc* (abstract and title)		
		3. 1 AND 2		
	1	I		

MeSH = medical subject heading

2.2.2 Study selection / Eligibility criteria

Competence, as defined in this thesis as: 'The extent to which a therapist has the knowledge and skill required to deliver a treatment to the standard needed for it to achieve its expected effects" (62)p374 can be assessed in several different ways. Knowledge tests, practical examinations and observation of performance are used commonly as assessment methods for professional qualification (72). Therefore any CAT which assesses discrete knowledge, skills or performance can contribute to the overall assessment of competence. Studies were included in this review if they objectively assessed knowledge/skill/performance of a health professional delivering an intervention founded on a cognitive behavioural approach. Tools were included if they were being used within a physical health problem or were designed to assess a health professional including those working at a lower level within psychological services (e.g. Improving Access to Psychological Therapies [IAPT]) not a psychological specialist (e.g. psychotherapist, psychologist, high level IAPT therapist). The rationale was that skills/knowledge/competence required for physiotherapists applying a simplified CB approach in a primarily physical health problem (LBP), would be significantly different to psychological specialists applying cognitive behavioural therapy in a mental health problem. In addition, only papers that provided an adequate description of the tool, or reference to a description that was adequate to replicate the tool from were included.

Studies were excluded if they assessed competence in an isolated component of a CB technique e.g. graded exposure or questioning skills or tools that checked adherence to trial procedures with no reference to skill/competence in delivery of intervention. For pragmatic purposes articles not written in English were excluded.

2.2.3 Data collection process / Data items

Validity evidence was extracted from each paper using a data extraction tool structured using the *Standards* and originally devised for a similar systematic review to the current one (22). The extraction tool only required minor alterations to account for the differences in search aims to be used within this study. Each item in the abstraction tool related to guidance in the *Standards* which were used to define if each item was met or not. For example the first item was; were characteristics of study participants reported? This item was regarded as met if relevant characteristics of the study participants were presented such as profession, training level, and years of experience (92)p18.

Two reviewers were involved in selecting, appraising and abstracting data from the papers. The first reviewer screened all titles and abstracts for inclusion criteria. Those that did not meet inclusion criteria were rejected. A random 10% selection of titles/abstracts was screened by the second reviewer to check for consistency; discrepancies were discussed and resolved. Where it was unclear from the title/abstract whether the study met inclusion criteria then the full paper was retrieved. The two reviewers independently conducted data abstraction on all papers as blinding may slightly improve consistency of assessment between authors (94), discrepancies were discussed and resolved without the need for a third reviewer.

2.2.4 Synthesis of results

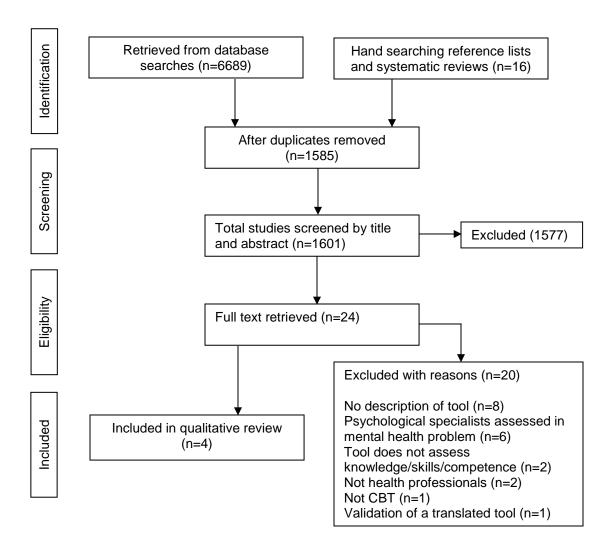
The results were tabulated (Table 5) using the domains/items contained in the data extraction tool. This allowed for a comparison of the results and for the overall level of evidence for each CAT to be examined. Although a structured and standardised assessment was used, this was not transformed into a numeric score or grade (for

example high, low or medium risk of bias as in Cochrane tools). Scoring each item would require a weighting of the importance of each area of validity evidence, for which it is difficult to justify weights allocated to each item. The scoring of validity has also been found to be unreliable within clinical trials (107). In addition, with reference to the domains of validity evidence contained within the Standards, AERA state that 'these sources of evidence may illuminate different aspects of validity, but they do not represent distinct types of validity' (92)p11. Thus due to problems with scoring and overlap of criteria, a structured assessment was used which was then summarised. Each tool was then evaluated as to its suitability for the target audience. This involved considering whether the constructs and skills that the tool attempted to assess were generic enough to be applied to a physiotherapy CB intervention for LBP. Finally, given the evidence presented on validity and the judgement on whether the tool could be adapted for purpose, a decision was made by the thesis author as to whether the tool was fit for purpose. As some of these assessments were subjective, and as such at risk of bias, a transparent method of reporting was adopted in line with recommendations from qualitative methods of analysis (108)p220.

2.3 Results

The number of studies identified and excluded at each stage is summarised in Figure 3 below. Appendix 1 lists the excluded studies (n=20) with reasons for exclusion.

Figure 3 Systematic review: PRISMA flow diagram



2.3.1 Study characteristics

Four studies met criteria for inclusion in this review. Competency assessments were applied to a range of health professionals using both performance based tools and attitude/knowledge based tools. The four studies assessed competency of health

professionals in four different patient populations, three of which were within physical health and the fourth in mental health. The study characteristics are summarised in Table 4 below.

There was variation between the four studies as to the methods used to develop and then test the CAT. This validity evidence is summarised using the data extraction tool in Table 5.

Table 4 Summary of studies included in the review

Source, instrument name	Written or performance tool	Target practitioner	Target patient population	Summary of assessment	Response options and scoring
Appleby 2003 (109)	Written and performance	Health visitors	Postnatal depression	1) Written: 6 statements assessing attitudes to postnatal depression 2) Performance: 7 skills. 4 specific (e.g. advice on child care, practical support). 3 non-specific counselling skills (e.g. enquiring about depressed mood, addressing the patient's concerns).	 4 point agree or disagree on a Likert type scale. Each performance item rated between 0-2 or 0-4; no details on criteria
Godfrey 2007 (110)	Performance	CBT therapists	Chronic fatigue syndrome / ME	3 domains 21 items; 1) Alliance scale, 2) CBT scale, 3) Counselling scale	7 point Likert scale with 4 anchors along scale; not at all (1), somewhat (3), considerably (5) and extensively (7)
MacLaren 2008 (111) Knowledge and attitudes questionnaire	Written and performance	Nursing students	Paediatric pain	4 assessments; 1) 3 vignettes to identify appropriate strategies 2) 6 multiple choice questions and 3 short answer questions on pain related concepts 3) 3 items attitude assessment of effectiveness of pain management approaches 4) Role-play scenario 5 minutes long	1) 1 point scored for each CB strategy identified 2) MCQ – 1 point for each correct answer and 2-4 points for short answer 3) 5 point Likert scale, not at all to very much 4) scored as no.1 and also quality (present or absent) on; rationale, instruction, modelling, coaching, and parental involvement. Score of 1-5 for each CB intervention used; averaged.
Mannix 2006 (112) Cognitive First Aid Rating Scale	Performance	Palliative care nurses, occupational therapists, social workers	Palliative care	10 items based on the CTSR: e.g. focus/structure of session, integrating CBT into the therapist's professional model of care, guided discovery, eliciting key components of a CBT based model.	7 point scale (0-6) with maximum score of 60 (no further details provided on scale)

MCQ = Multiple choice questionnaire

Table 5 Summary of validity evidence for each study included in the review

Validity Evidence	Appleby	Godfrey	MacLaren	Mannix
Test content				
Were characteristics of study participants reported?		✓	✓	✓
Were personnel involved in the instrument development specified?				
Was a pool of items generated?		✓		
Were the criteria for item pool reduction to the final item list specified?				
Were performance indicators included	√	✓	✓	✓
Was the rating scale described: format, width, descriptors and scoring criteria?		√	√	✓
Was information provided on compilation and interpretation of total score?	✓		✓	√
Was the instrument tested in a clinical environment?		✓		✓
Internal structure	L	·		1
Was Cronbach's alpha calculated and between 0.70 and 0.95?¥		✓		✓
Was any investigation using IRT or Rasch analysis conducted?				
Reliability	L	·		1
Was an intra-rater reliability study conducted?				
Was an inter-rater reliability study conducted?		✓	✓	✓
If reliability studied, was the number of raters specified?		✓	✓	✓
If reliability studied, was the number of students assessed specified?		✓	✓	
If reliability studied, was the number of paired assessments provided?		✓	✓	✓
If reliability studied, were raters blinded to other rater test scores?		✓	✓	✓
If reliability studied, were Test 1-2 mean score differences (d) & SD of diff (sd) or comparable data reported?				
If reliability studied, was the test1 /test 2 correlation specified?		/	/	/
Response Processes		1 -	1 -	1
Was there any assessment on the ease of use?				
Were details of the content of training reported?		✓		
Relationship to other variables	I	ı	_l	1
Were relationships to other tests hypothesised to measure related or different constructs analysed?				
Consequences (educational impact)		1	1	
Was the instrument used to provide feedback to the students?				
Was student learning evaluated?		1	+	
Was student learning evaluated? Was feedback on instrument use sought from students?			+	
Acceptability	l	ı	1	1
Was the acceptability of instrument to stakeholders formally investigated?				
Was the time taken to complete the instrument reported?		1	+	+
Costs	l	ı	1	1
Was there any information provided on costs related to instrument use?				
was there arry information provided on costs related to institument use:	<u> </u>			

^{✓ =} Yes, criteria addressed; No tick = criteria not addressed or there is insufficient information to decide; *= multiply, #=number, DIF=differential item functioning, IRT=item response theory, ¥= values chosen based on recommendations from Terwee et al (113). Tool adapted from Dalton (77).

2.3.2 Tool development

MacLaren et al (111) designed the Knowledge and Attitudes Questionnaire to evaluate the effectiveness of a 20 minute brief training program in evidence based CB pain management strategies on 58 nursing students' attitudes, knowledge, and skill acquisition. The tool was designed by the primary author in collaboration with colleagues from psychology and nursing although there were no details on this process which precludes assessment of validity. Knowledge was assessed via vignettes and a short answer questionnaire. Attitudes were assessed with a Likert scale rating the perceived effectiveness of pharmacological, physical and psychological interventions in pain management. Performance was assessed in a five minute role play scenario where students were asked to deliver strategies for pain management. Scoring involved rating whether rationale, instruction, modelling, coaching and parental involvement was present or absent. Inter-rater reliability was found to be good (kappa 0.72) in a 20% sample coded by a second rater. This Knowledge and Attitudes Questionnaire attempts to assess knowledge and performance in a thorough manner given the brevity of the training (20 minutes) and the limited scope of skills taught – students were only instructed on the use of distraction and guided imagery, a form of relaxation technique. These two behavioural techniques are included within a CB approach to pain management, more typically for the immediate relief of short-term pain increases. As such the Knowledge and Attitudes Questionnaire does not provide a broad enough scope of CB skills for application to chronic LBP.

Appleby et al (109) assessed the impact of a two day training programme for health visitors of an intervention which they had previously designed and found effective for post-natal depression: cognitive behavioural counselling. The objective CAT consisted

of an attitude assessment and a performance assessment. No details were provided on the development of the attitude assessment tool which consisted of six statements which the health visitors rated using a Likert scale. A role play scenario with an actor was videotaped before and after training in a sample of the health visitors (n=17) who were rated on seven counselling skills. Four of these skills were specific for the target population such as 'child care' and three were described as generic counselling skills such as 'offering emotional support'. No information was provided on the development of the CAT and no reliability testing was conducted although internal consistency was calculated as acceptable (Cronbach's α = 0.61). The Appleby tool had very limited reported evidence of validity, furthermore, four of the seven items in the performance tool were very specific to problems faced by mothers with post-natal depression and as such could not easily be adapted to a chronic LBP population.

Godfrey et al (110) conducted a process evaluation to examine which elements of a CBT intervention delivered by psychological specialists for chronic fatigue syndrome were associated with positive outcomes. The study also aimed to design a tool that could differentiate between the two treatment modalities that were delivered in a randomised controlled trial as part of the trial's fidelity checks. A literature review was conducted to generate items for a performance CAT that assessed therapeutic alliance, elements of CBT and counselling. Two validated CATs were found to be appropriate to use as a basis for selection of items, and the authors report using 'expert consensus' to select items from each of the two scales to form the new CAT. No further details of the consensus method for item selection are provided, which precludes further assessment of validity. The new CAT was piloted in six consultations with minor adjustments made after feedback. The CBT sub-scale does appear to have significant cross over with other CATs used for assessment of CBT competence (85) and appears to cover a

broad range of CB skills. Audio-recordings of 71 patients undergoing CBT or counselling with one of six therapists were made. These recordings were then independently assessed by two raters from a pool of four available raters. The authors report that inter-rater reliability was mostly adequate with weighted kappa between 0.2-0.8, although no further details are provided and so we are unable to evaluate the reliability in the CBT sub-scale.

Mannix et al (112) developed the Cognitive First Aid Rating Scale (CFARS) in order to assess whether palliative care practitioners could deliver a CBT intervention after brief training and also whether the skills would maintain after the course. A ten item scale based on an existing CAT (Cognitive Therapy Scale Revised: CTS-R) was developed by the research team to reflect the skills and competencies taught on the training programme and those skills deemed appropriate in the client group. No details were provided as to the processes used by the research team to develop the CFARS. Twenty practitioners from a nursing, occupational therapy, or social work background took part in the study. Audio recordings of sessions were made prior to training, after 6 months of supervised practice, and at 12 months when half the subjects had stopped supervision. All recordings were independently rated twice from a pool of four raters. The inter-rater reliability was found to be 0.66 to 0.82 using the intra-class coefficient for pairs of raters and internal consistency was found to be high (Cronbach's Alpha 0.93). Although the CFARS was found to have good psychometric properties it lacks validity in the development process, similar with several of the tools in this review. The CFARS was not available to be able to review the content and so its suitability cannot be ascertained.

2.4 Discussion

2.4.1 Summary of evidence

The primary aim of this review was to find CATs that could be used to assess competency of physiotherapists delivering a CB approach in LBP. The secondary aim was to establish the validity of the CATs using both the structure of the AERA *Standards* of validity assessment and also judgements on whether the tool was broadly fit for our purpose. Although the review found 4 potential tools, none would appear suitable for assessing physiotherapists applying a CB approach in LBP.

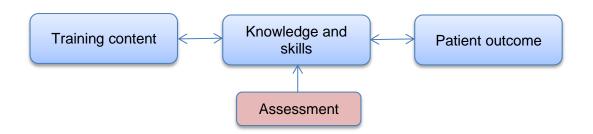
Within evidence on test content, all four studies described the items included and scoring system but none presented evidence to support CAT development. There was limited evidence on internal structure with only two studies evaluating internal consistency and none undertaking further analysis such as differential item function analysis.

However, three of the four reports did include an appraisal of reliability of their respective tools (110-112). Inter-rater reliability was overall very good across the three tools although the reliability for CBT sub-scale was not reported in the Godfrey study (110). Validity evidence on the response processes was absent in all but one study (110) for one type of evidence on training. None of the studies reported on ease of use, acceptability or costs. None of the four studies presented any validity evidence on relationship to other variables or consequences of testing. Three of the four tools were available to be able to review the content. Two of the tools were highly specific and limited in the number of CB skills they assessed (109, 111). The third tool appeared appropriate in breadth of competencies but lacked validity in its development (110).

2.4.2 Motivation for tool development

The Maclaren and Appleby tools were designed to evaluate whether learning objectives in a training programme had been met (109, 111). In this way the tools were attempting to measure the specific skills or knowledge taught on the course.

This is appropriate if there is a pathway from training content to required outcome in the patient, demonstrated diagrammatically below;



As seen in the diagram above, training content needs to be selected based on the knowledge and skills likely to produce the patient outcome. Assessment in the Maclaren and Appleby studies targeted the knowledge and skills based on the content of the training programme. It is difficult to evaluate the validity of the assessment in these circumstances as there is no justification for the content of the training programme. Therefore, the Maclaren and Appleby assessment tools were reliable in assessing student's skills and knowledge post-training, but we have no way of judging whether the skills or knowledge seem appropriate, i.e. there is no evidence based on test content.

Similar methodological issues were found in the study by Mannix et al (112) where the CAT was developed to reflect the training programme and also any skills that the team thought were appropriate in the patient group, but the process used to design the training programme or CAT was not described. However, this may have been due to

the primary aim of the study to evaluate the effect of on-going supervision on maintenance of competence level.

2.4.3 Other content validity considerations

Assessment of content validity is also difficult in the tool developed by Godfrey (110). The authors describe using two existing CATs as a basis for their CAT and that decisions over which items to include were made by 'expert consensus' although no details on the experts, criteria, or decision making process are provided. Godfrey et al then used their new CAT to see if any items were predictive of clinical change in patients. This information contributes to content validity indirectly by providing potential predictive validity. For example, if specific competency items in the new CAT are strongly associated with clinical change then they can be used to make a prediction of outcome (evidence based on relationship to other variables). This adds weight to their inclusion in a CAT (evidence based on test content) although ideally a causal link needs to be established. Unfortunately none of the factors found within the Godfrey tool using factor analysis were associated with clinical outcome in this study. This finding could be due to many factors, further explored in Chapter Five, but this lack of association means that overall the Godfrey CAT lacks validity evidence on test content.

A further problem with using the Godfrey CAT is associated with the weighting of items towards assessing the therapeutic alliance. The CAT was devised as part of a clinical trial where both counselling and CBT were compared. The CAT had three domains, one each for skills specific to counselling or CBT and the third category for therapeutic alliance which is intrinsic in both therapies. The alliance scale was more detailed than the skill specific scale (14 items and 7 respectively), which may have been related to

the hypothesis the authors were testing on alliance being more important for predicting clinical change than the specific skills of each therapy. Whilst therapeutic alliance is seen to be important in CBT it is emphasised less than within counselling models (34) and so much of the alliance scale is more strongly related to counselling theoretical perspectives and could provide a source of bias in a cognitive behavioural CAT.

2.4.4 Selection of competency items for tools

Whilst there is no agreed definition of the components of a CB approach with which to map any CAT to, expert consensus forms an important part of tool development (38). No evidence was presented in the four studies included in this review that would allow the reader to judge who was involved in tool development and how items were selected for the CAT, along with interpretations of test scores. This lack of information is not unique to this review. Schoenwald (114) found 249 assessment tools that measured adherence to psychological treatment protocols within mental health, of which 59% were CBT related. Only 35% of the 249 tools provided information about psychometric properties. Dalton (77) conducted a review of undergraduate CATs for assessment of physiotherapists reported that only five of the eight tools (63%) presented some information on content validity. Only one tool stated explicitly how items were generated for the CAT and none of them described how they had developed the rating scale of the CAT, or indeed how they had determined what level would be a pass score. Similar to the Schoenwald review, only four of the eight CATs reported psychometric data (interrater reliability).

This review has shown that there is currently no valid CAT available with which to assess physiotherapists delivering a CB approach.

2.5 Chapter summary

This chapter describes a systematic review to search for tools to assess competence in physiotherapists delivering a CB approach in LBP. Four CATs were found that met inclusion/exclusion criteria. The validity evidence for each CAT was examined from the published findings using the AERA *Standards*. Judgements were also made as to the suitability of each CAT for our purpose. All four CATs were found to have limited validity evidence particularly within the tool design. A new CAT needs to be developed in order to explore the influence of competence on the effectiveness of CB approaches for LBP.

3 Chapter Three - The development of a competency tool

3.1 Introduction

Assessment of competence and performance in healthcare professionals delivering an intervention to enhance patient outcomes is important for many reasons including; maintaining public confidence in health professionals, understanding the mechanisms of an intervention and improving the quality of interventions (115).

The systematic review in chapter two found no existing tools suitable to assess the competency of physiotherapists adopting a CB approach. There is therefore a need for a tool to be developed.

3.1.1 The Cognitive Therapy Scale

As discussed in chapter one, there are several tools for the assessment of competency in CBT (85). The Cognitive Therapy Scale (CTS) has remained the most widely used and researched tool (86, 87).

Cognitive therapy was developed in the 1960s by Aaron T Beck as a new framework for understanding emotional problems (33). In 1980, along with Jeffrey Young he developed an instrument to assess competency in CBT and called it the Cognitive Therapy Scale (116). This instrument was subject to testing and was found to have generally good reliability and internal consistency (117-120). However, it had two items added to the scale in 1988 and although in common use, this version has not been subject to testing. To take account of evolutionary changes to CBT and questions

raised over reliability of some items (86) it was revised in 1997 (121). The newer version, CTS-R (shown in Table 6), still used a six item score for each item but the levels were more clearly defined and linked to the Dreyfus model of skill acquisition (66, 68). Using the Dreyfus model, competence was defined as a score of 3 or 4 for each item (122).

Table 6 Items in the Cognitive Therapy Scale - Revised

	Item title
1	Agenda setting and adherence
2	Feedback
3	Collaboration
4	Pacing and efficient use of time
5	Interpersonal effectiveness
6	Eliciting of appropriate emotional expression
7	Eliciting key cognitions
8	Eliciting behaviours
9	Guided discovery
10	Conceptual integration
11	Application of change methods
12	Homework setting

Subsequent testing has shown the CTS-R to have a greater level of inter-rater reliability compared to the CTS (123, 124). In studies by Reichelt et al (123) and Gordon et al (87) the average ICCs increased from around .40 without training on the tool to around .70 after training.

The CTS-R has been adapted several times for use within specific clinical presentations including severe mental illness (125), psychosis (126), substance abuse (86), palliative care (112) and diabetes (127).

The development of the CTS by the main originators of the therapy suggests that competencies contained within the tool should represent the key components of the therapy. The revised CTS remains the most widely used performance tool to assess fitness to practice as a CB therapist in post graduate courses (87).

In summary, the CTS-R is a tool with evidence of validity and reliability and previous adaptations of the tool to specific patient groups has proved an acceptable method. Hence it provided a good starting point to measure competence in physiotherapists adopting a CB approach. The next stage was to consider which tool development method would be used.

3.2 Assessment tool development methods

Eraut (60) highlights that competence assessment in higher education is somewhat more refined than workplace based assessment which tends to rely on experienced practitioners without explicit criteria and/or verification procedures. Where explicit competence tools have been developed, a range of different methods have been used. Within clinical intervention trials, researchers have produced checklists of skills to be demonstrated as part of their fidelity checks (128). Whilst this method assesses the treatment enactment, i.e. whether the trial intervention was delivered as intended, it is usually a checklist of observed behaviours which does not make a judgement as to the skill level to be demonstrated. New competence tools have also been adapted from existing, overly complex tools by a process of factor analysis to identify key competencies (for example: (129)). As found in the systematic review contained in chapter two, competency tools have also been developed without any clear description of the process, personnel involved or method used.

There are several methods that can be used for developing assessment tools depending on the extent to which knowledge/skills/attributes have already been determined for the specified purpose. Methods range from deconstructing existing tools such as through functional analyses (110), to deconstructing effective treatments to identify important skills and knowledge (e.g.(130). Where there is no clear evidence or tool in existence, expert opinion is required for the development of an assessment tool (38).

3.2.1 Consensus research methodology

Consensus methods ask experts in the field to answer a question based on their experience and knowledge (131).

3.2.1.1 Validity of consensus methods

Consensus methods are used where there is no existing clear evidence; where there is evidence available, any experts within a field will be aware of the general findings and their opinion will more or less reflect the evidence (132). In addition, if there were clear guidelines as to what skills or competencies were important to demonstrate in a LBP population, then a systematic, peer reviewed process would be more likely to produce a tool that was acceptable and easily reviewed with emerging evidence. As discussed in chapters one and two, no such evidence exists and so a consensus method would appear the most valid method for defining competence in physiotherapists adopting a CB approach in LBP. A consensus method can provide a theoretical framework for peer review and further research. The AERA guidelines recommend that in this instance the personnel selection and the process used to form consensus is clearly outlined (92)p19.

In general, the consensus process can be achieved through face-to-face meetings or through a postal questionnaire system. Murphy et al (132) have described the three main types of formal consensus method used within healthcare.

3.2.2 Nominal Group Technique

In a nominal group technique experts meet face-to-face. Ideas are generated independently and privately which are then fed back to other members. Each idea is then discussed by the group with judgements recorded privately. The stages can be repeated and the results are aggregated statistically to derive group judgement. The nominal group technique is most commonly used within healthcare for the purpose of guideline development. Face-to-face consensus is difficult to organise and as a consequence can have less members which can limit the range of opinions (133). It has also been criticised in that one or two dominant opinions could bias the process early on suppressing novel ideas (134).

3.2.3 Consensus Development Conference

In a consensus development conference the evidence is presented to a select group of experts in an open meeting. The evidence is submitted by people that are not part of the decision making process. The group then deliberate the evidence in private. This method is subject to the same limitations of face-to-face consensus as in the nominal group technique.

3.2.4 Delphi Method

The most commonly used postal questionnaire consensus method in healthcare research is the Delphi method (135). Linstone and Turoff (136) offer this broad definition of the Delphi method: 'Delphi may be characterised as a method for structuring a group communication process so that the process is effective in allowing a group of individuals, as a whole, to deal with a complex problem'(p3). This approach typically uses a questionnaire sent out to experts several times (rounds), each time with the results/feedback from the previous round. Rounds continue until consensus is agreed. This method allows for greater numbers of members and therefore theoretically allows for a greater diversity of opinion and is possibly more representative of a wider group. The members of the group can be known to each other but answers to questions are anonymous which suppresses dominant opinion. This anonymity does not provide accountability and it has been suggested that hasty decisions can be made as a result (132). In addition the anonymity does not allow for discussion of ideas or theories. The Delphi method has not been tested for reliability and is also difficult to assess for validity (137). This can be partially countered by having a robust and detailed methodology for the Delphi process (134) although there are no available strict guidelines on the application of this method. The Delphi method has been used diversely within healthcare from identifying research priorities and service planning to development of education and competencies (132).

3.2.5 Selection of consensus method to be used

Both the Nominal Group Technique and Delphi Method would be appropriate within the context of developing a competency tool. The Delphi Method was selected for several reasons. The tool to be developed is specific to the application of CB approaches in LBP

by physiotherapists. Experts for the study would need to be drawn from a small field with expertise in each of these areas. The small numbers of potential study participants would be reduced further by using a Nominal Group technique due to the logistics of getting all participants to a face-to-face meeting.

There is likely to be a range of perceived statuses within the group. High status has been associated with increased participation in group discussion and increased influence on group decision making where the group has diverse status (132). Participants are likely to be healthcare practitioners such as physiotherapists and clinical psychologists. Training for psychologists is currently a post graduate doctorate with a significantly higher salary compared to professions with undergraduate training. It could be argued that psychologists within the Delphi experts would have higher perceived status and could influence the decisions of other Delphi members. The psychologists may also be perceived to have more relevant knowledge. This could mean that the resulting competency tool could be biased towards constructs and skills valued within psychology but less so within physiotherapy. In addition, the potential study participants would range from practitioners to international speakers in the field. International speakers are likely to be influenced by current constructs being explored within research which may be perceived as irrelevant to practitioners. Therefore, to allow all members regardless of status to influence the outcome, a method which keeps all members opinions anonymous would be favourable.

Lastly, the research costs associated with a questionnaire format methodology are significantly less than the costs associated with a face-to-face consensus method. This was a significant consideration within the context of the current study which received limited funding.

3.3 Methods

3.3.1 Participants

The output of the Delphi method is largely reliant on the participants and as such due consideration needs to be given to the selection of participants.

3.3.1.1 Inclusion criteria

Murphy et al (132) identify two types of question to be answered using a consensus method; 'Value' questions which ask about competing social goals and as such have no correct answer, and 'Technical' questions which ask for judgements due to insufficient data and as such have a correct answer, albeit unidentified. Jairath and Weinstein (138) stated that 'experts should reflect current knowledge and perceptions, yet be relatively impartial to the findings' and Powell (139) adds that experts 'should work in the appropriate area and have credibility with the target audience'. It is also important to consider whether participants should be lay or professional, uni or multi professional, national or international. In general it is felt that the more heterogeneous the panel can be the more reliable and 'acceptable' the results are (131).

Within this study, experts are required to define the competencies for physiotherapists to apply a CB approach in LBP. Therefore experts require knowledge of the CB model, a good understanding of the way in which physiotherapists work, and knowledge of the specific problem of LBP, and experience of applying the CB model in this group of patients.

Knowledge of the CB model may well have been achieved through informal learning and self-directed teaching but cannot be assumed, therefore a minimum level of knowledge

as demonstrated through validated courses was used. An understanding of the current practice of physiotherapists was assumed if participants were currently practicing as a physiotherapist or were working closely with a physiotherapist. Knowledge of LBP and application of CB approaches within the LBP population was assumed through experience in relevant working fields e.g. pain management programmes or within musculo-skeletal out patients. On considering further demographics of the experts it was clear from the requirement of further professional training that lay persons would not be suitable, however, professionals that met the criteria could be drawn from a variety of professions such as Occupational Therapy, Psychology, Medicine, and Physiotherapy. In addition experts were required to be working within the UK to understand the current working practices of UK physiotherapists as the level of autonomy and basic training of physiotherapists internationally is variable.

In summary, inclusion criteria for experts in this study were;

- 1) Health professionals working in the UK
- 2) Practicing physiotherapists or working closely with physiotherapists
- 3) CBT trained at 'M' level (i.e. postgraduate certificate, diploma, or masters)
- 4) Experienced in applying CB approaches in patients with low back pain

3.3.1.2 Recruitment of experts

An outline of the study was distributed to potential participants through the following methods:

Within the professional body for physiotherapists, The Chartered Society of
 Physiotherapy, there are two relevant special interest groups; Physiotherapy Pain

Association and the Association of Chartered Physiotherapists in Mental Health.

Emails were sent to all members in both groups.

- Email to all CBT post graduate courses in UK asking for the email to be passed to any students present or past who were physiotherapists or working within pain management.
- Advert placed in magazine received by 98-99% of all physiotherapists.
- Flyers at a National Physiotherapy conference.
- Mail-shot to all pain management programmes in UK.
- Personal contact with known researchers in the field.

Potential participants of the Delphi Panel were screened to see if they met the inclusion criteria and were provided with further information about the study aims and requirements of participation. There is no consensus on the number of participants required for a Delphi study although suggested numbers have ranged from 6-12 participants (131, 132).

The Central Office for Research Ethics Committees (now called National Research Ethics Service) ruled that no ethical approval was required for this study.

3.3.2 Procedures

3.3.2.1 *First round*

Most studies that have used a Delphi methodology have adapted the process to meet their specific research demands (131). However, there are typical methodological features that appear consistent across the majority of Delphi studies. The initial round in a Delphi is concerned with identifying or generating ideas through open, unstructured questions. In modified versions, interviews or focus groups have been used (140-142) or alternatively items are generated through literature review by the researcher (e.g (143)) which could have the potential for biasing the process initially, for example, current literature might not be consistent with current or acceptable practice. In this study the generation of items for the new assessment tool went alongside adaptation of existing items in the current CTS-R. This had the benefit of using a well validated tool to provide a framework of core CBT competencies whilst allowing flexibility for items to be adapted or new items to be introduced.

The first round questionnaire (Appendix 2) was sent out to all eligible participants who had expressed an interest in taking part in the study. Returning the questionnaire implied consent to take part in the study.

The first round questionnaire collected information on the experts and provided information on:

- purpose of the study and outline of Delphi stages
- information on the typical complexity of primary care patients that physiotherapists would be applying a CB approach within

There has been much debate around the information provided to Delphi members alongside the rounds of the questionnaires. It is acknowledged that the cues provided in information or through the questions can influence the decision making process (132). Specifically, participants will generally only consider the cues that have been provided to them, potentially negating or undervaluing the excluded cues (144).

Information was provided on the profile of the typical LBP population managed in primary care. This was highlighted as CB approaches are currently predominantly used within

secondary or tertiary care where the LBP patients typically have more complex psychological and physical needs. It can be postulated that the skills required to treat a more complex population vary from the primary care population, therefore, information was provided to highlight these differences (see Appendix 2).

Questions asked in the first round

Participants were asked to make a judgement as to whether each item of the existing CTS-R was appropriate for the stated purpose by either selecting 'Include', 'Do not include', or 'Unsure'. They were then asked to suggest up to 6 additional competencies in a free text section. The purpose of limiting the suggestions was to focus participants on key items and to prevent an impractical number of items being generated (145).

Analysis of the additional competencies suggested by Delphi participants in round one Typically within a Delphi study the results of the first round are subject to qualitative analysis via content analysis to check for and group similar items (132).

The free text information provided by the Delphi experts was initially grouped into broad themes. Where it was clear that experts were describing the same skill, these were developed from the information given into a proposed new item. Where there was any ambiguity, the expert was asked for more information. The new competencies needed to be consistent with the style and scoring system of the existing CTS-R for ease of use and hence an identical structure was used for the response categories for the new items. Each new competency item was then reviewed by the expert/s who had suggested the item for comments or editing. Changes were negotiated between the experts by the thesis author prior to being presented as new items in the second round.

3.3.2.2 Second round

Subsequent rounds in a Delphi ask participants to rank or rate the items generated by the first round using appropriate criteria, such as a priority rating. Results are fed back to members using basic statistics such as means with standard deviations / inter-quartile ranges (132).

The second round questionnaire (Appendix 3) provided the following information:

- reminder of target population
- characteristics of the other Delphi experts; profession and work area
- results of the suggested inclusions and exclusions elicited in the first round using frequency counts of Delphi experts and percentages. The responses were anonymised to prevent the opinions of members with higher perceived status from being influential (146)
- additional suggested competency items generated through the first round
- information on the definition of minimum competency as provided in the manual for the CTS-R

Questions asked in the second round

In the second round experts were required to re-vote on the items that did not reach consensus for inclusion or exclusion and also to vote on the inclusion of the additional suggested competency items.

This round also asked for experts to vote on the minimum competency score on the scale of 0-6 that they believed would need to be demonstrated for the intervention to be effective. This additional task was added at this stage to reduce the total number of rounds that would be required.

3.3.2.3 Third round

The number of rounds in a Delphi study varies from two to four as it has been found that more than four rounds will generally cause respondent fatigue (145).

It is recognised that consensus increases through rounds but the mechanism for this is poorly understood. It has been suggested that consensus may be due to experts reviewing their opinion after further consideration, experts conforming to the general opinion, or through experts trying to sway opinion through tactical voting (132). The latter two points can be avoided through the removal of experts who significantly shift opinion or through contacting experts for a rationale of their decision (135). A decision was made to limit the process to three rounds to reduce respondent fatigue whilst providing opportunity for consensus to be achieved.

