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Cognitive Behavioural Therapy for Non-Cardiac Chest Pain.

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Contents

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Firstly, I would like to thank the participants without whom this research would not be possible. I sincerely hope that these findings can contribute to improving the experience of patients.

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Finally a big thanks to Matt for graphic design input on the intervention booklet, help with formatting and IT issues but mostly for reminding me what I truly value in life. I could not have done this without you.

I dedicate this thesis to Neale.

List of Tables and Figures

List of Tables

List of Figures

Overview of Thesis

This thesis follows the portfolio format and constitutes part-fulfilment of the degree of DClinPsychol at the University of Edinburgh.

An abstract outlines a summary of the thesis portfolio, including aims, findings and conclusions. Chapter One contains a systematic review aiming to explore the evidence for the effectiveness of cognitive behavioural therapy (CBT) for non-cardiac chest pain, that is chest pain found not to be cardiac in origin. This review was prepared in accordance with the author guidelines for the journal Psychosomatic Medicine. Chapter Two links the systematic review with the empirical study by outlining the rationale, aims and hypotheses of the study.

Chapter Three constitutes Journal Article One and Chapter Four constitutes Journal Article Two. These chapters were written in accordance with the author guidelines for the journal Psychosomatic Medicine.

Chapter Five provides additional information regarding the study methodology. The final sections of the thesis portfolio contain a full reference list and appendices.

The thesis portfolio will adopt the referencing guidelines for the specified journal for Chapter One: Systematic Review and Chapters Three and Four: Journal Articles. The British Psychological Society's editorial style (BPS, 2004) will be used in additional chapters.

Thesis Abstract

Objectives: This thesis aims to explore evidence for the effectiveness of cognitive behavioural therapy (CBT) for non-cardiac chest pain (NCCP).

Design: The systematic review aimed to evaluate evidence for CBT as an effective intervention for anxiety in the NCCP population. Study one describes the chest pain characteristics, illness beliefs and prevalence of anxiety in a NCCP sample in a cross-sectional design. Study two explores the acceptability and clinical effectiveness of a CBT-based self-help intervention for NCCP patients, using a between subjects, repeated measures design.

Methods: A systematic review was completed via a comprehensive literature search for comparative studies examining CBT-based interventions for NCCP including a measure of anxiety. In the empirical study, participants completed measures of anxiety, illness beliefs and indices of chest pain (self-reported frequency, severity and impact on activities) at baseline. Comparisons between illness beliefs and anxiety were undertaken using descriptive statistics and Pearson correlations. Participants were randomised to receive a CBT-based self-help intervention booklet or treatment as usual, with questionnaires re-administered at three-month follow-up. ANOVAs were used to evaluate whether the intervention led to improvements in anxiety levels, or increased belief in participants' personal control of symptoms.

Results: Ten studies met inclusion criteria for the systematic review, with four studies showing evidence regarding the effectiveness of CBT for anxiety. Approximately two thirds of the thesis research sample reported on-going pain following clinic attendance, for the majority this was 'very mild' or 'mild' pain.

Almost half (47%) reported experiencing clinically significant anxiety. Stress was the most common causal attribution advocated by the sample to explain their chest pain. Anxiety scores were significantly associated with psychological attribution scores, but not with personal control or illness coherence beliefs. In study two, 87 participants completed the study and ITT analyses were completed on 119. There were no significant differences between the groups in terms of reduced anxiety or self-reported belief in personal control of symptoms. The intervention booklet was evaluated largely positively by those who reported reading it.

Conclusions: CBT-based self-help appears an acceptable intervention for those diagnosed with NCCP. Further research is needed to identify those who are most likely to benefit from such self-help intervention.

Chapter 1: Systematic Review

Cognitive-Behavioural Therapy for Non-Cardiac Chest Pain – A Clinically Effective Intervention for Anxiety? A Systematic Review

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Written in accordance with the instructions for authors for the journal Psychosomatic Medicine (see Appendix I, p. 117 for author guidelines).

Abstract

Objectives: Individuals experiencing non-cardiac chest pain (NCCP) report a high prevalence of psychological morbidity, impaired quality of life and high healthcare utilisation. Cognitive-Behavioural Therapy (CBT) interventions have sought to target anxiety in this population, with some reporting effectiveness. However, the mechanism of action of CBT, and the causal role of anxiety in NCCP morbidity remains a source of debate. This review aims to summarise and integrate research findings investigating the effectiveness of CBT-based interventions for NCCP in relation to anxiety reduction.

Method: A literature search for comparative studies examining CBT-based interventions for NCCP including a measure of anxiety was conducted. Multiple electronic databases were searched; in addition to examining article reference lists and contacting relevant first authors to obtain further information regarding included studies. The resulting ten articles were systematically reviewed according to predefined quality criteria.

Results: The articles reviewed revealed mixed results regarding the effectiveness of CBT for anxiety. The studies were heterogeneous with various implementations of CBT interventions, a range of outcome measures and differing study populations, limiting comparisons of results between studies.

Conclusions: CBT is an effective treatment for anxiety for some NCCP patients; further work is required to clarify for whom. Further mediational studies, with longer follow-up periods, should be conducted to clarify mechanisms of action for CBT.

Further research is required before any conclusions regarding a possible aetiological role of anxiety are drawn.

Key words: CBT, non-cardiac chest pain, anxiety, systematic review.

NCCP=Non-Cardiac Chest Pain; CBT=Cognitive-Behavioural Therapy

Introduction

Background

Patients presenting in health services with chest pain are referred to cardiologists and chest pain clinics in order to investigate whether their chest pain is related to potentially life threatening coronary artery disease. However, a high proportion (50-80%) referred for cardiology investigation have non-cardiac chest pain (NCCP) i.e. angina like chest pain in the absence of detectable coronary artery disease (1-3). Once cardiac causes have been ruled out, there is often an assumption that patients will be reassured and return to life as normal (1). However, this is not necessarily the case as those with NCCP have been shown to experience high psychological morbidity, impaired quality of life, functional impairment and to be high users of healthcare systems (2,4-8). Research has also found that this population has a favourable long-term survival prognosis (9,10).

Cognitive behavioural therapy as an intervention.

Cognitive behavioural therapy (CBT) interventions have been applied to this population in order to target the reported difficulties and optimise the poor outcomes associated with this group. Several researchers have reported effective outcomes following CBT for NCCP. The Cochrane Collaboration first published a systematic

review regarding psychological interventions for the "symptomatic management of non-specific chest pain in patients with normal coronary anatomy" in 2005 (11). The most recently updated review published in 2012 (12) identified fifteen randomised controlled trials meeting their inclusion criteria. The authors concluded that there is evidence for the effectiveness of CBT in this population, but that studies in this area are limited by small sample sizes and short follow-up periods. A variety of outcome measures were reported including psychological morbidity, chest pain frequency, duration and intensity and various measures of quality of life. This limits the comparison of results between studies. The Cochrane authors used chest pain intensity and pain diaries as the primary outcome for their review, with psychological symptoms considered as a secondary outcome measure. They were able to combine data from eight studies measuring anxiety, revealing a significantly greater reduction in the intervention groups compared to control groups, up to three months post-intervention.

There is evidence regarding the efficacy of CBT for medically unexplained symptoms (e.g. 15) and for anxiety disorders such as health anxiety and panic disorder (e.g. 16). It could be argued that anxiety is particularly relevant as an outcome measure in the NCCP population. A recent systematic review found similar levels of anxiety in NCCP and in cardiac patients accessing Emergency Departments, which was higher than those found in the general population (17).

Conceptualising anxiety and understanding its role in NCCP.

Only four studies reviewed by the most recent Cochrane Review (12) used a measure of cardiac specific (as opposed to generalised) anxiety and no significant differences

were found on this construct over time. Cardiac anxiety is considered to be a unique construct, although related to other psychological factors linked to the development and maintenance of anxiety problems, such as anxiety sensitivity (13). Since the publication of this Cochrane review, additional studies have been published measuring anxiety (generalised and/or cardiac specific) in NCCP groups. It would therefore be beneficial to further review the evidence of effectiveness of CBT interventions for anxiety.

The relevance of anxiety to NCCP treatment outcome research is often unspecified and it is unclear whether the heightened anxiety reported in this population is purely reactive, or may play a causal or maintaining role in NCCP. Some researchers have proposed anxiety as a causal mechanism, in particular those studies relating the chest pain to panic disorder (e.g. 18). Others have suggested a multifactorial aetiology whereby physiological sensations, related to minor problems such as reflux, are interpreted as evidence of serious illness, usually coronary artery disease (e.g. 19). Salkovskis (20) has proposed that the misinterpretation of benign physiological sensations as evidence of organic pathology, combined with maladaptive coping strategies related to this misinterpretation, are relevant in understanding medically unexplained chest pain. He also suggested that changes following CBT are mediated by changes in anxiety. However, CBT intervention studies for NCCP have found mixed results in relation to anxiety, even when chest pain symptoms have decreased in frequency, calling into question the aetiological role of anxiety.

Defining the population.