Questions asked in the third round

The third round required the experts to re-vote on any items that had not reached consensus both on the inclusion of items and the minimum competency required. The format of the questionnaire was the same for rounds one and two and due to concerns of respondent fatigue the format was adjusted for round three. It was intuitively felt that this would maintain interest in the study although changing formats in this way has not been investigated in studies looking at response rate (147). In this round the feedback on the second round voting was provided by the use of graphs (Appendix 4).

3.3.2.4 Format and follow up procedure

The delivery format of the questionnaire can have an effect on response rate. In the current study all Delphi members had requested information through email and therefore an email format was used to mail questionnaires to members with the option of a paper

version if required. Participants were given one month initially to complete the first questionnaire with a reminder sent through five days before the deadline. Once the deadline had elapsed participants were followed up with a further email to stress the importance to the study of their participation and to see if further time would enable them to still take part.

3.3.2.5 Data Analysis

Consensus level

There is no clear definition of consensus within Delphi studies which is most likely a reflection of the wide variation in the application of the technique (148). A review of the literature shows that a Delphi technique is commonly used within healthcare to define competencies required in practice. However, most of these studies use a ranking process which aims to prioritise a list of competencies and as such no cut off level of consensus is required (for example see (149)). The cut off point for consensus varies considerably in the literature and varies between 51-80% (145) depending on the aims of the study and the number of rounds that are practical to achieve. In studies with similar methodologies as the current study, consensus has been defined as between 60% and 80% but without any justification of the consensus level (for examples see (150-152)). In some Delphi studies voting of experts is weighted towards those with perceived higher levels of expertise (132). This method was not selected in the current study as it was felt that expertise levels were similar. The consensus level in this study was predefined as 70% as it was felt that this level was in line with previous studies and would be a significant majority, increasing confidence in the output.

Stability

The aim of a Delphi study is to establish what agreement there is between participants on a given issue, and this can be defined by the degree of consensus or convergence in the final output (132, 136). However, this may omit important information about how opinion changed between rounds which would give an indication as to the stability, and as such the reliability, of the final output (135). There have been limited attempts to statistically analyse stability within the Delphi method (153) although Greatorex et al (135) described a method of graphically representing means and standard deviations across questionnaire rounds to visually display the degree of stability. This technique appears suitable when there are a number of items being voted upon which can treated as an incremental scale. In the current study this method was applied to the voting on the minimum competence score voting (a scale of 0-6). Stability of voting on inclusion of competency items (scoring options of: agree, disagree, unsure) will have a narrative description of change between rounds.

All data were double entered to ensure accuracy.

3.4 Results

3.4.1 Participants

It is difficult to estimate how many health professionals were contacted via adverts or communications in the varied contact methods, however, three potential participants were contacted personally and agreed to participate. In total, fifteen potential participants responded to the initial approach. Six potential participants were excluded for not meeting the inclusion criteria as shown in Table 7 below.

Table 7 Excluded participants profession, work area, method of recruitment and reason for exclusion

Profession	Work area	Method of recruitment	Reason for exclusion
Clinical Psychologist	Pain Clinic	CBT course mailshot	No experience LBP
Physiotherapist	Head Injuries	Flyer at conference	No CBT qualification
Physiotherapist	Pain Clinic	Flyer at conference	No CBT qualification
Physiotherapist	PMP	PPA mailshot	No CBT qualification
Physiotherapist	PMP	PPA mailshot	No CBT qualification
Physiotherapist	MSK	PMP mailshot	No CBT qualification

PMP Pain Management Programme, PPA Physiotherapy Pain Association, MSK Musculoskeletal out-patients

Three potential participants met inclusion criteria but did not respond to the first round questionnaire: two clinical psychologists working in pain management and a physiotherapist working in mental health, all were contacted via mailshot. In total, nine participants took part in the study from two professional backgrounds, clinical psychology and physiotherapy (Table 8).

Table 8 Delphi participants' profession, work area and method of recruitment

Profession	Work area	Method of recruitment
Clinical Psychologist	PMP	Personal Contact
Physiotherapist	MSK	CPMH mailshot
Clinical Psychologist	PMP	Personal Contact
Clinical Psychologist	PMP	CBT course mailshot
Physiotherapist	MSK	CBT course mailshot
Physiotherapist	Mental Health	CPMH mailshot
Physiotherapist	MSK / PMP	PPA mailshot
Physiotherapist	MSK	CBT course mailshot
Clinical Psychologist	Pain Clinic	Personal Contact

PMP Pain management programme, PPA Physiotherapy Pain Association, MSK Musculoskeletal out-patients, CPMH Chartered Physiotherapists in Mental Health

Rounds 1 to 3 were conducted from October 2006 to December 2007.

3.4.2 First round results

The response rate for Round 1 was 100% (9 out of 9).

Participants voted to include 11 of the 12 original items as shown in Table 9 below. Item 6, 'Eliciting of appropriate emotional expression', was voted to be included by six of the nine Delphi experts, the other three experts voted 'unsure'.

Table 9 Voting results of round one; participants asked whether to include each item of the original Cognitive Therapy Scale - Revised

Item	Details	Response	Votes (%)
1	Agenda setting & adherence	Yes No Unsure	8(88.9%) 1(11.1%) 0(0%)
2	Feedback	Yes No Unsure	9(100%) 0(0%) 0(0%)
3	Collaboration	Yes No Unsure	9(100%) 0(0%) 0(0%)
4	Pacing and efficient use of time	Yes No Unsure	8(88.9%) 0(0%) 1(11.1%)
5	Interpersonal effectiveness	Yes No Unsure	9(100%) 0(0%) 0(0%)
6	Eliciting of appropriate emotional expression	Yes No Unsure	6(66.7%) 0(0%) 3(33.3%)
7	Eliciting key cognitions	Yes No Unsure	8(88.9%) 1(11.1%) 0(0%)
8	Eliciting behaviours	Yes No Unsure	8(88.9%) 0(0%) 1(11.1%)
9	Guided discovery	Yes No Unsure	9(100%) 0(0%) 0(0%)
10	Conceptual integration	Yes No Unsure	8(88.9%) 1(11.1%) 0(0%)
11	Application of change methods	Yes No Unsure	8(88.9%) 1(11.1%) 0(0%)
12	Homework setting	Yes No Unsure	8(88.9%) 0(0%) 1(11.1%)

In total 14 extra items were suggested by five experts. These items were subject to content analysis, and collated into nine items.

One expert had suggested three items as alternatives to the original items. The expert had adapted the original item to make it more applicable to the patient group and

requisite skills. In the 2nd round the other experts were asked to vote on whether these alternative items should replace the original items.

Table 10 shows the new or alternative items as suggested by the Delphi experts.

Table 10 Extra items as suggested by Delphi experts

	Item title	
7a	Eliciting key pain relevant cognitions	
8a	Eliciting pain management behaviours	
10a	Developing a cognitive behavioural conceptualisation of the patient's	
	pain related distress and disability	
13	Appreciating patient's model of the problem	
14	Dealing with motivational issues	
15	Facilitating behavioural change	
16	Supporting change	
17	Recognition of professional boundaries	
18	Affect and influence of depression on musculoskeletal patients	
19	Dealing with painful emotions and patient distress	
20	Reflective practice	

Items 7a, 8a and 10a are the alternative items to the original CTS-R items 7, 8 and 10

3.4.3 Second and third round results

The response rate in the 2nd round was 100% (9 out of 9) and the third round was 88.9% (8 out of 9). The responses for the non-responder in the third round were carried forward from their second round responses. After the second round the consensus level was modified to include agreement in six of the nine experts (66.7%). This represented a pragmatic 5% 'rounding up' to the a-priori consensus level of 70%.

Delphi experts voted to replace three of the existing items of the CTS-R with the alternative items as suggested by the Delphi expert. Thus Item 7 'Eliciting key cognitions' became 'Eliciting Key pain relevant cognitions' with an increased focus on

linking thoughts about pain with pain management behaviours, rather than the link between thoughts and distressing emotions as is the focus in the original item.

Item 8 'Eliciting behaviours' was replaced with 'Eliciting pain management behaviours' with the specific focus on linking pain management behaviours with continued disability. This item did not represent a significant shift from the original but rather labelled the behaviours and resultant problem more specifically.

Item 10 'Conceptual integration' became 'Developing a cognitive behavioural conceptualisation of the patient's pain related distress and disability'. The changes to this item are similar to the changes to item 8; however, the item also draws in the use of key pain management models and concepts such as the fear avoidance model.

The Delphi experts voted to include three of the eight optional extra items. These include 'Facilitating behavioural change' which is concerned with the teaching or training of discrete pain management skills such as activity pacing, communication skills, and goal setting. The second additional item 'Supporting change' is concerned with promoting and developing self-management with specific reference to flare-up management. The third item 'Recognition of professional boundaries' is concerned with appropriate and timely referral to other professionals when the individual is outside their scope of professional boundaries.

3.4.3.1 Assessment of stability

Change between rounds for voting of inclusion of items

Agreement in Round 1 was high, leaving only one item (Item 6) that didn't reach consensus.

Change between Round 1 and 2:

Item 6: consensus to include after two experts switched their vote from 'unsure' to 'yes' whist the third switched from 'unsure' to 'no'. One expert that had previously voted 'yes', switched to 'no'.

Change between round 2 and 3:

Item 8a: consensus to include after two experts switched their vote to 'yes' and one switched to 'no'.

Item 13: No consensus and no change in voting

Item 14: No consensus and no change in voting

Item 17: Consensus to include after one expert switched from 'unsure' to 'yes'

Item 20: No consensus, one expert switched from 'yes' to 'no' and one expert

switched from 'no' to 'yes'.

Change between Rounds 2 and 3 for voting of minimum competency score

Figure 4 below shows the change in mean score and standard deviation for each item that did not reach consensus at first vote in Round 2. The graphs show several features indicating stability across rounds 2 to 3: small standard deviations, small changes in mean from Round 2 to 3, and small decreases in standard deviations for each item in Round 3 indicating increasing consensus (135).

Figure 5 below shows a summary of the voting through the three rounds. The final measure, named the CTS-R-Pain, is summarised in Table 11 and in full in Appendix 5.

Figure 4 Graphical representation of stability across Rounds 2 and 3 for the voting on minimum competency

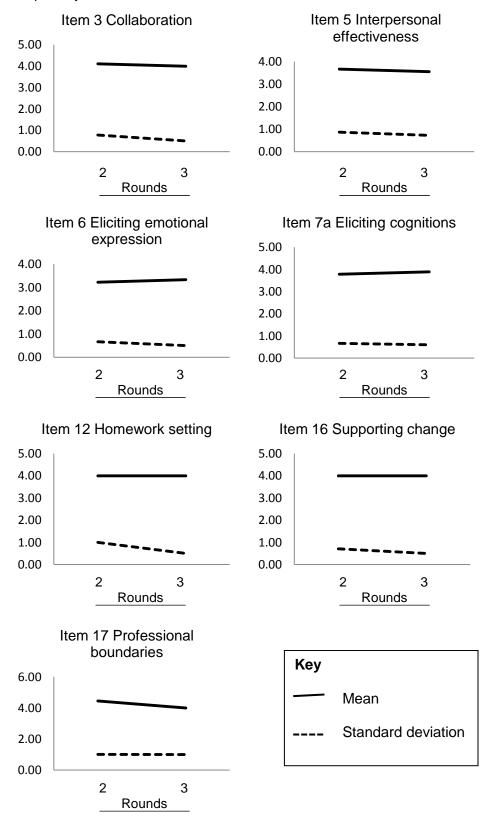


Figure 5 Summary of voting in all three rounds of the Delphi study

ROUND 1

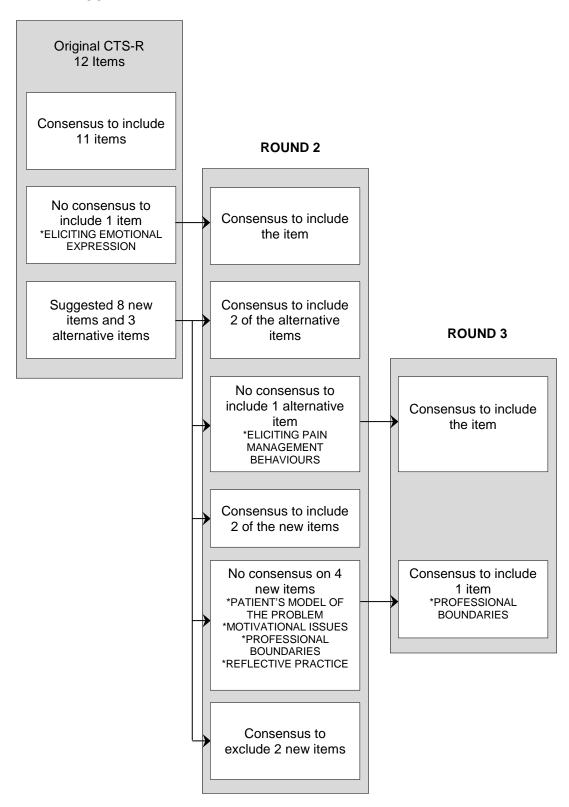


Table 11 Summary of final competency tool Cognitive Therapy Scale - Revised - Pain

	Item title	Minimum
		Competency
1	Agenda setting and adherence	4
2	Feedback	4
3	Collaboration	4
4	Pacing and efficient use of time	3
5	Interpersonal effectiveness	3
6	Eliciting of appropriate emotional expression	3
7a	Eliciting key pain relevant cognitions	4
8a	Eliciting pain management behaviours	4
9	Guided discovery	3
10a	Developing a cognitive behavioural conceptualisation of the	4
	patient's pain related distress and disability	
11	Application of change methods	4
12	Homework setting	4
13	Facilitating behavioural change	4
14	Supporting change	4
15	Recognition of professional boundaries	4

One of the new competency items; item 13 'Facilitating behavioural change', is shown below to provide context of the information provided for each item including the scoring range and anchors.

ITEM 13 - FACILITATING BEHAVIOURAL CHANGE

Key features: Patients may require discrete skills training in order to facilitate behavioural change. These skills or techniques can include communication skills, activity pacing and goal setting skills, time management, and general problem solving.

There is a typical framework to follow with skills training: rationale, instruction, demonstration/modelling, practice, feedback, rehearsal, and generalisation. These require an understanding of behaviour change and learning.

This item also includes, where appropriate, helping the patient devise and carry out appropriate behavioural experiments.

Three features need to be considered:

- (i) the appropriateness and range of skills / techniques being taught in line with the shared understanding of the problem
- (ii) the proficiency demonstrated in the training of skills / techniques
- (iii) the suitability of the skill / technique for the needs of the patient (i.e. neither too difficult nor complex).

Competence Level	Examples NB: Score according to features, not examples!
0	Therapist fails to use or misuses appropriate skills training
1	Therapist trains the patient in either insufficient or inappropriate skills or techniques, and/or with limited proficiency or flexibility.
2	Therapist trains the patient in appropriate skills or techniques, but major difficulties evident.
3	Therapist trains the patient in a number of skills or techniques in competent ways, although some problems evident (e.g. framework for learning the skill incomplete).
4	Therapist trains the patient in a range of skills or techniques with proficiency and flexibility, enabling the patient to develop new perspectives. Minor problems evident.
5	Therapist systematically trains the patient in an appropriate range of skills or techniques in a creative, resourceful and effective manner. Minimal problems.
6	Excellent range and training, or successful training in the face of difficulties.

Minimum competency ratings

Experts were required to vote on minimum competency scores for all items including any items that they had voted not to include. This was done to ensure full responses from all experts as items that they might not want to include could still be included by majority voting from others. The responses were checked to see if there were any patterns in the voting in this situation in case of tactical voting. When experts voted on the competency level required for items they did not want to include, they voted above their overall mean in 11 cases (26.8%), below in 22 cases (53.7%) and around their mean in 8 cases (19.5%). Therefore, the experts had a tendency to downgrade competence levels on items they did not want to include.

Minimum competency ratings were checked for patterns according to profession. As shown in Table 12 both clinical psychologists and physiotherapists voted in a similar pattern.

Table 12 Frequency of minimum competency rating by profession

Minimum competency	Clinical psychologists	Physiotherapists
rating	Count (percentage)	Count (percentage)
2	4(4.3%)	0(0%)
3	31(33.7%)	44(38.3%)
4	45(48.9%)	54(46.9%)
5	11(11.9%)	16(13.9%)
6	1(1.1%)	1(0.9%)

Overall the experts voted for the minimum competency to be at a level 4 in 11 of the competencies and level three in four of the competencies. Only two items did not reach consensus for minimum scores. This was item 5 'Interpersonal effectiveness' and item

15 'Recognition of professional boundaries'. In these two cases a decision was made by the thesis author to use the majority vote.

3.5 Discussion

This Delphi study was successful in that it produced a competency tool to assess physiotherapists' competency in delivering a CB approach in patients with LBP. This discussion will consider the quality of that output and whether alternative methodologies would have improved the quality of the output.

3.5.1 Participants

Arguably the most important stage of a Delphi method study is defining the inclusion criteria for the experts since the quality and expertise of the participants will have a direct relationship with the quality of the output (132). The participants in this study all met tight criteria which adds validity to the output.

The number of participants fell within the recommended number for a Delphi panel by Murphy et al (132) of 6 to 12 participants. However, the range of professions was limited with only physiotherapy and clinical psychology. Although letters were sent to pain management programmes that employ a range of health professionals, recruitment via other professional forums may have been more successful in recruiting a wider range of health professionals. A more heterogeneous group may have increased validity (131).

3.5.2 Choice of consensus method

Delphi methodology was chosen over the Nominal group technique for predominantly practical reasons. There was likely to be a small group of individuals who met the inclusion criteria and as such they would be geographically dispersed. This would present difficulties in organising a face-to-face consensus method and would be likely to further limit participant numbers. The other significant benefit of the Delphi is that it prevents dominant or high status individuals from biasing group opinion (132). This decision is supported in retrospect as the study recruited two participants who are internationally recognised and well published in the field. This could have been a threat to the validity of the results if a face-to-face method was used. However, the Delphi process was limited by the lack of interaction between members. Questionnaire responses frequently had comments attached to the email that explained why the individual felt that the item was important or why they had voted in a certain way. For example, one Delphi expert had voted for a minimum competency rating of six (the highest score) for 'Professional boundaries'. She had written next to this the comment "with my manager's hat on!" The decision was taken not to share these comments with the other Delphi members. In the initial design of the questionnaires there was an option to ask participants for comments or justifications of each decision. Value judgements are complex in these situations and could require significant free text in order to explain them comprehensively. It was felt that in the context of a postal questionnaire that this requirement could reduce the response rate as the task would require significantly more time. In addition, it would only be those individuals that spent the time justifying their responses that would have their opinions heard. A face-to-face consensus method would have allowed for full discussion and progression of ideas but with all the previously noted caveats. An alternative to this has been proposed whereby

online forums for discussion of ideas amongst the Delphi experts have been used (132). Although this process is anonymised it has been found that experts of high status will often identify themselves by discussion of research that they have conducted which is known to the other participants (132).

3.5.3 Stability and convergence

The current study demonstrated some degree of stability with analysis of change between rounds being conducted on the minimum competence scoring in line with recommendations by Greatorex et al (135). In addition there were small changes in voting, towards agreement, on the voting of inclusion of competency items. However, more detailed analysis on the stability could not be conducted due to the number of response items which is a limitation of the current study.

3.5.4 Other methodological considerations

In this study, three rounds were used, although there were items and minimum competency ratings that did not reach consensus by the final round.

A decision was made to limit the Delphi to three rounds as Keeney (145) advised that after two rounds response rate can start to decline, especially in busy experts. This also prevents items being included that did not have enough support initially and are only included due to a prolonged consensus forming process (132).

Competency is defined in the original CTS-R as a score of 3 or 4 in the item rating (116, 122). This study asked the experts to define minimum competency in the new tool for each item as it was assumed that the skill level required for physiotherapists applying a CB approach in LBP would be perceived to be lower than the skill required for fully

qualified therapists applying CB therapy. It is interesting to note that the experts in the study voted in the majority of the competencies (11 of the 15) for a higher competency level, that of a 4. The remaining four competencies were scored at a level 3.

One of the Delphi experts commented on this and postulated that the other Delphi experts had been developing the competency tool for the treatment of the more severe group of patients that are typically seen on pain management programmes. This was expected to be a potential problem due to several Delphi experts being based within pain management programmes, and CB approaches already established in this clinical area. Frequent reminders of the target audience were attached to the questionnaires but this may not have addressed the problem adequately.

Further limitations of the Delphi methodology

Several limitations and strengths of the Delphi method have been discussed in both the introduction to this chapter and this discussion. It is worth noting a further significant weakness is that minority voices are not heard in the final output. The Delphi method assumes that the majority opinion is the best available where there is no other existing evidence (132). This rationale clearly has the potential to be flawed, and in addition, the process of gaining consensus through a Delphi method could lead to the suppression of novel ideas.

3.6 Chapter summary

A Delphi consensus method was used to develop a competency assessment tool in physiotherapists delivering a CB approach in LBP patients. Expert participants who met strict inclusion criteria were recruited through a comprehensive process with minimal

drop out. The experts were drawn from physiotherapy and clinical psychology professions and worked within musculoskeletal and pain management services. The experts voted to include all items of the original CTS-R but adapted three of the items for the specific setting. Eight additional competencies were suggested, of which three achieved consensus on voting and were incorporated into the final measure. The overall minimum competency level was set at a higher level than the original CTS-R.

4 Chapter Four – Validity and reliability of the Cognitive Therapy Scale - Revised - Pain

4.1 Introduction

This chapter will consider validity evidence for the CTS-R-Pain before presenting a reliability study on the CTS-R-Pain tool.

4.2 Validity

The CTS-R-Pain is predominantly a tool to assess the performance of skills with the presumption that a certain level of knowledge/understanding underlies these skills. As such, guidance on its validity assessment is best provided within an educational paradigm. Within the field of education, this change in validity conceptualisation has been encapsulated in the *Standards for Educational and Psychological Testing* introduced in chapter two. Validity evidence for the CTS-R-Pain will now be discussed in relation to each domain outlined in the *Standards* (section 2.1.1).

Evidence based on test content

One way of assessing the validity of content of the CTS-R-Pain is to look at the evidence that the items in the tool reflect the skills contained within a CBT approach for LBP. Whilst there is no definition of a CB approach for LBP the following evidence can be presented to support the content validity of the CTS-R-Pain;

 The original items of the CTS were generated by the originators of the CBT approach and thus reflect generic CBT skills

- Experts who met strict criteria with appropriate qualifications and experience generated the additional items
- New or modified items were written in same style and using same behavioural indicators of competency level (same language) as the original CTS
- The modified and new items directly target key modifiable risk factors described in the literature (catastrophic pain thoughts and passive coping strategies)(20)

Evidence based on response processes

The following points reflect evidence based on response processes for the CTS-R-Pain. Potential sources of bias are highlighted:

- In previous studies the scale of the CTS has been found by users to be simple to use (87). The adaptations are in line with the original scoring and the simplicity would be expected to minimise scoring errors.
- Content analysis of the CTS-R during the Delphi study of each item
 revealed a high level of consistency in the score assigned to each skill
 level in each item, indicating that similar levels of skill need to be
 demonstrated in each competency in order to get the same score.
- No competencies have been identified as significantly more important than others (154) so therefore weighting is inappropriate, however this can be checked with further studies looking at specific competencies as predictors of outcome.
- The minimum competency score per item as defined by the experts in the Delphi study has not yet been validated although it could be expected to be a source of error as it is higher than the levels defined in the original CTS-R (see further discussion in 'Consequences' below).

In order to administer the CTS-R-Pain, a lengthy clinical scenario will be
observed or the audio recording of the session listened to. The
significant amount of time involved in this assessment will need to be
resourced appropriately when used clinically or educationally.

Evidence based on internal structure

With regards to the CTS-R-Pain, the appropriate psychometric assessments are internal consistency and reliability. Reliability refers to the reproducibility of assessment data or scores, over time or occasions (100). There are several different types of reliability that can be assessed to establish reproducibility; within the context of performance assessment it is the rater that is of most interest (100). The rater can be assessed for consistency over time (intra-rater reliability) or can be assessed for consistency with other raters (inter-rater reliability). In addition, when a tool uses many items to generate a scale, the individual items should be assessed for reliability (77, 92). This involves checking that the individual items all measure the same constructs, and as such, correlate with one another (98). This is called internal consistency and is most commonly measured using Cronbach's Alpha (98).

Evidence based on relationship to other variables

As the CTS-R-Pain is a novel tool, there are no gold standards to compare it with and indeed there are no suitable competence tools to use as a comparison either (see Chapter 2). We hypothesised that the competence score determined by the CTS-R-Pain should be related to specific previous experience in CB approaches based on the learning model of deliberate practice presented in chapter one (section 1.7.1). Other validity evidence that can be presented includes the ability of the tool to predict an outcome of

relevance, previously known as predictive validity (95) and this will be examined in chapter five.

Evidence based on the consequences of testing

Within the context of CTS-R-Pain this area is problematic to analyse. Currently the tool has been developed to attempt to define the competencies appropriate in delivering a CB approach in LBP and to explore whether these competencies can be demonstrated in physiotherapists who have undergone two days of training in the approach. The cut off point for 'competent' practice within each competency in the CTS-R-Pain has been selected by experts within the Delphi study.

In summary, validity of any assessment tool can be scrutinised through gathering and synthesising the appropriate evidence; the *Standards* provide a useful framework to do this. The next section of this chapter describes reliability testing of the CTS-R-Pain.

4.3 Reliability testing of the Cognitive Therapy Scale – Revised - Pain

4.3.1 Methodology

4.3.1.1 Overview

In order to be confident in the output of any measurement tool, we need to know that it would measure reasonably consistently over time, contexts and assessors (100). This defines the construct of reliability which is necessary for a tool to be considered valid (92).

Two reliability studies were conducted using recordings of BeST trial group sessions: an intra-rater study and an inter-rater study. An intra-rater study was conducted to ensure that the tool measures consistently within one rater over time (99)p706. The physiotherapists in the recordings were rated using the CTS-R-Pain tool. In the intra-rater study all recordings were rated twice with a significant time delay between ratings. To assess whether the tool produces consistent results regardless of who takes the measurement, an inter-rater study was conducted (99)p707. In the inter-rater study, several assessors rated the same recordings. Statistical analyses were conducted to look for agreement within and between assessors and to calculate internal consistency, a further measure of reliability (99) p708.

4.3.2 Participants and data collection

Physiotherapists delivering the BeST trial group sessions were asked to audiorecord sessions for quality assurance checks and competency assessment. Audio
recording was selected for data collection over direct observation or video recording
for several reasons. Direct observation of a group intervention has the potential to
impact upon group dynamics (155). In addition the therapist can perceive more
pressure to perform and thus their performance can be adversely affected (156).
These issues are shared with video recording of group sessions which is perceived
as more intrusive by participants and therapists (157). In addition, video recording
raises extra issues for ethical approval where participants can be easily recognised
(158). However, both direct observation and video recordings have the benefit of
being able to observe non-verbal communication which is important in the context of
an intervention which focuses on some specific communication skills (159). Audio
recordings in CBT sessions have been found to be acceptable to therapist and

patients alike (160) and are routine as part of CBT training and recommended as part of on-going supervision (159).

Audio and video recordings eliminate one potential cause of measurement error. If the construct being measured varies over time, then the tool measuring it could be evaluated as unreliable. With an audio or video recording this is not an issue.

Audio and video recordings also provide a practical solution for the inter-rater reliability study whereby many raters can assess the therapist easily. On balance, the overall acceptability and ease of use for audio recordings was felt to out-weigh the loss of information on non-verbal communication. However, it is accepted that this may impact on the reliability of any competency items which would be expected to significantly encompass non-verbal communication, such as 'interpersonal effectiveness'.

Digital audio recorders were used (Olympus digital recorder (DM-10)) to record the sessions. These small recorders can be placed on the floor in close proximity to the group and are minimally intrusive.

The choice of sampling method for the recordings raised several issues. Recordings of the same session, for example session number 3, would allow for direct comparison across physiotherapists. However, assessment scores could be inflated if physiotherapists rehearsed for the session that they knew would be recorded. Whilst this would not impact on the reliability studies directly, it would have implications for the follow-on study exploring relationships between competence score and clinical outcome. The contents of each BeST group session were evaluated against the CTS-R-Pain and it was considered that each session offered equal opportunity to demonstrate the competencies contained within the assessment tool. This allowed for a random selection of the sessions to be

recorded, which would be more likely to reflect subject's typical competence level by reducing the chance of selection bias. The session to be recorded was selected using an online random number generator (http://www.random.org/integers/) to prevent any systematic bias that could be introduced through the thesis author or the physiotherapist selecting the sessions to be recorded.

The data collection for this study also served a dual purpose within the BeST trial by checking for adherence to protocol as part of the quality assurance checks necessary in a controlled clinical trial.

4.3.3 Raters

An intra-rater study was conducted by the thesis author who was familiar with the CTS-R-Pain from conducting the Delphi study to develop the tool. At the time of the study, the thesis author had 11 years' experience as a physiotherapist and four years' experience as a CB therapist. All recordings were collected during the BeST trial and initially rated using the CTS-R-Pain over a three week period in January 2008 to improve consistency. The BeST group sessions were up to 90 minutes in duration and rating of each recording took approximately 2 to 2.5 hours. The process of rating over three weeks was repeated after six months to prevent recall of initial ratings.

Participants for the inter-rater study were recruited from the Delphi expert panel (Chapter 3). This eliminated the need to familiarise raters with the CTS-R-Pain and ensured that raters were experienced in the application of CB approaches in LBP as they had met the same inclusion criteria for the Delphi study. The current study was not funded to reimburse participants for their time, and as each recording would take up to 2.5 hours to rate, it was felt that three recordings was a reasonable number to

ask participants to assess. Three recordings were purposively sampled to represent high, medium, and low levels of competence from the ratings done on all recordings during the intra-rater study. This was done to ensure that ratings were representative of the breadth of the potential range of competence (161).

Of the nine Delphi experts invited to take part in the study, three agreed to participate, of which one was a clinical psychologist, and two were physiotherapists working across a mix of pain management programmes and out-patient services. The thesis author was the fourth rater for this study. It was felt that this would not bias the results as the thesis author had already rated the three recordings as part of the intra-rater study and this provided an opportunity to increase the sample size of this study.

A rater information pack was sent to all raters with the relevant software to enable listening to the recordings in addition to full written material detailing the manualised content of each BeST group session. In keeping with the Delphi study, raters were not informed of the other participants in the study to prevent any discussion between them; all ratings were collected independently. Each rater was instructed on a randomly selected order in which to rate their recordings to minimise learning effects impacting on the level of agreement. Ratings were conducted between September and December 2008.

4.3.4 Ethical approval

Ethical approval was applied for and granted though the Central Office for Research Ethics Committees (now called National Research Ethics Service, see Appendix 6). At the initial one-to-one therapist assessment session as part of the BeST trial protocol, patients were provided with information about the audio recording of the

session (see Appendix 7) and written consent was obtained. No group participants or physiotherapists refused consent to record at assessment or at any subsequent time point.

4.3.5 Statistical analysis

All statistical analysis used SPSS (version 15). Prior to data analysis all data were double entered into a spread sheet for accuracy and visually checked for plausible values as part of data cleaning (162).

Assessment of inter-rater reliability involves an assessment of the amount of agreement between raters when they use the assessment tool. Reliability is calculated as a ratio of the variation between subjects to the total variation (which is the sum of subject variation and measurement error). The resultant reliability coefficient expresses the proportion of the variation that is due to 'true' differences between subjects. The choice of statistical test to calculate the reliability coefficient in this context has been widely debated within the literature (101). Pearson's correlation coefficient is based on a regression analysis and is used erroneously in reliability studies using continuous data. It has been criticised for 'measuring the strength of relation between two variables, not the agreement between them' (163) and as such systematic biases in the agreement can be obscured in the analysis. Where there are multiple observers within a study, the Pearson's correlation coefficient will calculate the agreement between pairs of observers which can be useful for identifying outliers. However, as there is no agreed way of combining the coefficients of paired observers (101) and given the previous caveats, the Pearson correlation coefficient is unsuitable for use in this study.

The intra-class correlation coefficient (ICC) overcomes these problems and has varying forms according to the assumptions that are made. In this analysis, an ICC [2,1] was used where the 2 is 'class 2' to reflect that all subjects were rated by all raters and the 1 to reflect that it is the reliability of a single rater (164). Raters were treated as a random factor. These tests rely on the data having a normal distribution (i.e. parametric), this assumption was checked prior to analysis by visual checking of distribution graphs and quantitative analysis of the data using a Shapiro-Wilk W test as this statistic is suitable for small samples (162).

Internal consistency was assessed using Cronbach's Alpha (98). Within Cronbach's Alpha, the means and standard deviations of each item from the assessment tool are assessed for correlation. Perfect correlation = 1, for clinical applications, scores of $\alpha > 0.95$, indicating high internal consistency, are desirable (98). The following calculation was used:

$$a = \frac{k}{k-1} \left(1 - \frac{\sum s_i^2}{s_T^2} \right)$$

Where k is the number of items, s_i^2 is the variance of the ith item and s_T^2 is the variance of the total score formed by summing all the items.

Justification of analysing the data as continuous

Each competency item within the CTS-R-Pain is scored on a 0-6 scale that is broadly comparable for competence levels across each item. Thus scoring on each item is ordinal; however, each increment on the scoring system represents an increment of increasing competency with 'anchor points' at each end. There is some debate as to whether the data collected from such scoring systems should be analysed as continuous data or as ordinal data. Kinnear and Gray (165) consider that the decision will depend on several factors including the distribution of the data

and the number of points on a scale. The CTS-R-Pain has a relatively large number of points, seven, and would therefore approximate to the normal distribution. As a result, it was decided a priori to analyse the data as continuous using the ICC if the data were normally distributed (parametric). In the case of the data being non-parametric then the Kappa statistic would be applied.

Other analyses

Validity evidence for the CTS-R-Pain can be provided by finding relationships between the CTS-R-Pain output and other variables expected to correlate with competence. It could be hypothesised that competency might be related to:

- Previous biopsychosocial attitudes and beliefs that fit in with the culture of a CB approach (3)
- 2) Previous relevant experience (68)

Attitudes and beliefs were measured using the *Pain Attitudes and Beliefs Scale* – *Physiotherapists* (PABS-PT; (51)) prior to the training course for the BeST trial. The scale measures relative rates of biomedical and biopsychosocial beliefs with lower scores indicating more biopsychosocial beliefs. The tool is reported to have good validity and reliability (166). We could expect that higher levels of biopsychosocial beliefs are positively correlated with greater competence.

Previous experience of running similar groups was determined by the physiotherapist as a yes/no answer on a data collection form prior to the training course. We would predict that specific experience would be correlated with competence due to the theories of deliberate practice (70) outlined in Chapter 1 (section 1.7.1).

Correlational analyses were conducted to explore the hypothesised relationships between competence and physiotherapist beliefs and previous specific experience.