The Cochrane Review (12) includes four studies with Cardiac Syndrome X patients, which other authors have suggested considering separately from NCCP patients given that Cardiac Syndrome X (thought to be linked to an abnormality in the small blood vessels which supply blood to the heart muscle) is a distinct group with a specific diagnosis and may therefore potentially differ in treatment outcomes (14). It can be defined by the presence of chest pain, a positive exercise test for myocardial ischaemia and smooth coronary arteries, thus differing from the NCCP group who test negative for myocardial ischaemia on exercise testing (14). Given that CBT for NCCP includes a focus on the individual's interpretation of their symptoms, there may be differences in outcome between those in a non-specific category defined by exclusion (i.e. non-cardiac) versus those with a specific diagnosis (Cardiac Syndrome X). It would therefore appear beneficial to review the literature excluding Cardiac Syndrome X studies.

Aims and scope of current review.

The current literature therefore does not allow a specific appraisal of the effectiveness of CBT for NCCP. The Cochrane review in this area examined the evidence for the effectiveness of psychological interventions for anxiety in individuals with non-specific chest pain. However they included interventions such as relaxation in their inclusion criteria and also reviewed studies recruiting patients with Cardiac Syndrome X. Therefore it remains unclear if CBT specifically for NCCP is an effective intervention for anxiety. Based on the issues identified in the current literature on NCCP and CBT interventions, this review aims to summarise,

critically appraise and integrate research findings regarding whether CBT treatments are an effective treatment for anxiety in patients with NCCP. This will allow further exploration of the causal role of anxiety in NCCP and possible mechanisms of action of CBT for NCCP.

Method

The systematic review procedure was based on guidance for the completion of systematic reviews advocated by the Centre for Reviews and Dissemination (CRD), The University of York (www.york.ac.uk/inst/crd/). This included the development of *a priori* inclusion and exclusion criteria regarding the populations and interventions studied, the methodological designs used to compare groups, the outcome measures employed and what language the article was published in. Inclusion and exclusion criteria are outlined below.

Inclusion and exclusion criteria

Participants

Studies were eligible for inclusion if they reported data solely for adult participants (18+ years) with a diagnosis of NCCP. Participants must have undergone investigation within a cardiology department in order to reach diagnosis of NCCP.

Interventions

Interventions described as 'CBT' often vary in terms of form and content. Kisely *et al*.'s (12) Cochrane review of CBT for NCCP based their definition on that of a

previously published review of CBT (21). They state that a 'well defined' CBT intervention is one in which:

1. The individual is encouraged to make links between their thoughts, feelings and behaviours with respect to the target symptom.
2. Restructuring of the individual's misinterpretations and unhelpful thoughts related to the target symptom are part of the therapeutic focus.
3. The intervention encourages the individual to monitor their thoughts, feelings and behaviours in respect to the target symptom and/or promotes alternative methods to cope with the target symptom.

For the purpose of this review, articles stating the intervention to be any one of: cognitive behavioural therapy, behavioural therapy, cognitive therapy, relaxation, hyperventilation control, pacing activity, psychological therapy were examined in more detail. Studies were included in the review if they met criteria 1-3 above in relation to a 'well-defined' CBT intervention.

Comparison

Eligible studies must have included at least two groups – one with intervention and one without. The control group could be a treatment as usual or waiting list control group, or a group receiving placebo medication.

Outcome Measures

Anxiety post-intervention was the primary outcome measure. Thus, at least one validated measure of anxiety was required for inclusion in the review. This could include a validated psychometric self-report questionnaire (such as the Hospital

Anxiety and Depression Scale (HADS, 22) and/or a validated structured clinical interview schedule (such as the Anxiety Disorders Interview Schedule for Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (ADIS-IV, 23). Anxiety at follow up was also examined to allow comparison of results over follow-up periods.

Study Design

Comparative studies of any design examining the effectiveness of CBT interventions on at least one validated measure of anxiety were eligible for inclusion. A Cochrane Review in a similar area included only RCTs (12). However given that a preliminary literature search identified comparative studies using non-randomised designs the decision was made to include non-randomised trials in which there was both an intervention group and a separate group of control participants not receiving the intervention. These criteria were based on the CRD guidance.

Additional Exclusion Criteria

The authors had no means to translate non-English language articles - therefore these were excluded.

Literature Search Strategy

The following electronic bibliographic databases were searched: EMBASE, Medline, PsycINFO and CINAHL. Databases were searched with no early date restriction to 01 May 2012. The databases were searched using a combination of search terms and Boolean operators. The terms “CBT”, “"cognitive behavio?r therap*", “relax* adj3 therap*”, “(cognitive adj3 therap*)” were searched in combination with “Chest

Pain", "(chest adj3 pain*)", ""non?cardiac chest pain". Techniques were used to account for truncation and differences between British and American spellings of 'behaviour'. Searching for a key word within three words of another key word was used to search for the concepts of 'relaxation' and 'therapy'; 'cognitive' and 'therapy' as well as 'chest' and 'pain'.

The titles and abstracts of the search results were reviewed and articles deemed not relevant to the primary research question were excluded. Titles and abstracts were examined if they included any of the following terms for chest pain: non-cardiac chest pain, non-specific chest pain, atypical chest pain, chest pain with normal coronary anatomy and benign chest pain. A record was kept of all excluded papers and the reasons for exclusion. Reference lists of the included studies were also hand searched to identify further relevant papers. Lead authors, or when unavailable second named authors, were contacted in order to gather further information about included studies. Where there were multiple publications regarding the same study, all papers were examined but the results were presented as one study.

Quality Assessment of Included Studies

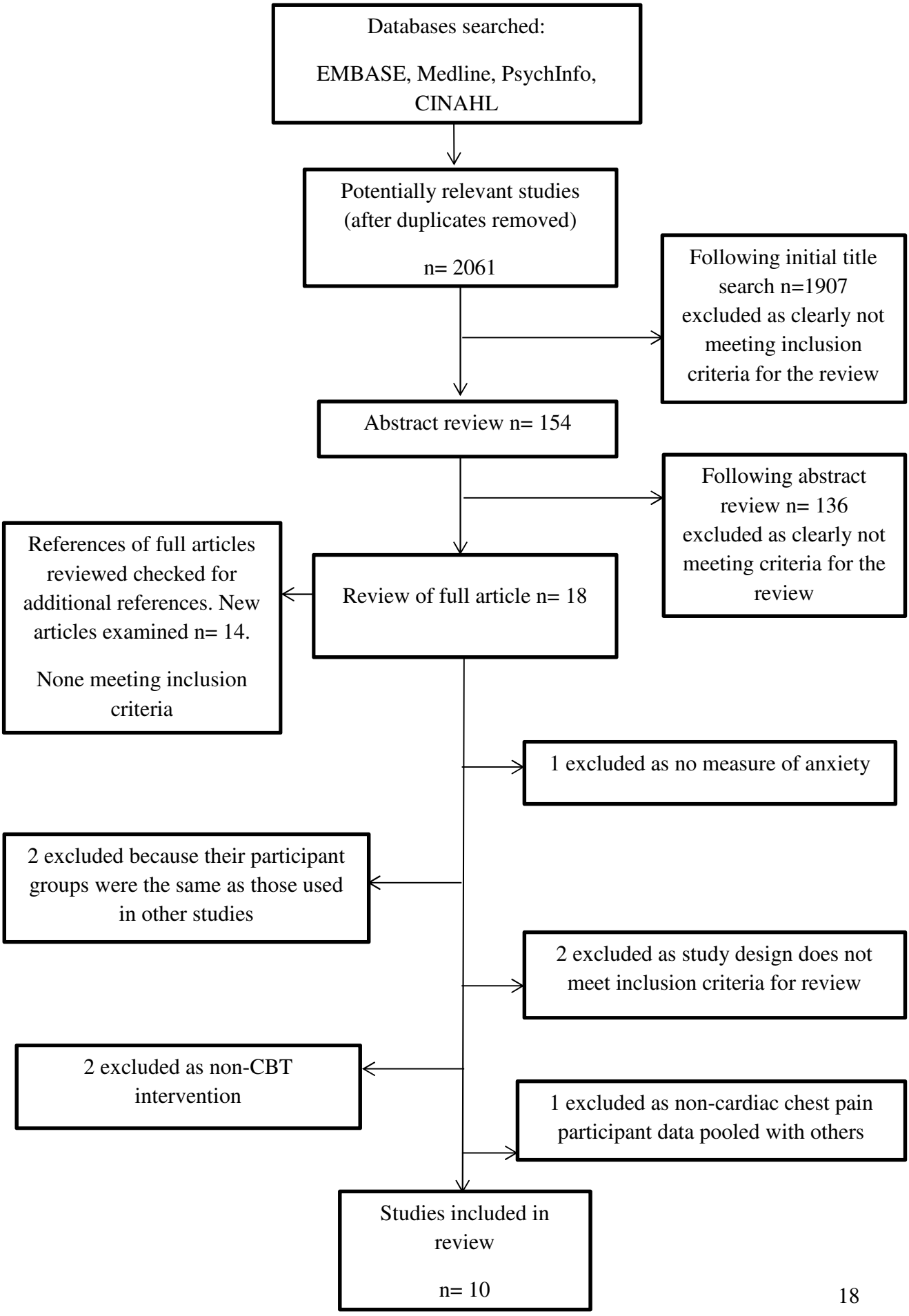
A rating checklist was devised to rate the methodological quality of the included studies. This was based on the methodology checklists outlined in the Scottish Intercollegiate Guidelines Network (SIGN) 50 Guideline Developer's Handbook (24) and the Cochrane Review Handbook (25). It underwent five revisions before the final checklist was used to rate studies (see Appendix II, p.119 for final version). In order to ascertain the reliability of the rating scale a random sample of five papers were coded by a separate investigator (P.G.M). There was full agreement on 75%

(41/55) of ratings, a difference of one point on 20% (11/55) of ratings and a difference of two points on 5% (3/55) of ratings. Where discrepancies occurred these were reviewed and amended through discussion where appropriate.

Results

The search yielded 2061 studies after duplicates were removed. Figure 1.1 outlines the systematic review process utilised to identify studies included in the review. Appendix III (p.125) details a list of the number of articles examined and excluded, with reasons for exclusion. Ten studies were eligible for inclusion in the current review.

Figure 1.1: Systematic Review Process.



Characteristics of Included Studies

Eight of the studies included in the review were RCTs (26-33) and two were quasi-experimental designs (34, 35). Two of the RCT studies included crossover designs in which participants in the usual care condition then received a CBT intervention (26, 30). The ten included studies involved a total of 602 participants with 46% of these being male. Table 1.1 provides a summary of the characteristics of included studies and key findings. All but one study (33) described evaluating a CBT intervention. Keefe and colleagues (33) described a coping skills training intervention, on examination this met the *a priori* inclusion criterion for a CBT study adopted in this review.

Quality of Included Studies

Table 1.2 outlines the quality ratings for each study. This provides a guide as to the relative methodological quality of each study in relation to the systematic review question. According to these criteria Potts *et al.* (30) and van Peski-Oosterbaan *et al.* (29) conducted the methodologically strongest studies. The majority of studies were of average methodological quality, with one study by Mayou *et al*. (27) of relatively poor methodological quality in relation to the review question.

Table 1.1: Characteristics of Included Studies

Study	Subjects Total CBT	Mean age at baseline	Gender (% male)	Participation rate in study	Mean duration of chest pain at baseline	Treatment characteristics	Anxiety Outcome Measure	Key findings
Klimes *et al.* (1990)	35 18	Median 41 years (range 42 years)	57	62.5%	Median 3 years (range 25 years)	Outpatient sample 1:1 Max. 11 sessions over 3 months Delivered by psychologist	STAI-T; Psychiatric 'caseness' (PSE)	No change on STAI-T after CBT but significant improvement on general measure of distress (Symptom Rating Test) compared to control. Those meeting PSE 'caseness' non-statistically significant decrease.
Mayou *et al.* (1997)	37 20	49.40 years (range 31-63)	40	66%	< 6 months: 25% 6-23 months: 35% 2 years or more: 40%	Outpatient 1:1 Max. 12 sessions, unclear time span Delivered by psychologist	SCID psychiatric diagnosis. General measure of distress (BSI)	No specific measure of anxiety. High prevalence of psychiatric disorder at baseline (20% general anxiety, 35% panic, 2% somatoform). No significant difference pre- and 6 months post-CBT. BSI anxiety subscale not reported.
Sanders *et al.* (1997)	57 33	Not reported	37	40%	< 6 months: 29% 6-23 months: 38% 2 years or more: 34%	Inpatient – cardiology department 1:1 1 hour long session Delivered by a cardiac nurse under the supervision of a psychologist.	STAI-T; SCL-90 Anxiety subscale	No significant difference between treatment and control groups on either measure of anxiety. Both groups improved over time.
van Peski-Oosterbaan *et al.* (1999)	65 32	49 years (+- 11 years)	45	34.2%	50 +- 59 months	Outpatient 1:1 4-12 sessions in total, mean = 9 sessions.	HADS; ADIS-R – baseline only	Clinically significant scores on HADS anxiety pre-intervention. CBT group significantly greater reduction in HADS anxiety score compared to control group

						Delivered by a physician/ psychologist		post intervention and at follow-up. Baseline ADIS-R: 29% met criteria for 1 diagnosis; 23% met criteria for 2 or more.
Potts *et al.* (1999)	60 34	Treatment 52.8 years (8.6 *S.D.*) Control 55.4 years (7.7 *S.D.)*	39	Not reported	Not reported	Outpatient Group treatment 6 x two hour sessions delivered by psychiatrist & psychologist.	HADS	Significant reduction in HADS anxiety scores post intervention in CBT group compared to control group.
Esler *et al.* (2003)	59 17	40.73 years (12.04 *S.D.*) Range 19-70	54.2	63%	< 1 month: 45.8% 1-6 months: 15.3% 6 month –2 year : 5.1% 2 or more years: 33.9%	Inpatient – delivered in Emergency Department 1:1 1 hour long session Delivered by psychologist	CAQ; ASI	CBT group greater decrease compared to control group on ASI and CAQ fear subscale at 1- and 3-month follow-up. No significant difference between CAQ avoidance or attention subscales between groups.
Spinhoven *et al.* (2010)	69 23	CBT 53 years (12.2 *S.D.*) Paroxetine 57.7 years (8.4 *S.D.*)	53.6	20%	CBT 4.4 yr (4.7 S.D.) Placebo 6.8 yr (8.2 S.D.)	Outpatient 1:1 6-12 sessions, unclear time span Delivered by 1 of 4	HADS; CAQ; MINI-PLUS	CBT group significant reduction in CAQ total score post intervention compared to placebo and paroxetine groups. No significant difference on HADS anxiety score. Pre- to mid-treatment reduction in CAQ total score (i.e. cardiac anxiety) predicted reduction in NCCP.

		Placebo 57.1 (11.4 *S.D.*)				psychologists		
Keefe *et al.* (2011)	115 29 CBT & placebo	48 years (12 *S.D.*) Range 22-74	33	56.6%	Not reported	Outpatient 1:1 11 sessions over 34 weeks. Delivered by psychologists	STAI; PCS	'CBT and placebo' did not result in significant reduction of STAI state or trait anxiety scores. 'CBT and placebo' group significant reduction in PCS post intervention. No pure CBT group studied.
Pelland *et al.* (2011)	47 19	42.5 years (12.8 *S.D.*)	53	57.8%	Not reported	Outpatient 1:1 7 sessions over 14 weeks Delivered by psychologist	ASI; CAQ; ADIS-IV – panic disorder severity	No significant difference between CBT and control on ASI and CAQ scores. Both improved over time. Reduction of panic disorder severity and panic attack frequency in CBT group compared to control.
Lessard *et al.* (2012)	58 24 1 session CBT 19 7 session CBT	42.41 years (13.42 *S.D.*). Range 21-81	53	51.3%	Not reported	Outpatient 1:1 Intervention i) 1x two hour session Intervention ii) 7 sessions over 4 weeks Delivered by psychologist	ASI; CAQ; ADIS-IV - panic disorder severity	No significant difference between groups on ASI or CAQ. All groups improved over time. Both interventions (1 session and 7 session CBT) showed significant reduction in panic disorder severity compared to control group.

STAI- State Trait Anxiety Inventory; PSE- Present State Examination interview; SCID- The Structured Interview for DSM-II-R; BSI – Brief Symptom Inventory; SCL-90- Symptom Checklist-90; HADS- Hospital Anxiety and Depression Scale; ADIS-R- Anxiety Disorder Interview Schedule for DSM-IV.; CAQ- Cardiac Anxiety Questionnaire; ASI – Anxiety Sensitivity Index; MINI-Plus – Mini International Neuropsychiatric Interview- Plus.

Table 1.2: Ratings of Quality for Included Studies

Study	(i) Sampling method	(ii) Attrition	(iii) Baseline similarity/ confounds controlled	(iv) Rigorous design	(v) Randomis-ation	(vi) Adequate concealment	(vii) Suitable follow-up	(viii) Adequate Power	(ix) Treatment Fidelity	(x) Suitable measure of anxiety	(xi) Statistical Analysis	Total Quality Score (/22)
Klimes *et al.* (1990)	Adequately addressed	Well covered	Adequately addressed	Well covered	Adequately addressed	Not reported	Adequately addressed	Poorly addressed	Adequately addressed	Well covered	Adequately addressed	12
Mayou *et al.* (1997)	Adequately addressed	Poorly addressed	Not reported	Well covered	Well covered	Adequately addressed	Not reported	Poorly addressed	Adequately addressed	Poorly addressed	Not reported	7
Sanders *et al.* (1997)	Poorly addressed	Adequately addressed	Well covered	Well covered	Well covered	Well covered	Adequately addressed	Poorly addressed	Adequately addressed	Well covered	Poorly addressed	13
van Peski-Oosterbaan *et al.* (1999)	Poorly addressed	Well covered	Well covered	Well covered	Well covered	Adequately addressed	Well covered	Poorly addressed	Well covered	Well covered	Adequately addressed	16
Potts *et al.* (1999)	Not reported	Well covered	Well covered	Well covered	Well covered	Adequately addressed	Well covered	Poorly addressed	Adequately addressed	Well covered	Well covered	16
Esler *et al.* (2003)	Adequately addressed	Poorly addressed	Well covered	Well covered	Well covered	Adequately addressed	Adequately addressed	Poorly addressed	Adequately addressed	Well covered	Poorly addressed	12
Spinhoven *et al.* (2010)	Poorly addressed	Adequately addressed	Well covered	Well covered	Well covered	Well covered	Poorly addressed	Poorly addressed	Adequately addressed	Well covered	Adequately addressed	13
Keefe *et al.* (2011)	Poorly addressed	Poorly addressed	Well covered	Well covered	Well covered	Adequately addressed	Poorly addressed	Poorly addressed	Well covered	Well covered	Well covered	13
Pelland *et al.* (2011)	Poorly addressed	Well covered	Well covered	Adequately addressed	Not applicable	Adequately addressed	Not reported	Poorly addressed	Well covered	Well covered	Adequately addressed	11
Lessard *et al.* (2012)	Poorly addressed	Adequately addressed	Adequately addressed	Adequately addressed	Not applicable	Adequately addressed	Adequately addressed	Poorly addressed	Well covered	Well covered	Well covered	11

(i) The sampling method ensures that the sample is representative of a general clinical sample.
(ii) The study clearly states attrition rates for each group and this is similar for each group.
(iii) Participants in each group are sufficiently alike at baseline in terms of key variables that may impact on intervention outcome. Any difference controlled for appropriately.
(iv) A rigorous research design is applied to address the study question.
(v) If RCT assignment to groups should be randomised.
(vi) Assignment to groups should be adequately concealed on participant entry into the study and to those scoring the results.
(vii) Follow-up assessment at a suitable time period completed and acceptable attrition rate.
(viii) Sample size adequate.
(ix) Fidelity/ compliance check regarding well specified intervention.
(x) Anxiety measured in a standard valid, reliable way.
(xi) The analysis is appropriate to the design and type of outcome measure.