Sensitivity and responsiveness of the tool were investigated using a one way ANOVA and one-sample t-test respectively. However, due to the small numbers of measurements available for these tests they were considered at high risk of error and have not been reported.

4.4 Results

Eleven of the fourteen physiotherapists delivering the back skills training intervention provided recorded sessions for the reliability study. The three physiotherapists who did not provide tapes had started delivery of groups before the reliability study had been designed, and had not recorded the sessions. The demographic details of the included physiotherapists are shown in Table 13.

Table 13 Characteristics of the 11 physiotherapists who delivered the Back Skills Training trial intervention (based on data for 2006)

Therapist code	Age	Gender	Years qualified	Grade	Experience of running similar groups	Number of groups run in trial	
1	31	F	9	Senior I	Yes	12	
2	43	M	10	ESP	Yes	5	
5	45	M	14	Senior I	No	4	
6	42	F	9	Senior I	No	5	
7	52	F	31	Senior I	Yes	6	
11	33	F	12	Clinical Specialist	Yes	3	
12	43	F	21	Clinical Specialist	Yes	3	
15	24	M	2	Senior II	No	1	
16	29	F	7	Senior I	No	2	
18	46	F	25	Senior I	No	3	
19	37	F	12	Senior II	No	3	

NB; Grade provides the level at which the therapist is working within the NHS, with increasing levels of responsibility and expertise the titles of the grades are Junior, Senior II / Band 6, Senior I, Clinical Specialist / Extended Scope Practitioner (ESP) / Band 7. Gender; M = Male, F = Female

The reliability study commenced approximately half way through the main BeST trial when there were 33 groups still to be delivered. Ten of these groups were felt unsuitable for recording due to several reasons; potential bias associated with a large

number of recordings from one therapist (eight groups excluded on this basis), one physiotherapist was very nervous delivering her first group and recording was felt to be likely to adversely affect performance, one group was felt to be non-representative as it ended up with two participants and was condensed into four sessions. A further six groups were not recorded due to forgetting to record (4), communication mix up (1) and unknown reason (1).

Of the potential 33 groups that could have been recorded, 17 were recorded which comprised six physiotherapists who recorded two groups and five physiotherapists who recorded one group.

The results of scoring the 17 session recordings using the CTS-R-Pain are shown in Table 14.

The recordings broadly represented a spread of sessions 1 to 6 with a majority of the groups run on a Tuesday with a spread across times and location. Within the BeST trial, no relationship was found between attendance/competence and the day/venue/time variables (88).

4.4.1 Normality testing

Many of the individual competency items showed a normal distribution (Figure 6 and Figure 7 below) although two were skewed: item 6 and item 14. This is in line with expectations as item 6 is more often associated with complex CBT processes (Eliciting of appropriate emotional expression) and item 14 is about teaching self-management, the focus of the BeST trial intervention.

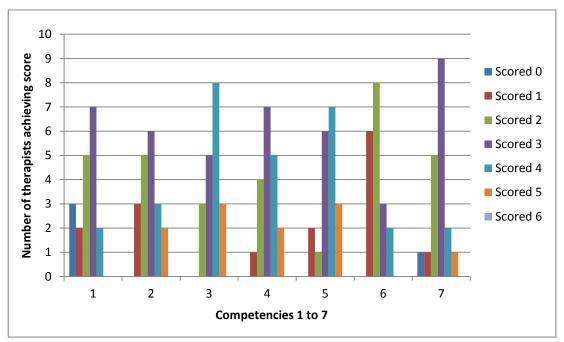
Table 14 Results from the 1st rating in the intra-rater reliability study; scores achieved on Cognitive Therapy Scale-Revised-Pain for each recording

Therapist code	Session (1-6)	Group	Day/Venue/Time	CTS-R-Pain Item number				Total score	Mean score											
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15		
12	1	2 of 3	Weds/Comm/6-8pm	3	2	4	4	4	2	2	2	3	1	n/a	3	n/a	3	n/a	33	2.8
18	1	3 of 3	Fri/Comm/4-6pm	2	3	3	3	3	1	2	2	3	2	n/a	3	n/a	3	n/a	30	2.5
19	2	2 of 3	Tues/Comm/10-12am	2	1	2	2	1	1	1	2	1	2	1	1	2	2	n/a	18	1.3
11	2	3 of 3	Tues/Comm/10-12am	3	4	5	5	4	2	3	4	3	3	1	3	4	4	n/a	48	3.4
5	2	3 of 4	Tues/PCT/2-4pm	2	3	3	3	3	2	2	3	3	2	1	1	2	3	n/a	33	2.4
7	2	3 of 6	Tues/PCT/4-6pm	3	2	4	3	5	1	3	3	4	3	2	1	3	3	n/a	40	2.9
18	3	2 of 3	Friday/Comm/4-6pm	0	2	2	3	2	1	2	2	2	2	2	0	2	1	n/a	23	1.6
6	3	4 of 5	Tues/PCT/2-4pm	1	1	3	2	3	1	2	1	2	1	1	1	1	1	n/a	21	1.5
1	3	12 of 12	Tues/Comm/4-6pm	4	5	5	4	5	4	5	5	5	5	4	3	4	4	n/a	62	4.4
16	4	1 of 2	Thurs/Comm/4-6pm	3	3	4	3	3	2	4	4	3	3	3	3	4	3	n/a	45	3.2
12	4	3 of 3	Tues/PCT/4-6pm	0	3	4	4	4	3	3	4	3	4	3	2	4	4	n/a	45	3.2
5	4	4 of 4	Tues/PCT/2-4pm	2	2	3	2	3	2	3	3	2	3	2	2	2	3	n/a	34	2.4
15	5	1 of 1	Mon/PCT/12-2pm	0	1	2	1	1	1	0	0	1	1	0	1	0	0	n/a	9	0.6
1	5	5 of 12	Thurs/PCT/2-4pm	4	4	5	5	5	4	5	5	4	5	3	2	3	3	n/a	57	4.1
2	5	5 of 5	Fri/Comm/8-10am	3	3	4	3	4	3	4	3	2	4	2	2	3	3	n/a	43	3.1
11	6	2 of 3	Tues/Comm/10-12am	3	5	4	4	3	2	4	4	3	4	3	n/a	4	4	5	52	3.7
7	6	5 of 6	Fri/PCT/4-6pm	1	4	4	3	4	2	3	3	3	3	2	n/a	3	4	n/a	39	3.0
		1	Mean	2.2	2.8	3.6	3.2	3.4	2.1	2.8	3.0	2.7	2.8	2.1	2.0	2.7	2.8	5		

Group indicates which group was recorded out of the total number of groups that the physiotherapist delivered in the BeST trial, Day/Venue/Time indicates when the group took place with *Comm* indicating a community setting such as a church hall and *PCT* indicating healthcare premises

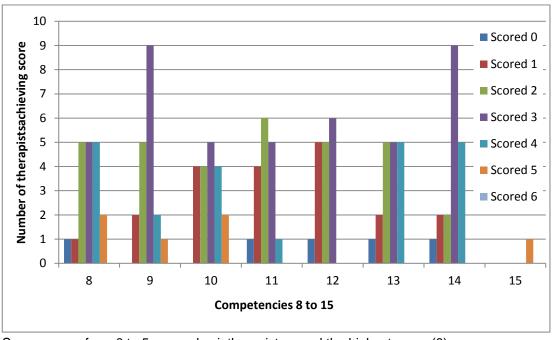
n/a indicates that the item was scored as *not applicable* as the item could not be tested in the session e.g. homework setting on the last session or the situation did not arise to be assessed e.g. item 15 which scores how well a physiotherapist copes if the subject matter goes outside their professional boundaries.

Figure 6 Scoring patterns for each item on the Cognitive Therapy Scale-Revised-Pain; competency items 1 to 7



Scores range from 0 to 5 as no physiotherapist scored the highest score (6) on any assessment

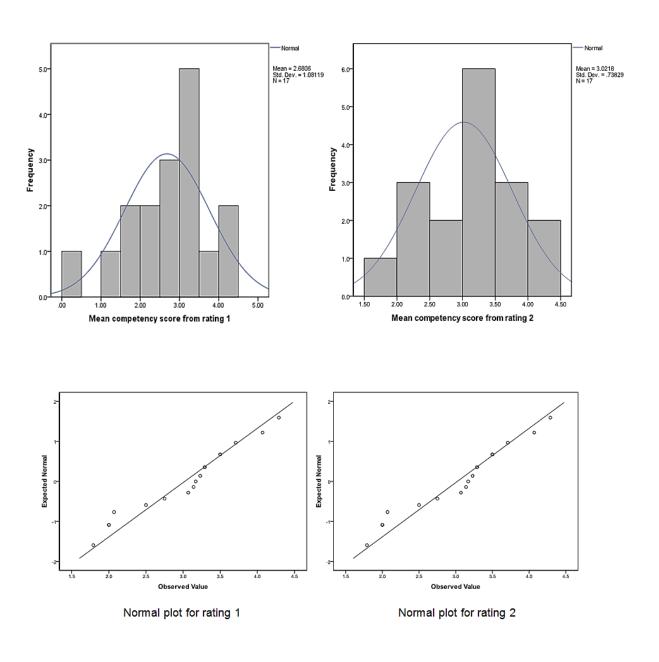
Figure 7 Scoring patterns for each item on the Cognitive Therapy Scale-Revised-Pain; competency items 8 to 15



Scores range from 0 to 5 as no physiotherapist scored the highest score (6) on any assessment

The overall mean competency scores were tested for normality by producing histograms and normal plots shown in Figure 8. This revealed a normal distribution confirmed by a Shapiro-Wilk W test for normality (Rating 1; W = .962 P = .662 and Rating 2; W = .944 P = .369).

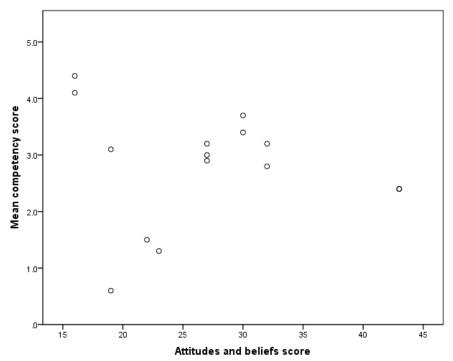
Figure 8 Histogram and normal plots of mean competency scores (using Cognitive Therapy Scale-Revised-Pain) for recordings 1-17 in ratings 1 and 2



4.4.2 Relationship to other variables (other factors expected to correlate with competence)

Pain Attitudes and Beliefs Score – Physiotherapist (PABS-PT) varied between 16 and 43 (mean 25.8) where a lower score indicates more biopsychosocial beliefs. Figure 9 below shows a scatterplot of mean competence score vs PABS-PT score with no identifiable correlation, this was confirmed with a non-significant Pearson correlation (p=.160). This refutes the prediction of a relationship between prior levels of biopsychosocial beliefs and competence.

Figure 9 Scatterplot of mean competence score (Cognitive Therapy Scale-Revised-Pain) vs Pain Attitudes and Beliefs Score - Physiotherapist



N.B. PABS-PT Physiotherapist Attitudes and Beliefs Score taken pre-training. Lower score indicates better attitudes and beliefs. Missing data from 1 therapist.

Five physiotherapists reported experience of running similar groups. This was positively correlated to the mean competency scores and is shown in a boxplot below (Figure 10). An independent samples T-test found a mean difference of 1.58

(95% confidence interval 0.55-2.60 p= 0.007) indicating that mean competence score was able to discriminate between those with previous experience, or not, in the anticipated direction.

4.04.02.01.0Yes

Experience of running a similar group

Figure 10 Box plot of experience of running a similar group vs. mean competence score (Cognitive Therapy Scale-Revised-Pain)

4.4.3 Study 1 – Intra-rater study

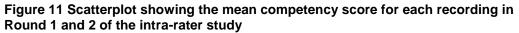
Results from the intra-rater study are presented in Figures 11-13 below. Figure 11 shows a scatterplot to demonstrate the variation from Rating 1 to 2 for each recording. This shows that most ratings had small variation apart from one outlier with a very large variation (recording 13).

When ratings 1 and 2 are plotted against each other in the scatterplot of Figure 12 there appears to be good correlation. However, this type of plot has been criticised by Altman (167) as having limited value in interpreting the data. An alternative

method involves plotting the difference in the ratings against the average of the ratings. This allows a visual inspection of the data to check that the differences between the two ratings do not alter as the competence score increases. This is shown in Figure 13 and reveals that lower scores may have been increased on second rating whereas higher scores may have reduced on second rating. This is possibly the effect known as 'regression to the mean' where outlier variables will have a tendency to move towards mean values on repeated measurements (168). To make the variation clinically meaningful, Altman suggests that 95% limits of agreement should be calculated by;

 $mean \pm 2s_{diff}$ where the mean of the differences is 0.341 (SD 0.465) which gives; $0.34-2 \times 0.465$ to $0.34+2 \times 0.465$ which is -0.59 to 1.27.

So we would expect that a new recording would be rated within a 1.3 mean score on repeated ratings, with the discrepancy more likely towards a higher rating.



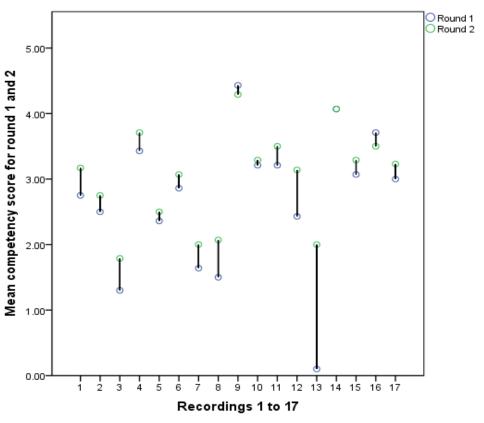


Figure 12 Mean competency score (Cognitive Therapy Scale-Revised-Pain) from rating 1 plotted against rating 2

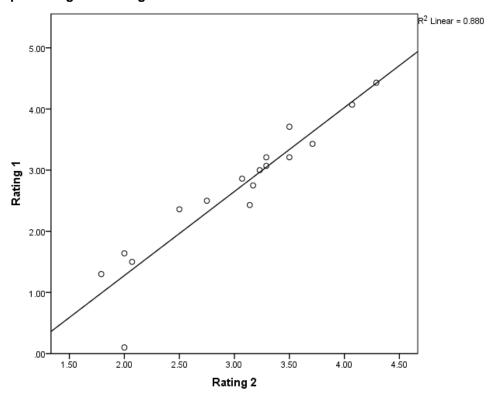
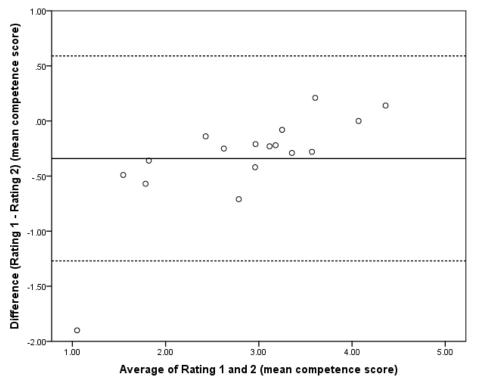


Figure 13 Difference between mean competence score (Cognitive Therapy Scale-Revised-Pain) in rating 1 and 2 plotted against average rating (rating 1 + rating 2)/2



N.B Solid intercept line shows mean difference, dashed intercept line shows the 95% confidence intervals (Limits of Agreement – LoA)

The higher scores seen on the second rating could be due to a learning effect as raters may become more attuned to the scoring criteria with successive ratings.

The results are summarised with the ICC values below in Table 15. The intra-rater study showed very good levels of agreement, although confidence intervals are quite wide.

Table 15 Intra-rater reliability correlation scores by competency item and total score (Cognitive Therapy Scale-Revised-Pain)

Competency / Skill from CTS-R-Pain	Intraclass Correlation	95% Confidence Interval	F Test Significance	Strength of Agreement**	
Agenda Setting and Adherence	.906	.760965	.000	Very good	
2. Feedback	.686	.320873	.001	Good	
3. Collaboration	.934	.827975	.000	Very good	
Pacing and efficient use of time	.471	.003769	.024	Moderate	
5. Interpersonal effectiveness	.850	.634943	.000	Very good	
6. Eliciting of appropriate emotional expression	.850	.634943	.000	Very good	
7. Eliciting key pain relevant cognitions	.784	.499916	.000	Very good	
8. Eliciting pain management behaviours	.678	.307870	.001	Good	
9. Guided discovery	.731	.400893	.000	Good	
10. Developing a CB conceptualisation	.752	.438903	.000	Good	
11. Application of change methods	.797	.497927	.000	Good	
12. Homework setting	.806	.516930	.000	Very good	
13. Facilitating behavioural change	.668	.255875	.002	Good	
14. Supporting change	.624	220845	.003	Good	
15. Recognition of professional boundaries	*Unable to assess				
Total score	.919	.792970	.000	Very good	

N.B Using single measures *Only one score on one tape. Too few for analysis

4.4.4 Internal consistency

Cronbachs alpha was calculated as 0.99, therefore the CTS-R-Pain shows a high degree of internal consistency.

^{**}Interpretation according to Altman (167)

4.4.5 Results Study 2 Inter-rater reliability

All four raters completed the inter-rater study; the results of the ICC analysis are shown in Table 16 below.

Table 16 Inter-rater reliability study correlation scores by competency item and total score (Cognitive Therapy Scale-Revised-Pain)

Competency / Skill from CTS-R-Pain	Intraclass Correlation	95% Confidence Interval	F Test Significance	Strength of Agreement**
Agenda Setting and Adherence	.765	.188993	.05	Good
2. Feedback	.524	068981	.46	Moderate
3. Collaboration	.880	.443997	.001	Very good
Pacing and efficient use of time	†229	470845	.671	Poor
5. Interpersonal effectiveness	.941	.546998	.02	Very good
6. Eliciting of appropriate emotional expression	.385	-1.49972	.098	Fair
7. Eliciting key pain relevant cognitions	.842	.342995	.002	Very good
8. Eliciting pain management behaviours	.556	045983	.037	Moderate
9. Guided discovery	.700	.096990	.011	Good
10. Developing a CB conceptualisation	.667	.057989	.016	Good
11. Application of change methods	.528	066982	.044	Moderate
12. Homework setting	.730	.136991	.008	Good
13. Facilitating behavioural change	.528	066982	.044	Moderate
14. Supporting change	.167	395954	.309	Poor
15. Recognition of professional boundaries	*No variance			
Total score	.823	.298995	.002	Very good

N.B Using single measures

The strength of agreement found using the ICC was very good when using the total score. Individual items ranged from poor to very good, with 11 of the 14 items showing moderate agreement or greater. However, as for the intra-rater study, the

^{*} No variance in score across all raters as item rated as not applicable in all 3 recordings therefore unable to calculate the ICC

^{**}Interpretation according to Altman DG (1991)

[†]Negative values in an ICC are theoretically impossible as the between and within-subject variation included in the analysis cannot have negative values, however it is observed (169) and indicates poor agreement.

confidence intervals are very wide and many cross 0 and so these results have to be interpreted with caution. To explore the impact of the items with poor reliability on the overall mean score further checks were conducted. Items that had poor reliability or where the confidence interval crossed 0 were removed leaving the following items; 1, 3, 5, 7, 9, 10, 12. The mean total scores generated using these 7 items were compared with the mean total scores from the full 15 item tool. This difference was 0.17 (range 0 to 0.43 SD 0.12) in the intra-rater study and 0.20 (range 0.03 to 0.81 SD 0.21) in the inter-rater study. Therefore, removing the items with low reliability did not considerably alter the mean competency score.

The scatterplot shown in Figure 14 below gives a visual representation of how the scoring varied between raters and recordings.

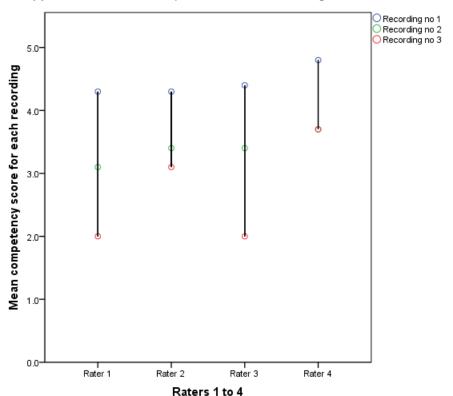


Figure 14 Scatterplot to show variance in mean competency ratings (Cognitive Therapy Scale-Revised-Pain) across the 3 recordings for all 4 raters

N.B. In rater number 4, the red dot represents the mean for both recording number 2 and 3 which achieved the same mean score.

There appears to be greater agreement between raters for the two highest scoring recordings, recording 1 shown as a blue dot and recording 2 shown as a green dot (mean scores ranged from 4.3 to 4.8 and 3.1 to 3.7) and the greatest variance in the lowest scoring one, recording 3 shown as a red dot (mean scores ranged from 2.0 to 3.7).

4.5 Discussion

In the introduction to this chapter evidence was presented on the validity of the new competence tool. This was presented in line with the *Standards for Educational and Psychological Testing*. Two reliability studies were then conducted to look at how the tool performed in practice within the population it was designed to assess: physiotherapists, delivering a cognitive behavioural approach with LBP patients. This discussion will review the findings of the reliability studies with reference to similar research on versions of the CTS. In addition, the limitations of the current study will be appraised.

4.5.1 Comparison with other studies

One of the first studies to examine the reliability of the CTS was conducted by Dobson, Shaw and Vallis (118) where four CBT experts rated 21 recordings. They found high internal consistency (Cronbach's alpha .95) and Pearson correlations for each item ranging from .54 to .87 and a correlation of .94 for the total score. The same research group conducted another study where five experts rated 10 recordings of trainee therapists and found lower reliability scores for individual items using an intra-class correlation coefficient (ICC .27 to .59)(119). The use of a Pearson correlation may have inflated agreement in the first study compared to the second which used an ICC.

Blackburn et al (121) found an overall inter-rater reliability of 0.63 for the CTS-R (using an ICC). This is somewhat lower than the current study which found correlation of 0.82 and could be explained by two effects that have the potential to deflate reliability coefficients. If the sample in question has a wide variation in competence levels then raters will appear to be closer in agreement even when large differences occur. For that reason a narrower band of competence can artificially deflate agreement (161). Nearly all the therapists in the Blackburn trial were on higher level CBT training and we would expect them to be similar in competency level although ranges of the raw data were not presented which precludes checking this assumption. In addition, whilst four raters each rated 51 recordings in total, the sampling method meant that only 17 recordings were rated by each pair of raters. The correlation coefficients achieved between each pair of raters was averaged out to produce the overall correlation coefficient. With increasing raters comes increased opportunities for agreement and thus using average correlation coefficients from two raters may have deflated the agreement levels.

In contrast a high level of agreement was found by a group of authors who modified the CTS over two stages for use in psychosis (125, 126). They removed several skills from the original CTS as they felt these inappropriate to the client group; pacing, empathic skills, and case conceptualisation. Two items were combined into one; use of cognitive interventions and the use of behavioural interventions, and a new item relating to the overall quality of the intervention was added. The resultant tool, the CTS-Psy, was 10 items long and underwent reliability testing by four raters assessing five audio recordings from trainees undergoing specialist CBT training for patients with psychosis. Inter-rater reliability was very good for the total score (ICC 0.94) and moderate to very good for individual competencies (ICC range 0.41 to 0.95). There was no discernible pattern in the reliability of individual competencies

between the Haddock study and the current one. One reason for the high levels of correlation seen in the Haddock study could be due to the 'intensive training' for raters in addition to a manualised approach for tool use. In support, Barber et al (86) observed that many studies appear to show greater levels of inter-rater reliability when the raters work together, which is typical practice within clinical trials but less so in clinical training programmes.

At the same time as the CTS-Psy was developed, the original CTS was revised into the CTS-R (121). These two tools were directly compared in a study by Gordon (87). In this study a pool of nine raters were randomly selected to rate 26 recordings (two ratings for each of the 26 recordings). The ICC for the CTS-R was relatively low at .38 (95% CI .01 - .67) but rose to .76 (CI .33 - .94) when the authors excluded raters who had not attended training sessions on the use of the CTS-R. This finding is in line with a study which demonstrated increased reliability of the CTS-R after a 3.5 hour training session (123). In this study 24 students submitted two videotaped recordings to be rated, one prior to the raters training session and one subsequently. A pool of 10 raters then assessed approximately four tapes each. The Pearson's correlation rose from .44 pre-training to .67 post training for overall score although a wide variation was seen in individual competency items which were reduced by the training (pre-training range -0.04 to 0.59 and post training range 0.26 to 0.62). No specific pattern can be seen between the reliability for the individual competency items in the Reichelt study and the current one although the same item achieved the lowest reliability score; pacing/efficient use of time. This may reflect a poorly defined competency.

High levels of internal consistency were seen in the data presented in this thesis on the Cognitive Therapy Scale (86); this may imply a high degree of overlap of the items and skills. Alternatively, the internal consistency could have been inflated by the halo effect where a rater has decided a level of competency for a physiotherapist and is then influenced on this for each competency item and clusters all scores around that level (121).

Overall, the reliability scores within this study are encouraging given that the raters did not have extended training to use the tool or worked together. In addition, many of the reliability studies described used Pearson's correlations which could have inflated agreement compared to the ICC.

Whilst the CTS-R and CTS-R-Pain have high levels of total score reliability, the individual items can be very variable. However, all results have to be interpreted with caution due to the small sample size, and resultant wide confidence intervals, discussed further in the limitations section below.

4.5.2 Correlation with other factors

The pain attitudes and beliefs scale did not correlate with the competency score as expected. This could indicate that practitioners can hold relative biomedical beliefs about pain and still be competent at delivering a biopsychosocial approach, or alternatively, they can hold biopsychosocial beliefs but that their behaviour is still relatively biomedical as in the Stevenson et al study (54) described in section 1.6.3. Another explanation for the lack of relationship between beliefs and competence could be that the time point for collection of data on beliefs could be significant. The questionnaire was administered prior to the BeST training course. Overmeer et al (53) found that the biomedical beliefs of physiotherapists shifted significantly to more biopsychosocial beliefs over an eight day training course in biopsychosocial approaches. In addition, beliefs may have simply shifted over time as the recordings

would have been collected over the course of the trial, a period of up to two years between physiotherapist training and the last groups.

In this study, previous experience of delivering similar groups was found to be correlated with competence scores. Similar findings were observed when the CTS-R was used to assess competence in a study examining moderators of competence in CBT trainees (68). It was only the number of patients that the trainee had previously treated with CBT that significantly predicted competence.

4.5.3 Methodological considerations

In both the intra-rater and inter-rater reliability studies, the reliability coefficients were very good. Whilst this finding is encouraging for the CTS-R-Pain, it may be inaccurate as both studies are limited by low power which increases the chance of error. The sample size was one of convenience due to the extensive time required to rate each recording and the limited number of people who could be recruited without further training. However, in order to assess the risk of error a sample size calculation was conducted and is shown in Box 1 below (170). For this calculation the null hypothesis (H0) was set at 0.21 as the minimally acceptable level of agreement which according to Altman (167) represents fair agreement. The hypothesis (H1) was set conservatively as 0.41 as a desirable level of agreement (moderate agreement, again according to Altman). The power calculation shows that there is a 1 in 20 risk of a type 1 error (false positive) and with 49% power; a 1 in 2 risk of a type II error (false negative).

Box 1 Sample size calculation for the inter-rater study

Walter, Eliasziw, and Donner (171). This method is simplified version of the original method of calculating sample size as described in Donner and Eliaswiz (170) and has adequate agreement with the original.

The calculation is;

$$K = 1 + \frac{2(\mu_{\alpha} + \mu_{\beta})^{2}n}{(\ln Co)^{2}(n-1)}$$

As the sample size and number of raters are fixed, the calculation can be rearranged to produce a constant value for the power.

The calculation is now;

$$\frac{\textit{K}-1}{2(\mu_{\alpha}+\mu_{\beta})^{2}} = \, \frac{\textit{n}}{(\textit{In Co})^{2}(\textit{n}-1)}$$

In order to calculate the power of the study, different values of β are imputed until both sides of the calculation are equal.

Where;

```
\begin{array}{l} \rho_0 = 0.21^* \\ \rho_1 = 0.41^{**} \\ \alpha = 0.05 \\ \beta = 0.52 \\ n \; (recordings) = 3 \\ K \; (raters) = 4 \\ \theta_0 = \rho_0 / \; (1 - \rho_0) = 0.21 / \; (1 - 0.21) = 0.2658 \\ \theta = \rho_1 / \; (1 - \rho_1) = 0.41 / \; (1 - 0.41) = 0.6949 \\ Co = \; (1 + n\theta_0) / \; (1 + n\theta) = \; [1 + (3x0.2658)] / \; [1 + (3 \times .6949)] = 0.5827 \\ \mu_\alpha = 100(1 - \alpha) = 100(0.95) = 95 = at \; the \; 95\% \; point \; in \; the \; cumulative \; unit \; normal \; distribution = 1.6449 \\ \mu_\beta = 100(1 - \beta) = 100(0.48) = 48 = at \; the \; 48\% \; point \; in \; the \; cumulative \; unit \; normal \; distribution = 0.0490 \end{array}
```

$$\frac{(4-1)}{2(1.6449+0.0490)^2} = \frac{3}{(In0.5827)^2(3-1)}$$

0.5889 = 0.5833

*Fair and ** Moderate agreement according to Altman (167)

The audio recordings of the intervention provided a stable format for this reliability study with minimal intrusion although video recordings could have provided further nonverbal information to add to the reliability of the scoring. The relative reliability of both methods could easily be investigated by both audio and video recordings being rated independently to observe the level of bias introduced with the lack of nonverbal information. To the best of the authors knowledge this has not been investigated despite the debate in the literature about which method of data collection is most reliable (159).

4.5.3.1 Minimum level of competency

For those completing postgraduate diplomas or certificates in CBT the original CTS and CTS-R defines minimum competency as items generally scoring three. Within the Delphi study the level of minimum competency was defined by the experts as most items scoring four with some items scoring three (see Table 11). Using the Delphi study minimum score, none of the 17 recorded sessions demonstrated this level of competence (although the two recordings from the thesis author dual trained as a physiotherapist and CBT therapist only fell short on one item; homework setting). Eight recordings made by six physiotherapists achieved a mean score of over three (Table 14) which would put them on a par with those undergoing the post graduate training. Five of the six physiotherapists achieving this score had only received minimal formal training in CBT approaches. This could either mean that a high level of competence was achieved with minimal training in half of the BeST therapists, or that the scores were relatively inflated compared to CBT trainees. Streiner and Norman point out that the reliability of a measure only applies to the population it is tested in (101). Therefore we cannot make presumptions on comparing the competence levels in the different populations that the CTS-R or CTS-R-Pain will be applied to. The issue that no physiotherapists achieved all item

minimum competence scores in our cohort may indicate that the level has been set too high, or that none of the physiotherapists were indeed competent enough. This issue can be investigated by exploring what level of competence is required to observe a change in outcome in the target population. This will be the focus in chapter 5.

Comparison of CTS-R-Pain with AERA Standards

Each domain from the Standards is presented below with a discussion of the existing validity evidence.

Evidence based on Test Content

There is strong evidence supporting the CTS-R-Pain in this domain. The tool was adapted from an existing tool that was developed by the originators of CBT (116). As such, the items reflect the key skills advocated in the delivery of CBT and the original tool, the CTS-R, continues to be widely used in CBT training programmes (87). The new tool contains all of the original 12 competencies with 3 of them adapted to be more specific to the patient population with an additional 3 skills, also specific to the patient and professional population. This close alignment to the original tool provides evidence on the validity of the test items. In addition, the way that the items were selected for inclusion, from a pool of items generated by the experts, is also in line with the Standards (92)p44. The Delphi study used a transparent and thorough methodology in the recruitment and inclusion criteria for the experts involved in developing the tool, also in line with the Standards (92)p19. The final tool was detailed with a rating scale with descriptors, scoring criteria and a consensus on a competency cut point for interpretation of the score achieved (92)p44. However, it is acknowledged that interpretation of the minimum competency score requires further research. In line with the Standards, the tool was tested in a clinical setting, although the treatments were delivered as part of a trial (92)p44.

Evidence based on response processes

This evidence for the CTS-R-Pain in this domain is mixed. The scoring criteria in each competency item is highly consistent, and experts reported that the tool was easy to use overall, in line with recommendations from the *Standards* (92)p47. Whilst the inter-rater reliability was good, this does not ensure that each expert is indeed interpreting each item in the same way. This can only be established through the use of a detailed user manual and/or training programme followed by user interviews to check the interpretation of each point (92)p47-48,68 (77). This work has not been conducted yet and is therefore an area for development.

Evidence based on Internal Structure

There is fair evidence within this domain for the CTS-R-Pain. The intra-rater and inter-rater reliability studies were well designed utilising recordings from appropriate treatment sessions which were assessed by professionals likely to be typical users of the tool (92)p33. Furthermore, those using the CTS-R-Pain in the inter-rater reliability study did not receive training on the tool or work closely together. This is likely to reflect how the tool will be used in practice which could be seen to provide support for the reliability scores that were achieved. However, the study did not recruit as many participants to the inter-rater study as desired and so the results were underpowered. The number of available measurements also limited further psychometric analysis. Cronbach's Alpha (98) was conducted and showed high levels of internal consistency but the further analyses recommended by the *Standards*: Item Response Theory, Rasch Analysis and Differential Item Function techniques could not be conducted (92)p45. Further work with a larger sample

needs to be conducted on the CTS-R-Pain to provide further validity evidence on the psychometric functioning of the tool.

Evidence based on relationship to other variables

There is some evidence within this domain as discussed in section 4.5.2. As there is no other specific competence tool to use as a comparison, evidence needs to be gathered alternatively in variables expected to correlate with competence (92)p20. The competence scores as assessed by the CTS-R-Pain correlated positively with specific previous experience as would be expected (68). Correlation with relative biomedical/biopsychosocial beliefs was not supported and potential reasons for this were discussed in section 4.5.2. This domain also includes the ability of the tool to predict an outcome of relevance, sometimes referred to as predictive validity (95). The outcome of interest in this thesis is whether competence can predict patient clinical outcome, and this is the focus of the next chapter.

Evidence based on the consequences of testing

The CTS-R-Pain has no evidence within this domain.

Feedback on skills has been found to improve performance, both in students and their teachers (72)p436 and whist it can be assumed that the CTS-R-Pain could be used to increase competence as part of reflective practice, this assumption will need checking with further research. For the tool to be used to determine whether a physiotherapist has reached a pre-specified level of competence, i.e. a cut-score for competence, research will need to be conducted on the appropriateness of the minimum competence scores as determined by the experts in the Delphi study (92)p21, 53-54. This is also explored in the analysis in the next chapter.