The two methodologically strongest studies were the only studies completing follow-up at a suitable time period and with an acceptable retention rate. Table 1.3 outlines the duration of follow-up and retention of participants in the six studies providing adequate information for follow-up to be assessed. Several studies reported follow-up as time since completion of baseline measures. Mayou *et al.* (27) did not report treatment duration therefore it is unclear if data represent post-treatment or follow-up assessment. Pelland and colleagues (34) reported completing follow-up at 6-months, however the drop-out at follow-up is unclear meaning that insufficient information was provided in order to assess potential bias.

Table 1.3: Follow-up duration and retention.

Study	Length of post treatment follow-up and % retention
Esler *et al.* (31)	3 months, 60% retention
Potts *et al.* (30)	6 months, 94% retention
Van Peski-Oosteraan *et al.(*29)	6 months, 87.5% retention
Sanders *et al.(*28)	3 months, 71% retention
Klimes *et al.* (26)	4-6 months; 71% retention
Lessard *et al*. (35)	3 month post treatment 62% retention, 6 months 50% retention - additional data provided by author

The two relatively strongest studies also reported low attrition pre- to post-intervention. However the differences between the research designs limit comparison between studies in relation to attrition. Esler *et al.* (31) studied a brief one session intervention with provision of self-help materials; therefore completion of the post-intervention measure was 1-month after completion of pre-intervention. Sanders and colleagues (28) also studied a one session plus self-help intervention, with post-measures completed 3 months after assessment. These differing designs limit comparison of the attrition rates pre- and post-intervention between

these studies, and studies completing interventions of more than one session completing pre- and post-intervention outcome measures.

The majority of studies (6/10) were poor at ensuring the generalisability of their results which primarily related to poor participation rates, such that 59% or less of eligible participants agreed to participate (28, 29, 32-35). Two studies (34, 35) included only those meeting diagnostic criteria for panic disorder, limiting the generalisation of their results out-with this population. Most studies excluded those with severe psychopathology (e.g. depression) with the exception of one (28). A minimum frequency of NCCP was specified by some (26, 27, 29, 30, 32). All studies were underpowered according the definition for adequate sample size adopted in the current review resulting in an increased risk of a Type II error. This definition was based on calculating an adequate sample size for studies based on a medium effect size. Cohen's definition of a medium effect size was used as the literature specifies this as the magnitude of effect deemed to be desirable (Cohen, 36). Maxwell (37) states that researchers should estimate desired sample size using methods that incorporate effect size. Cohen (36) states that setting desired power at 0.80 and alpha at 0.05 is considered convention.

All studies reported following an operationalised treatment, with four also reporting completion of a rigorous fidelity check (29, 33-35). Supervision alone without additional verification of adherence to the treatment protocol was an insufficient check of treatment adherence for this review as supervision is considered a fundamental part of routine clinical practice (38).

A variety of anxiety outcome measures were used, with the majority of studies (9/10) using a standardised outcome measure with well reported psychometric properties in the NCCP population. Where psychometric properties were not reported in the paper, a literature search was undertaken to clarify the psychometric properties of the measure for this group. Only one study (27) was rated not 'well covered' on this construct as this study did not report the

results of the anxiety subscale of the measure used. Only the prevalence of those meeting diagnostic criteria for psychiatric diagnoses was reported in this study.

A number of studies reported prevalence of psychiatric disorder. Van Peski-Oosterbaan *et al.* (29) also reported this only at baseline. One study (26) reported the proportion meeting criteria for "caseness" pre- and post-treatment and at follow-up. The prevalence of DSM-IV anxiety disorders was explored in one study (32) who found that 32% of patients met criteria for an anxiety disorder (mainly panic disorder). Two studies (34, 35) included only those meeting diagnostic criteria for panic disorder and used panic disorder severity as measured by the ADIS-IV as their primary outcome measure.

Synthesis of study findings in the context of relative methodological strengths and weaknesses.

Four studies reported evidence of a significant reduction in anxiety following CBT compared to a control group (Table 1.1). This included the two methodologically strongest studies which found a significant reduction in anxiety measured using the HADS (29, 30). Spinhoven *et al.* (32) did not find a significant reduction on the HADS post-CBT but did report a significant reduction in anxiety measured using the Cardiac Anxiety Questionnaire (CAQ, 13). Esler *et al.* (31) observed a significant reduction on the fear subscale of the CAQ, post-CBT. Two other studies (34, 35) measured anxiety using the CAQ but did not find evidence of post-CBT reductions in anxiety. However, it is notable that these studies included only participants meeting diagnostic criteria for panic disorder. The other studies reporting no effect measured anxiety using the State Trait Anxiety Inventory (STAI, 39) and Pain Catastrophising Scale (PCS, 40).

There was no clear pattern of difference between studies reporting CBT to be an effective intervention and those reporting no effect in terms of number of treatment sessions, duration of treatment, duration of chest pain on entering treatment, baseline anxiety levels or mean age of participants. Studies whose interventions required a more significant investment of time

from participants tended to include those with a longer duration of chest pain than brief intervention studies.

Studies that demonstrated the effectiveness of CBT in reducing anxiety (29 - 32) varied in terms of important variables. One (30) involved a group intervention whereas others utilised one-to-one interventions. The length of treatment ranged from a brief one-hour intervention followed by provision of a self-help booklet delivered in the Emergency Department (31), to up to twelve hours of intervention (30). Two studies (29, 32) were similar in terms of the sample recruited and treatment delivered however one (29) had a physician or psychologist deliver treatment, the other (32) one of four psychologists. The studies that reported no evidence of the effectiveness of CBT for reducing anxiety also varied on key factors including chest pain and treatment characteristics.

Discussion

This systematic review aimed to summarise and integrate research findings regarding CBT for NCCP with the aim of assessing if CBT is an effective treatment for anxiety in this population. Overall the review yielded mixed findings, with evidence of statistically significant decreases in anxiety post-CBT intervention reported in some studies but not in others.

The wide variation across the ten studies reviewed on a range of key variables linked to outcomes is crucial in understanding these differing results. A range of self-report measures have been used in the literature and this limits comparison between studies. Early studies did not include a specific measure of cardiac anxiety, nor measures specifically designed for medical populations such as the HADS. The studies that observed a significant reduction on a measure of anxiety post-treatment, measured anxiety using the HADS or CAQ. All studies using these measures found a reduction in anxiety post-treatment, apart from the two studies including only those meeting diagnostic criteria for panic disorder. If anxiety regarding the

heart specifically is crucial to understanding NCCP, and a potential mechanism through which CBT operates, perhaps it is unsurprising that non-specific measures of general anxiety such as the State Trait Anxiety Inventory did not reveal any change following CBT.

The clinical characteristics of chest pain also differed significantly between studies. The duration of chest pain on entering the study varied from one study in which the majority of participants were experiencing NCCP for less than one month on entry (31), compared with another study whose sample had been experiencing chest pain for a mean of 4.4 years on entry (32). Other studies did not measure duration of chest pain, which appears to be a significant limitation. The duration of chest pain has been identified as a factor affecting participant engagement in non-medical treatment not necessarily aiming to cure chest pain but develop understanding of, and strategies to manage, symptoms (29). Esler *et al.* (31) suggest that recruiting all patients with NCCP, with no minimum inclusion criteria for the symptoms experienced, such as duration of chest pain or frequency of chest pain, may impact on treatment outcome research. They propose that a ceiling effect could be reached in those studies that do not specify minimum chest pain criteria, in that there may be little scope for improvement from baseline scores. This could also apply to the measurement of anxiety as an intervention outcome.

The characteristics of the CBT varies across the literature in terms of important factors such as number and time span of sessions delivered, and the training and experience of those delivering treatment. Considering a 'dose–response' relationship, it seems likely that a brief one hour session would result in a different outcome to a 12 session intervention delivered over several months. There was no evidence to support this in the current review, although the brief interventions consisting of one hour of face-to-face intervention also provided a self-help booklet for patients to use in their own time. Future research should explore this 'dose-response' issue and studies of brief interventions should measure total intervention time, even if this is self-directed by patients.

The number and duration of sessions is also likely to impact on attrition and affect recruitment to the study. In this review studies involving interventions requiring a more significant time investment from participants tended to include those with a longer duration of chest pain than brief intervention studies.

The low participation rates of reviewed studies limits the generalisability of the results, and suggests that CBT interventions are often not acceptable to those diagnosed with NCCP. Spinhoven *et al*. (32) suggest that this may be due to the possibility of being randomised to receive medication, however not all studies in this review included a medication condition. Once recruited, attrition pre- to post-intervention was broadly acceptable in the studies included in this review, suggesting that CBT is an acceptable intervention to those who agree to participate in it.

Only one study completed a mediation analysis aiming to explore if pre- to mid-treatment reduction of anxiety mediated mid- to post-treatment pain reduction (32). Pre- to mid-treatment reduction in heart-focused anxiety predicted mid- to post-treatment chest pain reduction in a group who received CBT compared to a placebo medication control group. There were limitations to this study, in particular the low participation rate, which limits generalisability, in addition to lack of follow-up. It would also be beneficial to compare a CBT group with an attention placebo control group. Future research could extend this study and further explore the potential mediating role of anxiety in NCCP. This would also allow investigation of the role of reduction in cardiac anxiety as a potential mechanism of action for CBT in this group.

Anxiety is an important issue for individuals with NCCP due to associated distress and decreased quality of life, as well as the hypothesised causal link between anxiety and pain symptoms. The implications in terms of healthcare utilisation are also vital to consider, as the NCCP population are frequent users of healthcare resources (29). It seems likely that the

continued use of healthcare services following a diagnosis of NCCP is related to the anxiety associated with continuing symptoms.

Previous systematic reviews (11, 12) have primarily aimed to explore the efficacy of CBT in reducing the severity of chest pain. One article in the current review (33) reported that the interpretation of pain experiences may be a key target for intervention. This reflects the chronic pain literature which has suggested that interventions are effective when targeting the distress caused by pain symptoms rather than aiming to reduce symptoms per se (33). It is feasible that following CBT treatment there may be no change in chest pain symptoms, but if a reduction in anxiety regarding symptoms was found this could potentially be of great clinical significance, as well as economically significant in relation to reduced healthcare utilisation. Future research should include measures of beliefs regarding chest pain, such as the PCS (38) and should include a cardiac specific measure of anxiety, such as the Cardiac Anxiety Questionnaire (CAQ) (13).

Elucidating the mechanism of action for CBT in this population is important in order to clarify the active components of this treatment. The majority of this research has involved study of one-to-one sessions varying in duration but commonly over 9 – 16 sessions. This represents a considerable cost to health services. If the key components of this treatment can be identified, CBT approaches could be further developed and more targeted, resulting in more efficient delivery of interventions. Future researchers are urged to be clear when reporting the length of the follow-up periods and, as noted by the Cochrane reviewers (12), longer follow up periods are required.

Strengths and limitations of the review

In terms of strengths, relevant authors were contacted to obtain additional information relevant to answering the review question. In addition an independent rating of methodological quality using the rating checklist was conducted with a high degree of inter-

rater reliability thus reducing the potential for subjective bias in study ratings and increasing the reliability of the results.

However, a meta-analysis of the results was not undertaken, which would have enabled more accurate comparisons to be drawn across the ten studies. Calculation of a weighted average from the results of the studies would also have been beneficial in order to answer the review question. However, the heterogeneity between studies, particularly in terms of the clinical outcome measures used and differing results, indicated that calculation of an average value for the effect of CBT in this area would have been misleading (25). A further limitation is that unpublished papers were not requested and thus the issue of publication bias is raised. The exclusion of non-English language papers, and use of a particular search strategy with specified electronic databases, search terms and inclusion/ exclusion criteria may have excluded potentially relevant articles.

Conclusions

In summary, this systematic review of the effectiveness of CBT interventions for anxiety in the NCCP population found that the current evidence is inconclusive. CBT is a promising treatment for this population, and there is evidence that CBT can result in a reduction in anxiety, as measured by self-report questionnaires. These conclusions must be treated with caution, due to the methodological issues evident in the literature. The aetiological role of anxiety is unclear and thus future research needs to explore this further, in particular through mediational analysis. Further high quality research with adequate post-treatment follow-up periods of 6 months or more is also indicated.

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Chapter 2: Introduction to Thesis Aims and Hypotheses

The aim of this bridging chapter is to link the systematic review findings with the research questions forming this thesis. Study one aimed to explore the chest pain characteristics, prevalence of anxiety and illness beliefs in a non-cardiac chest pain (NCCP) sample. This sample then participated in study two which explored the acceptability and clinical effectiveness of a cognitive behavioural therapy (CBT) based self-help intervention.

Rationale for the current studies

Rapid Access Chest Pain Clinics (RACPC) are designed to identify those with potentially life threatening ischaemic heart disease (Newby *et al.,* 1998). However up to seventy per cent of those who attend are discharged with a diagnosis of non-cardiac chest pain (McGavigan *et al*., 2003). Previous research has identified high psychological morbidity and impaired quality of life in NCCP samples (e.g. Arnold *et al.* 2009; Robertson *et al*. 2008). The systematic review outlined in the previous chapter suggested that there is evidence for the effectiveness of CBT in reducing anxiety for some NCCP patients (Esler *et al*., 2003; Potts *et al*., 1999; Spinhoven *et al*., 2010; Van Peski-Oosterbaan *et al*., 1999). A recent Cochrane review (Kisely *et al*., 2012) in this area concluded that there is evidence that CBT is an effective intervention to reduce the frequency of chest pain in this population in the short-term. The authors stated that there is less evidence in relation to brief interventions and conclusions must be limited by the short follow-up periods of included studies. The studies that these systematic reviews evaluated consisted of face-to-face or group interventions.

An important limitation of the current evidence base relates to low participation rates in studies which restricts the generalisability of the results. Mayou *et al.* (1997) speculated that, on the basis of their previous research, low participation rates are related to the fact that individuals are seeking intervention in a medical setting and may therefore decline to engage in an approach viewed as ‘too psychological’. They advocate a stepped care approach that

includes ‘low intensity’ interventions which may be more acceptable to NCCP patients. Stepped care is a model of service delivery designed to overcome the scarcity of specialised practitioners delivering psychological therapy. Minimal interventions such as self-help based on psychological therapies are offered with the assumption that these will be sufficient for some, thus allowing therapists to allocate resources to those requiring more intensive treatment (Bower & Gilbody, 2005). The acceptability and effectiveness of CBT-based self-help interventions is an area receiving increasing interest in physical health settings. Self-help interventions may be more acceptable to patients seeking help for symptoms in a medical setting and may form one of the early tiers of a stepped care approach (Bower & Gilbody, 2005). Studies have shown CBT self-help interventions to be acceptable and effective with patients diagnosed with physical health presentations such as angina (Lewin *et al*., 2002), irritable bowel syndrome (Moss-Morris *et al.,* 2010) and chronic pain (Buenaver *et al.,* 2006). It remains unclear whether NCCP patients view self-help interventions based on CBT as acceptable.

Illness beliefs appear relevant in understanding participant response to psychological intervention. Robertson *et al.* (2008) examined beliefs regarding chest pain in a NCCP sample using the Illness Perceptions Questionnaire-revised (IPQ-R, Moss-Morris *et al*., 2002), which is based on Leventhal and colleagues’ Common-Sense Self-Regulation model (Leventhal *et al*., 1980, 1997). This model purports that an individual constructs beliefs about their symptoms when confronted with a threat to their health and that these cognitions consequently influence behaviour and emotional reactions. There has been little consideration of the potential impact of interventions on beliefs about chest pain in an NCCP population, and it is unclear if illness beliefs are related to anxiety in this group. Therefore, the two studies that form the remainder of this thesis sought to investigate these issues in more detail, with the aims of adding to the research literature in this area and informing clinical practice and service delivery. The aims and hypotheses of the two studies will now be outlined.

Study one

Study one aimed to explore the characteristics of chest pain, anxiety and illness beliefs in patients attending a RACPC with chest pain of non-cardiac origin. In addition to this study one aimed to explore any association between illness beliefs and self-reported anxiety. The following hypotheses were generated:

1. Levels of perceived personal control regarding chest pain and illness coherence (self-reported understanding of chest pain) would be inversely correlated with the level of anxiety reported.
2. The level of anxiety reported would be positively correlated with the psychological attribution score on the IPQ-R.

Study two

Study two aimed to explore the acceptability and clinical effectiveness of a CBT based self-help intervention for NCCP patients. The following hypotheses were generated:

1. A CBT-based self-help intervention would reduce anxiety in a sample of NCCP patients compared to a treatment as usual group.
2. A CBT based self-help intervention would increase belief in personal control of symptoms in a sample of NCCP patients compared to a treatment as usual group.
3. A CBT based self-help intervention would be acceptable to NCCP participants.

In order to explore the acceptability of a CBT-based self-help intervention for this group the following research questions were generated:

1. Do participants read the intervention booklet and report finding it useful?
2. Which components of the intervention do they report using and finding useful?

Chapter 3: Journal Article One

Non-cardiac chest pain: Chest pain characteristics, illness beliefs and prevalence of anxiety in a rapid access chest pain clinic sample.

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Abstract

Objective: Patients attending Rapid Access Chest Pain Clinics and discharged with non-cardiac chest pain have been found to have high anxiety, low quality of life and different illness beliefs to those with a cardiac cause for chest pain. This study aimed to characterise patients diagnosed with non-cardiac chest pain and to examine the relationship between self-reported anxiety and illness beliefs.