In conclusion, so far in this thesis, good evidence has been provided on the validity of the CTS-R-Pain using the domains outlined in the *Standards*. There is still

significant research that needs to be conducted before the tool can be recommended for clinical use widely.

4.6 Chapter summary

In this chapter evidence was presented to support the validity of the CTS-R-Pain using the domains described in the *Standards for Educational and Psychological Testing*. Two reliability studies were described, intra-rater and inter-rater which found very good reliability for the overall competence score generated by the measure although individual competency items had some variability. The tool was also found to have a high degree of internal consistency. Whilst there were no gold standards to compare the new tool to, it was found to correlate with some other variables that it would be expected to. Whilst the psychometric properties of the new tool appear promising, caution needs to be applied due to the 49% power level.

5 Chapter Five - Competency as a predictor of clinical outcome in patients

This study aims to investigate whether there is a relationship between competency and clinical outcomes in patients in the BeST trial. This analysis will be hypothesis generating as sub-groups were not selected a-priori and multiple analyses will be conducted.

5.1 The relationship between competency and clinical outcome

The definition of competency used in this thesis is; "The extent to which a therapist has the knowledge and skill required to deliver a treatment to the standard needed for it to achieve its expected effects' (62)p374. This definition makes explicit links between competence and outcome. In chapter 2 a competence tool, the CTS-R-Pain, was developed to assess physiotherapists' competence in delivering a CB approach for chronic LBP. Therefore, as part of the tool's validation process, it is important to see whether it is able to predict patient outcomes. Furthermore, analysis of competence/outcome data should start to explore the relative importance of therapist competence in the effectiveness of CB approaches in LBP. This analysis is the focus of this chapter which will start with a relevant literature review.

The main trial analysis in the BeST trial found no evidence of clustering effects related to the group or therapist (therapist intra-cluster correlation coefficient at 12 months for the RMQ was -0.0001, CI -0.04 - 0.04). However, this was contrary to findings by Lewis et al (172) who sought to estimate the percentage of clinical change that could be attributed to differences between physiotherapists, so called

'therapist effects'. In a pooled analysis of three trials of treatments for back and neck pain they found that 2.6 - 7.1% of the variance in clinical change was attributable to 'therapist effects' with the greatest estimate of effect being in interventions that utilised psychosocial based interventions. Whilst this 'therapist effect' gives weight to the suggestion that intervention delivery is important, it does not tell us about the relative importance and interactions between the components that will contribute to the overall 'therapist effect'. These components could include non-specific therapist effects such as empathy and specific effects such as competence (173, 174).

The importance of therapist competence within psychological treatments was explored in a meta-analysis by Webb et al (175) who also used moderator analyses to explore the effect sizes in relation to; the psychological approach used e.g. CBT; the problem targeted e.g. depression; temporal confound i.e. early improvement; and therapeutic alliance. The pooled, weighted effect size of competence or adherence and outcome was non-significant (.07 and .02 respectively). The moderator analyses showed larger effect sizes associated with interventions that targeted depression (r = .28 p=<.001). In addition, where therapeutic alliance was controlled for, the effect sizes were much smaller. The authors note that the pooled effect sizes needed to be interpreted with caution as the population was significantly heterogeneous ($I^2 = 47-60\%$; moderate to high levels of heterogeneity). All of the trials in this meta-analysis were delivered by psychological practitioners at various stages of training. Whilst there will have been some scope for variation in levels in competency, it is likely that the therapist population was drawn from a fairly narrow band of competency and as noted by Webb et al, this means a large sample is required to detect small effect sizes.

This issue was addressed to some extent in a meta-analysis to assess the effectiveness of psychological interventions delivered by specialist and non-

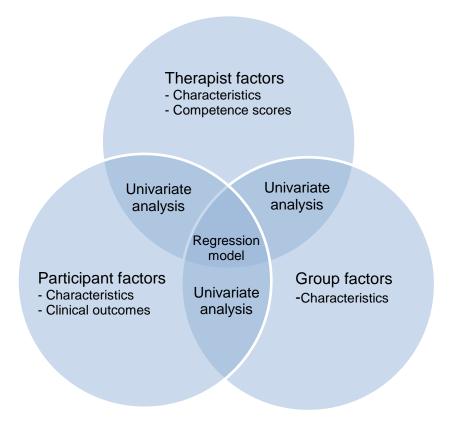
specialist therapists in the treatment of diabetes (176). Of the 19 trials that had results pooled, equal numbers were delivered by diabetes/general clinicians or psychological specialists. There was no significant difference in effect size between the two groups for the main outcome measure of change in HbA_{1C} (a measure of glycaemic control). Whilst most of the psychological interventions were described as CBT, the authors note that half of the trials described an educational component to the intervention. Although we could assume that the psychological practitioners were more likely to be competent at delivering the psychological component, it may be that the change in glycaemic control could be attributed to the education component of the programme for which the diabetes/general clinicians may have been more competent.

Clearly, there is a need to explore the relative contribution of competency within clinical outcome, especially in the context of therapists applying new skills outside of their core skills and training.

There are two aims with the following analysis. The first is to explore the data to see what it can tell us about competence in physiotherapists, for example: are there any particular sub-groups of physiotherapists who score higher/lower on competence assessment? Is there anything about the participants themselves or where/how/when the group intervention was delivered that can influence competence? Secondly, are there any factors about the participants/groups/physiotherapists that influenced clinical outcome? If there are any relationships between these factors, when their influence is removed, do we see a relationship between competence and outcome? This analysis is demonstrated using a Venn diagram (Figure 15). Firstly the baseline data for physiotherapist, patient and group factors will be presented. Secondly, univariate analysis of each of the overlap areas

will be presented and finally a regression analysis will be conducted to model the relationships found.

Figure 15 Venn diagram to show the overlap areas that will be analysed in this chapter



5.2 Methodology

5.2.1 Overview

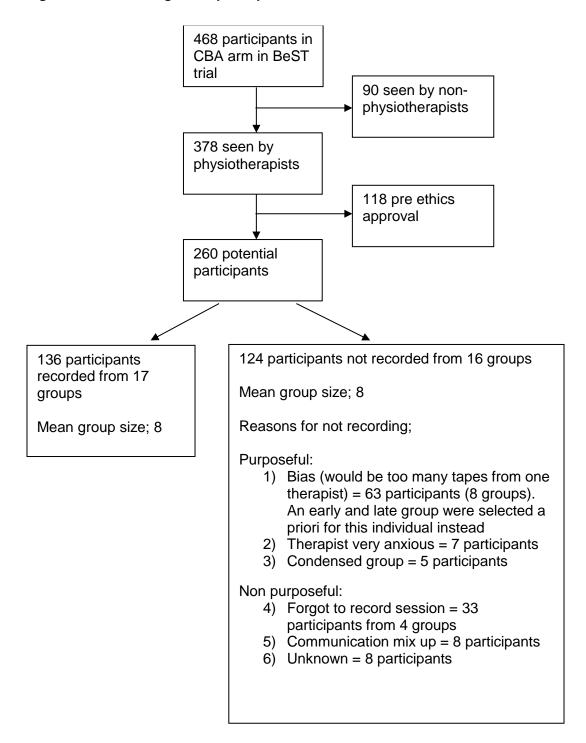
In the validity studies detailed in chapter four, 17 recordings of BeST group sessions were collected and the physiotherapists were rated for competence levels using the new tool, the CTS-R-Pain. Each group that was recorded had between five and 11 participants (mean 8.0) and in total the 17 recordings relate to a pool of 136 participants. All participants had baseline data and follow-up data collected as part of the BeST trial; the current study will explore the relationship between the competency data of the physiotherapists and the outcome data of the participants.

5.2.2 Participants and data collection

Recordings were made of 17 group sessions in the BeST trial; the method of data collection is detailed in section 4.3.2 and the ethical approvals in 4.3.4. Figure 16 shows the participant flow through the study.

The 17 recordings represent 17 independent group sessions delivered by 11 physiotherapists (i.e. each recording is of a different set of participants) relating to 136 participants in total. A range of data on the participants, physiotherapists, and groups was collected. Participant data included; age, gender, self-rated severity of back pain, employment status and outcome measures collected at baseline, 3, 6 and 12 months (details in section 5.2.3) and number of sessions attended. Physiotherapist data included; age, gender, years qualified, grade, PABS-PT score, and competence score measured by the CTS-R-Pain. Group data included details of the session that was recorded; session number, day, time, venue, group size, and percentage of group that attended three or more group sessions.

Figure 16 Consort diagram of participant flow



5.2.3 Outcome measures

A range of outcomes were collected as part of the BeST trial. The measures targeted the domains which were expected to be directly changed by the intervention, such as the primary outcomes of disability and pain. In addition, other measures collected data on domains that were postulated to be implicated in the change in primary outcomes such as changes in self-efficacy. Each outcome measure is briefly summarised in Table 17 below;

Table 17 Outcome measures overview

Outcome measure	Response options and scoring	Description and evidence
Roland Morris Disability Questionnaire (RMQ) (177)	Disability scale with 24 items. 0-24 score with lower scores indicating less disability	Widely used outcome measure in trials of LBP disability. Each item asks about aspects of function typically affected by LBP such as getting out of bed. Good reliability (garratt 2001) but problems with sensitivity to change at high and low end of scale (178, 179).
Modified Von Korff Scale (MVK-pain or MVK- disability) (180)	Pain and disability scale with 3 items each. Score 0- 100% with lower scores indicating less pain or disability	Each item asks participant to rate 0 (no pain/disability) to 10 (worst pain/disability). 3 disability items relate to daily activity, recreation and work. 3 pain items relate to worst pain, average pain and pain today. Good reliability and correlation with other measures (180) (181)
Short-form Health Survey (SF-12) (182)	Health related quality of life scale with 12 items. Score 0 -100 on physical and mental sub-scale, lower scores indicate poorer quality of life	Each item has different response codes using a Likert type scale. E.g. How much of the time in the last 4 weeks have you felt calm and peaceful 1 (all of the time) to 5 (none of the time). Good psychometric properties and correlation with the longer version (SF36) (183)
Fear Avoidance Beliefs Questionnaire –Physical (FABQ) (184)	Beliefs scale with 4 items. Score 0-24 with lower scores indicating less fear avoidance beliefs	Each of the 4 items relates to beliefs about physical activity scored from 0 (completely disagree) to 6 (completely agree) e.g. physical activity might harm my back. Good reliability but possible ceiling effects in maximum score (185)
Pain Self Efficacy Scale (PSE)((186) referenced in (187))	Confidence/self-belief scale with 10 items. Score 0-60 lower scores indicate less self-efficacy	Each of the 10 items asks the participant to rate confidence to carry out a range of activities despite back pain e.g. Scoring 0 (not at all confident) to 10 (completely confident). E.g. I can gradually become more active despite the pain. Good psychometric properties and correlation with other measures/constructs (187)

5.2.4 Statistical analysis

Data were checked for normal distribution using scatterplots, normal plots and the use of the Shapiro-Wilk-W tests where appropriate. Where data were normally distributed parametric statistical tests were used. Initial univariate analysis was conducted followed by regression analysis to account for interactions between covariates.

Univariate analysis

Univariate analysis was conducted to explore the influence of physiotherapist characteristics, group characteristics and participant characteristics on physiotherapist competence and participant clinical outcome. As recommended by Altman (167), graphs were visually inspected for emerging patterns prior to statistical analysis using Pearson correlation coefficients or chi squared statistic for nominal data. A significance level of p=0.05 was chosen for all analyses to balance risk or error with sample size constraints. Participant outcome data used the change from baseline scores for each of the outcome measures as this provided a normalised score because the absolute scores were skewed. The time point selected for this analysis was 12 months as improvements in outcome were seen within the BeST trial to be most significant at 6 and 12 months (30). The response rate was slightly better for 12 months (85.3% compared to 83.0% at 6 months) and for this reason 12 month data were used to increase the sample size. Three month data are also presented as it can be argued that the effect of competence may be more likely to be observed shortly after contact with the therapist as a relationship between competence and outcome is seen most strongly at this time point in cognitive therapy for depression (188). Some analyses involved dichotomising the CTS-R-Pain score. The cut-point used was a mean score ≥3.0. This represented the original guidance for the CTS competence level (122) and provided two samples for

analyses (≥3 included 8 groups with 58 participants, ≤2.9 included 9 groups with 78 participants).

Selection of covariates for the regression model

There have been many studies into the predictors of outcome in interventions for LBP (189). Whilst there are a large number of possible covariates, the practicality of sample size in any study limits the number of covariates that can be entered into a model without adversely affecting the model's stability. Altman (167)p349 acknowledges that there is no clear evidence on this matter but advises that either the square root of the number of data is used or the number of data divided by 10. Another approach is to consider the effect size required using Cohen's benchmark (99)p313. The dependant variable (RMQ 12 month change score) is available for 107 of the 136 participants. With this sample size, large effect sizes ($R^2 = .26$) would be detectable with over 20 covariates, a maximum of 8 covariates could detect a medium effect ($R^2 = .13$), but small effect sizes ($R^2 = .02$) would not be detected as this would require a sample size of 387 for just one covariate (99)p314. A maximum of 8 covariates was selected in order to detect the smallest effect sizes possible within the sample size.

This limitation in number of covariates requires the researcher to be stringent in the selection of covariates and consequently there is some debate on how they should be selected in exploratory research. One method is to base the selection on covariates that have shown a correlation with initial univariate analysis, the second method is to use only covariates that have been shown in previous studies to be correlated with the outcome of interest or where there is sound theoretical reasoning as to their inclusion (99)p321, (167)p336-337. Inclusion of known covariates from previous literature can be defined as hypothesis testing when assessed as part of an RCT and selected a-priori, whilst inclusion of covariates with theoretical influence

or from exploratory data analysis can be described as hypothesis generating (190). Therefore, the strongest predictors of outcome from the literature were included as covariates along with covariates found to be significantly associated with competence or outcome as part of the univariate analysis.

Summary of research on predictors of outcome in LBP trials

There have been many studies and subsequent systematic reviews that have sought to identify prognostic factors for poor outcome in low back pain (191). There are often conflicting results and the validity of the studies has been called into question due to a lack of consistency in obtaining and reporting baseline characteristics (191, 192). In a comprehensive review article, Hayden et al (20) summarised the evidence on prognostic factors associated with chronicity/disability and report that the following factors are consistently reported;

Low back pain episode characteristics: Higher level of functional disability

Sciatica

Individual characteristics: Older age

Work environment:

Poor general health

Psychological characteristics: Increased psychological or

psychosocial stress

Negative cognitive characteristics
Poor relations with colleagues

Heavy physical work demands

Social environment: Presence of compensation claim

In addition to these prognostic factors which predict poor outcome in LBP, several factors have been identified as treatment effect moderators. These are factors that define which group of patients benefit most from an intervention and can only be reliably determined by the use of a priori subgrouping as part of a randomised trial (193). There are a limited number of these studies within the area of CBA interventions for low back pain (194). Of relevance to this study, the BeST trial data were examined for moderators of outcome by Underwood et al (194). Initial univariate analysis found younger age, positive employment status, no benefits and

higher Modified Von Korff (MVK) disability baseline score were all predictors of positive outcome in the three outcome measures; RMQ, MVK disability and MVK pain. In addition troublesomeness, duration, baseline RMQ, and MVK pain predicted some outcome measures, although not consistently. Multivariate modelling was conducted to test the pre-specified moderators and also the covariates found to be associated through the exploratory univariate analysis. The model improved with inclusion of the latter but only younger age and positive employment status reached statistical significance as a moderator (0.04 and <0.001 respectively) and only in one outcome, the Roland Morris Disability questionnaire.

The selection of covariates for the regression model was finalised after univariate analysis and is summarised in section 5.3.5.

Method of covariate entry into model

Variables can be entered into a regression using several different methods, the most common being forced entry, stepwise and hierarchical (99)p322. The difference between these methods is an assumption made about whether there is a superiority of one variable over another and whether the variables are correlated with each other. Hierarchical can be used where some variables are known to be more important than others due to previous research. In stepwise methods the decision about variable superiority are made by mathematical criteria. This method has been criticised as the model can be over-fitted with variables that have little importance whilst significant variables can be excluded due to the order in which variables are selected (99). Forced entry assumes that all variables are equally important and was used in this study as there is no clear evidence of superiority of the variables to be entered.

Missing data

In a final regression model cases were excluded that had a missing value for any of the variables. An alternative to this option would have been to enter average values although this could have the effect of suppressing the standard deviation and standard error (99). This would be a significant risk due to the small sample size. The final regression used 107 of the 136 cases (78.7%). The participants with missing values were similar to the participants without missing data on the whole except for a large difference in the number of participants attending three or more sessions (63.3% attended 2 or less group sessions in the missing data group compared to 18.7% in the complete data group). Therefore, the participants that did not provide follow-up data tended to be the participants that did not attend the group sessions. In the main BeST trial, participants that did not attend sessions were broadly similar to participants that did attend, except they were slightly younger and had slightly higher pain scores at baseline (88). On this basis, excluding these cases was not expected to bias the regression analysis.

5.3 Results

5.3.1 Check for normative data

The therapist competency data underwent checks for normality in the previous study (section 4.4.1). All participant outcomes were also checked using histograms and normal plots to check for normality. Whilst the Shapiro Wilk W test revealed some significant findings, all plots were normal and therefore the statistical finding of non-normality was assessed to be an artefact of the outliers that were present in the normal plots (167). Histograms of the main outcome measures are shown below in Figures 17-19.

Figure 17 Histogram of participant 12 month change score disability outcome (Roland Morris Disability Questionnaire)

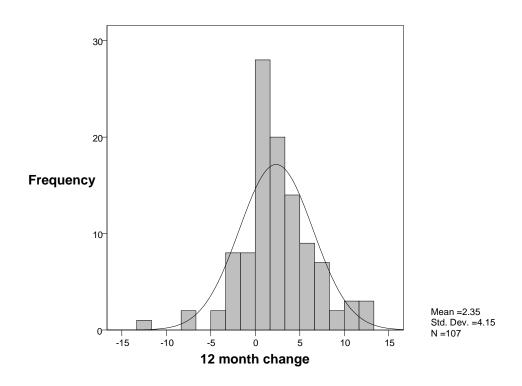


Figure 18 Histogram of participant 12 month change score disability outcome (Von Korff Disability Score - Physical)

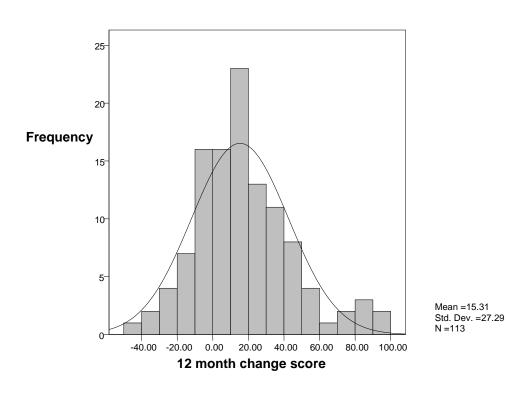
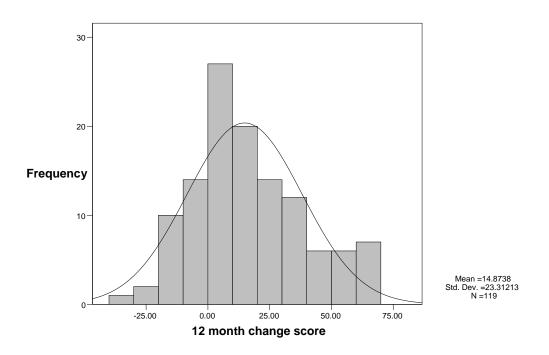


Figure 19 Histogram of participant 12 month change score disability outcome (Von Korf Disability Score - Pain)



Due to the normal distribution parametric statistical tests will be used in the analysis.

5.3.2 Baseline characteristics

Baseline characteristics of the participants, groups and therapists are presented below. As shown in the participant flow diagram (Figure 16), 17 of a potential 33 sessions were recorded for a variety of reasons. Table 18 provides a comparison of the baseline data of participants recorded in the trial and those not recorded to check for any bias in the recordings. There were no significant differences between recorded and non-recorded participants. The baseline characteristics of participants in each group are detailed in Table 19.

Table 18 Baseline demographics of recorded and non-recorded participants

	Recorded (n=136)	Not Recorded (n=332)
Age (years)	54.1 (14.4)	53.1 (14.6)
Sex (female)	79 (58.1%)	199 (59.9%)
Ethnic origin	79 (38.178)	199 (39.976)
White	127 (93.4%)	285 (85.8%)
Mixed	2 (1.5%)	2 (0.6%)
Asian	1 (0.7%)	20 (6%)
Black	1 (0.7%)	6 (1.8%)
Chinese	0 (0%)	1 (0.3%)
Missing / Other	5 (3.7%)	3 (0.9%)
Severity of back pain	0 (0.1 /0)	0 (0.070)
Moderately troublesome	75 (55.2%)	175 (52.7%)
Very or extremely troublesome	59 (43.4%)	157 (47.3%)
Age left full-time education (years)*	00 (10.170)	101 (11:070)
≤16	85 (62.5%)	181 (54.5%)
17–19	30 (22.1%)	74 (22.3%)
≥20	20 (14.7%)	53 (16%)
Still in full-time education	0 (0%)	1 (0.3%)
Other	1 (0.7%)	7 (2.1%)
Missing	0 (0%)	16 (4.8%)
In employment		,
Yes	63 (46.3%)	127 (38.3%)
No	67 (49.3%)	136 (41.0%)
Other	2(1.5%)	5 (1.5%)
Roland Morris questionnaire	7.8 (4.4)	9.2 (5.2)
Modified Von Korff disability	47.9 (24.1) miss=1	48.7 (23.8) miss=12
Modified Von Korff pain	57.8 (17.5) miss=1	59.9 (19.9) miss=4
Pain self-efficacy	40.9 (11.7) miss=2	40.0 (14.0) miss=13
Fear-avoidance beliefs	13.1 (5.9) miss=6	13.8 (6.5) miss=19
SF-12 physical	37.9 (9.2) miss=13	36.8 (9.3) miss=34
SF-12 mental	45.9 (10.5) miss=13	43.8 (11.9) miss=34

Data are mean (SD) or n (%). SF-12=12-item short-form health survey. miss=n Data not available for participants who did not complete the question on the questionnaire.

Table 19 Baseline characteristics of each recorded group

	Group number																	
	24	25	33	34	35	37	42	44	47	49	50	51	53	59	60	61	62	Range
Mean age of participants (years)	49.4	53.7	56.6	57.9	49.1	53.2	55	51.3	50.1	59.3	56.8	53.9	54	53	54.1	57.4	53.7	49.1-59.3
Gender – Female (%)	60	66.7	28.6	75	57.1	36.4	50	70	66.7	28.6	60	88.9	50	50	66.7	50	83.3	28.6-88.9
Severity of back pain – Very or Extremely (%)	40	50	14.3	62.5	42.9	72.7	40	50	55.6	28.6	20	33.3	33.3	37.5	44.4	50	33.3	14.3-72.7
Employment – yes (%)	50	66.7	66.7	37.5	28.6	54.5	44.4	50	44.4	50	33.3	44.4	50	85.7	33.3	37.5	50	28.6-85.7
Roland Morris Questionnaire	8.0	8.6	7.7	9.8	7.6	8.1	6.8	8.3	9.4	5.1	5.4	8.9	7.2	7.3	8.7	8.1	7.7	5.1-9.8
Modified Von Korff - Disability	40	57.8	52.4	55.4	56.2	45.8	43.0	53.7	58.9	30.5	31.1	47.0	42.2	57.1	42.6	49.2	60.0	30.5-60.0
Modified Von Korff – Pain	49.3	60.6	54.8	64.2	61.9	65	57.3	59.7	64.8	45.7	42.0	59.6	54.4	64.2	58.9	57.9	58.3	42.0-65.0
Pain self-efficacy	40.2	41.2	45.2	40.6	38.3	40.6	40.9	32.5	38.7	46.7	46.6	36.2	43.3	38.4	44.4	41.8	42.7	32.5-46.7
Fear Avoidance Beliefs Questionnaire	13.8	12.6	11.6	11	15.6	16.2	10.2	13.1	13.6	10.2	13.4	13.9	15.5	9.9	13.1	13.8	15.2	9.9-16.2
Short Form 12 - Physical	40.0	28.1	42.4	34.5	35.0	35.9	40.2	36.8	38.6	43.2	42.8	32.2	41.5	39.0	36.6	37.8	35.6	28.1-43.2
Short Form 12 - Mental	45.6	43.2	47.9	47.0	49.3	45.0	50.4	41.8	44.6	53.6	43.5	41.3	47.0	44.9	48.8	46.8	41.0	41.0-53.6
Physiotherapist mean competence score (CTS-R-Pain)	0.6	3.2	4.1	2.4	2.8	1.5	2.9	2.4	1.3	3	1.6	3.2	3.7	3.4	4.4	2.5	3.1	0.6-4.4

Roland Morris Questionnaire – a disability measure Short Form 12 - a health related quality of life measure consisting of physical and mental health sub sections

5.3.3 Analysis of participant/group factors

Whilst Table 18 shows that recorded participants were broadly comparable to non-recorded participants, and therefore representative of participants within the BeST trial, Table 19 shows a wide variation of many baseline characteristics within each group. This table and associated data were examined and no discernible patterns emerged. There was no 'typical group', and where group characteristics were at either end of a range, they were not linked with other group characteristics. For example, in groups with a high percentage that reported to be working, we might expect to see low levels of disability. However, this was not the case and there was a spread of high, medium and low levels of disability.

In order to check if group variation influenced competence, each mean group variable, e.g. mean age of the group, percentage of group reporting severe back pain etc. was plotted against the physiotherapist competence score for that group using scatterplots and checked visually in addition to statistical tests. No significant patterns or values were found.

The groups recorded for this analysis represented a spread of groups over the: session, day, time, venue, and group size (see Table 14 in previous chapter). Whilst there was some minor variation in these group characteristics in this correlational study, none of these group factors were found to be related to competence and clinical outcome within the BeST trial data (88) and within this sample with the exception of one variable in this sample: venue.

Venue

Physiotherapists appeared more competent in the community setting and less competent in the PCT setting, although this did not meet the set criteria for significance of p=0.05 (p= 0.053).

Table 20 Number of participants seen in each setting by competent or not competent physiotherapists (dichotomised using a mean score of ≥3 on the Cognitive Therapy Scale-Revised-Pain)

	PCT (%)	Community (%)
Competent	23 (39.7)	35 (60.3)
Not competent	44 (56.4)	34 (43.6)

PCT = Venues associated with the Primary Care Trust e.g. a doctors surgery or hospital setting. Community = venues not associated with the PCT such as community centres or church halls

It has already been shown that experience is strongly linked to competence (see section 5.3.4 for more details). Within the BeST trial, more experienced physiotherapists tended to be recruited independently to take part in the trial and were therefore delivering groups outside of their work places in the community. Less experienced physiotherapists were 'volunteered' by their PCT when the PCT was recruited to take part in the trial. However, within this sample, there were equal numbers of groups delivered in the community and PCT settings by experienced and non-experienced physiotherapists. As such, venue may have independently impacted on competence and was entered as a covariate into the regression analyses.

Participant attendance with cognitive behavioural intervention

A desired threshold of attendance at the BeST group sessions was defined a priori within the BeST trial as attendance at the assessment sessions and three of the six group sessions (88). The impact of attendance on both competence and clinical outcome was explored.

Initially, attendance rates were checked in the recorded participants compared to non-recorded participants in the BeST trial (shown in Table 21).

Table 21 Number of participants attending group sessions in recorded sample and the non-recorded participants of the Back Skills Training trial

	Attended ≥ 3 group sessions (%)	Attended ≤ 2 group sessions (%)
Recorded	97 (71.3)	39 (28.7)
Not recorded	197 (59.3)	135 (40.7)

It appears there was a bias towards recordings being made in groups that had greater attendance. This is difficult to explain as selection of groups was at random. It could be theorised that the three groups that were forgotten to be recorded were difficult or had low attendance and that this contributed to the physiotherapist forgetting to record the session. In addition, the group that was condensed into four sessions was not recorded as it would have not been representative. This group was condensed due to low attendance.

There were no significant differences between rates of attendance in physiotherapists with higher or lower competence level (p=0.994). Furthermore there was no relationship between attendance and clinical outcome across all outcome measures apart from a negative correlation with the mental health subscale of the SF12 (r=-.218 p=0.023). Due to this inconsistency, attendance was not considered in the regression analyses.

5.3.4 Analysis of therapist factors

Baseline characteristics of the physiotherapists are contained in Table 13 of the previous chapter and have been reproduced below in Table 22 dichotomised

according to competence level using the CTS-R-Pain (using a mean score cut-off of 3).

Table 22 Baseline characteristics of physiotherapists defined by competence dichotomised at mean score of 3 (Cognitive Therapy Scale-Revised-Pain)

	Higher	Lower
	competence	competence
Mean age (years)	38.5 (SD 8.9)	37.0 (SD 9.3)
Gender; female	5 (83.3%)	3 (60.0%)
male	1 (16.7%)	2 (40.0%)
Mean years qualified	15 (SD 9.2)	9.3 (SD 5.3)
Grade; Band 5	0 (0%)	2 (40.0%)
Band 6	3 (50.0%)	3 (60%)
Band 7	3 (50.0%)	0 (0%)
Experience of running		
similar groups;		
Yes	5 (83.3%)	0 (%)
No	1 (16.7%)	5 (100%)
Mean PABS-PT Score*	25.2 (SD 6.3)	26.8 (SD 11.0)

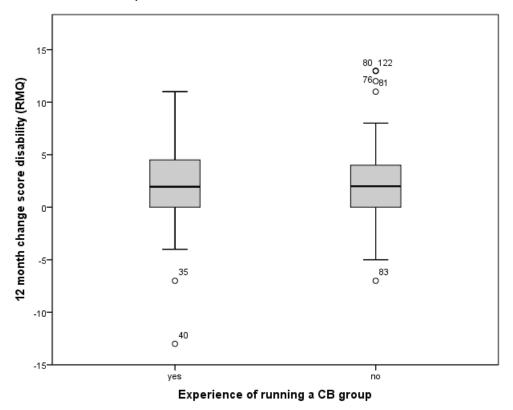
^{*} PABS-PT Physiotherapist Attitudes and Beliefs Score taken pre-training. Lower score indicates better attitudes and beliefs. Missing data from 1 therapist who was in lower competence group.

In this initial comparison of the data, it appears that therapists with a higher level of competence have been qualified more years, are of a higher grade and with specific previous experience of running similar groups. This will now be explored further including the relationship to participant clinical outcome.

Therapist experience

Prior experience in delivering similar groups was strongly related to competence (p=<0.001). For this reason we could expect that participants in groups run by experienced therapists would have a better outcome if the hypothesis of a relationship between competence and clinical outcome is supported. As shown in the box plot in Figure 20, there was no significant difference between the disability outcome (RMQ) for those participants in experienced therapists groups compared to those in non-experienced therapist's groups (p= 0.639). There was also no difference between the other outcomes and previous experience.

Figure 20 Box plot of prior experience against changes in disability score (Roland Morris Questionnaire) at 12 months



In Table 22 it appeared that therapists with a higher level of competence had been qualified longer. However, a Pearson correlation of the continuous data on competence and years of qualification showed no such relationship (p= 0.90). Years of qualification did correlate negatively to participant 12 month change score in disability (r=-.259 p=0.007) although this relationship was not seen in the other outcome measures. This could indicate that less years since qualification is associated with greater improvements in participant outcome.

Previous specific experience and competence are closely correlated and likely to be measuring similar constructs; as such, previous specific experience will not be entered into the regression. Years since qualification will be entered into the regression model with close monitoring for collinearity.

Competence

The direct relationship between competence and clinical outcome was explored using scatterplots and Pearson correlations for competency scores against change from baseline scores for each of the outcome measures (or chi squared statistic for nominal data). For all outcomes shown in Table 23 below, there were no observable patterns in the scatterplots and no significant relationships were found statistically.

Table 23 Summary of correlation analyses using Pearsons and Chi squared statistic between competence scores (Cognitive Therapy Scale-Revised-Pain) and clinical outcome

Outcome	Pearson Correlation (r)	Significance	Competence dichotomised at 3 Chi squared Significance*
RMQ 12 month change score	.082	.399	.765
RMQ 3 month change score	.133	.174	
Von Korff disability 12 month change score	.048	.616	.952
Von Korff disability 3 month change score	.106	.270	
Von Korff pain 12 month change score	.109	.236	.422
Von Korff pain 3 month change score	.123	.196	
FABQ 12 month change score	.031	.761	.406
FABQ 3 month change score	.065	.520	
Pain self-efficacy 12 month change score	.074	.740	.576
Pain self-efficacy 3 month change score	098	.327	
SF-12 physical 12 month change score	049	.610	1.0
SF-12 physical 3 month change score	070	.487	
SF-12 mental 12 month change score	.067	.486	1.0
SF-12 mental 3 month change score	.021	.838	
EQ-5D 12 month change score	026	.796	.179
EQ-5D 3 month change score	084	.396	

SF12 is Short Form 12, a health related quality of life measure consisting of physical and mental health sub sections

Correlation between specific competence skills and clinical outcome

Physiotherapist competency scores for items 1-14 were correlated with each of the three main outcome measures to see if scores on specific competencies correlated with outcome. Of the 42 analyses run, two items had significant results, shown in Table 24 below.

EQ-5D measures health status

^{*}as there are so many boxes with minimum expected count then chi squared can be misleading as it inflates the statistic with higher expected frequencies (195) p403. To avoid this, the 'exact' significance was used which accounts for low frequencies.

Table 24 Significant findings in correlation between individual competency items (Cognitive Therapy Scale-Revised-Pain) and outcome measures

		12 month change score RMQ - disability	12 month change score Von Korff - disability	12 month change score Von Korff - pain
Competency 1	Pearson	.135	.159	.192*
Agenda setting	Correlation			
	Sig. (2-tailed)	.166	.093	.037
	N	107	113	119
Competency 6	Pearson	.205*	.105	.158
Eliciting emotional	Correlation			
expression	Sig. (2-tailed)	.034	.267	.086
	N	107	113	119
Competency 9	Pearson	.114	012	.160
Guided discovery	Correlation			
	Sig. (2-tailed)	.243	.897	.082
	N	107	113	119

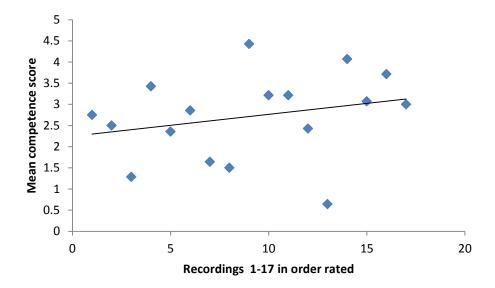
^{*}correlation is significant at the 0.05 level (2-tailed)

Competency items 1 and 6 are correlated with outcome but not across all the outcome measures. These items were checked for correlation against all other outcome measures collected for participants and there were no other significant correlations. Given the lack of consistency across outcome measures, these results are likely to be spurious.