Methods: One hundred and nineteen recent consecutive attenders of Rapid Access Chest Pain Clinics discharged with non-cardiac chest pain completed self-report questionnaires assessing generalised anxiety, cardiac anxiety, illness beliefs and chest pain characteristics. Completion of these questionnaires was an initial stage in a randomised trial aiming to explore the effectiveness of a self-help intervention booklet which has been reported separately.

Results: Approximately two thirds of respondents reported on-going pain following clinic attendance. For the majority this was 'mild' or 'very mild' pain, but for 19% this was 'moderate' or 'severe'. The majority (62%) reported that chest pain was not impacting on their ability to engage in activities, however 8% reported that chest pain was having a significant impact on their ability to engage in activities. Almost half (47%) of the sample reported experiencing clinically significant anxiety. Stress was the most common causal attribution advocated to explain chest pain. Anxiety scores were significantly associated with psychological attribution scores, but not with personal control or illness coherence beliefs.

Conclusion: Anxiety and illness beliefs should be assessed in this population, particularly attributions for chest pain. This will allow targeted interventions to be delivered.

Keywords: Non-cardiac chest pain, anxiety, illness beliefs.

Introduction

Rapid Access Chest Pain Clinics (RACPCs) were developed in acute healthcare settings to reduce waiting times for assessment and rule out potentially life threatening cardiac disease (1). However, even if cardiac disease is ruled out, continuing chest pain can affect quality of life adversely. Up to 70% of those who attend present with non-cardiac chest pain (NCCP) (2). Studies have found high psychological morbidity, impaired quality of life and functional impairment in those receiving a diagnosis of NCCP following RACPC attendance (3, 4). Various causes for NCCP have been suggested, including organic causes such as gastrointestinal and musculoskeletal disorders, as well as suggested links to panic disorder and anxiety (5). However patients often do not receive a definitive diagnosis in relation to their chest pain following clinic attendance (6). Healthcare utilisation is high in this population and represents a significant cost to healthcare providers (7).

Qualitative research has revealed that NCCP patients reported poor understanding of their chest pain and little sense of what might be helpful to them following attendance at a RACPC (8). In a study based on Leventhal and colleagues' Common-Sense Self-Regulation model (11, 12), Robertson *et al.* (9) examined beliefs regarding chest pain in a RACPC sample experiencing NCCP using the Illness Perceptions Questionnaire-Revised (IPQ-R) (10). This model suggests that individuals construct beliefs about their symptoms when confronted with a threat to their health and that these cognitions subsequently influence behaviour and emotional reactions. Various dimensions of these beliefs have been proposed: 'Identity' referring to the symptoms experienced; the perceived 'cause' of the illness; 'time line' referring to the duration of the symptoms; 'consequences' of the symptoms, 'controllability' of the symptoms and self-reported 'coherence' or understanding of symptoms. Robertson *et al.* (9) found that non-cardiac patients believed that their symptoms were less controllable, had significantly lower belief that they understood their symptoms, and were also more

anxious compared to those who received a cardiac diagnosis for their chest pain. Their study did not examine the relationship between anxiety and illness beliefs.

Researchers have explored the relationship between psychological distress and illness beliefs in a variety of health conditions. Hagger and Orbell (13) in their meta-analytic review of Leventhal's model report that perceived controllability is associated with the use of active coping strategies and cognitive reappraisal across a range of health conditions. They report that low belief in controllability is associated with increased psychological distress. It follows that NCCP patients with low self-reported belief in the controllability of their chest pain would be predicted to be more anxious than those who have a high belief that their symptoms can be managed.

Research with a cardiac population using the IPQ-R found that low self-reported understanding of symptoms (illness coherence) was associated with increased psychological distress (14). It therefore seems possible that NCCP patients reporting low understanding of their chest pain will score more highly on the anxiety measures than those reporting a high understanding of their chest pain. A study of chronic headache patients using the IPQ-R found that those experiencing clinically significant anxiety or depression (measured using the Hospital Anxiety and Depression Scale) were more likely to attribute their headaches to psychological factors (15).

A recent systematic review reported poor psychological outcomes in patients with NCCP assessed in Accident and Emergency settings, with 21% to 53.5% of NCCP patients having probable clinically significant anxiety (16). They highlighted the need to determine predictors of these poor outcomes and criticise current research for the narrow focus on medical, psychiatric and demographic variables. Taking all of this into account, the exploration of illness beliefs appears important to enable better understanding of the distress experienced by non-cardiac patients.

Most studies to date in this area have used the Hospital Anxiety and Depression Scale (HADS) (17), a measure of generalised anxiety. Eifert *et al.* (18) describe the development of a specific measure of cardiac anxiety (i.e. anxiety related to cardiac symptoms), which is directly relevant to this area of research. Measures of generalised anxiety may not be sufficiently sensitive and are unlikely to measure the unique aspects of cardiac anxiety. It has been proposed that anxiety regarding the heart is crucial to understanding NCCP, although it is unclear if this is a consequence or causal factor (19, 20, 21).

The aim of the study was to explore the characteristics of chest pain, anxiety and illness beliefs in patients attending a RACPC with chest pain of non-cardiac origin, and to explore any association between illness beliefs and anxiety. It was hypothesised that there would be an inverse correlation between scores on anxiety measures and measures of personal control and illness coherence (understanding of symptoms). It was hypothesised that there would be a significant positive correlation between scores on anxiety measures and the psychological attribution score on the IPQ-R. This study formed part of a larger study recruiting NCCP patients to a randomised trial of a cognitive behavioural therapy (CBT)-based self-help intervention booklet, which will be reported separately.

Methodology

Design

A cross-sectional self-report questionnaire study following attendance at a RACPC from three large Scottish hospitals over a one year period from August 2011. All consecutive attenders meeting inclusion criteria were telephoned two to six weeks following their attendance at the clinic and invited to participate. If they consented, study questionnaires were posted with a stamped addressed envelope provided for their return. If completed questionnaires were not returned within two weeks a reminder letter and a further copy of the questionnaires was sent. The gender, and where possible the reason given for refusal, of those who declined participation was recorded. Ethical approval was obtained from the South East Scotland Research Ethics Committee Two and the local Research and Development department.

Participants

Patients are referred to the clinic by their General Practitioner (GP) for specialist assessment when they present with symptoms suggestive of new onset angina (a symptom of coronary artery disease). Alternatively they can be referred to the clinic following presentation with chest pain in Accident and Emergency if the evidence suggests that the chest pain is not the result of an acute cardiac event but could be angina. They are assessed by a cardiology specialist nurse, under the supervision of a cardiologist, for any form of cardiac explanation for chest pain. Assessment consists of a clinical interview and, if patients are able, an exercise tolerance test using the Bruce protocol (1).

Inclusion criteria

- Over 18 years of age.
- Diagnosis of NCCP.

- Able to understand written English. Five attendees were omitted from the study due to difficulty understanding written English.

Exclusion criteria

- Known history of coronary artery disease or any other cardiac pathology. This information is noted in the GP referral to the clinic. This criterion was rechecked electronically by the principal researcher prior to inviting patients to participate in the study.

- Cognitive impairment. This was not formally assessed, however if clinical judgement suggested that the individual would have difficulty understanding the measures due to cognitive impairment, these participants were excluded. Three patients were omitted from the study on the basis of this criterion.

- Obvious proximal cause of the chest pain (e.g. chest trauma, pneumonia, pulmonary embolism).

Measures

Hospital Anxiety and Depression Scale (HADS, 17) Anxiety subscale. This comprises seven items rated on a four-point Likert scale and assesses symptoms of generalised anxiety over the past week, with a higher score indicating greater anxiety. The HADS anxiety scale has been used to measure anxiety in NCCP populations (see 16 and 22 for reviews). The HADS anxiety scale has good internal consistency (23, 24). Cronbach's alpha in the current study was 0.866. Bjelland *et al's*. (25) review of 747 papers using the HADS reported that most factor analyses found evidence of a two factor structure in good accordance with HADS anxiety and depression subscales.

Cardiac Anxiety Questionnaire (CAQ, 18). This 18-item questionnaire aims to measure heart-focused anxiety. Each item is rated on a five-point Likert scale as to how frequently the

behaviour typically occurs (from 'never' to 'always'), with a higher score indicating greater anxiety. Factor analysis of CAQ data (26) found a four-factor solution with heart-focused attention (e.g. 'I pay attention to my heart beat'), avoidance of activities that bring on symptoms (e.g. 'I avoid exercise or other physical work'), worry or fear regarding symptoms (e.g. 'I worry that I may have a heart attack') and reassurance seeking (e.g. 'I like to be checked out by a doctor') identified. A total score is computed by summing responses to individual items. The CAQ has been used in prevalence and intervention studies with NCCP patients (23, 26, 27) with evidence of validity in this population. Cronbach's alpha in the current study was 0.819.

The cause, personal control and illness coherence subscales of the Illness Perceptions Questionnaire – Revised (IPQ-R, 10). These subscales comprise a total of 11 statements about chest pain and a list of 18 possible causes for symptoms. The participant is asked to rate the extent to which they agree or disagree with the item on a five-point Likert scale. The full IPQ-R questionnaire was used by Robertson *et al.* (9) with RACPC attendees pre- and post-attendance and indicated that beliefs regarding cause and controllability appear to be key to NCCP patients. The IPQ-R has good psychometric properties. Factor analysis usually extracts the dimensions in Leventhal's model, thus providing evidence for their use as subscales (10, 13, 28). Previous researchers have used specific subscales in isolation (e.g. Cameron *et al.* (29) with a breast cancer sample). A psychological attribution score was calculated using the items specified in the IPQ-R development paper (10). High scores indicate a greater endorsement of psychological explanations for chest pain (e.g. 'Stress or worry'). The personal control subscale has a possible range of scores of 6 to 30, with higher scores indicating greater belief in personal control. The illness coherence subscale has a possible range of scores of 5 to 25, with higher scores indicating a greater perceived understanding of the symptoms

Chest pain frequency and severity over the previous week. Participants were asked to self-report the frequency of the pain over the previous week on a four-point Likert scale from 'once a week or less' to 'more than once a day'. This method of assessing chest pain frequency was used by Dumville *et al.* (6) in their retrospective cohort study of patients who had attended a RACPC. Participants were asked to self-report the severity of their chest pain over the previous week on a five- point Likert scale from 'no pain' to 'severe' pain, as used by Dumville *et al.* (6).

Impact of chest pain on the ability to carry out activities in life, e.g. work, family, social life, hobbies or other daily activities, over the past 2 weeks. Participants were asked to rate the degree of impact on a four-point Likert scale from 'most of the time' to 'not at all'. This method was used to obtain an estimate of the impact of chest pain on quality of life and was adapted from a previous study (30) which asked about the impact of NCCP on family, social life and work in three separate questions on a four-point scale from 'high impact' to 'no impact'.

Statistical analysis

Exploratory data analysis checked for missing data or data entry errors and ensured that data met assumptions for parametric statistics. Missing values were managed according to the HADS and IPQ-R manuals. There is no agreed method to manage missing data on the CAQ therefore expectation maximisation was used when the frequency of missing values on the CAQ was less than 20% per participant and 10% per variable (31). Descriptive statistics were used to summarise the demographic and chest pain characteristics of the participants. Data were graphed using scatterplots and Pearson correlation coefficients examined the relationships between illness beliefs and anxiety.

Results

Of the 294 clinic attendees who met inclusion criteria, a total of 237 potential participants were contacted by telephone. Fifty-seven potential participants (19%) were uncontactable within six weeks following their attendance at the clinic, either because no valid telephone number was available or there was no answer on available numbers despite multiple attempts at contact. Following the telephone call, 195 potential participants consented to have the questionnaire pack posted to them. Forty-two participants (18% of those contacted) declined to participate when telephoned. Questionnaires were returned by 119 participants (61%). The demographic and chest pain characteristics of the sample are shown in Table 3.1. Approximately two thirds of the sample reported experiencing chest pain in the week prior to completion of the measures. For the majority this was very mild or mild pain (49%), however for 19% this was moderate or severe pain. The majority reported that chest pain had not impacted on their activities (62%) in the previous two weeks.

Just over a third of those who declined to participate in the study at the telephone invitation stage were male (n=15). A variety of reasons were provided by those declining participation, including no current chest pain (n=11), lack of time to participate (n=8), no concern about their chest pain (n=8) and not being interested in participating in research (n=5). Three of those who declined to participate stated that they were dissatisfied with the results of their clinic attendance and planned to seek re-referral to cardiology to further investigate their chest pain.

Table 3.1: Demographic and chest pain characteristics of sample

N=119	Total n	Percentage of sample
Male Gender	62	52
Mean age in years (S.D; range)	55.2 (9.9; 27-78)	
Employment status	n=118	
Full-time work	55	46
Part-time work	16	13
Voluntary work	5	4
No	42	35
Education	n=116	
None	31	26
Standard/ O' Grade	21	18
SVQ/ NVQ	8	7
Highers	11	9
HNC/ HND	13	11
Degree	11	9
Post graduate qualification	11	9
Other	10	8
Severity of chest pain	n= 118	
No pain	38	32
Very mild pain	34	29
Mild pain	23	20
Moderate pain	17	14
Severe pain	6	5
Frequency of chest pain	n=118	
Once a week or less	74	62
Not every day but more than once a week	33	28
Every day	8	7
More than once a day	3	3
Activities affected by chest pain	n=117	
Not at all	72	62
Time to time, occasionally	35	30
A lot of the time	4	3
Most of the time	6	5

Anxiety

Table 3.2 provides the summary statistics (mean scores, score ranges and standard deviations) for the anxiety measures. Two participants were excluded from the analysis due to multiple

missing values on the HADS, and two participants were excluded due to multiple missing values on the CAQ. Overall, 56 participants (47%) had probable clinically significant HADS scores i.e. a score greater than, or equal to, eight.

Table 3.2: Summary statistics for outcome measures.

Measure	Mean (S.D.)	Range
HADS Anxiety n=117	7.74 (4.45)	0-21
CAQ total score n=117	1.24 (0.53)	0-4
CAQ heart focused attention subscale	1.11 (0.82)	
CAQ avoidance subscale	1.25 (0.88)	
CAQ worry subscale	1.16 (0.66)	
CAQ reassurance seeking subscale	1.51 (0.92)	
IPQ-R personal control subscale n=114	19.18 (4.32)	6-30
IPQ-R illness coherence subscale n=114	11.93 (4.51)	5-25

Illness beliefs

The mean score of this sample on the personal control subscale was 19.18, which is similar to the mean of 18.42 reported by Robertson *et al*. (9) in their NCCP sample recruited from a RACPC. The IPQ-R development paper (10) reports a mean score of 18.4 (*SD* = 4.0) on the personal control subscale in a chronic pain sample. These scores are lower than those found in cardiac samples (23.5 ± 3.4 (14) and 24.8 ±2.3 (32)). This suggests that participants have little belief in their ability to control their chest pain.

The mean score on the illness coherence subscale in the current sample was 11.93, which is lower than the mean score of 17.5 reported by Robertson *et al.* (9) for NCCP patients, and the mean score of 13.37 (SD = 4.8) reported for a chronic pain sample (10). This indicates that

the current sample had lower levels of endorsement of the belief that they understood their symptoms than samples in previous studies. The observed mean value in this study is also lower than mean scores found in cardiac samples (19.3±4.2 (14) and 18.6±3.9 (32)). Therefore participants do not have a clear understanding of their chest pain following clinic attendance.

Causes

Stress was the most commonly reported attribution with 67.3% of participants stating that they 'agreed' or 'strongly agreed' that stress was a causal factor in their chest pain. The percentage responses for all 18 causal attributions are summarised in Table 3.3.

Table 3.3: Percentage agreement with possible causal attributions for chest pain.

Possible Cause	**Agree or Strongly Agree Frequency (%)**
Stress*	67.3
Hereditary	44.5
Germ/virus	18.5
Diet/eating habits	48.7
Chance/bad luck	17.7
Poor medical care in past	3.3
Pollution in environment	11.7
Own behaviour	41.1
Mental attitude*	23.5
Family problems or worries cause by my chest pain*	32.8
Overwork*	35.3
Emotional state*	39.5
Ageing	44.6
Alcohol	16.0
Smoking	25.5
Accident or injury	14.3
My personality*	12.6
Altered immunity	8.4

*Indicates item contributes to the psychological attribution score

Association between anxiety scores and illness beliefs

Table 3.4 shows that psychological attribution scores were positively correlated with HADS anxiety (r=0.401, p<.001, medium to large effect size (33)) and CAQ total scores (r=0.233, p=0.007, small to medium effect size (33)). Those with higher anxiety scores were therefore more likely to also believe that psychological causes were relevant in explaining their chest pain. There were no significant correlations between the measures of anxiety and personal controllability or illness coherence scores.

Table 3.4: Pearson correlations between measures of anxiety and illness beliefs.

	HADSA	**CAQ total**	**IPQ Personal control beliefs**	**IPQ Illness coherence beliefs**	**IPQ Psychological attribution**
HADSA		0.466 p<0.001	-0.049 p=0.305	0.058 p=0.272	0.401 p<0.001
CAQ total			-0.079 p=0.203	-0.111 p=0.121	0.233 p=0.007
Personal control beliefs				0.506 p<0.001	0.376 p<0.001
Illness coherence beliefs					0.128 p=0.088

Illness coherence and personal belief scores were significantly positively correlated (r=0.506, p<0.001, large effect size (33)) indicating that if participants reported that they understood their symptoms; they were also more likely to report that they had a high sense of personal control regarding their symptoms.

Discussion

This study aimed to explore the chest pain characteristics, level of anxiety and illness beliefs in a series of consecutive attenders to a RACPC who were discharged with a diagnosis of non-cardiac chest pain. A secondary aim was to explore any association between illness beliefs and anxiety.

Chest pain characteristics and impact on functioning.

The findings indicated that approximately two thirds of patients experienced chest pain in the week prior to the completion of questionnaires, with almost half (49%) reporting 'mild' or 'very mild' pain. The proportion with on-going symptoms was comparable to other studies, such as Mayou *et al.* (5) who followed up NCCP patients 6 weeks following cardiology assessment and found that just under half of their sample had continuing chest pain (once a week or more). Dumville *et al*. (6) followed up NCCP patients a mean of eight months post-RACPC attendance and found approximately half of their sample reported continuing chest pain. It would be expected, given that individuals are referred to the clinic after presenting with even a one-off episode of chest pain, that for some chest pain symptoms will decline following clinic attendance (1). The clinic is not designed to diagnose the cause of NCCP, but to rule out potentially lethal ischaemic heart disease. Data from the current study followed the same pattern as previous studies with approximately one third of the sample reporting no chest pain in the week preceding the completion of the questionnaires, which were sent 2-6 weeks post-clinic attendance. It is notable that a substantial proportion of attendees in this sample continued to have symptoms.