Learning effects / Session number

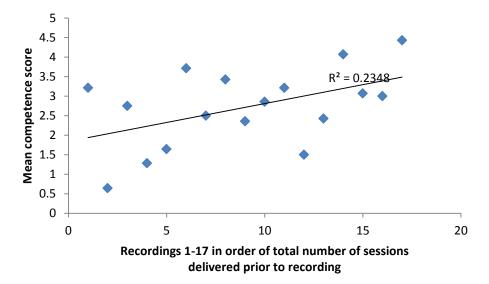
In the intra-rater reliability study, the second ratings were slightly higher than the first ratings and this was postulated to be due to a rater learning effect. This effect was explored further. The ratings of each recording were done systematically with Session 1 recordings rated first and Session 6 recordings rated last. Mean competency score for each recording is shown in Figure 21 below.

Figure 21 Mean competency score (Cognitive Therapy Scale-Revised-Pain) plotted against order of rating



From Figure 21 above it appears that competence scores increased slightly according to the order of rating (R^2 =0.07). To check that this is not a therapist learning effect i.e. the more sessions a therapist delivers the more competent they become, the competence scores were plotted according to how much experience the therapist had at time of recording i.e. how many sessions had they already delivered before they were recorded (Figure 22). This shows a therapist learning effect (R^2 = 0.23) which is likely to account for the small apparent rater learning effect seen in Figure 21 previously.

Figure 22 Mean competence score (Cognitive Therapy Scale–Revised-Pain) plotted against total number of sessions delivered prior to being recorded



Due to this learning effect, session number is too closely related to competence to be used as a covariate in the regression model as this is likely to cause multicolinearity.

5.3.5 Summary of univariate analysis

Participants recorded were broadly comparable to the wider sample from the BeST trial. Whilst the groups were very varied, this appeared not to impact on therapist competence. We can speculate that group dynamics may be influenced by the group demographics which may in turn impact on an individual's outcome, however, the subtleties of the interactions within a group could only be studied quantitatively with a very large sample size. In this sample, venue appeared to have an impact on competence levels with therapists demonstrating higher competence in the community settings. There was a small bias towards recordings being made in groups with a higher rate of attendance. Participant attendance was not associated with competence or clinical outcome. Competence was strongly linked to previous experience running similar groups although experience and competence was not

related to clinical outcome in the initial analysis. Years since qualification did correlate strongly with clinical outcome although not as predicted; the less years the therapist had been qualified, the greater the clinical improvement in their patients. Competence appeared to improve the more sessions that the therapist had delivered at the time of recording which could be evidence of a learning effect.

5.3.6 Linear regression

The sample size allowed for eight covariates to be entered into the regression model which were selected based on the literature review as detailed in Section 5.2.3 and from the preceding univariate analysis.

In addition there was a clustering of participants within their groups and by physiotherapist (six physiotherapists delivered two groups each whilst five physiotherapists delivered just one group). To account for this 'therapist' was included as a covariate and 'group' was added to a later model to see if it improved the fit.

Using forced entry method, covariates were entered into the model in stages to gain a better understanding of their influence on the model. The dependent variable was participant 12 month change score in RMQ (disability score) with the predictor variable as the physiotherapists mean CTS-R-Pain score (competence score). Covariates were baseline RMQ, participant age, participant gender, therapist, and baseline fear avoidance beliefs (FABQ).

Regression coefficient (R^2) was .01 for Step 1; change in R^2 (ΔR^2) was .22 for Step 2 (ps = <0.001).The model was re-run testing the proposed predictors of outcome. Participant work status and therapist years qualified contributed to the model whilst

venue, group number and therapist prior experience did not and as such were excluded from the final model which is shown below (Table 25).

Table 25 Linear regression model of predictors of participant outcome at 12 months

	b (95% CI)	SE B	β	p
Step 1				
Constant	1.41 (-1.23, 4.06)	1.33		p = .291
CTS-R-Pain Score	0.36 (-0.57, 1.29)	0.47	.078	p =.439
Step 2		L		
Constant	-1.24 (-7.93, 5.45)	3.37		p = .713
CTS-R-Pain Score	-0.26 (-1.36, 0.84)	0.55	057	p = .636
RMQ – baseline	0.44 (0.26, 0.63)	0.08	.384	p = .000
FABQ - baseline	-0.18 (-0.31, -0.04)	0.07	251	p = .012
Participant age	-0.01 (-0.07, 0.05)	0.03	036	p = .732
Participant gender	1.53 (-0.57, 3.63)	1.06	.169	p = .151
Therapist	-0.15 (-0.32, 0.03)	0.09	209	p = .095
Participant work status	2.83 (1.07, 4.59)	0.88	.336	p = .002
Therapist years qualified	-0.11 (-0.21,01)	0.05	202	p = .037

NB. $R^2 = .01$ for Step 1; $\Delta R^2 = .33$ for Step 2 (ps = <0.001)

Assessment of bias

The model was assessed for bias caused by outliers using case-wise diagnostics. There were six cases (of the 137) lying outside a +/- 2 threshold. This is within ordinary sample expected values. Cases were further examined using Cook's distance, Mahalanobis distance and DF Beta statistics. Only a few values were significant with none across more than one statistic which would indicate that no cases are likely to have caused bias. Plots of standardised residuals against standardised predicted values were examined for funnels or curves which could

indicate heteroscedasticity and non-linearity respectively. All plots were randomly and evenly dispersed throughout the plot supporting the statistical assessment of non-bias in the model. Partial plots were also examined, RMQ change was regressed against RMQ baseline and showed some funnelling indicating heteroscedasticity with a greater spread in change scores at higher levels of disability.

Summary of regression

The regression analysis indicated that 1% of the variance in patient outcome score (RMQ 12 month change score) could be attributed to therapist competence. A further 33% of the variance in the outcome score could be attributed to the covariates with significant predictors of positive outcome being higher baseline disability (RMQ), higher baseline fear avoidance beliefs (FABQ), being in work, and less therapist years since qualification. Whilst the sample was small, there did not appear to be any cases exerting significant bias within the model.

5.4 Discussion

This study had several interesting findings;

- There was an association between greater competence and delivering interventions in the community setting.
- Competence was linked to previous experience running similar groups.
- 3) Years since qualification correlated with clinical outcome although not in the expected direction; the fewer years the therapist had been qualified, the greater the clinical improvement in their patients.
- 4) Competence increased over time.
- 5) Only 1% of the variance in patient outcome score (RMQ 12 month change score) could be attributed to therapist competence. A further 33% of the

variance in the outcome score could be attributed to the covariates with significant predictors of positive outcome being higher baseline disability (RMQ), higher baseline fear avoidance beliefs (FABQ), participant being in work, and fewer therapist years since qualification.

These findings will now be discussed in relation to the literature.

5.4.1 Community settings

In this study venue appeared to impact on competence with physiotherapists demonstrating greater levels of competence when in a non-healthcare setting such as a community centre or church hall. A brief literature review could not find reference to this observation in other studies. Looking wider to evidence of efficacy for interventions delivered in different settings was also difficult. Interventions reported as being delivered in the community typically refer to NHS facilities in the community such as substance abuse drop in centres.

As this appears to be a novel finding, further research will need to be conducted to establish if it is a true effect and also the clinical implication, if any.

5.4.2 Competence linked to experience of running similar groups

It is perhaps not surprising that higher levels of competence can only be achieved through domain specific experience and practice, and that competence continues to improve over time with practice (70). In keeping with this, only specific experience of delivering similar groups to BeST was found to correlate with competence and competence was seen to improve over the trial duration.

It might be predicted that general clinical experience could impact on the competence level of specific skills after training in these skills. In a review of

evidence based training in CBT, Rakovshik (196) reported on several trials that have found no relationship between competence and years of general clinical experience. The current study went further than this and observed a negative relationship between years since qualification and competence. This finding may relate to previous research about changing physiotherapist's behaviour. It has been observed that physiotherapist's beliefs can be shifted from a biomedical to biopsychosocial perspective post training although this does not always change their behaviour (section 1.6.3)(47, 54). However, physiotherapy students, with minimal clinical experience, can have beliefs shifted in the same way with training but then appear to have behaviour change (55).

5.4.3 Prognostic indicators or moderators of outcome

Since most treatment effects in LBP trials are small, there is great interest in attempting to establish who responds to the different interventions.

Kraemer et al (197) have defined the difference between mediators and moderators (also known as modifiers) of clinical outcome in trials. Treatment moderators specify which type of patient will respond best to the treatment and under which conditions whereas "Treatment mediators identify the possible mechanisms through which a treatment might achieve its effects" (197)p878. In this way mediators are causal in the outcome such as therapist competence, whereas moderators identify subgroups within the treatment group such as depressed and non-depressed patients. Furthermore, treatment effect moderators need to be distinguished from prognostic factors. Kamper at al (193) offer this distinction; prognostic factors are predictive of patient outcomes whilst treatment effect modifiers (moderators) predict treatment effects. Some factors can be both prognostic factors and treatment effect moderators, for example; High levels of disability typically predict a poor outcome

over time (prognostic factor) but high levels of disability can also predict a better outcome with CBA intervention (treatment effect moderator).

These distinctions are important when drawing conclusions from analyses done post hoc as was the case in this study. As a single arm has been used, i.e. all participants have received the CBA treatment; assumptions cannot be made as to whether covariates are prognostic or moderators of outcome. This study found some evidence of a relationship between outcome with well-known covariates; baseline disability, baseline fear avoidance beliefs, and work status. The covariates were responsible for 33% of the variance in outcome in keeping with a similar study reported by Grotle et al (198) who used data merged from two large studies in primary care to compare prognostic factors in acute (<3 months) and chronic (>3months) LBP. The primary outcome measure was the RMQ disability score at 12 months. Variance in the 668 cases in the chronic LBP group was explained by baseline RMQ (44%), work status (4.2%), widespread pain (2.5%), chronic pain grade (a disability grading tool; 1.8%) and catastrophising (2%).

5.4.4 Possible explanations for a lack of correlation between competence and clinical outcome

The current study found no correlation between therapist competence and clinical outcome. There are two possible explanations for this, the first is that no relationship exists; the second is that a relationship exists, but this study failed to demonstrate it. This latter point will be explored first in relation to limitations of this study.

Sampling

If the effect of competence on clinical outcome is small, this study was not powered to detect it. A study with at least 700 participants would be required to detect small

effect sizes (99). We would expect small effect sizes where there is little variation in the competence level of the physiotherapists. In common with many other trials that examine the effect of competence, the therapists delivering the interventions have all received the same level of training and most will have similar profiles of relevant experience which is likely to result in clustering of competency levels around a relatively small band.

Selecting one session at random to record may not have reliably reflected the competence level across the six sessions. Studies from other areas of psychotherapy have shown variation in demonstrated competence across sessions (199). Therapists were pre-warned which session they would be required to record. This may have led some therapists to rehearse the skills required for the recorded session more than the other sessions which could bias the competence score. It could be postulated that less competent or experienced physiotherapists would be more likely to rehearse their recorded session thus inflating their score and diminishing effects seen in any competence-outcome relationship.

Biased allocation of therapists to 'difficult' groups

Within the BeST trial, patients were randomly allocated to groups. Most groups were delivered in each geographical area by a specified physiotherapist. However, three geographical areas in close proximity were covered by several physiotherapists and their allocation to groups was not randomly selected. Allocation to a group was influenced by perceived difficulty of the group with more experienced physiotherapists allocated to some of the perceived most difficult groups. For example the groups run in the areas of low socioeconomic status. This could impact on the current study if the most competent therapists delivered the intervention in the groups most at risk of a poor outcome, as this might diminish effect sizes in the most competent therapists. In the Underwood et al analysis of the BeST data set

(189), it was found that only work status was predictive of outcome with participants in work having a better outcome. In the current study of the 67 working patients, 42 were seen by therapists scoring below the competency threshold and 25 by competent therapists (p=.001) which may have decreased any effect on outcomes of competent physiotherapists.

Other explanations for lack of correlation between therapist competence and patient outcome

As demonstrated by Webb et al (175) in their meta-analysis of competence/adherence and clinical outcome of CBT interventions, a correlation between the two variables appears elusive. There are several factors that Webb et al point to as explanation for this unexpected finding. *Therapist responsiveness* refers to the phenomenon that therapy is delivered flexibly according to the emerging pattern of response in the patient. If the therapist perceives that a patient or group is at high risk of a poor outcome they could be more likely to adhere to the methods of the intervention. This would mean that they achieve higher scores when assessed for competency or adherence to protocol. These cases would then weaken the competence/outcome relationship in the cohort. In the moderator analyses Webb et al found a stronger association between competence and clinical outcome in the treatment of depression. This may have been an artefact of more studies being done in this sub-group and therefore greater power to detect differences rather than a true sub-group effect.

Competence may not be important with this intervention in this group of patients

Another plausible explanation for a lack of correlation is that competence may not
be important in delivering the BeST intervention in the group of patients studied.

The BeST intervention was structured and manualised which removes the need for
therapists to make decisions on what skills/topics are appropriate. It is recognised

by the British Association of Behavioural and Cognitive Psychotherapists, the main professional body for CB therapists, that manualised approaches require less skill/training to deliver (34). An early meta-analysis conducted by Crits-Cristoph et al (200) on two forms of psychotherapy (CBT and psychodynamic) specifically investigated the effects of manualised treatments versus non-manualised treatments to look at treatment/therapist effects. The 15 studies were heterogenous and had relatively small sample sizes but Crits-Cristoph et al reported the greatest treatment outcomes in manualised approaches. Furthermore, the manualised approaches were associated with smaller differences in treatment outcomes between therapists compared to the non-manualised approaches. In support of this, a retrospective analysis was conducted on a cohort of patients (n = 374) with chronic fatigue syndrome treated with CBT by trained psychotherapists (n = 12) using a manualised approach (201). Modelling revealed that therapist effects accounted for 0% and 2% of the variance in fatigue and disability scores accordingly. These findings are similar to the regression analysis of the current study which found 1% attributable to therapist competence.

What is it about a manualised approach that could be helpful in providing positive outcomes? Shaw et al (120) found a relationship between competence and clinical outcome in CBT for depression for specific clinical skills associated with structuring sessions; agenda setting, pacing and homework review. It may be that it is not the *therapist's ability* to structure the session but rather the *structure itself* that affords the changes in clinical outcome.

Intuitively, the more complex the problems of a patient, the more skilled a therapist will need to be in dealing with them. It could be postulated that the level of complexity of problems seen within the BeST trial did not require high levels of competence. Overmeer et al (53) trained physiotherapists over eight days to identify

and manage psychosocial risk factors in LBP patients. Overall the patients seen by physiotherapists that had been trained were no better than the control physiotherapists with no training. However, for the patients with high psychosocial risk factors there was a small observed difference in disability outcomes if they were treated by physiotherapists that demonstrated the greatest biopsychosocial beliefs post training.

5.5 Chapter summary

Seventeen sessions were recorded in the BeST trial and the physiotherapists delivering the sessions were assessed for competency level using the CTS-R-Pain. Competence was then explored in relation to information collected on the demographics of the physiotherapists and the participants, characteristics of the groups and the clinical outcomes of the participants. Relationships were found linking aspects of experience and the setting the BeST intervention was delivered in. No direct relationship was found between competence and clinical outcome through analyses and potential reasons for this was discussed.

6 Chapter Six - Experiences of physiotherapists adopting a cognitive behavioural approach

Physiotherapists historically have been trained in a predominantly biomedical framework (6, 48). This framework conceptualises illness or disorder using biological factors (25) and excludes psychological or social factors which have been increasingly recognised as important in the aetiology of many disorders, including low back pain (202). The biospsychosocial model incorporates all of these factors and was first described in 1977 by George Engel (203). However, a shift in practice has been slow with studies in recent years showing that a biomedical framework is still the predominant model within physiotherapy (6, 47, 204). Indeed, interventions aimed at specifically training physiotherapists to adopt a biopsychosocial approach have not yielded changes in practice or patient outcome (53, 54).

There is a recognition that physiotherapists need to incorporate psychological models into their existing biomedical paradigm (3). However, there is no research to suggest what issues may arise during or as a result of this process. Therefore the primary aim of this chapter is to investigate the integration of a psychological model into physiotherapy practice.

The research question to be answered is;

What factors influence the successful or unsuccessful integration of a CB approach into physiotherapy practice?

This is a specific question with no current evidence base. For this reason a qualitative paradigm will be used to generate theories and ideas.

Qualitative research methods allow us to explore the human experience (205). They do not seek to provide a quantified answer to a particular research question (206) such as *how many* physiotherapists are trained in CBT approaches. Rather, qualitative studies seek to understand the 'what' and 'why' by exploring the experiences, perspectives and beliefs of the participants (108).

In this way, qualitative research methods have an important role to play within healthcare in understanding complex health problems for new perspectives on management (207).

A secondary aim of this study is to compare the responses of more or less competent physiotherapists to see if anything can be learned about the development of competency.

6.1 Background

A few studies have investigated the implications to health professionals of being trained in a cognitive behavioural approach, none with physiotherapists.

Studies report that General Practitioners (GPs) given in-depth training in CBT for mental health problems can be effective within a primary care setting (208).

However, such extensive training is impractical for most GPs and a trial of brief training for GPs managing depression was not successful (209). Wiebe and Griever (210) conducted semi-structured interviews and a grounded theory approach with 42 GPs six months after they attended a five hour training session on CBT for depression and anxiety. Most of the GPs reported using elements of CBT within their practice although there were many barriers to implementation. Perceived time pressures were commonly cited, especially in GPs working on a fee-for-service basis. Conversely some GPs felt that using the CBT structure improved their time

management reducing the amount of time spent with patients and the need for follow-up. Other barriers included lack of confidence, interruptions, and a perceived lack of suitable patients. Cognitive behavioural skills were more likely to be applied to patients when the GPs had applied the skills to aspects of their own lives. Overall Wiebe et al reported a greater number of GPs using the technique than previous studies where more extensive training was provided (211). Wiebe et al attributed this to their training techniques. They felt that as the trainers were GPs, they were able to use their experience to make the training applicable to general practice which made it easier to implement. This study collected information on the experience of training and implementing CB approaches, but as no objective information was collected on performance or clinical outcome, no judgement can be made on the effectiveness of the brief training.

Aschim et al (211) used phenomenological analysis and studied GPs who had received more extensive training. The barriers reported were very similar to Weibe et al, but also found that structured supervision and experiencing a sense of mastery promoted the use of the techniques. No data were collected on patient outcomes or clinical performance.

Nurses (n=7) taking part in a cluster randomised controlled trial into CBT approaches for palliative care patients were given basic training in CBT for use in advanced cancer patients with anxiety or depression (212). The nurses were interviewed after training and at the end of the trial to explore their experiences of implementing the approach and transcripts were reported to be summarised into themes although no analysis was undertaken (213). The nurses reported feeling more able in assessing, supporting and facilitating change in their patients with psychological symptoms. They reported using a range of CB strategies and expressed most confidence in the techniques they used most often. They also

reported improved communication skills such as listening skills and ability to summarise and feedback to patients. Clinical supervision was regarded positively and felt essential to on-going CB practice. Barriers to implementation included time pressures, cognitive impairment, language barriers and difficulty with engaging the patient. As part of the main trial this interview study was linked to, Mannix et al developed the Cognitive Therapy First Aid Rating Scale (CFARS) (112). The main trial and CFARS development study reported that the nurses achieved satisfactory competence using their tool. However, the tool lacked validity as there was no description of the process used to develop it. Overall the main trial showed that patients seen by the nurses trained in the CBT skills had lower anxiety scores compared to their usual care counterparts (212).

These three qualitative studies provide some useful reflections on the experience of integrating CB approaches into clinical practice. They indicate that health professionals value being taught CBT skills but the probability of applying the techniques to a patient population is dependent upon personal, organisational and perceived difficulty of applying the techniques with particular patient groups.

The effectiveness of the training cannot be assessed in the two studies of general practitioners as no data on competence assessment or clinical outcomes were collected. Whilst the training received by the palliative care nurses appears to have been effective at changing patient outcomes there are issues of validity around the competence/performance assessment and it appears that the transcripts of the interviews were summarised with no mention of an analytic framework or process.

6.2 Methods

The successful integration of a CB approach into practice will be explored in two ways in this qualitative study; firstly, by asking physiotherapists directly if they have

any insights into influential factors, and secondly, by looking in depth at the response pattern in those physiotherapists that were more or less competent. For the purposes of this study higher level competence physiotherapists will be defined as those that scored a mean of 3 or more on the CTS-R-Pain, assessed as part of the reliability study (Chapter 4). Lower level competence physiotherapists will be defined as those scoring 2.9 or less.

6.2.1 Participants and ethical approval

Participants were sampled purposively from the cohort of physiotherapists that had undergone CB training to deliver the BeST trial intervention and had subsequently delivered more than one group (nine physiotherapists). These physiotherapists were selected as they had current experience of adopting a CB approach, and also had previously collected competence data.

Initial approach was via email accompanied by the participant information sheet (Appendix 8 dated 29/03/05) and the consent form (Appendix 9). This study was granted ethical approval through the University of Warwick Medical School Ethics Committee (Appendix 10). All nine physiotherapists provided informed written consent to participate in the study.

6.2.2 Participant characteristics

Interviews were conducted with nine physiotherapists who delivered groups in the BeST trial. Two were male and seven were female. The mean age of the physiotherapists in this study was 41.1 years (range 29 to 52); further characteristics are shown in Table 26 below.

Table 26 Physiotherapist characteristics qualitative study

Therapist reference number	Years qualified	Grade (increasing number indicates seniority)	Age	Gender	Experience of running similar groups	PABS- PT Score*	CTS-R- Pain Score
2	10	Band 7	43	М	Yes	19	3.1
5	14	Band 6	45	М	No	43	2.4
6	9	Band 6	42	F	No	22	1.5
7	31	Band 6	52	F	Yes	27	3
11	12	Band 7	33	F	Yes	30	3.6
12	21	Band 7	43	F	Yes	32	3
16	7	Band 6	29	F	No	27	3.2
18	25	Band 6	46	F	No	missing	2.1
19	12	Band 5	37	F	No	23	1.3

^{*} Pain Attitudes and Beliefs Scale – Physiotherapists; lower score indicates more biopsychosocial scores

Cognitive Therapy Scale-Revised-Pain; mean score is either the single score or the mean of two scores if the physiotherapist had two competence ratings as part of the reliability study

6.2.3 Data collection

One of the most common methods of collecting data in qualitative research is through interviews that are designed to allow the perspective of the participant to be ascertained (108). There are many different theoretical stances about how an interview should be conducted dependent on the context of the research. Some theorists state that the knowledge uncovered in an interview is a given, whilst other theorists suggest that knowledge is constructed in the interview between the participant and the interviewer (214).

Interviews were conducted by the thesis author who is a physiotherapist and cognitive behavioural therapist (see sections 1.1, 1.2 and 6.2.7 for more details). Semi-structured interviews were used so that specific topics of interest to the interviewer were covered. This interview style is more restrictive than in-depth or narrative interviews which allow for the interviewee to determine topics of interest or

importance (108). To address this, open questions were used and the interviewer was flexible in following emergent themes (214).

All interviews were audio recorded using a digital voice recorder (Olympus digital recorder (DM-10)) and transcribed verbatim. Transcripts were loaded into a computer software program to assist in carrying out the analyses (NVIVO version 7-10 (215)).

6.2.3.1 Timing and location of interviews

All physiotherapists were interviewed within three months of delivering a group in the BeST trial. This time frame was selected to increase the chance of recall of relevant issues surrounding implementing the intervention. For the majority of physiotherapists this was after delivering their first group, for two physiotherapists after their second group and for another two physiotherapists after delivering their third group. Interviews were conducted between March and September 2006 in a place of the physiotherapists choosing. This was in the physiotherapist's home (four interviews) or in a quiet room in their workplace (five interviews).

6.2.4 Interview schedule

The questions asked in a structured interview are important in determining the quality of data obtained during the interview. Green and Thorogood (108)p113 acknowledge that this process is cyclical, in that asking the right questions requires an understanding of how the participants think about the topic of interest. However, they do provide some guidance which was used in the development of the interview schedule by the thesis author:

- 1. Participants were not asked the specific research question. In this study the research question related to factors influencing successful or unsuccessful integration of CB skills into physiotherapy practice. Instead, questions were developed to tease out these details based on potential influencing factors. For example, the influence of experience was explored through the question 'Tell me about your previous use of the cognitive behavioural model, prior to the BeST training'.
- 2. Technical language was avoided, for example in asking about 'questioning style' rather than their use of Socratic questioning/guided discovery.
- 3. Leading questions were avoided and open questions were used in preference to closed questions, such as: 'Has the training had any personal implications?' not 'Did you find it helpful to apply the techniques to yourself?'.
- 4. Questions that suggest a judgement were avoided such as: 'Can you tell me about any difficult sessions or difficulties with running the group or using this approach?' not 'tell me about sessions that you found difficult'.
- 5. Participants should be asked about their experiences rather than theoretical questions for example: 'How did you find introducing the following concepts with patients?' However, a theoretical question was also asked: 'Who is this approach most / least appropriate for?' as the subject of suitability was raised by the first two physiotherapists interviewed and represented a potential barrier to integration/implementation.

The interview schedule is shown below in Table 27.

Table 27 Interview schedule for the qualitative study

- 6. Tell me about your previous use of the cognitive behavioural model, prior to the BeST training
- 7. Any formal or informal training on its use?
- 8. Any training on other psychological models?
- 9. Did your understanding of the CB model change after the training course? How?
- 10. Did the model fit in with your previous understanding of pain management?
- 11. How did you find using a more discussion based / questioning style in sessions?
- 12. How did you find introducing the following concepts with patients? (each topic in BeST asked about)
- 13. Can you tell me about any difficult sessions or difficulties with running the group or using this approach?
- 14. Can you tell me about any sessions that went well?
- 15. Who is this approach most / least appropriate for?
- 16. Did the training impact on your management of patients outside the trial?
- 17. Has the training had personal implications?

Interviews lasted on average 34 minutes (range 22 to 48 minutes).

6.2.5 Analytic framework

Qualitative research varies enormously in the level to which data are analysed from simple reporting of empirical data through to theoretical analysis (108). In most qualitative research the researcher attempts to use some interpretation or seek some meaning from the data in order to provide a structure from which the information can be understood and used. The methodology used will depend primarily on the research question to be answered but in practice Green and Thorogood (108) feel that most researchers uses a pragmatic mix of methods within any study.

6.2.5.1 'Framework' analysis

Methods for qualitative analysis were reviewed by the thesis author and Framework analysis was selected as the method best suited to the study aims. The method of 'Framework' originated in an independent qualitative research unit, National Centre for Social Research (NatCen (216)). The unit specialises in applied policy research in which qualitative studies are undertaken in order to generate policy and practice orientated findings. 'Framework' method of analysis is commonly used in healthcare research (108) and is part of the group of analytical methods called thematic analysis or qualitative content analysis. The main defining feature and strength of the method comes from the structured production of a framework or a chart which is used to examine data for patterns within and between participants (207). This approach allowed for a structured comparison of response patterns between physiotherapists with different levels of competence.

Framework Analysis is not associated with a particular philosophical stance and is rather guided by the research question. In this study the perspective of the participant was sought on the integration of CB skills into practice. This draws on interpretative and phenomenological approaches which seek to understand the experiences and perspectives of the subject (108)p13-15.

Overview of the method

Following familiarisation, the data were organised according to recurrent or common themes. These themes were given a code to aid quick labelling of the data. Once all the interviews were coded, data were collected together according to themes in a chart. The data within each theme were then examined for patterns within and between physiotherapists and for patterns with outside variables such as experience and competence. These first stages are very similar to thematic content analysis,

however, within Framework analysis relationships between themes are also mapped diagrammatically. The final analysis should involve some interpretation by the researcher (207, 216). 'Framework' consists of five stages that can be followed in a linear fashion but frequently the process of analysis will involve reworking of previous stages as theories are tested.

6.2.5.2 Stages of 'framework' analysis

(See Ritchie and Spencer in Huberman and Miles 2002 Chapter 9 (216))

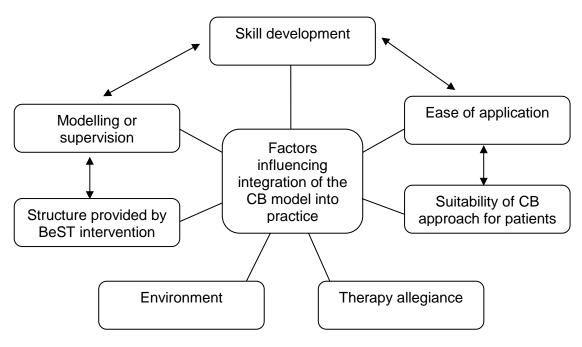
Familiarisation

The process began with becoming familiar with the data. Interviews were listened to and notes made on the transcripts of key ideas and recurrent themes.

Identifying a thematic framework

From the general notes made in the familiarisation stage, an initial coding framework was developed which reflected the range of themes emerging from the physiotherapists responses. A second researcher also developed an initial coding framework using a sample of three interview transcripts. This was done to challenge the primary researcher's interpretation of the data and to check that the themes that were emerging from the data were discreet. Differences in coding were discussed and resolved. Both researchers then applied the coding to three interview transcripts independently. Again differences were discussed which enabled clarification and refining of the themes. At this stage the relationship between codes was also mapped diagrammatically to aid initial theory formation. An example of one diagram is shown below in Figure 23;

Figure 23 Early stages analysis diagrammatic mapping of emergent themes in qualitative study



Indexing

The thematic framework was then applied to all interview transcripts. This was a thorough process which involved looking beyond the simple responses of physiotherapists for alternative meanings and then indexing (also known as coding) appropriately. In the process of indexing all nine interviews the codes were refined further as new themes and patterns emerged from the data.

Charting

In this stage the data were collected together in a condensed version within a table (Appendix 11). Data were arranged according to each physiotherapist and further categorised into three subheadings; factors associated with the therapists, the CB intervention and the patients. Arranging the data in this way allowed for comparisons to be made both within and across physiotherapists. At this point the data has been lifted out of its original context but still represents what the physiotherapist said.

Mapping and Interpretation

Using the charts, the data were then analysed looking for associations in an iterative process using inductive reasoning. This process involved several different analyses:

- Defining concepts, e.g. how the physiotherapists defined a successful group or session
- Mapping the range and nature of phenomena e.g. aspects of confidence in integrating CB approaches
- Creating typologies where two factors are found to relate at different points which produces a graphic representation of types of cases e.g. which skills were defined as more or less difficult to implement
- Finding associations e.g. patterns in the beliefs held by those more or less competent
- Providing explanations of beliefs e.g. how insight into performance was linked with competence level
- Developing strategies in light of the findings e.g. implications for training or supervision

6.2.6 Rigour in qualitative analysis

Qualitative research is often perceived by the scientific community as unstructured, biased and as such unreliable (217). To address this, many different methods or criteria have been suggested to reduce bias in qualitative research in line with similar check-lists or criteria for quantitative research (205). As to be expected there is no universal agreement about quality assessment in qualitative research (218) but several key concepts discussed below have emerged and were used in this study.

Transparency

Transparency involves providing a clear and accurate report of the methods used in the analysis (108). 'Framework' provides a structured and staged approach to analysis which allows clear reporting of each stage (216).

Comparison

Hypotheses formed in the analysis can be checked across the data set to see if they hold true in other situations, times, physiotherapists etc. (219)

Deviant case analysis

Alike 'comparison', this involves checking for cases that do not adhere to the norms or fit with the emerging theories. Deviant cases help to explain the range of behaviour and to further refine hypotheses (219).

Validity

In presenting the results, the use of counts and exemplars can help to provide some evidence of how themes and theories were formed (108). The 'validity' of the analysis can also be checked by a second researcher, not with the aim of reaching consensus but to challenge the main researcher's interpretation of the data (108). Validity can also be provided by a process of triangulation where results are compared to the results obtained by other methods to look for convergence (206). This concept will be used in Chapter 7 (Discussion).

Reflexivity

Using a constructivist paradigm, the thesis author's background and beliefs will be intrinsic in the final output of the study (220). Whilst the other methods described in this section were applied to reduce bias, the concept of reflexivity is acknowledged, and as advised by Koch et al (220), a reflexive statement is included below.

6.2.7 Reflexivity statement

I am a trained physiotherapist and cognitive behavioural therapist (CBT). My reasons for training in CBT were primarily to improve my management of patients with chronic pain. I feel that the CB model and skills are very useful to apply both within my practice as a physiotherapist and personally to manage my emotional states. I feel that physiotherapists may benefit from training although I hold no strong beliefs about many of the details around training requirements.

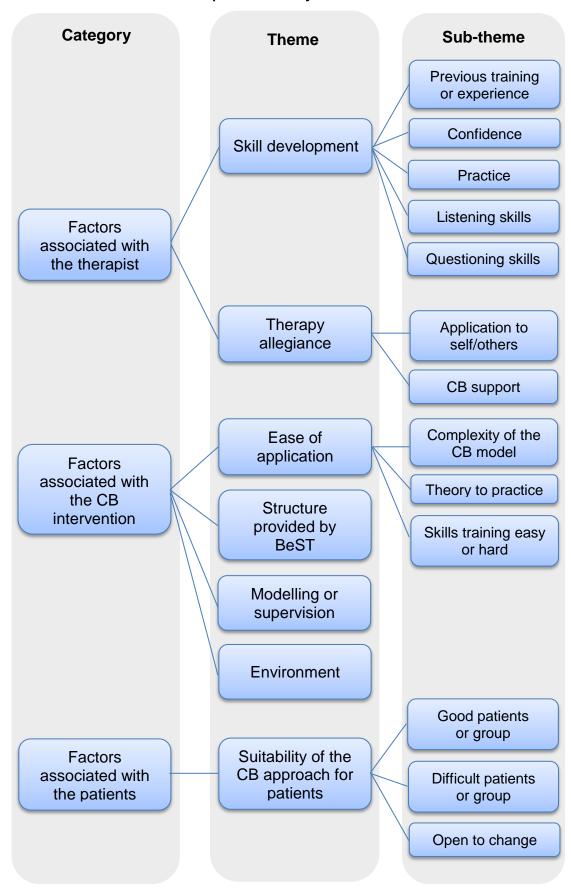
6.3 Results

Each theme and sub-theme will now be summarised with the use of narrative exemplars from the interviews using their study number to protect anonymity. The category of higher competence (HC) or lower competence (LC) is assigned to each participant exemplar accordingly. Analyses of the data will also be presented within each theme.

6.3.1 Summary of codes

The thematic framework is shown in Figure 24 below.

Figure 24 Diagrammatic representation of thematic framework showing the categories, themes and sub-themes of the qualitative study



6.3.2 Factors associated with the therapist

6.3.2.1 Theme: Skill development

Definition:

Anything the physiotherapists suggest to be involved in their skill development

Skill development, Previous training or experience

Definition:

Any previous training or formal/informal experience that influenced integration of skills into practice

All physiotherapists reported that they had no formal training on a CB approach. Despite this, most physiotherapists reported informal learning through a variety of other channels. Four of the five HC level physiotherapists described specific previous experience of running similar groups compared to none in the LC level group. The HC level physiotherapists were also more likely to cite informal learning from colleagues (three in the HC group compared to one in the LC group). However, for five physiotherapists, previous attendance on a pain management course that gave them some skills in CB approaches was not related to competence level. Two physiotherapists reported that they were already doing parts of the approach within their practice.

"I think you pick up parts of that approach anyway, just clinically practising, actually encouraging patients to do their exercises. Trying to find ways to get them on board, you kind of develop that instinctively or as part of your clinical experience but I have had no kind of formal training in this approach, no"

Physiotherapist 16 (HC)

It was acknowledged by several physiotherapists that the BeST training had given them a structure to what they had learned informally prior to the BeST training.

"I think from previously to the course in my understanding, was to take

particular pieces of what I now understand to be a CBT model and then sort of adapt
that to what I felt comfortable with really and now I can see how everything
interrelates"

Physiotherapist 2 (HC)

Several physiotherapists spoke about the difference between their previous training in physiotherapy which they perceived as a more didactic approach, compared to the collaborative approach in the CB training.

"As physio's I think we're very didactic and tell people what to do, whereas my take on the cognitive behavioural course was trying to get participants onto a self discovery journey really with their back pain and it was much more taking a back seat and letting them do the work rather than us telling them what to do"

Physiotherapist 12 (HC)

Lack of specific experience of back pain was seen by one physiotherapist as linked to her difficulty in delivering group sessions.

"I think I just sometimes would have liked to have had more examples in my head, or more information there because it maybe would have helped and filled in the gaps of time with people"

Physiotherapist 18 (LC)

• Skill development, Confidence

Definition:

Statements explicitly or implicitly suggesting confidence about implementation of CB skills

As could be predicted, confidence was linked with previous experience and clinical practice by several physiotherapist. They were more confident delivering familiar material and less confident with the material relating to new skills for them.

"I think my confidence in delivering things at the beginning was the hardest and I think that's the same with anything new isn't it, is that you just become more experienced don't you and you have some background knowledge you can draw on"

Physiotherapist 18 (LC)

"Because it's quite a comfortable concept, I'd say that was one of the easiest things to introduce. So, I was happier with that than some of the later ideas that were probably a bit more challenging for me when it came to being at the front of the group, or was guiding the group. It's easier to be a guide when the material is very familiar"

Physiotherapist 6 (LC)

"That was the session that I was probably most concerned about because that was something quite new to do"

Physiotherapist 19 (LC)

Confidence was also linked by one physiotherapist to patients being on board with the concepts in the session.

"It was good because you could see people reacting and thinking 'My goodness that's me' and you do get more confidence delivering these things as people recognise themselves in different modes"

Physiotherapist 3 (HC)

One physiotherapist spoke about the trial giving them confidence with difficult patients outside of the trial.

"Because it was presented so well in the BeST trial, some aspects of it filtered over which was really helpful [pause] I think it gave me much more clarity of thinking which enabled me to [pause] facilitate people more, and I think it took the fear factor away"

Physiotherapist 16 (HC)

Skill development, Practice

Definition:
The role of practice in skill development

Nearly all physiotherapists spoke about practice in relation to skill development, particularly with introducing thought challenging and their use of questioning.

"Right this is the one that I found the hardest because this is new stuff to me really and I need to practice this, I think this is the one that's new to physio's"

Physiotherapist 12 (HC)

Three of the four LC level physiotherapists explicitly stated that they needed to practice, whilst only one in the HC level group did which may indicate some insight into their lack of skills.

Physiotherapists also spoke about feeling clumsy or stilted with the approach and not covering subject matter in enough depth.

"I think you need to be quite practised and skilled to actually say 'oh right very good point see what you're saying' and then make them turn it around and challenge themselves that is, just requires practice practice like a lot of things we do and at the moment I feel bizarre and quite clumsy with it but I'm learning"

Physiotherapist 5 (LC)

"I've gone and I've done it, but then I'd think afterwards 'well have I covered everything that I should have done?', 'have I covered everything the way I should've done', 'have I reinforced and gone back to cycles and things enough' or cause you can whiz through certain elements very quickly, and then you think have I really brought it home, have we discussed it enough"

Physiotherapist 19 (LC)

This 'clumsiness' with the approach was eased by one physiotherapist who felt that

using the terms outside of the trial led to becoming more comfortable within the trial sessions.

"I'm starting to feel more comfortable with it now and I can see how it works and again, I'm starting to talk in those terms in clinical practice again just to...with patients that I see. So it makes life a little bit easier"

Physiotherapist 2 (HC)

• Skill development, Listening Skills

Definition:
The role or importance of listening skills

Two competent physiotherapists mentioned listening skills within the framework of allowing a patient to discuss their back pain using their own terms and giving their own opinions.

"what I learnt from the sessions was actually to take even more of a back seat and actually listen to the patient far more and get...almost get the patient's narrative and give them time to express that and to give you their story. I think that's certainly one thing I've learnt and has changed"

Physiotherapist 2 (HC)

• Skill development, Questioning Skills

Definition:
The role or importance of questioning skills

Questioning skills were described as difficult to master by all physiotherapists with most stating that questioning was not a normal approach for them. They felt that they would slip back to a more didactic approach, especially in difficult situations such as time pressure.

"I think it's because it's a new skill and I think it's partly to do with not realising quite how ingrained my normal way of presenting information was and that... the de-learning, rather than the new learning was probably more difficult.

Stopping yourself from being a teacher is very difficult"

Physiotherapist 6 (LC)

"You're still trying to revert back to your old...you know...you're still trying to be a bit didactic in trying to guide the patient and you have to keep having to remind yourself to sit back, shut up and let them get on with it" Physiotherapist 2 (HC)

Despite this, questioning was acknowledged by most physiotherapists to be a useful skill that they were attempting to master.

"I really enjoyed bringing it in, I thought it was actually, [pause] when it
worked well I thought it was much more powerful than me sitting there telling them I
think it was much more effective"

Physiotherapist 16 (HC)

Four of the five HC level physiotherapists reflected that they could revert back to a didactic non-questioning style, whilst none of the LC level group did. Three of the HC level group also discussed how they felt their skills were better than they were until they reflected on their practice.

"I think the BeST trial was the first time, really, where you actually spent a bit of time actually thinking, well, in the treatment am I trying to get them to come to the conclusion or am I being much more directive in saying this is how it is? Because I think before I always wanted to communicate how things were and were waiting for them to kind of agree along the way, so I got agreement which is great, but it wasn't, I was trying to get them to verbalise it before I did, does that make sense? So this was quite a new thing I think for me, which I thought was really helpful."

Physiotherapist 16 (HC)

This suggests that HC level physiotherapists had insight into when they were using a CB approach and when they were not and also some insight into quality of specific skills. This could be supported by a statement from one LC level physiotherapist who felt they had always used a questioning approach.

"...whenever I've taught patients in a group, I've tried to lead them to give me the answers. Rather than, yes, lead them to the answers so that they get the answers rather than me telling them the answer. So I've always used that sort of approach"

Physiotherapist 19 (LC)

However, one physiotherapist from the LC level group did reflect on their questioning skills.

"I had always thought I wasn't particularly dictatorial, but I was amazed at how often I had to bite my tongue, or didn't manage to bite my tongue when it came to giving someone information, rather than trying to get it out of them"

Physiotherapist 6 (LC)

Subject matter or the size of group was reported as factors that made applying questioning skills easier or more difficult, such as smaller groups making questioning more difficult.

"A couple of times there were smaller groups and certain... I think depending on how chatty those people are, you just have...you felt sometimes you were having to lead it a bit more and then I'd think 'Am I saying too much?"

Physiotherapist 18 (LC)

Physiotherapists on the whole felt that they would continue to improve with practice.

6.3.2.2 Theme: Therapy Allegiance

Definition:

The overall support that an individual has for the intervention they are delivering

A physiotherapist's relative support of a CB approach could influence how successful integration into practice is. Within this study several potential indicators of support for a CB approach were seen. Evidence of application of the techniques to self, evidence of application of the techniques to people outside of the trial (friends/family/other patients), positive or negative statements about the CB approach and explicit criticisms or lack thereof regarding the trial intervention and/or the patients that were included into the trial.

Therapy Allegiance; Application to self or others

Definition:

Any indication of the physiotherapist using the skills outside of the trial

Most physiotherapists (n=7) identified that they had applied the skills either to themselves or to patients/friends that they saw outside of the trial. They were more likely to mention using the specific CB skills of thought challenging and vicious cycles (n=6) than the discrete self-management skills such as goal setting and pacing (n=2). In addition, four physiotherapists mentioned non-discrete changes such as how they had changed the way they talked with or listened to patients.

"It has potentially made me become a little bit more tolerant of some patients that perhaps in the past that I wouldn't have been but sometimes that goes a bit with you know what the rest of my week has been like and how knackered I am"

Physiotherapist 5 (LC)

This was supported by another physiotherapist who also mentioned that whether the

skills were applied in clinical practice outside of the trial was influenced by 'time and

energy'.

"I'm sure there must be elements where I'm attempting to be slightly less

leading with patients and there is the time element. There is also the energy

element"

Physiotherapist 6 (LC)

There was wide support for applying the skills personally although only three had

actually done so. One physiotherapist had explicitly applied the skills to her own

health problems and another had applied the skills to herself in order to be able to

teach the skills to others better. One of the physiotherapists who expressed that

they would benefit from applying the skills to themselves had applied the skills to a

friend with depression which indicates a wider impact of the training. This was also

expressed by another physiotherapist who described how they had changed the

way they looked at things;

"I don't think it's particularly changed who I am but I think I can look at things

a bit differently, you perhaps see people arguing and you think why are you getting

so upset about this sort of thing (laughs), you can look at why that's happening, the

way you are at work, different ways that people approach things"

Physiotherapist 12 (HC)

Those applying the skills personally were no more or less likely to be competent.

Therapy Allegiance; CB support

Definition:

Any statement about the CB approach in

general that is positive or negative

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A majority of physiotherapists gave positive statements about the approach.

"Yer, this was the biggest area that was new for me, I found it fascinating

and I really enjoyed it, I think [pause] I think this is an area that is definitely important

and would benefit physio from knowing more to be honest, because it's so ingrained

into how they are going to act then isn't it and if they will do the things we think are

helpful for them or they think are helpful"

Physiotherapist 16 (HC)

"Well my belief is that anybody that's had on-going low back pain, that there

is something in this group that would help them really"

Physiotherapist 12 (HC)

"I found that that was very helpful to try it myself. Well it is really useful – let's face

it. Who could deny it?"

Physiotherapist 6 (LC)

Whilst a couple of physiotherapists felt that they thought the approach would be

helpful for everybody, four physiotherapists made explicit statements that were

critical of the patients that had gone into the trial, i.e. they felt that they were not

suitable for the approach. Most of these were the HC level physiotherapists. Patient

suitability is discussed in more detail in section 6.3.3 below.

6.3.3 Factors associated with the cognitive behavioural intervention

6.3.3.1 Theme: Ease of application

Definition:

Anything about the CB approach itself that impacts on ease of application

and impacts on sace of application

This theme was made up of three sub-themes; complexity of the CB model itself,

theory to practice issues and specific skills that were easy or hard to implement.

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Ease of application; Complexity of the CB model

Definition: How easy or difficult the CB model was to understand

Whilst most physiotherapists found the CB model easy to understand, a couple also felt that it would not be so easy for their patients to understand and that they would need to pitch it at the right level or keep reinforcing the principles.

"...I mean academically I was concerned that the group that I was going to be running in (Place), the 3 clients, making a judgemental decision (little laugh), making a judgement about their academic abilities, I felt they were relatively low and I was concerned about whether they would take on board concepts but I think in the end they did, I think we had to pitch it slightly applied level to them but they were still able to take on the concepts that were taught to everyone else"

Physiotherapist 11(HC)

Whereas other physiotherapists expressed that they found the model easy to understand and patients would find it easy as well.

"....it felt quite logical and ()... It felt quite easy to talk, in I suppose, the terms that were appropriate for the people that were in the group as well, if that makes sense?"

Physiotherapist 18 (LC)

Ease of application; Skills training easy or hard

Definition: Specific skills that were easy or hard to implement Physiotherapists classified specific session topics as being easy or hard to implement. This is shown in the graph below (Figure 25).

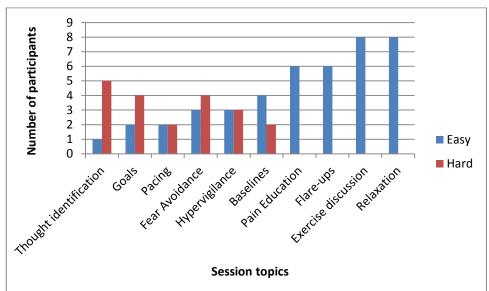


Figure 25 Session topics in the Back Skills Training trial intervention that participants expressed were easy or difficult to deliver

Several session topics were consistently rated as easy to deliver and this was attributed to the topic being very familiar; pain education, exercise discussion, relaxation and flare-ups. When a session topic was rated as being hard it was most commonly attributed to the content being new to them with the 'hardest' topic being thought identification.

"I think the areas I was already working in, in terms of the more physical side of things like exercise and pacing and grading that was quite easy and quite simple to build into my current practice, I think the new areas like 'thought identification' and thinking about 'vicious cycles', of 'hyper vigilance' and our worries is a much newer areas and I guess I was much more cautious in using that, as I didn't want to get out of my realm of abilities and my scope of practice"

Physiotherapist 16 (HC)

Goal setting is a familiar topic to physiotherapists (221) and four of the physiotherapists reported this was a difficult topic. Of those reporting it was a difficult

topic, three of whom were in the LC level group. They attributed this to the difficulty in getting patients to decide on goals, difficulty setting goals in those that were minimally disabled and those that just wanted less pain as this was not a functional goal.

"...but getting people to decide on goals – never mind the fitness goal, just at times...and that's when the teacher element started to come out. 'Ok, so you kind of like walking? Let's do walking shall we?' (both laugh) () Yes, you're pulling teeth and it almost seemed to hamper the whole assessment – dragging that goal out of people"

Physiotherapist 6 (LC)

"I mean goal setting is always hard isn't it, because you're trying to make it functional and they just want to say I want to get rid of my pain"

Physiotherapist 19 (LC)

"...because I'd got this preconceived idea as to how able people were going to be and what they were actually doing, so I think I was expecting my goal setting to be more... If somebody was perhaps quite limited in their walking distance for example, that I could slowly build that up and that... and in fact they were all doing a lot more than I expected, so suddenly I was thinking 'Oh Gosh, what's my goal here?"

Physiotherapist 18 (LC)

Subject matter was not the only reason for stating that a session was hard to deliver.

Factors about the group participants impacted on ease of implementation and are discussed further in section 6.3.4.1.

• Ease of application; Theory to practice

Definition:
Ease of putting the theoretical knowledge into clinical practice

Most physiotherapists spoke about how the CB approach was easier to understand than it was to put into practice and some of these felt that they slipped back into their old practice as a result.

"I'd been using it in my clinical practice, but I hadn't been focussing on just that model as intensely as I had before, so I found I was tempted to be, actually, this is the way it is, this is what you need to do, and less trying to facilitate them in their thinking"

Physiotherapist 16 (HC)

6.3.3.2 Theme: Structure provided by Back Skills Training trial

Definition:

How the structure provided by the BeST intervention impacted on the implementation of the CB approach

All physiotherapists spoke about how they felt the structure within BeST helped them to implement the approach.

"I can think about diagrams I could use or questions I could bring in, it's given me a structure to start approaching some of those areas"

Physiotherapist 19 (LC)

Some physiotherapists made reference to the written material such as the crib sheets and suggestive scripts in the manual for providing a useful structure.

"The crib sheets were very helpful and well, the whole of the information that's been given has been good – if that's any help, but it was helpful having the crib sheets there, just to make sure that we stuck to the script because it's very easy to go off and talk about other things"

Physiotherapist 3 (HC)

Several contrasted the structure provided in BeST with previous training that had equipped them with the CB conceptual model but had not been suggestive in the way that concepts could be explained to patients.

"(My previous training) was almost sort of high – almost like high temple

CBT, whereas the training from Warwick and then applying that was, I think, at a

level that certainly seemed more user friendly for somebody from my background"

Physiotherapist 2 (HC)

Within the BeST intervention, a certain amount of repetition was purposively included to ensure that trial participants learnt key skills. Interestingly, several of the physiotherapists mentioned that they felt that the content of the sessions could be repetitive.

"Well, I know a lot of it is reinforcing all the way through what we've done and I felt that was reiterating what was already covered in sessions before about what do you do to cope, so they were coming up with the same kinds of things"

Physiotherapist 3 (HC)

"Yes, well you're reinforcing similar messages aren't you? The first few classes, there were some new ideas being thrown around and then its similar ideas being reinforced and coming up in a slightly different form, but the principles are the same"

Physiotherapist 6 (LC)

"You did sometimes feel as though you were perhaps repeating things a lot so you know and that is fine but I, perhaps I'm so used to my time constraints see people pop pop pop to spend so much time on things that you know you'd thought that the broad concept was easy enough to grasp, to work with and finally you're going back repeating it looking at it again"

Physiotherapist 5 (LC)

It could be postulated that if the intervention was not so structured, that physiotherapists would omit to repeat skills which may have an effect on learning/implementation.

6.3.3.3 Theme: Modelling or supervision

Definition:

How supervision or modelling of the skills impacts on implementation

Four physiotherapists spoke about how they found in-session supervision useful to

see some of the skills modelled or to moderate when they were straying off the

subject.

"That was quite useful as it highlighted how much quicker you picked up on

things that I didn't you know I was sort of behind a second or so in my thoughts from

where you were at and you were able to drop hints to guide things a bit better and

that was quite useful for me to sort of see and to work with" Physiotherapist 5 (LC)

One physiotherapist spoke spontaneously about wanting to have more training. This

could reflect how other physiotherapists perceived the training they had received for

BeST, or the usefulness of further skill development, or could simply reflect that this

topic was not included in the semi-structured interview.

6.3.3.4 Theme: Environment

Definition:

Anything about the environment that was

linked to implementation of skills

It may be important to consider environment when delivering a CB approach

according to a couple of physiotherapists. One felt that a noisy and busy department

was not right for using the skills and the other felt that a large room did not help with

discussing personal topics.

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6.3.4 Factors associated with the patients

6.3.4.1 Theme: Suitability of a cognitive behavioural approach for patients

Definition:

Any factors associated with the patient that could impact on integration of a CB approach

Physiotherapists described features of patients or groups that made them easy or difficult to implement the CB approach. Their language often referred to 'good' or 'bad' patients or groups. In addition concepts of readiness to change were also mentioned and formed a further sub-theme within the *Suitability* theme.

Suitability of CB approach for patients; Good patients or group /
 Difficult patients or group

Definition:

Features or the patient/group/session that made it easy or difficult to implement a CB approach

Physiotherapists defined characteristics that were associated with being a;

- 1) Good / difficult patient
- 2) Good / difficult group
- 3) Good / difficult session

This is summarised in Table 28 below.

Table 28 Features of good or bad patients/group/sessions defined by physiotherapists in the interview study

Good patient	Difficult patient
Ready to accept approach; seen lots of professionals with no change, not seeking a fix, willing to try something different, not still looking for medical management	Still seeking cure/diagnosis; or feel they have not been looked at medically Mechanical back pain that needs manual therapy, those that need and want medical model management Those that are not ready to listen or try change
Most disabled Using a lot of healthcare resources Fear avoidant / over-doing it and not pacing	Most disabled; difficult to set baselines Lots of psychological issues or yellow flags Ingrained in unhelpful beliefs Least disabled; difficult to set goals
Self-responsibility Started the process of self-managing	Already coping well Busy people wanting a fix
Negative – group can effectively challenge Non argumentative	Negative Talk lots and will not listen
Back pain the most important problem	Not in bad patch (will not take on skills)
Approach suitable for a lot of back pain patients	Concerned about benefits being stopped
Good group	Difficult group
Suitable group as not seeking tests or treatment	Other significant health problems Small group
Patients keen to participate and reflect on skills learnt Positive group	Patients throwing up difficult situations
Group with good problem solving ability	
Good session	Difficult session
Some skills not suitable for some (e.g. cognitive skills) but they benefited from other skills Relaxation although not sure how much patients apply skills taught	Attention to pain difficult if no insight Identifying thoughts difficult if patients not academic, might lose people Pacing in real life scenarios or working population Fear avoidance difficult as no-one with that problem Pain education when patients have acute pain

Many of the characteristics that made a patient a 'good patient' were also seen as characteristics for a 'good group' such as those not seeking a cure. As discussed in the previous section, sessions could be perceived as easy or difficult to deliver. This perception was often due to patient factors such as the *identifying thoughts* session being difficult if the patients were not 'academic' enough.

There were some interesting patterns in the responses of physiotherapists. Five physiotherapists perceived a good group or group session to be one where group discussion flowed well. However, four of them attributed this externally to the group members rather than any facilitation skills they might have.

"It's a real skill I think to get the group talking and actually my group were fairly good at that"

Physiotherapist 12 (HC)

"I think I've been quite lucky with the group I've had, they've been quite good at joining in"

Physiotherapist 19 (LC)

Several commented that small groups with fewer patients were more difficult to facilitate a discussion within and that with fewer people talking they resorted to leading the group 'too much'.

"A couple of times there were smaller groups and certain... I think depending on how chatty those people are, you just have...you felt sometimes you were having to lead it a bit more and then I'd think 'Am I saying too much?" Physiotherapist 18 (LC)

Several physiotherapists spoke about the level of self-management a patient was engaged in. Too much or too little self-management was described as making the patient difficult and this level of self-management was tied with the extent to which someone was still seeking diagnosis or a cure.

"I think sometimes people who are already very well motivated perhaps are already putting a lot of these things into practice and perhaps don't need the group almost () but maybe they are useful because they can show other people () So you are kind of looking at missing out the two extremes, those who are already well on the route perhaps are not so suitable and those who are so far off the route that they are never.."

Physiotherapist 11 (HC)

Suitability of CB approach for patients; Open to change

Definition:

Perceptions of readiness to change as important in ease of implementation of a CB approach

Most physiotherapists spoke about patients being suitable for the approach when they were open to change. This was defined using terms such as 'motivational stage' or that the patients were not still seeking a cure.

"I think people who are still searching for the exact diagnosis so that they can find the cure, although I have had a few convertees as it were in some of the groups that I've run, I think on the whole they can be quite resistant to change"

Physiotherapist 11 (HC)

It was felt that several skills would not work unless the patient was motivated and practised the skills including goal setting, thought challenging and relaxation.

"I think the 'thought identification' and 'self challenging', [pause] they do get, but it is harder for them to get and to have a long term effect with that they would have to put more work into that, outside the course, it depends on the motivation levels"

Physiotherapist 16 (HC)

Despite the perceived association between 'openness to change' and outcome two physiotherapists were disappointed when they had patients they felt would have benefitted from approach, who did not attend or make the changes.

"I really felt 'Oh this person needs the support to pace themselves, to set goals and things and that would help them', but you... They've got to be willing to do that as well haven't they? Yes. You can give somebody the ideas but they've actually got to keep at it and...but with them having encouragement to keep at it, so I don't know. I just felt as if they were a potential...potentially could have done well, but it didn't turn out as I'd expected"

Physiotherapist 18 (LC)

Other explanations were given when patients that were perceived as 'open to change' did not do as well as expected. One physiotherapist spoke of a patient open to change but not able to apply any changes due to circumstances.

"She wanted to, she was very keen and very open and ready to change things if it was going to help, but the business just didn't allow for that really pragmatic approach"

Physiotherapist 6 (LC)

Lack of engagement with the intervention was perceived as a resistance to change by one physiotherapist.

"You're like no, perhaps you're resting a bit too much and need to be building up and doing a bit more, but they're happy with their status quo, so they're not pushing things (right), but at the same time they're moaning an awful lot about it at all"

Physiotherapist 19 (LC)

General comments about suitability

One physiotherapist commented that different sessions were suitable for different patients and outside of the trial they would choose to tailor the programme more for individuals.

"...people that I've met and come through, I've often found that, you know, session 3 and 4 they'll be good for you, the other weeks I'm not so sure about, and then someone else, well you need session 1 and 6, you know, something along those lines () So if you were to use it more on a one to one basis I'd probably tailor it much more as I think some people are getting more information than they actually require"

Physiotherapist 5 (LC)

There was no identifiable pattern in the specific responses on suitability and competence level of the physiotherapist. However, the three most competent physiotherapists all felt that there was a target audience for the intervention whist the other physiotherapists did not express this.

In general, within the theme *Suitability of the CB approach*, physiotherapists appeared to be attributing ease of implementation of the CB approach on characteristics of the patient, the group or the session topic itself. It could be conceptualised that all of these factors are not barriers to implementation but could form targets for the intervention and may just represent situations where greater competence level is required.

6.3.5 Results summary

Key findings from this interview study are summarised below.

Higher competence level physiotherapists were more likely to:

- Have specific previous experience running similar groups
- Have received informal learning from colleagues
- · Report they needed more practice
- Believe that listening skills are important
- Be aware of when they slipped back into a didactic style
- Find goal setting easy
- Believe there was a target audience for a CB intervention and were critical of the kinds of patients that went into the BeST trial

General summary points:

- The training in a CB approach was distinct in its collaborative stance which contrasted with a didactic approach they had previously trained in
- Formal training can provide a structure to what is learned informally
- Confidence was linked with specific previous experience or gained through practicing the skills
- Practice with patients outside of the trial improved confidence within the trial intervention
- There was a specific need to practice the questioning skills
- Subject matter or size of group may influence ability to use a questioning approach
- Physiotherapists used thought challenging and vicious cycles outside the trial as well as some discrete pain management skills
- Physiotherapists generally perceived the skills to be useful to apply to patients and to themselves
- Some topics within a CB approach were perceived as more difficult than others to deliver, this was usually linked with familiarity but contrary to this goals were perceived as difficult.
- Physiotherapists found the model easy to understand but more difficult to put into practice
- The structure provided in BeST including written prompt sheets and information on suggested dialogue helped to implement the CB approach
- Some physiotherapists perceived BeST to be repetitive and would have omitted to repeat skills if not given the structure
- Supervision was felt to be helpful by physiotherapists
- Physiotherapists defined good/bad patients/groups/sessions and expressed that characteristics influenced their ability to implement the approach, this may define the situations where greater skill level is required
- Physiotherapists perceived good group sessions to be one's where discussion flowed well although they attributed this to the patients rather than their own facilitation skills
- Being open to change was seen as important in implementing a CB approach and this was linked to participants seeking or not seeking a cure for their problem

6.4 Discussion

This discussion will consider the findings in relation to the wider literature and will consider issues of rigour and generalisability.

Physiotherapists in this study had no formal experience of CBT training which is reflective of the low number of CBT trained physiotherapists in the UK (6). Most of the physiotherapists reported having some informal experience which was then formalised through the BeST training. This high rate of informal experience is unlikely to reflect UK practice. Most of the physiotherapists involved in the BeST trial had volunteered to take part in the trial and we would assume that interest in the trial was sparked by prior knowledge or experience of CB approaches.

Previous experience of running similar groups to BeST was positively associated with their competence score (p=0.033). This is unsurprising as most models of skill acquisition have experience or practice integral to the process of the development of competence (for example; deliberate practice: (222), Dreyfus five-stage model: (223)). Confidence was linked by physiotherapists to both practice and experience with those that reported using the skills outside of the trial feeling more confident in those skills. This was also found in the Wiebe and Griever study (210) where GPs who used the techniques in daily life were more confident to use them in clinical practice. In addition, the palliative care nurses in the Cort study (213) expressed higher confidence in the techniques they used more often. This is clearly a cyclical process but the application of skills outside of a clinical context, in order to gain clinical confidence, is not a new concept. Students within CBT diploma training programmes are encouraged to use the techniques as part of self-reflection of their own beliefs (224). The aim is to provide

some element of practice but also for students to understand their own belief systems which can impact on therapy aimed at challenging patient's beliefs (224). However, the four physiotherapists that described using the techniques personally had a range of competence scores so this self-application and confidence had not always manifested in higher levels of competency.

Questioning skills were consistently found to be the most difficult skill to master by physiotherapists. Those that identified that they slipped back into a didactic style in difficult situations had the highest scores on the competency tool. This fits well with the conscious competence model (225) which suggests that students progress through four stages; unconscious incompetence, conscious incompetence, conscious competence, and unconscious competence. In the conscious competence stage the student is unable to perform the skill unless they are thinking about it. At this stage the skill has not yet become automatic but the person has moved from the stages of incompetence to competence.

The fact that these physiotherapists were able to identify situations in which they found applying the skill more difficult might indicate that some reflective practice had occurred which is linked with increased skill/competence (69, 226). Adding to this, one physiotherapist [16] with a high competence score discussed an example of reflecting on her practice in relation to her current and past questioning skills.

Physiotherapists discussed that small groups made questioning difficult. This most likely ties in with identified optimum sizes of groups of 7 or 8 (ranges 5 to 10) with regard to general group dynamics (227).

Familiar topics were found to be easier to deliver than the less familiar topics such as thought identification. All physiotherapists found that the structure of BeST helped them with implementation along with in session supervision which provided modelling of skills. The physiotherapists' appreciation of a manualised approach fits with the Dreyfus model of skill acquisition where the novice is defined by rigid adherence to taught rules or plans (60).

Overall the physiotherapists externally attributed ease of integration to patient or group factors, key ones being: acceptance, motivation, and current levels of disability and coping. These same issues were found in two qualitative studies conducted with physiotherapists to examine beliefs around treating low back pain (50, 204). In these studies good patients were perceived as those that were motivated and engaged in their treatment and difficult patients were those seen as wanting a cure and those not attempting any self-management (i.e. passive). In addition, in the Daykin study (204) difficult patients were those that the physiotherapist did not know how to treat or those that were not responding to treatment as expected. These issues did not arise in the current study, presumably because the physiotherapists were not involved in diagnosis or asking for specific information about how the patients were responding to the intervention within the BeST trial. However, the same issues about complexity arose in both the Daykin and current study where patients with co-morbidities were perceived as difficult. This is interesting because low back pain is associated with very high levels of comorbidity, for example pain at another site other than back pain (90% (202)) and anxiety/depression (25% (202)). Therefore it would be a common experience for a physiotherapist to encounter a patient with co-morbidity, with or without the additional issues of acceptance, motivation, and coping skills. We can perhaps conclude from this

that it is unlikely that many back pain patients are seen by physiotherapists as 'good' patients regardless of the intervention they are attempting to implement.

Therapy allegiance was indicated in this study by the presence (or absence) of several behaviours; evidence of application of the techniques to self, evidence of application of the techniques to people outside of the trial (friends/family/other patients), positive or negative statements about the CB approach and explicit criticisms or lack thereof regarding the trial intervention and/or the patients that were included into the trial.

Many of the study physiotherapists applied the skills to themselves or patients outside of the trial which indicates that many felt confident enough to try the skills in other settings. This may reflect the nature of the way in which they were trained over the two-day BeST trial intervention training whereby the therapists were encouraged to apply the thought challenging to their own beliefs. In addition it may reflect the generic nature of many of the skills that are encompassed under a CB approach heading but are actually tools for managing any health problem, for example goal setting and pacing (228).

A majority of the physiotherapists gave positive statements about the approach. This may have been anticipated as most had volunteered to get involved in the trial and the physiotherapists knew that the interviewer was a CBT therapist. Social desirability describes how respondents in surveys or interviews will express the views that they think will make them appear in a more positive light to the interviewer or wider society (108). Therefore, the physiotherapists in this study are more likely to have expressed positive statements about the approach. In some way this can be countered as a significant number (n=4) made statements that were critical of the types of patients who

had been entered into the trial knowing that the interviewer was heavily involved in the design and implementation of the trial.

6.4.1 Rigour

Good practice guidelines for qualitative research were in the main adhered to during this study (108) with a clear account of the methods used and evidence provided for each conclusion drawn from the data with comparisons both within cases and with other studies where they could be found. A second researcher participated in the first two stages of analysis to ensure that general themes identified by the primary researcher were identifiable by the second researcher. The later stages did not involve a second researcher as these were intensely time consuming and involved complete emersion in the data. Therefore the final analysis could be biased by the primary researcher in this study. However, this method is reflective of typical qualitative research where one person usually knows the data far better than members of their team and additional researchers unfamiliar with the data may be more prone to using preconceptions when checking themes (217).

6.4.2 Generalisability

Generalisability is a key issue within qualitative research that has the potential to undermine important findings. The issues that are raised within qualitative research frequently do not have the ability to be extrapolated to a wider audience simply by the nature of the narrow sampling framework when compared to larger survey based research. Green and Thorogood (108) argue that qualitative findings need to be viewed with reference to their ability to raise issues and generate concepts. In this study

several important issues were raised which will need consideration for improving the training of physiotherapists in CB approaches; these will be expanded in the next chapter.

6.5 Chapter summary

A qualitative interview study was conducted with 9 physiotherapists who delivered the BeST trial intervention. This study sought to explore which factors influenced the successful integration of a CB approach into physiotherapy practice. Several factors were found to be important for the physiotherapists in this study including past experience, training and practice, structure of the intervention and perceived difficulty of patients or groups. Some differences were found between physiotherapists classified as higher competence level and those classified as lower competence level that may help to improve training in future.

7 Chapter Seven - Discussion

This thesis aimed to contribute to the wider evidence base of psychosocial approaches in the management of LBP by exploring the role of competence in the delivery of interventions. This is an area with limited research and there were no tools in existence that could be used to assess competence in this capacity. A consensus study involving experts meeting tight criteria produced a competence tool that then underwent further validity and reliability testing. Earlier in this thesis good evidence was presented to support the validity of this tool for its designed purpose. A correlational study was conducted to explore the relationship between competence and clinical outcome utilising patient data collected in the BeST trial and competence level of physiotherapists, as assessed by the newly validated tool. Along with the interview study conducted with physiotherapists, new insights were provided into the development of competence and its role in the outcome of the BeST trial patients.

Several models were introduced in Chapter 1 to understand the development of competence. No one model has emerged as superior in explaining the findings contained within this thesis. Miller's pyramid (64) provided a useful rationale as to the utility of a performance tool in implicitly assessing knowledge and skills through the assessment of performance. The Dreyfus model (66) provided a justification for using a dichotomous point for competence or lack thereof, which allowed for the hypothesis generating in Chapters 5 and 6. Theories of reflective and deliberate practice provided context when these factors were associated with greater levels of competence.

This discussion will now consider the value of the CTS-R-Pain and will compare the results of the correlational study with the interview study. Recommendations for practice and further research will be provided.

7.1 The Cognitive Therapy Scale - Revised - Pain

7.1.1 Defining competence or defining a cognitive behavioural approach?

In designing a tool to assess competence of physiotherapists to deliver a CB approach in LBP, the Delphi experts had to define key behaviours or competencies that they felt were important. In this way the tool provides a theoretical definition of the essential ingredients of a CB approach in LBP. Whilst the physiotherapists in the BeST trial were able to demonstrate many of the competencies in the CTS-R-Pain, it should be noted that the BeST intervention was designed before the tool was developed. The BeST intervention was developed utilising CB theory and a literature review of modifiable risk factors associated with chronic LBP (91). Further research could now investigate whether the CTS-R-Pain could help to refine CB approaches in LBP and provide more structure to the training of physiotherapists, with the aim of improving patient outcome.

7.1.2 Robust design

The methodology used to develop the CTS-R-Pain was robust and in line with the AERA *Standards* for educational and psychological testing (92). As discussed in Chapter 2, many assessment tools are developed to evaluate training programs or interventions. This does not provide quality evidence as the assessment tool is only as robust as the design of the training programme or intervention, which is often not

reported. The CTS-R-Pain was developed by a relatively heterogeneous, highly experienced and qualified group of experts not associated with the BeST trial. In the absence of agreed definitions of a CB approach in LBP, they provided an assessment tool that can provide a foundation for further research.

7.1.3 Reliability

The CTS-R-Pain was found to have good internal consistency and reliability although further testing needs to be conducted on the reliability due to the reduced power of the inter-rater reliability study. However, the reliability scores were encouraging; although raters were familiar with the original CTS, and were involved in the design of the tool, there was no training provided them on the use of the tool, apart from guidance notes. Furthermore, the raters did not work together - training in assessment tool use and raters working together has been found to significantly increase reliability scores (86, 87, 123). If a tool has acceptable reliability with minimal training on its use, then it is likely to be easier to implement on a wider basis.

7.1.4 Other applications for the Cognitive Therapy Scale - Revised - Pain

It is worth considering possible applications for the tool outside of its design. The tool was designed for physiotherapists applying CB approaches in LBP. Within the BeST trial a range of health professionals were trained to deliver the BeST intervention on the premise that the skills were generic and that the needs of a large nationwide population of low back pain sufferers was unlikely to be met by physiotherapists alone (30). It would be interesting to see how/if experts would adapt the tool for other health professionals. Research is not as advanced in

applying CB approaches to other discrete chronic pain problems as LBP, although trials are emerging, for example in neck pain (229). It may be that the CTS-R-Pain has wider application in the competence of a range of health professionals applying CB approaches in a range of pain conditions. This is pertinent when it is considered that 90% of patients with LBP report pain in at least one other site (202). However, a competence tool is only valid in the population it was designed for and validity testing would need to be conducted before it was applied in other therapist or patient populations (92, 101).

7.2 Comparison of results from correlational and interview study

This section will discuss agreement or discrepancy between the correlational study and the interview study.

7.2.1 Experience

Previous specific experience was found to be important in the development of competence. The most competent physiotherapists as assessed by the CTS-R-Pain were those that reported previous experience of delivering groups similar to BeST. Experience was also found to be important in the interview study where the most competent physiotherapists reported additional specific learning of CB approaches informally from colleagues. The correlational study found some evidence of competence improving with time and/or additional experience which was supported in the interview study where physiotherapists reported that their skills were improving with practice.

7.2.2 Environment

The correlational study found that physiotherapist competency was associated with venue. The interview study did not provide further clarity on this as the two physiotherapists who mentioned environment had differing opinions. One physiotherapist reported a noisy or busy out-patient department was not appropriate for delivering the approach whist the other physiotherapist reported that large rooms were not helpful for discussing personal topics. The community settings in the BeST trial tended to be community centres or church halls; these were generally quieter than NHS clinic settings but were typically large rooms. Environment, i.e. community or NHS setting, did not predict outcome in the BeST trial (88) but it is reasonable to suggest that a quiet, distraction free setting might enable a physiotherapist to demonstrate greater competence in a new skill.

7.2.3 'Good' and 'bad' patient and group factors

There was correlation between the moderators or prognostic factors of poor outcome in this study and the factors that physiotherapists defined as a bad patient/group/session. Higher levels of baseline disability and fear avoidance beliefs were moderators/prognostic of poor outcome in the regression analysis and physiotherapists described bad patients as the 'most disabled' or 'those with lots of psychological issues or yellow flags' and 'ingrained in unhelpful beliefs'. Other studies have found also that physiotherapists are able to identify risk factors associated with poor outcome (see section 1.6.2) although they typically report a lack of confidence or skill in addressing these factors (50, 59).

Groups varied in their characteristics within the study, for example some groups were older or younger, and some groups had higher or lower levels of disability.

These variations did not impact on the competence of the physiotherapist delivering the group intervention. In keeping with this, the physiotherapists did not mention any

particular group characteristics that would make implementation easier or more difficult.

7.3 Were the physiotherapists in the Back Skills Training trial competent?

The definition of competence this thesis used was;

'The extent to which a therapist has the knowledge and skill required to deliver a treatment to the standard needed for it to achieve its expected effects'

Fairburn and Cooper (62)p374

Minimum competence was defined by the Delphi study experts as mostly scores of 4 out of 6 for each competency item in the CTS-R-Pain. No physiotherapists met this minimum competency level and yet the intervention was found to be effective (30). This suggests that the physiotherapists were competent enough to deliver the BeST trial intervention to produce the modest treatment effects seen. It may also add weight to the suggestion, made earlier in this thesis, that the Delphi experts set the minimum competence threshold too high. Further research, utilising the CTS-R-Pain, can now be conducted to see if improving the level of competence has the potential to improve patient outcomes.

7.4 Recommendations for practice / further research

7.4.1 Structured interventions

Of the nine physiotherapists that were interviewed for this study, eight reported some level of informal training in a CB approach. However, these skills were generally pain management skills rather than specific cognitive or behavioural skills which they lacked confidence in. Most were novices and as such appreciated the

structure of a manualised approach and semi-structured supervision. Therefore, structured interventions could provide a useful foundation to develop confidence and skills in novices applying a CB approach, particularly for the new specific CB skills such as questioning. In support of a structured manualised approach, some physiotherapists found the BeST intervention repetitive as it consolidated key skills at several points - in an unstructured intervention they may have omitted this repetition which would have lost opportunities for patients to learn the new skills. In the competence/clinical outcome study no effect was found for competence which is in keeping with other research of limited therapist effects where a manualised approach is used (200, 201).

7.4.2 Developing competence

Findings in this thesis can provide some guidance to help refine training in CB approaches for physiotherapists.

Timing of training

In the outcome study years since qualification were negatively correlated with back pain disability in patients (measured by the RMQ). This finding may have been spurious as years since qualification did not correlate with any of the secondary measures. However, years since qualification negatively correlating with patient outcome does relate to research presented in the introduction (section 1.6.3) showing that trained physiotherapists were less likely to change their behaviour after biopsychosocial training compared to students (47, 54, 55). If this is a causal relationship then it could have implications for the amount of training required to shift physiotherapists to a biopsychosocial perspective dependant on the stage of their career. However, there may be other explanations for this relationship, further research will be required. As a first step, if possible, other data-sets from RCT's of

CB approaches in LBP could be analysed to see if the finding of a relationship between years of qualification and clinical outcome is replicated.

Type of training

Physiotherapists valued formal training, often to put a structure to what they had learned informally. The value of formal didactic training in addition to other methods of training could be investigated to see which types of training are best suited to the acquisition of CB skills in physiotherapists.

Competence was highest in those who reported running similar groups in the past and had received informal learning from colleagues. Physiotherapists were more confident in their application of the techniques when they practised the techniques outside of the trial context, in particular within personal contexts. This suggests that practice based learning is also of value within CB approaches and that students could be encouraged to apply the skills across several domains whilst learning. If possible, novice physiotherapists may benefit from delivering a CB approach alongside experienced therapists so that they have specific experience prior to delivering interventions on their own. This could also address difficulty with implementation; physiotherapists in the interview study reported that CB approaches are easy to understand but more difficult to put into practice. Delivering groups with experienced physiotherapists would allow modelling of the skills in practice. This evidence ties in with theories and research base of deliberate practice (70) which has implications for further refining of competence towards the development of expertise.

Specific skills training

It can be argued that the core skill within CBT is the ability to apply questioning skills in order to challenge unhelpful beliefs. Physiotherapists recognised that a

collaborative CB approach was significantly different from their previous more didactic stance. Physiotherapists consistently found questioning skills the most difficult to master, this linked with their acknowledgment that this was a paradigm shift from their usual didactic style. For this reason, questioning skills need to be focussed on within training.

Training needs to include specific work on goal setting, as whilst this is a skill that should be familiar to all physiotherapists, it was one that was reported to be difficult with the patients in BeST. Furthermore, competent physiotherapists were unlikely to indicate that goal setting was a problem.

Physiotherapists may benefit directly from more group facilitation skills as they tended to attribute whether the group was flowing well with the participants being 'good' rather than their own skills.

Reflective practice

Higher competence level physiotherapists reported; they needed more practice, they noticed slipping back to didactic methods, they thought listening skills were important, and they believed there was a target audience for the interventions.

Together these statements may suggest that competent physiotherapists reflected on their skills more than the less competent physiotherapists. This would tie in with models of reflective practice which are becoming increasing recognised and integrated into education in the health professions (69, 230). These findings could lend support for reflective practice to be incorporated into training of CB approaches.

Targets for intervention

Overall the physiotherapists in the study provided rich information about patient factors that influenced the success of applying the CB approach. Ironically, these

factors such as poor coping skills, high levels of distress and co-morbidities are exactly the psychological and social risk factors that have driven the rationale for a cognitive behavioural approach in these patients. Taken individually these factors should not provide a barrier for implementation of a CB approach but provide targets for the intervention. To address this, training could highlight how different aspects of the intervention address patient factors that are seen as inhibitory to applying the CB approach.

Summary of recommendations for training physiotherapists in cognitive

behavioural approaches for low back pain

- The CTS-R-Pain can be used to help structure necessary skills and knowledge required in a training programme.
- The CTS-R-Pain can be used to monitor the development of competence within an individual and help shape training needs.
- Specific experience of delivering a CB approach, either through supervision with experienced colleagues or via in situ peer modelling is likely to increase competence.
- Physiotherapists should be encouraged to apply the techniques both to themselves and wider populations of patients where appropriate to increase confidence and competence.
- There needs to be a focus on the acquisition of questioning skills in CB training.
- Training needs to include goal setting skills and group facilitation skills.
- Reflective practice needs to be encouraged in the development of competence.
- Training needs to focus on matching CB strategies with the different risk factors for poor outcome that patients present with. This may prevent physiotherapists from believing that patients with high risk factors are too difficult to apply a CB approach with.

Summary of further research recommendations

- Refine the BeST intervention and training in light of the competencies specified in the CTS-R-Pain.
- Consider developing a structured, manualised approach to LBP that can be delivered on a 1:1 basis using the BeST protocol and considerations from the first point above.
- Further testing of the reliability of the CTS-R-Pain, including reliability when used by different populations, e.g. novice raters.
- Research into the transferability of the CTS-R-Pain in different pain populations and different healthcare professionals.
- The role of environment on therapist competence.
- The relationship between years of qualification and patient outcome needs to be explored, possibly with larger data sets from other trials of CB interventions. If a relationship is found then further research will need to explore this finding.
- Experiential models of training appear to offer benefits in the acquisition
 of CB skills for physiotherapists, the relative benefit of didactic training
 needs further exploration in relation to the cost effectiveness for level of
 competency attained.

7.5 Contribution of this thesis to the research evidence base

This thesis has progressed the understanding of competence in physiotherapists delivering a CB approach. This was an area that had received little attention despite international interest in improving the outcomes from CB approaches for LBP.

The competence tool, CTS-R-Pain, was developed using robust methodology in line with guidance from AERA *Standards*. It provides a framework which goes someway to defining the key components of a CB approach in LBP. This can be used to refine treatment interventions and could also provide an opportunity through methods such as factor analysis to determine the relative importance of the different intervention components in clinical outcome.

The CTS-R-Pain provides detailed information for each of the competencies on observable behaviours associated with different skill levels. In this way, it will be a useful tool in identifying training needs.

The correlational study and interview study provided rich information on the competence of the physiotherapists delivering the BeST trial intervention. This information has provided a strong rationale for hypotheses on how competence can be increased in physiotherapists delivering CB interventions in LBP. Specifically, that experience of delivering a CB approach, either through supervision with experienced colleagues or via in situ peer modelling is likely to increase competence. Application of the skills to self and wider patient populations should also be encouraged to improve confidence/competence. Within training programmes there needs to be a focus on specific skill acquisition which includes questioning, group facilitation, and goal setting skills. This thesis also found an apparent

correlation between reflective practice and competence which provides potential guidance in the clinical application of these approaches.

As noted in the introduction, changing physiotherapists' beliefs from a biomedical to a biopsychosocial orientation has been successful with training, although changing subsequent behaviour in line with a biopsychosocial orientation has been more elusive. This thesis has provided a hypothesis for this phenomenon. The physiotherapists in the BeST study perceived that patients with significant psychosocial risk factors were the most difficult to apply a CB approach to. This lack of understanding or confidence in applying the techniques can be targeted in training programmes and may lead to physiotherapist behaviours more consistent with guidelines for best practice.

7.6 Chapter summary

This chapter presented an overview on the usefulness of the CTS-R-Pain and how it could be used within physiotherapist training and development of interventions.

Comparisons between the findings in the correlational and interview study were presented in relation to experience, environment and how physiotherapists related risk factors to suitability for a CB approach. Insights from the studies presented in this thesis were used to provide suggestions for the training of physiotherapists in CB approaches and recommendations for further research.

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- 228. Barlow J, Wright C, Sheasby J, Turner A, Hainsworth J. Self-management approaches for people with chronic conditions: a review. Patient Education and Counseling. 2002;48(2):177-87.
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Appendices

Appendix 1 Reference list of excluded studies in systematic review

Bold text signifies reason for exclusion.

- 1. Allen KW, Tolchard B, Battersby M. Behavioural psychotherapy training for nurses in Australia: a pilot program. Australian New Zealand Journal of Mental Health Nursing. 2000;9(2):75-81. **No description of tool**
- 2. Andersson G, Carlbring P, Furmark T. Therapist experience and knowledge acquisition in internet-delivered CBT for social anxiety disorder: A randomized controlled trial. PLoS ONE. 2012;7(5). **Not health professionals**
- 3. Cox D, Burgess M, Chalder T, Sharpe M, White P, Clark L. Training, supervision and therapists' adherence to manual-based therapy. International Journal of Therapy & Rehabilitation. 2013;20(4):180-6. **No description of tool**
- 4. Davidson K, Scott J, Schmidt U, Tata P, Thornton S, Tyrer P. Therapist competence and clinical outcome in the prevention of parasuicide by manual assisted cognitive behaviour therapy trial: the POPMACT study. Psychological Medicine. 2004;34(5). **No description of tool**
- 5. Devane SM, Haddock G, Lancashire S, Baguley I, Butterworth T, Tarrier N, et al. The clinical skills of community psychiatric nurses working with patients who have severe and enduring mental health problems: an empirical analysis. Journal of Advanced Nursing. 1998;27(2):253-60. **Psychological specialist assessed in mental health problem**
- 6. Donoghue A, Hodgins G, Judd F, Scopelliti J, Grigg M, Komiti A, et al. Training case managers to deliver focused psychological strategies. International Journal of Mental Health Nursing. 2004;13(1):33-8. **Tool does not assess knowledge/skills/competence**
- 7. Fujisawa D, Nakagawa A, Kikuchi T, Sado M, Tajima M, Hanaoka M, et al. Reliability and validity of the Japanese version of the Cognitive Therapy Awareness Scale: A scale to measure competencies in cognitive therapy. Psychiatry and Clinical Neurosciences. 2011;65(1):64-9. **Validation of a translated tool**
- 8. Hepner KA, Hunter SB, Paddock SM, Zhou AJ, Watkins KE. Training addiction counselors to implement CBT for depression. Administration and Policy in Mental Health and Mental Health Services Research. 2011;38(4):313-23. **Not health professionals**
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- 10. Jacob KL, Christopher MS, Neuhaus EC. Development and Validation of the Cognitive-Behavioral Therapy Skills Questionnaire. Behavior Modification. 2011;35(6):595-618. **Tool does not assess knowledge/skills/competence**
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- 13. Kobak KA, Craske MG, Rose RD, Wolitsky-Taylor K. Web-based therapist training on cognitive behavior therapy for anxiety disorders: A pilot study. Psychotherapy. 2013;50(2):235-47. **Psychological specialist assessed in mental health problem**
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- 15. Simons AD, Padesky CA, Montemarano J, Lewis CC, Murakami J, Lamb K, et al. Training and Dissemination of Cognitive Behavior Therapy for Depression in Adults: A Preliminary Examination of Therapist Competence and Client Outcomes. Journal of Consulting and Clinical Psychology. 2010;78(5):751-6. **Psychological specialist assessed in mental health problem**
- 16. Solomon R, Walco GA, Robinson MR, Dampier CD. Pediatric pain management: program description and preliminary evaluation results of a professional course. Journal of Developmental & Behavioral Pediatrics. 1998;19(3):193-5. **No description of tool**
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- 18. Westbrook D, Sedwick-Taylor A, Bennett-Levy J, Butler G, McManus F. A Pilot Evaluation of a Brief CBT Training Course: Impact on Trainees' Satisfaction, Clinical Skills and Patient Outcomes. Behavioural and Cognitive Psychotherapy. 2008;36(5):569-79. **No description of tool**
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- 20. Williams C, Martinez R, Dafters R, Ronald L, Garland A. Training the wider workforce in cognitive behavioural self-help: the SPIRIT (Structured Psychosocial InteRventions in Teams) training course. Behavioural and cognitive psychotherapy. 2011;39(2):139-49. **No description of tool**

Appendix 2 First round Delphi questionnaire

Delphi consensus method for assessment of competency of Physiotherapists to deliver a cognitive behavioural approach in the treatment of low back pain

Round 1 Information

Remit of Delphi members

'To review the appropriateness of the current measure of competency in CBT (the CTS) for assessing physiotherapists competency at delivering a CB approach in the management of sub-acute and chronic low back pain'

Key characteristics of patient population

Von Korff & Moore (2001) describe a stepped-care approach to low back pain in primary care that targets the necessary intensity of intervention to achieve a good functional outcome. This is shown in the table below;

Table 1: Stepped care approach to low back pain

	Intervention required	Where provided	Example intervention
Step 1	Information to address common fears and advice to return to normal activities as quickly as possible	Primary Care	'The Back Book' (Roland et al 2005)
Step 2	Brief targeted interventions that support physical exercise and return to normal activities	Primary Care Physiotherapy out-patients	One-to-one physiotherapy or a group approach led by a physiotherapist
Step 3	Intensive interventions with treatment for psychological illness if necessary	Secondary Care Pain Management Units	In patient pain management programme (PMP)

There is continued debate as to how best to deliver the interventions aimed at Step 2 (highlighted above in blue). Recent systematic reviews have pointed to the use of a cognitive behavioural approach (Ostelo et al 2004, Linton 2000). This is due to the relative success of cognitive behavioural interventions in Pain Management Programmes.

Traditionally in pain management programmes there are qualified psychological practitioners to deliver the cognitive behavioural component of the programme. It is recognised that there are not enough qualified psychological practitioners to deliver a cognitive behavioural approach in the Step 2 group of patients, and indeed this level of training/competence may not be necessary in this group. As a result several cognitive behavioural interventions have been designed to be delivered by

physiotherapists. This <u>delphi</u> study has been designed to ask a group of experts what competences are required to deliver a cognitive behavioural approach in the **step 2 group of patients**.

These patients are managed directly in primary care settings or less frequently through primary care and secondary care referrals to physiotherapy out patient departments based in acute trusts. The interventions can either be delivered one-to-one or within a group context.

To further illustrate the differences between the Step 3 and Step 2 group of patients, an outline of their likely characteristics are shown below;

Step 3: Pain Management Programme Patient;

Likely/Typical Characteristics

- Several year history of moderate to severe constant pain problem in status quo or worsening
- · Multiple investigations for cause of pain
- Numerous failed treatment attempts including physiotherapy and interventions through pain clinics such as spinal injections
- Poly pharmacy for pain management
- Very disabled with difficulty on many activities of daily living for example, needs help with domestic chores, difficulty mobilising and uses walking aids, difficulty lifting more than light loads
- Managing pain through avoidance of most movements and activities and over reliance on aids and other people
- More than likely not working and on incapacity benefit
- · Social activities significantly affected
- Relationship difficulties with friends and family
- · Frequently co-morbid depression / anxiety

Step 2: Patients seen in primary care or physiotherapy out-patients (patients this study is aimed at):

Likely/Typical Characteristics

- Low back pain of insidious or sudden onset lasting for longer than 6 weeks, usually overall in status quo or slowly worsening
- Manageable levels of pain with acute exacerbation managed by patient or via an increase in pain medication through the G.P
- Typically has had simple investigations such as blood tests and X-ray
- Some have had previous treatment e.g. physiotherapy or private osteopathy with limited success
- Levels of disability mild to moderate, for example limited to walking 1 mile or standing for more than 1 hour, difficulty lifting heavy items
- Difficulty participating in regular exercise
- Manages LBP through avoidance of feared movements or activities and/or through 'boom – bust' cycles of activity
- May have had to adapt working environment or reduce hours
- Emotionally can get worried, frustrated, and/or low when in exacerbation but not clinically diagnosable as depression or anxiety problem

The purpose of the first round of this Delphi questionnaire study is to identify the key competences that need to be demonstrated by physiotherapists delivering a cognitive behavioural approach in the Step 2 group of patients.

As a starting point in this process we will be using the Cognitive Therapy Scale. This is the main assessment tool that is used to assess competency in Cognitive Behavioural Therapists and as such lists the core skills required for treatment to be defined as cognitive behavioural therapy. The most recent version of the CTS is being used for this questionnaire; the CTS-R (Blackburn, James, & Milne 1997). This version is being used because it takes account of evolutionary changes to CBT and difficulty with using the previous CTS. Subsequent testing has shown the CTS-R to have a greater level of inter-rater reliability with significant correlation found on 11 of the 12 items (Reichelt FK, James IA, Blackburn I 2003).

Delphi Stages

Round 1 (this questionnaire)

In the first questionnaire you are asked to review the CTS core competences and mark whether you feel the competence item is an appropriate one in this context. The competence has to be appropriate in both individual and group treatment. You are also asked to list any additional competences that you feel appropriate.

Round 2

In this round the results of the first round will be reported. It will include all the items from the CTS that were felt to be appropriate along with the additional items that have been generated by the Delphi members. The percentage of Delphi members that opted for the item will be reported. You will be asked to:

- Review the results and mark which competences are appropriate to be tested
- Indicate a minimum competence level for every skill using the criteria (the new items generated in Round 1 will have competency criteria written for them to match the current style in the CTS-R)

Round 3

The results from the second round will be fed back to you in the third round. Any items in the second round that had less than 30% agreement will be automatically removed. Any items with more than 70% agreement will be automatically included. You will be asked to:

- Review the results from Round 2 for the skills with 30-70% agreement and mark which skills are appropriate to be tested
- Review the results from Round 2 on competence levels and indicate a minimum competence level for every skill using the criteria

Further Rounds (if necessary)

The results from Round 3 will be fed back in subsequent rounds until either a 70% agreement on items and competency level is achieved or the response rate from Delphi members falls below 50%.

Delphi consensus method for assessment of competency of Physiotherapists to deliver a cognitive behavioural approach in the treatment of low back pain

Round 1

Please fill in this questionnaire and return in the envelope provided to Zara Hansen by 2nd October 2006.

Name	Date			
Profession	-			
Current area of work (e.g. Pain Management)				
Qualification in CBT (e.g. Post Grad Diploma)				
Year of award of CBT qualification				

N.B Questions are in yellow box at end of each item

- Please select which items you feel are necessary for physiotherapists to demonstrate in a cognitive-behavioural intervention for sub-acute to chronic LBP (Step 2 patients as defined above). Please mark your selection by placing a tick in the appropriate box below the item. There are 12 items in this questionnaire, you can select as many or as few as you feel appropriate.
- At end of questionnaire (page 18) please indicate if there are any additional cognitive-behavioural skills that you feel need to be added to the instrument.

Please note the following pages in the questionnaire are taken directly from the CTS-R. The only additions are the questions highlighted in the yellow box at the end of each item. In this round you only need to place appropriate ticks in the yellow boxes and answer the free text question on page 18.

Remember that the competence needs to be appropriate for both individual and group treatment

COGNITIVE THERAPY SCALE - REVISED (CTS-R)

ITEM 1 - AGENDA SETTING & ADHERENCE

Key features: To address adequately topics that have been agreed and set in an appropriate way. This involves the setting of discrete and realistic targets collaboratively. The format for setting the agenda may vary according to the stage of therapy - see manual.

Three features need to be considered when scoring this item:

- presence/absence of an agenda which is explicit, agreed and prioritised, and feasible in the time available;
- appropriateness of the contents of the agenda (to stage of therapy, current concerns etc.), a standing item being a review of the homework set previously;
- (iii) appropriate adherence to the agenda.

Mark with an 'X' on the vertical line, the level to which you think the therapist has fulfilled the core function. The descriptive features on the right are designed to guide your decision.

NB: Agenda setting requires collaboration and credit for this should be given here, and here alone. Collaboration occurring at any other phase of the session should be scored under Item 3 (Collaboration).

Competence level	Examples NB: Score according to features, not examples!		
° T	No agenda set, highly inappropriate agenda set, or agenda not adhered to.		
1 —	Inappropriate agenda set (e.g. lack of focus, unrealistic, no account of patient's presentation, homework not reviewed).		
2 —	An attempt at an agenda made, but major difficulties evident (e.g. unilaterally set). Poor adherence.		
3 —	Appropriate agenda, which was set well, but some difficulties evident (e.g. poor collaboration). Some adherence.		
4 —	Appropriate agenda, minor difficulties evident (e.g. no prioritisation), but appropriate features covered (e.g. review of homework). Moderate adherence.		
5 —	Appropriate agenda set with discrete and prioritised targets, reviewed at the end. Agenda adhered to. Minimal problems.		
6 _	Excellent agenda set, or highly effective agenda set in the face of difficulties.		
Include th	Please tick YES NO UNSURE is item		

ITEMS 2-12 FOLLOW SAME FORMAT AS ITEM 1 ABOVE

Please indicate below up to 5 additional cognitive-behavioural skills that you feel need to be added to the instrument. Please give an indication as to how these skills might be observed / assessed (continue onto separate sheets if necessary).

1. Item Title Key features
2. Item Title
Key features
They realised
3. Item Title
Key features
Ney leatures
4. Item Title
Key features
Ney leatures
5. Item Title
Key features
Ney leatures

Appendix 3 Second round Delphi questionnaire

Delphi consensus method for assessment of competency of Physiotherapists to deliver a cognitive behavioural approach in the treatment of low back pain

Round 2

The results of the first round are reported below. Nine Delphi members responded to the initial questionnaire and are included in this study. The demographics of the Delphi panel are shown in Table 1 below;

Table 1; Demographics of experts recruited to Delphi study

Participant	Profession	Current clinical area of work
1	Physiotherapist	Musculoskeletal
2	Physiotherapist	Musculoskeletal
3	Physiotherapist	Musculoskeletal
4	Physiotherapist	Mental Health
5	Clinical Psychologist	Pain Clinic
6	Clinical Psychologist	Pain Management Programme
7	Clinical Psychologist	Pain Management Programme
8	Physiotherapist	Clinical education
9	Clinical Psychologist	Pain Management Programme

In the first round, Delphi experts indicated whether an item from the original CTS-R should be included in the adapted CTS for physiotherapists using CB approaches to treat low back pain. An agreement of 70% or more from Delphi members would mean automatic inclusion. This was the case in 11 of the 12 items. You are asked to reconsider the 12th item in this questionnaire.

In the first round you were also asked for additional competency items that you considered important. These additional items have been added in this questionnaire and you are asked to vote on their inclusion.

One Delphi member provided additional items that were intended to act as replacements for items 7, 8 and 10. The purpose of providing alternatives for these items was to make minor changes so that they were more focussed for pain problems. For example, in the original CTS, Item 7 relates to the elicitation of key cognitions and then linking these cognitions to emotions. In the proposed alternative item 7 there is a stronger focus on eliciting key cognitions and linking these to specific pain management behaviours. You are asked to consider whether you would rather include the original or the proposed alternatives for items 7,8 and 10.

For all items you are requested to consider the minimum competency that needs to be demonstrated in that skill / area regardless of whether you feel the item should be included.

To summarise: in this questionnaire you are required to;

- 1. Reconsider whether Item 6 should be included. In Round 1 it achieved a 55.6% agreement for inclusion (5 out of 9 members)
- 2. Indicate which of the additional competencies (items 13 to 20)
- generated by Delphi members should be included
 3. Consider whether you would rather have the original or proposed alternative items 7,8, and 10
- 4. Indicate a **minimum** competency that you feel needs to be achieved on the 1-6 scale. Please do this for every item and indicate the choice either by circling the number or highlighting it.

An example is shown below;

EXAMPLE ONLY

Competence level	Examples NB: Score according to features, not examples!
° T	No agenda set, highly inappropriate agenda set, or agenda not adhered to.
1 —	Inappropriate agenda set (e.g. lack of focus, unrealistic, no account of patient's presentation, homework not reviewed).
2 —	An attempt at an agenda made, but major difficulties evident (e.g. unilaterally set). Poor adherence.
3	Appropriate agenda, which was set well, but some difficulties evident (e.g. poor collaboration). Some adherence.
4 —	Appropriate agenda, minor difficulties evident (e.g. no prioritisation), but appropriate features covered (e.g. review of homework). Moderate adherence.
5	Appropriate agenda set with discrete and prioritised targets, reviewed at the end. Agenda adhered to. Minimal problems.
6 📙	Excellent agenda set, or highly effective agenda set in the face of difficulties.

Delphi members' agreement to include this item In first round = 55.6%

	Please tick
Include this	1
item	/
Don't include	
this item	
Unsure	

ITEM 6 - ELICITING OF APPROPRIATE EMOTIONAL EXPRESSION

Key features: The therapist facilitates the processing of appropriate levels of emotion by the patient. Emotional levels that are too high or too low are likely to interfere with therapy. The therapist must also be able to deal effectively with emotional issues which interfere with effective change (e.g. hostility, anxiety, excessive anger). Effective facilitation will enable the patient to access and express his/her emotions in a way that facilitates change.

Three features have to be considered:

- (i) facilitation of access to a range of emotions;
- (ii) appropriate use and containment of emotional expression;
- (iii) facilitation of emotional expression, encouraging appropriate access and differentiation of emotions.

Competence level	Examples NB: Score according to features, not examples!
0	Patient is under-or overstimulated (e.g. his/her feelings are ignored or dismissed or allowed to reach an unmanaged pitch). Or the therapist's own mood or strategies (e.g. intellectualisation) adversely influences the session.
1	Failure to facilitate access to, and expression of, appropriate emotional expression.
2	Facilitation of appropriate emotional expression evident, but many relevant opportunities missed.
3—	Some effective facilitation of appropriate emotional expression created and/or maintained. Patient enabled to become slightly more aware.
4	Effective facilitation of appropriate emotional expression leading to the patient becoming more aware of relevant emotions. Minor problems evident.
5	Very effective facilitation of emotional expression, optimally arousing the patient's motivation and awareness. Good expression of relevant emotions evident – done in an effective manner. Minimal problems.
6 📥	Excellent facilitation of appropriate emotional expression or effective facilitation in the face of difficulties.

Delphi members' agreement to include this item in first round = 55.6%

Please indicate minimum competency score acceptable On 1 to 6 scale above by circling or highlighting number

	Please tick
Include this	
item	
Don't include	
this item	
Unsure	

EXAMPLE ITEM FROM 2ND ROUND DELPHI

New item generated by Delphi members

ITEM 19 - DEALING WITH PAINFUL EMOTIONS AND PATIENT DISTRESS

Key features: Therapists need to have an understanding of the role of patient's responses to their own emotions, for example, their emotional avoidance of belief that to feel emotions is harmful, the role of emotional exposure as a therapeutic process, and the role of the therapist responses in this process. Contact with painful experiences, for example, can either be therapeutic or re-traumatising, depending on how it is done. It can either enhance commitment to continued working together of lead to breakdowns in the relationship and mistrust. The appropriate skills here is for the therapist to be able to discriminate the direction that is therapeutic when painful emotions are present, whether to act to lessen the distress or encourage forward movement with it present. This also requires awareness by the therapist of their own feelings and urges and what will serve the patient best in the therapist's behaviour. Part of this is truly understanding methods of exposure therapy.

Two features need to be considered:

- the skill in assessing the role of potentially painful or discouraging emotional experiences in the patient's presenting problem
- (ii) the appropriate management strategies used

Competence Level	Examples NB: Score according to features, not examples!
0 +	Therapist fails to acknowledge or assess painful emotions / distress leading to potential re-traumatising of the patient
1 —	Therapist makes minimal attempt to assess painful emotions / distress
2 —	Therapist makes attempts to assess painful emotions / distress although major difficulties evident (e.g. inappropriate management)
3 —	Therapist assesses painful emotions / distress appropriately and attempts to manage appropriately although some difficulties evident (e.g. ineffective use of exposure)
4 —	Therapist assesses painful emotions/ distress appropriately and attempts to manage appropriately although some minor difficulties evident
5 —	Therapist assesses painful emotions/ distress appropriately and manages effectively
6	Excellent assessment of painful emotions / distress and effective management or very good in the face of difficulties

Please indicate minimum competency score acceptable On 1 to 6 scale above by circling or highlighting number

	Please tick
Include this	
item	1 1
Don't include	
this item	1 1
Unsure	

Appendix 4 Third round Delphi questionnaire

Delphi consensus method for assessment of competency of Physiotherapists to deliver a cognitive behavioural approach in the treatment of low back pain

Round 3 (FINAL ROUND)

The results from the second round are reported below using black text or graphs. All nine Delphi members responded to the second round. *Items have been included or excluded automatically if 6 of the 9 experts agreed (66.7%)*.

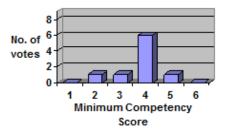
In this round you are required to re-vote on borderline cases, look for red text to indicate where voting is required.

Click on the blue text to go to the full details of the item. Click on; **Back to top** to bring you back to where you were in the questionnaire.

ITEM 1 - AGENDA SETTING & ADHERENCE

Automatically included from Round 1

Item 1 Minimum Competency Vote from Round 2



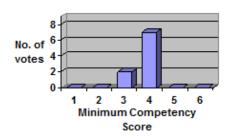
Votes in 2nd round as per chart:

No re-vote required – 6 out of 9 voted for **4** as minimum competency score

ITEM 2 - FEEDBACK

Automatically included from Round 1

Item 2 Minimum Competency Vote from Round 2



Votes in 2nd round as per chart:

No re-vote required – 7 out of 9 voted for **4** as minimum competency score

ITEM 3 - COLLABORATION

Automatically included from Round 1

Item 3 Minimum Competency Vote from Round 2



Votes in 2nd round as per chart:

Please re-vote on minimum competency required for Item 3

Score: _____

ITEM 4 - PACING AND EFFICIENT USE OF TIME

Automatically included from Round 1

<u>Vote from Round 2</u>



Votes in 2nd round as per chart:

No re-vote required – 7 out of 9 voted for 3 as minimum competency score

ITEM 5 - INTERPERSONAL EFFECTIVENESS

Automatically included from Round 1

Item 5 Minimum Competency Vote from Round 2



Votes in 2nd round as per chart:

Please re-vote on minimum competency required for Item 5

Score:

ITEMS 6-20 FOLLOWED SAME FORMAT

Appendix 5 Cognitive Therapy Scale – Revised - Pain (CTS-R-Pain)

ITEM 1 - AGENDA SETTING & ADHERENCE

Key features: To address adequately topics that have been agreed and set in an appropriate way. This involves the setting of discrete and realistic targets collaboratively. The format for setting the agenda may vary according to the stage of therapy - see manual.

Three features need to be considered when scoring this item:

- (i) presence/absence of an agenda which is explicit, agreed and prioritised, and feasible in the time available:
- (ii) appropriateness of the contents of the agenda (to stage of therapy, current concerns etc.), a standing item being a review of the homework set previously;
- (iii) appropriate adherence to the agenda.

Mark with an 'X' on the vertical line, the level to which you think the therapist has fulfilled the core function. The descriptive features on the right are designed to guide your decision.

NB: Agenda setting requires collaboration and credit for this should be given here, and here alone. Collaboration occurring at any other phase of the session should be scored under Item 3 (Collaboration).

Competence level	Examples NB: Score according to features, not examples!
0	No agenda set, highly inappropriate agenda set, or agenda not adhered to.
1	Inappropriate agenda set (e.g. lack of focus, unrealistic, no account of patient's presentation, homework not reviewed).
2	An attempt at an agenda made, but major difficulties evident (e.g. unilaterally set). Poor adherence.
3	Appropriate agenda, which was set well, but some difficulties evident (e.g. poor collaboration). Some adherence.
4	Appropriate agenda, minor difficulties evident (e.g. no prioritisation), but appropriate features covered (e.g. review of homework). Moderate adherence.
5	Appropriate agenda set with discrete and prioritised targets, reviewed at the end. Agenda adhered to. Minimal problems.
6	Excellent agenda set, or highly effective agenda set in the face of difficulties.

ITEM 2 – FEEDBACK

Key features: The patient's and therapist's understanding of key issues should be helped through the use of two-way feedback. The two major forms of feeding back information are through general summary and chunking of important units of information. The use of appropriate feedback helps both the therapist to understand the patient's situation, and the patient to synthesise material enabling him/her to gain major insight and make therapeutic shifts. It also helps to keep the patient focused.

Three features need to be considered when scoring this item:

- (i) presence and frequency, or absence, of feedback. Feedback should be given/elicited throughout the therapy with major summaries both at the beginning (review of week) and end (session summary), while topic reviews (i.e. chunking) should occur throughout the session;
- (ii) appropriateness of the contents of the feedback:
- (iii) manner of its delivery and elicitation (NB: can be written).

Competence level	Examples NB: Score according to features, not examples!
0	Absence of feedback or highly inappropriate feedback.
1	Minimal appropriate feedback (verbal and/or written).
2	Appropriate feedback, but not given frequently enough by therapist, with insufficient attempts to elicit and give feedback (e.g. feedback too vague to provide opportunities for understanding and change).
3	Appropriate feedback given and elicited frequently, although some difficulties evident in terms of content or method of delivery.
4	Appropriate feedback given and elicited frequently, facilitating moderate therapeutic gains. Minor problems evident (eg. inconsistent).
5	Highly appropriate feedback given and elicited regularly, facilitating shared understanding and enabling significant therapeutic gains. Minimal problems.
6	Excellent use of feedback, or highly effective feedback given and elicited regularly in the face of difficulties.

ITEM 3 – COLLABORATION

Key features: The patient should be encouraged to be active in the session. There must be clear evidence of productive teamwork, with the therapist skilfully encouraging the patient to participate fully (e.g. through questioning techniques, shared problem solving and decision making) and take responsibility. However, the therapist must not allow the patient to ramble in an unstructured way.

Three features need to be considered: the therapist style should encourage effective teamwork through his/her use of:

- (i) verbal skills (e.g. non-hectoring);
- (ii) non-verbal skills (e.g. attention and use of joint activities);
- (iii) sharing of written summaries.

NB: Questioning is a central feature with regard to this item, but questions designed to facilitate reflections and self discovery should be scored under Item 9 (Guided Discovery).

Competence level	Examples NB: Score according to features, not examples!
0	Patient is actively prevented or discouraged from being collaborative.
1	The therapist is too controlling, dominating, or passive.
2	Some occasional attempt at collaboration, but didactic style or passivity of therapist encourages passivity or other problems in the therapeutic relationship.
3	Teamwork evident, but some problems with collaborative set (e.g. not enough time allowed for the patient to reflect and participate actively).
4	Effective teamwork is evident, but not consistent. Minor problems evident.
5	Effective teamwork evident throughout most of the session, both in terms of verbal content and use of written summaries. Minimal problems.
6	Excellent teamwork, or highly effective teamwork in the face of difficulties.

ITEM 4 - PACING AND EFFICIENT USE OF TIME

Key features: The session should be well 'time managed' in relation to the agenda, with the session flowing smoothly through discrete start, middle, and concluding phases. The work must be paced well in relation to the patient's needs, and while important issues need to be followed, unproductive digressions should be dealt with smoothly. The session should not go over time, without good reason.

Three features need to be considered:

- (i) the degree to which the session flows smoothly through the discrete phases;
- (ii) the appropriateness of the pacing throughout the session;
- (iii) the degree of fit to the learning speed of the patient.

Competence level	Examples NB: Score according to features, not examples!
0	Poor time management leads either to an aimless or overly rigid session.
1	The session is too slow or too fast for the current needs and capacity of the patient.
2	Reasonable pacing, but digression or repetitions from therapist and/or patient lead to inefficient use of time; unbalanced allocation of time, over time.
3	Good pacing evident some of the time, but diffuse at times. Some problems evident.
4	Balanced allocation of time with discrete start, middle and concluding phases evident. Minor problems evident.
5	Good time management skills evident, session running smoothly. Therapist working effectively in controlling the flow within the session. Minimal problems.
6	Excellent time management, or highly effective management evident in the face of difficulties.

ITEM 5 - INTERPERSONAL EFFECTIVENESS

Key features: The patient is put at ease by the therapist's verbal and non-verbal (e.g. listening skills) behaviour. The patient should feel that the core conditions (i.e. warmth, genuineness, empathy and understanding) are present. However, it is important to keep professional boundaries. In situations where the therapist is extremely interpersonally effective, he/she is creative, insightful and inspirational.

Three features need to be considered:

- (i) empathy the therapist is able to understand and enter the patient's feelings imaginatively and uses this understanding to promote change;
- (ii) genuineness the therapist has established a trusting working relationship;
- (iii) warmth the patient seems to feel liked and accepted by the therapist.

Competence level	Examples NB: Score according to features, not examples!
0	Therapist's manner and interventions make the patient disengage and become distrustful and/or hostile (absence of/or excessive i, ii, iii).
1	Difficulty in showing empathy, genuineness and warmth.
2	Therapist's style (e.g. intellectualisation) at times impedes his/her empathic understanding of the patient's communications.
3	The therapist is able to understand explicit meanings of patient's communications, resulting in some trust developing. Some evidence of inconsistencies in sustaining relationship.
4	The therapist is able to understand the implicit, as well as the explicit meanings of the patient's communications and demonstrates it in his/her manner. Minor problems evident (e.g. inconsistent).
5	The therapist demonstrates very good interpersonal effectiveness. Patient appears confident that he/she is being understood, which facilitates self-disclosure. Minimal problems.
6	Excellent interpersonal effectiveness, or highly interpersonally effective in the face of difficulties.

ITEM 6 – ELICITING OF APPROPRIATE EMOTIONAL EXPRESSION

Key features: The therapist facilitates the processing of appropriate levels of emotion by the patient. Emotional levels that are too high or too low are likely to interfere with therapy. The therapist must also be able to deal effectively with emotional issues which interfere with effective change (e.g. hostility, anxiety, excessive anger). Effective facilitation will enable the patient to access and express his/her emotions in a way that facilitates change.

Three features have to be considered:

- (i) facilitation of access to a range of emotions;
- (ii) appropriate use and containment of emotional expression;
- (iii) facilitation of emotional expression, encouraging appropriate access and differentiation of emotions.

Competence level	Examples NB: Score according to features, not examples!
0	Patient is under- or overstimulated (e.g. his/her feelings are ignored or dismissed or allowed to reach an unmanged pitch). Or the therapist's own mood or strategies (e.g. intellectualisation) adversely influences the session.
1	Failure to facilitate access to, and expression of, appropriate emotional expression.
2	Facilitation of appropriate emotional expression evident, but many relevant opportunities missed.
3	Some effective facilitation of appropriate emotional expression, created and/or maintained. Patient enabled to become slightly more aware.
4	Effective facilitation of appropriate emotional expression leading to the patient becoming more aware of relevant emotions. Minor problems evident.
5	Very effective facilitation of emotional expression, optimally arousing the patient's motivation and awareness. Good expression of relevant emotions evident – done in an effective manner. Minimal problems.
6	Excellent facilitation of appropriate emotional expression, or effective facilitation in the face of difficulties.

ITEM 7 - ELICITING KEY PAIN-RELEVANT COGNITIONS

Key features: To help the patient gain access to his/her cognitions (thoughts and assumptions) and to understand the relationship between these and their pain management behaviours (e.g., activity cycling). This can be done through the use of questioning, diaries and monitoring procedures.

Three features need to be considered:

- (i) eliciting cognitions that are associated with unhelpful pain management behaviours (i.e. selecting key cognitions or hot thoughts);
- (ii) the skilfulness and breadth of the methods used (i.e. Socratic questioning; appropriate monitoring, downward arrowing, imagery, role-plays, etc.);
- (iii) choosing the appropriate level of work for the stage of therapy (i.e. automatic thoughts or assumptions).

NB: This item is concerned with the general work done with eliciting cognitions. If any specific cognitive or behavioural change methods are used, they should be scored under item 11 (change methods).

Competence level	Examples NB: Score according to features, not examples!	
0	Therapist fails to elicit relevant cognitions.	
1	Inappropriate cognitions and emotions selected, or key cognitions/emotions ignored.	
2	Some cognitions/emotions (or one key cognition, e.g. core belief) elicited, but links between cognitions and pain management behaviours not made clear to patient.	
3	Some cognitions/emotions (or one key cognition) elicited in a competent way, although some problems evident.	
4	A number of cognitions and pain management behaviours (or one key cognition) elicited in verbal or written form, leading to a new understanding of their relationship. Minor problems evident.	
5	Effective eliciting and selection of a number of cognitions/behaviours (or one key cognition), which are generally dealt with appropriately. Minimal problems.	
6	Excellent work done on key cognition(s) and behaviours(s), or very good work done in the face of difficulties.	

ITEM 8 – ELICITING PAIN MANAGEMENT BEHAVIOURS

Key features: To help the patient gain insight into the effect of his/her behaviours and planned behaviours with respect to the way they manage their pain. This can be done through the use of questioning, diaries and monitoring procedures. This item helps ensure that the therapy is fully integrated with the patient's environment.

Two features need to be considered:

- (i) eliciting behaviours that are associated with increased pain related disability;
- the skilfulness and breadth of the methods used (i.e. socratic questioning; appropriate monitoring, imagery, role-plays, etc.);

NB: This item is concerned with the general work done with eliciting behaviours. If any specific cognitive or behavioural change methods are used, they should be scored under item 11 (change methods).

Competence Level	Examples NB: Score according to features, not examples!	
0	Therapist fails to elicit relevant behaviours.	
1	Inappropriate behaviours focused on.	
2	Some behaviours elicited, but links between behaviours and pain related disability not made clear to patient.	
3	Some behaviours/emotions elicited in a competent way, although some problems evident.	
4	A number of behaviours/emotions elicited in verbal or written form, leading to a new understanding of their importance in maintaining pain related disability. Minor difficulties evident.	
5	Effective eliciting and selection of a number of behaviours/emotions, which are generally dealt with appropriately. Minimal problems.	
6	Excellent work done on behaviours and emotions, or very good work done in the face of difficulties.	

ITEM 9 - GUIDED DISCOVERY

Key features: The patient should be helped to develop hypotheses regarding his/her current situation and to generate potential solutions for him/herself. The patient is helped to develop a range of perspectives regarding his/her experience. Effective guided discovery will create doubt where previously there was certainty, thus providing the opportunity for re-evaluation and new learning to occur.

Two elements need to be considered:

Competence

- the style of the therapist this should be open and inquisitive;
- (ii) the effective use of questioning techniques (e.g. Socratic questions) should encourage the patient to discover useful information that can be used to help him/her to gain a better level of understanding.

Examples

level	NB: Score according to features, not examples!		
0	No attempt at guided discovery (e.g. hectoring and lecturing).		
1	Little opportunity for discovery by patient. Persuasion and debate used excessively.		
2	Minimal opportunity for discovery. Some use of questioning, but unhelpful in assisting the patient to gain access to his/her thoughts or emotions or to make connections between themes.		
3	Some reflection evident. Therapist uses primarily a questioning style which is following a productive line of discovery.		
4	Moderate degree of discovery evident. Therapist uses a questioning style with skill, and this leads to some synthesis. Minor problems evident.		
5	Effective reflection evident. Therapist uses skilful questioning style leading to reflection, discovery, and synthesis. Minimal problems.		
6	Excellent guided discovery leading to a deep patient understanding. Highly effective discovery produced in the face of difficulties, with evidence of a deeper understanding having been developed.		

ITEM 10 – DEVELOPING A COGNITIVE-BEHAVIOURAL CONCEPTUALISATION OF THE PATIENTS' PAIN-RELATED DISTRESS AND DISABILITY

Key features: The therapist should assist the patient in relating their beliefs concerning pain, activity and other related issues to the ways in which they manage their pain, and to pain-related distress. The patient should be helped to understand how their cognitions and associated behaviours may contribute to disability and distress, as a basis for considering change now and in the future. Psychoeducation regarding key pain management models and concepts (e.g., fear – avoidance, activity cycling, biopsychosocial factors) is integrated into this process.

One key feature needs to be considered:

(i) is the extent to which clear links between cognitions, behaviours and resultant disability and distress are elucidated

Competence level	Examples NB: Score according to features, not examples!		
0	Therapist does not enable the patient to understand how their cognitions are linked to behaviour and pain related disability or distress.		
1	Relevant cognitions and behaviours are discussed, but they are not meaningfully linked to the patient's pain-related disability or distress.		
2	Some linkage between cognitions, behaviours and resultant disability and distress are made, but important presenting issues (e.g., avoidance) are omitted.		
3	Good linkage between cognitions, behaviours and idiosyncratic features of the patient's distress and disability is evident; but no (or minimal) psychoeducation regarding key pain management models / concepts is integrated.		
4	The therapist effectively assists the patient to understand the links between their cognitions, behaviours and pain related disability / distress, integrating this with psycho-education on relevant pain management concepts where appropriate. Minor problems are evident.		
5	Therapist skilfully assists the patient to understand the links between their cognitions, behaviours and pain related disability / distress, integrating this with psycho-education on relevant pain management concepts where appropriate. Minimal problems.		
6	There is excellent work done in assisting the patient to understand the links between their cognitions, behaviours and pain related disability / distress. This is skilfully integrated with psychoeducation regarding relevant pain management models / concepts.		

ITEM 11 - APPLICATION OF CHANGE METHODS

Key features: Therapist skilfully uses, and helps the patient to use, appropriate cognitive and behavioural techniques in line with the formulation. The therapist helps the patient devise appropriate cognitive methods to evaluate the key cognitions associated with distressing emotions, leading to major new perspectives and shifts in emotions. The therapist also helps the patient to both apply behavioural techniques in line with the formulation, and develop suitable plans to promote effective change. The therapist helps the patient to identify potential difficulties and think through the cognitive rationales for performing the tasks. The methods provide useful ways for the patient to test-out cognitions practically and gain experience in dealing with high levels of emotion. The methods also allow the therapist to obtain feedback regarding the patient's level of understanding of prospective practical assignments (i.e. by the patient performing the task in- session).

Three features need to be considered:

- (i) the appropriateness and range of both cognitive methods (e.g. cognitive change diaries, continua, distancing, responsibility charts, evaluating alternatives, examining pros and cons, determining meanings, imagery restructuring, etc.) and behavioural methods (e.g. behavioural diaries, behavioural tests, role play, graded task assignments, response prevention, reinforcement of patient's work, modelling, applied relaxation, controlled breathing, etc.);
- (ii) the skill in the application of the methods however, skills such as feedback, interpersonal effectiveness, etc. should be rated separately under their appropriate items:
- (iii) the suitability of the methods for the needs of the patient (i.e. neither too difficult nor complex).

NB: This item is not concerned with accessing or identifying thoughts, rather with their reevaluation.

Competence Level	Examples NB: Score according to features, not examples!	
0	Therapist fails to use or misuses appropriate cognitive and behavioural methods.	
1	Therapist applies either insufficient or inappropriate methods, and/or with limited skill or flexibility.	
2	Therapist applies appropriate methods, but major difficulties evident.	
3	Therapist applies a number of methods in competent ways, although some problems evident (e.g. the interventions are incomplete).	
4	Therapist applies a range of methods with skill and flexibility, enabling the patient to develop new perspectives. Minor problems evident.	
5	Therapist systematically applies an appropriate range of methods in a creative, resourceful and effective manner. Minimal problems.	
6	Excellent range and application, or successful application in the face of difficulties.	

ITEM 12 - HOMEWORK SETTING

Key features: This aspect concerns the setting of an appropriate homework task, one with clear and precise goals. The aims should be to negotiate an appropriate task for the stage of therapy in line with the conceptualisation; to ensure the patient understands the rationale for undertaking the task; to test out ideas, try new experiences, predict and deal with potential obstacles, and experiment with new ways of responding. This item ensures that the content of the therapy session is both relevant to, and integrated with, the patient's environment.

There are three aspects to this item:

- (i) presence/absence of a homework task in which clear and precise goals have been set:
- (ii) the task should be derived from material discussed in the session, such that there is a clear understanding of what will be learnt from performing the task;
- (iii) the homework task should be set jointly, and sufficient time should be allowed for it to be explained clearly (i.e. explain, discuss relevance, predict obstacles, etc.).

NB: Review of homework from the previous session should be rated in Item 1 (Agenda Setting)

Competence Level	Examples NB: Score according to features, not examples!		
0	Therapist fails to set homework, or sets inappropriate homework.		
O	Therapist fails to set flomework, or sets inappropriate flomework.		
1	Therapist does not negotiate homework. Insufficient time allotted for adequate explanation, leading to ineffectual task being set.		
2	Therapist negotiates homework unilaterally and in a routine fashion, without explaining the rationale for new homework.		
3	Therapist has set an appropriate new homework task, but some problems evident (e.g. not explained sufficiently and/or not developed jointly).		
4	Appropriate new homework jointly negotiated with a clear goals and rationales. However, minor problems evident.		
5	Appropriate homework negotiated jointly and explained well, including an exploration of potential obstacles. Minimal problems.		
6	Excellent homework negotiated, or highly appropriate one set in the face of difficulties.		

ITEM 13 – FACILITATING BEHAVIOURAL CHANGE

Key features: Patients may require discrete skills training in order to facilitate behavioural change. These skills or techniques can include communication skills, activity pacing and goal setting skills, time management, and general problem solving.

There is a typical framework to follow with skills training: rationale, instruction, demonstration/modelling, practice, feedback, rehearsal, and generalisation. These require an understanding of behaviour change and learning.

This item also includes, where appropriate, helping the patient devise and carry out appropriate behavioural experiments.

Three features need to be considered:

- (iv) the appropriateness and range of skills / techniques being taught in line with the shared understanding of the problem
- (v) the proficiency demonstrated in the training of skills / techniques
- (vi) the suitability of the skill / technique for the needs of the patient (i.e. neither too difficult nor complex).

Competence Level	Examples NB: Score according to features, not examples!			
0	Therapist fails to use or misuses appropriate skills training			
1	Therapist trains the patient in either insufficient or inappropriate skills or techniques, and/or with limited proficiency or flexibility.			
2	Therapist trains the patient in appropriate skills or techniques, but major difficulties evident.			
3	Therapist trains the patient in a number of skills or techniques in competent ways, although some problems evident (e.g. framework for learning the skill incomplete).			
4	Therapist trains the patient in a range of skills or techniques with proficiency and flexibility, enabling the patient to develop new perspectives. Minor problems evident.			
5	Therapist systematically trains the patient in an appropriate range of skills or techniques in a creative, resourceful and effective manner. Minimal problems.			
6	Excellent range and training, or successful training in the face of difficulties.			

ITEM 14 – SUPPORTING CHANGE

Key features: Treatment should be aimed at developing self-management. Within this context it is important that patients are able to maintain the changes gained in therapy or able to progress with their therapy independently. This can include strategies for managing threats to self-management such as changes to work or 'flare-ups'.

Two features need to be considered:

- (i) the appropriateness of strategies selected to maintain changes or progress independently
- (ii) the appropriate complexity of the plan for the patient

Competence Level	Examples NB: Score according to features, not examples!		
0	Therapist fails to consider strategies for maintenance of change		
1	Therapist acknowledges but does not facilitate maintenance of change		
2	Therapist acknowledges maintenance of change but encourages inappropriate strategies (e.g. on-going therapy)		
3	Therapist encourages use of strategies that are mostly appropriate for maintenance of change but no plan considered		
4	Therapist facilitates use of appropriate strategies for maintenance of change and considers formulation of plan		
5	Therapist facilitates formulation of clear plan and use of appropriate strategies for maintenance of change		
6	Excellent facilitation of clear plan and use of appropriate strategies for maintenance of change or well done in the face of difficulties.		

ITEM 15 - RECOGNITION OF PROFESSIONAL BOUNDARIES

Key features: Therapists need to recognise their own clinical professional boundaries and adhere to their scope of practice. Therapists should be aware of the referral options available to them and understand the process for accessing these referral sources. However, a lack of referral options should not negate the need for complying with professional scope of practice.

Two features need to be considered:

- (i) the appropriateness of referrals (i.e. patient's problems appropriately identified as outside individual scope of practice and referral made to appropriate other professional / agency)
- (ii) the skill in negotiating this referral with the patient

Competence Level	Examples NB: Score according to features, not examples!	
0	Therapist fails to adhere to scope of practice	
1	Therapist has no awareness of referral process but does not access when appropriate	
2	Therapist shows some awareness of own limitations and sometimes responds with appropriate referral	
3	Therapist shows some awareness of own limitations and mostly responds with appropriate referral	
4	Therapist clearly identifies own limitations with appropriate referral but not always timely	
5	Therapist clearly identifies own limitations with timely and appropriate referral	
6	Therapist clearly identifies own limitations with timely and appropriate referral in the face of difficulties.	

Appendix 6 Ethical approval for the inter-rater reliability study

SL32 Favourable opinion of amendment Version 3, June 2005



West Midlands Multi-centre Research Ethics Committee

Chairman:

Dr Jammi Rao

Co-ordinator:

Mrs Anne McCullough

7 February 2006

27 Highfield Road Edgbaston Birmingham

Tel: 0121 245 2544

Birmingham B15 3DP

Professor S L Lamb Warwick Emergency Care and Rehabilitation Warwick Medical School RoomA104, Medical School Building Gibbet Hill Campus Coventry CV4 7AL

Fax: 0121 245 2519

RECEIVED 1 0 FEB 2006

Dear Professor Lamb

Study title:

A Multicentre, randomised controlled trial of primary care based

Cognitive behavioural programme for low back pain

REC reference:

MREC/03/7/04

Amendment number: 2

Amendment date:

5 January 2006

The above amendment was reviewed at the meeting of the Amendment Sub Committee [2] held on 25 January 2006.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

- Substantial Amendment Notification Form, dated 5 January 2006
- Tape Recording Information and Consent Form, version 1 dated 5 January 2006

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed below:

- Dr Jammi Rao, Chairman [Director of Public Health]
- Professor Alexander McNeish, Retired Consultant Paediatrician

Research governance approval

All investigators and research collaborators in the NHS should notify the R&D Department for the relevant NHS care organisation of this amendment and check whether it affects research governance approval of the research.

The Central Office for Research Ethics Committees is responsible for the operational management of Multi-centre Research Ethics Committees SL32 Favourable opinion of amendment Version 3, June 2005

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

[REC reference number]: MREC/03/7/04.

Please quote this number on all correspondence

Yours sincerely

Anne McCullough [Mrs] Committee Co-ordinator

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Appendix 7 Patient information sheet for audio recordings / consent form

Consent Form Version 6 15/12/05

Stud	y Number:			
LA	research trial int	o the effectiveness of dif experiencing low bac		s for people
				Please initial
1.	sheet dated 15 [ave read and understand the I December 2005 - version 6 for had the opportunity to ask que	the above	
2.	free to withdraw	t my participation is voluntary a at any time, without giving any cal care or legal rights being a	/ reason,	
3.	involved in my c in the study, and	t my GP and other health prof are will be informed of my part I consent to researchers whe o my medical records.	icipation	
4.	I agree to take p	art in the above study.		
5.	period of the tria	e invited for an interview during I. I understand that if I wish no n still participate in the trial.		
6.	recorded so that is delivering the	t one of the group sessions wi the research team can check programme. The tape will not nd will be destroyed by the end	how the therapist be used for any	
Nam	ne of Patient	Date	Signature	
	ne of Researcher ug consent	Date	Signature	

A randomised study of physical treatments for backpain in primary care, funded by the NHS R&D HTA programme (ISRCTN54717854)

Appendix 8 Participant information sheet for the interview study

Information for Participants

29/03/05

A study into the integration of cognitive-behavioural therapy skills into physiotherapy practice

You are being invited to take part in a research study looking into the implications of training physiotherapists in cognitive-behavioural therapy skills.

Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask us 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 purpose of the study?

Physiotherapists are integrating cognitive-behavioural (CB) therapy skills into their current practice, particularly in the management of chronic pain problems.

Physiotherapists are trained in a biomedical framework and attaining and integrating a psychological framework for understanding problems could pose a significant shift with inherent difficulties or benefits.

No research has been done to explore these issues and this interview-based study has been designed to meet this need.

Why have I been chosen?

You have been chosen because you are a physiotherapist who recently underwent some CB training as part of your role in delivering the CB intervention in the Back Skills Training Trial (BeST).

All of the physiotherapists that underwent this training will be invited to participate.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you decide not to take part in this study it will not affect your participation in the BeST trial. If you decide to take part you are still free to withdraw from the study at any time and without giving a reason. Again this would not affect your participation in the BeST trial.

What will happen to me if I take part?

You will be interviewed by Zara Hansen on two occasions. The time and place of the interviews will be negotiable and convenient for you. The first interview will take place soon after you return the attached consent form and the second interview 12-18 months later.

The interviews will last approximately 60 minutes and will be tape recorded so that they can be transcribed. The transcription of the interview will be sent to you so that you can confirm that its contents are accurate.

Will my taking part in this study be kept confidential?

Your participation in this study will be confidential. Any data collected in the form of tape recordings and transcriptions will only be accessible to the study team at The University of Warwick and will be destroyed once the study is completed.

What will happen to the results of this study?

The data collected will be analysed and the results used to write a research report and journal articles. In any report or publication we will not use your real name, and will not give out any details that could identify you. Direct quotes will not be used where they could identify you.

Contact for further information

For further information about this study please contact:

Zara Hansen – Clinical Research Fellow Warwick Emergency Care and Rehabilitation Division of Health in the Community Warwick Medical School University of Warwick Room B 161 Medical School Building Gibbet Hill Campus Coventry, CV4 7AL

Tel: 024 765 74651 Fax: 024 765 74657

Thank you for taking the time to read this leaflet.

If you would like to take part in this study, please fill in the enclosed consent forms and return one copy to Zara Hansen in the addressed envelope.

Appendix 9 Participant consent form for the interview study

Study Number:	
---------------	--

CONSENT FORM

A study into the integration of cognitive-behavioural therapy skills into physiotherapy practice

Please initial box

1.	I confirm that I have read and under sheet dated 29/03/05 for the above opportunity to ask questions.		e		
2.	I understand that my participation is free to withdraw at any time, without participation in the BeST trial or my	t giving reason, withou	t my		
3.	3. I agree to take part in the above study				
4.	I do not wish to take part in the above study				
Na 	me of participant	Date	Signature		

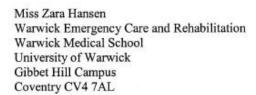
Please return one copy of this form in the enclosed envelope to:

Zara Hansen – Clinical Research Fellow Warwick Emergency Care and Rehabilitation Division of Health in the Community Warwick Medical School University of Warwick Room B 161 Medical School Building Gibbet Hill Campus Coventry, CV4 7AL

The other copy is for you to retain for your records.

Appendix 10 Ethics approval for interview study

21st April 2005





Dear Miss Hansen,

Ref: EtApp 5/04-05

The integration of cognitive behavioural therapy skills into physiotherapy practice. The Back Skills Training (BeST) trial experience

Thank you for submitting your project to the WMS Research Ethics Committee for approval.

The Committee approved your application subject to submission of the following information detailed below:

- Please confirm that the use of data from the BeST trial is permitted according to consents / approvals given at outset.
- Please ensure that while undertaking interviews at the homes of participants the researcher's safety is protected.
- Please clarify the methods to ensure patient data is anonymised and used appropriately.

The Committee noted that the researcher collecting the data is part of the training team. It is worth considering whether this could influence the responses.

You may also wish to consider obtaining statistical advice on the development of scale for this study.

When submitting your response to the Committee, please send relevant revised documentation, underlining the changes you have made where appropriate.

Once acceptable clarification has been received, a formal approval letter will be issued.

The Committee will expect to receive a response from you within three months of the date of this letter, or your application will be considered withdrawn.

Yours sincerely,

Sarah Abrahamson

Secretary to WMS Research Ethics Committee

WMS Research Ethics Committee Warwick Medical School Gibbet Hill Road Coventry CV4 7AL

Tel. 024 7657 4875 Fax. 024 7657 4879

s.abrahamson@warwick.ac.uk



Leicester Warwick Medical Schools 26 April 2005



Miss Zara Hansen Warwick Emergency Care and Rehabilitation Warwick Medical School University of Warwick Gibbet Hill Campus Coventry CV4 7AL

Dear Miss Hansen,

Ref: EtApp 5/04-05

The integration of cognitive behavioural therapy skills into physiotherapy practice. The Back Skills Training (BeST) trial experience

Thank you for providing the additional information recommended by the Committee.

We are pleased to advise you that, under the authority delegated to us by the University of Warwick Research Ethics Committee, approval for your project is hereby granted for the period of three years from the date of this letter.

Please note that any material changes to any aspect of the project will require further consideration by the Committee, and the PI is required to notify the Committee as early as possible should they wish to make any such changes.

May I take this opportunity to wish you the very best of luck with this study.

Yours sincerely,

Sarah Abrahamson

Secretary to WMS Research Ethics Committee

WMS Research Ethics Committee Warwick Medical School Gibbet Hill Road Coventry CV4 7AL

Tel. 024 7657 4875 Fax. 024 7657 4879

s.abrahamson@warwick.ac.uk



Leicester Warwick Medical Schools

Appendix 11 Qualitative study charting - example

Therapist (Competence score, clinical outcome score)	Factors associated with the therapist	Factors associated with patients	Factors associated with CB intervention
	APPLICATION TO SELF Has helped understand why others are the way they are and be more accepting. THERAPY ALLEGIANCE Discusses several people that weren't suitable for the trial. Core of people in the groups that seemed to take a hell of a lot out of it, it made sense to them from the start. Trial training has influenced practice positively SKILL DEVELOPMENT; LISTENING SKILLS Discussed developing listening skills and the importance of patients developing their own narrative of their problem. SKILL DEVELOPMENT; QUESTIONING SKILLS Already uses that approach but has enhanced skills. Difficult skill as trying to revert back to didactic approach.	SUITABILITY OF CB APPROACH FOR PATIENTS; GOOD PATIENTS OR GROUP Can't qualify which patients get the most out of the group, there's a spread but for them it seems to make sense from the start. Intervention most beneficial for those that are more disabled or have seen lots of professionals with no change — they are the most open to change. SUITABILITY OF CB APPROACH FOR PATIENTS; DIFFICULT PATIENTS OR GROUP Difficult patients, those that weren't suitable for the trial, mechanical back pain that needed manual therapy, younger males that weren't really disabled (still fairly active). Identifying thoughts might not be suitable for all — might lose people on that session. SUITABILITY OF CB APPROACH FOR PATIENTS; OPEN TO CHANGE Patients suitable for approach when not	COMPLEXITY OF THE CB MODEL Was able to understand model as taught on BeST better than that taught clinically on a pain management programme 'high temple' CBT on a different plain. SKILLS TRAINING HARD Thought identification was the toughie for him and patients. Took 3 groups to start feeling comfortable and get understanding in patients. Might be a bit too personal for some people. Hypervigilance difficult as almost infers that patient is responsible in part for their pain. Difficult as challenges long held beliefs. SKILLS TRAINING EASY Understanding pain, baselines, goal setting, relaxation, fear avoidance, coping with flare-ups easy. Exercise discussion and pacing easy and had an impact on patients. STRUCTURE PROVIDED BY BeST Since doing the trial realised how unstructured
	SKILL DEVELOPMENT; PRACTICE Took until 3 rd group to get comfortable with	seeking a fix.	he was. Training in BeST pitched at a user friendly level compared to his previous training

thought challenging session, coincided with using terms in other clinical practice.	in XXXX. Has helped him use the patient's narrative to guide what input he provides.
PREVIOUS TRAINING OR EXPERIENCE	
Self learning from texts. Worked in a pain management unit but not involved in any CBT. Trained as a physio to be didactic.	
CONFIDENCE	
Previous exposure to CBT but not the confidence you'd gain from doing it. Happy with fear avoidance vicious cycle. BeST given confidence to discuss thoughts and feelings.	