The majority of respondents in the current study (62%) reported that chest pain had not impacted on their activities (e.g. work, family, social life) in the previous two weeks. This contrasts with previous research reporting the impact of continuing pain on functioning (20, 27). The finding that a third of participants reported no pain, approximately half reported

'mild' or 'very mild' pain, and only 19% reported experiencing 'moderate' or 'severe' pain is relevant to this finding. It would be expected that those with no, or mild, symptoms do not experience impairment in everyday activities. This divergent pattern of results could also be explained by the sampling method adopted. The current study aimed to recruit consecutive attenders with NCCP regardless of their frequency of chest pain at that time. Previous research reporting a high prevalence of impaired quality of life in NCCP samples has often specified a minimum frequency of chest pain for inclusion in the study (e.g. 20) and may therefore recruit those experiencing greater impairment in functioning. The current study assessed frequency and severity of chest pain over the preceding week. However it is possible that this time frame is insufficient to obtain an accurate overview of symptom experience. In addition the minimum frequency of pain experience assessed was 'once a week or less' which does not allow those who have experienced no pain to be distinguished from those experiencing pain once per week. Future research should assess symptoms over a longer time frame, such as preceding four weeks, or use pain diaries to obtain a more accurate measurement of chest pain experienced. Quality of life measures such as the Medical Outcomes Study Short Form-36 (34) are also often used in these studies. This method exploring various facets of functioning may detect subtleties in different domains of life that a single question may miss. However, other researchers have asked more generic questions such as those used in this study (20, 30) and found evidence of impairment. Future research should explore whether this finding is a consequence of the method of measurement, or alternatively whether individuals may experience on-going pain, without a concurrent impact on their functioning.

Anxiety.

Just under half of respondents (47%) scored above the cut-off for clinical significance on the HADS anxiety subscale. Robertson *et al.* (9) reported that one week following RACPC attendance, 68.4% of their NCCP sample had a score greater than eight on the HADS anxiety

subscale. A recent systematic review (16) of the prevalence of anxiety following emergency department assessment of NCCP found between 21-53.5% of patients scored above the cut-off for clinically significant symptoms on the HADS, although comparison between studies is limited by the different cut-off points used on the HADS. The prevalence of clinically significant anxiety in this sample is therefore consistent with other studies with this population. It has been suggested that cardiac anxiety is an important construct in NCCP research (18). The level of anxiety reported on this measure in the current study is comparable to the results of other NCCP studies (23, 27) and cardiac studies (18). Current RACPC guidance (35) advocates giving reassurance to NCCP patients to explain that there is no evidence that the pain is cardiac in origin, with the implicit assumption that this will be sufficient in reducing anxiety. Findings from this study, and previous research, indicate that this is not necessarily the case and that a significant proportion of NCCP patients continue to experience clinical levels of anxiety, which could be treated via psychological intervention. There is evidence that cognitive behaviour therapy is an effective intervention in this population (see 22 for a review).

Illness Beliefs.

Leventhal's model suggests that an individual's beliefs about their symptoms affect their experience of, and psychological response to, these symptoms (11). Robertson *et al.* (9) found heightened anxiety and lower belief in personal control and illness coherence in NCCP compared to cardiac patients. Similar personal control belief scores were found in the current study. Illness coherence scores were lower, indicating poorer perceived understanding of symptoms of chest pain. Both personal control and illness coherence belief scores were lower than those found in studies recruiting cardiac patients (14, 32).

If patients do not understand their symptoms, and believe that there is little that they can do to manage their chest pain, it is important that clinicians identify and address these beliefs.

Leventhal *et al.* (12) suggest that if individuals are able to make sense of their symptoms they are likely to engage in treatments to manage their symptoms and perceive higher levels of control of their symptoms. Stress or worry was the most common causal attribution in the current study, contrasting with findings from cardiac patients (e.g. 36) who endorse lifestyle factors such as smoking and diet as the most common cause. Clinicians advocating participation in NCCP interventions should explore beliefs about symptoms and link treatment goals with these beliefs. Education regarding NCCP, and inclusion of strategies designed to increase participants' sense of personal management of the causes they believe to be relevant in explaining their symptoms is indicated.

Relationships between illness beliefs and anxiety.

A significant association was found between scores on anxiety measures and psychological attribution scores, indicating that those with higher anxiety scores were more likely to also believe that psychological causes were relevant in explaining their chest pain. This indicates that anxiety may play a causal and/or maintaining role in NCCP. The data are correlational and therefore no conclusions can be drawn about causality. Moss-Morris *et al.* (10) report a significant positive relationship between negative affect and psychological attribution scores in their sample of over 700 participants with various chronic illnesses. Longitudinal research is required before any conclusions can be drawn regarding a possible causal role of anxiety. These findings are important regardless of the mechanism of the relationship between anxiety and NCCP as they suggest that interventions including an anxiety management component will be acceptable to at least some NCCP patients.

It is notable that almost half of this sample reported mild or very mild pain and approximately one third reported experiencing no pain 2-6 weeks post-clinic attendance. It seems possible that perhaps respondents were anxious, but not about their symptoms of chest pain. Future research should seek to further explore this hypothesis, perhaps utilising qualitative

methodology in addition to quantitative methods. It is also possible that there is a response bias in terms of those recognising the role of psychological factors agreeing to participate in a study by completing questionnaires including measures of psychological constructs.

The hypothesis that there would be a significant negative correlation between scores on anxiety measures and measures of personal control and illness coherence (understanding of symptoms) was not supported and the reasons for this finding are unclear. These hypotheses were based on the fact that studies with cardiac patients have found a relationship between these constructs (e.g. 14). It may be that there is no relationship between these beliefs and anxiety in this population. If so, it would appear important to include a measure of illness beliefs in intervention studies, rather than evaluate the effectiveness of interventions solely on anxiety measures. Illness beliefs in themselves are important targets for intervention (12), and given the low personal control and illness coherence scores found in the current study, they appear particularly crucial for non-cardiac patients. Previous research has shown that the less individuals believe that they understand their symptoms, the more psychological distress they experience and the lower their quality of life (e.g. 10, 14). Similarly, patients reporting lower belief in the control of their symptoms have been shown to experience heightened distress and reduced quality of life (e.g. 13). The IPQ-R includes treatment control and personal control subscales as for some health conditions it is important to consider these as distinct (10). For example cardiac patients who hold a fatalistic model for their health may have low belief that they can personally control their illness, but strongly believe that it is controllable through adherence to medication. Given that the evidence suggests the majority of NCCP patients do not go on to receive a diagnosis and medical treatment for their symptoms (6), targeting their personal control strategies appears important. The current findings may also be a consequence of the sampling method involving a consecutive sample of patients recruited regardless of their current chest pain status. It is possible that patients may have experienced a one-off episode of chest pain and were then assessed at the clinic with no

further chest pain experienced. Future research should seek to explore the association between anxiety and illness beliefs further in a sample screened for the presence of on-going symptoms prior to participation.

Strengths and limitations.

Only 40% of those eligible to participate did so, limiting the representativeness of the sample. However, the participation rate of 40% is in accordance with that which would be expected of a postal questionnaire (37). Furthermore, missing data introduce a degree of bias and limit the conclusions that can be drawn. Reasons for declining participation were explored as part of the study and the most frequent reason given was that the individual was not currently experiencing chest pain. The prevalence of physical and mental illness comorbidity was not explicitly examined in the current sample and represents a possible confounding factor. In addition, the chosen sampling method recruited a mixed group in terms of chest pain characteristics and the impact of symptoms on functioning. However, the sampling method promoted external validity of the study and generalisability of the results.

Conclusion.

This study highlighted that almost half of patients with NCCP attending RACPCs have probable clinical levels of anxiety. It is recommended that those delivering RACPCs, or GPs reviewing patients following their attendance at these clinics, screen for anxiety and also assess patient's beliefs about their symptoms. Given that there is evidence from this and other studies that reassurance alone is insufficient in reducing distress in NCCP patients, it is clear that the provision of early information regarding symptoms and signposting to resources is indicated. A stepped care approach to the treatment of NCCP patients with a range of levels of intervention offered has been advocated (5). Reassurance is an important first step, with suggested interventions increasing in intensity to individual psychological treatment such as CBT (5). As many patients need more than reassurance, yet are unlikely to be able to access

individual CBT, there is a need to develop intermediate stepped-care interventions. The results of the current study suggest that identification and treatment of clinically significant anxiety and relevant illness beliefs should be key components of any intervention for this population.

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Chapter 4: Journal Article Two

Cognitive Behavioural Therapy-based self-help intervention for non-cardiac chest pain: A randomised pilot study to examine acceptability and clinical effectiveness.

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Abstract

Objective: This study aimed to assess the acceptability and clinical effectiveness of a cognitive behavioural therapy-based self-help intervention for non-cardiac chest pain.

Methods: Consecutive patients recruited from Rapid Access Chest Pain Clinics were randomised to either an intervention condition (receiving a self-help booklet) or to a 'treatment as usual' condition. Questionnaires measuring generalised and cardiac specific anxiety and illness beliefs relating to chest pain were sent pre-intervention, and at three month follow-up. Those in the intervention condition were sent additional questions to evaluate the acceptability of the intervention booklet.

Results: One hundred and nineteen participants were randomised, with thirty two lost to follow-up. Intent-to-treat analysis showed that there was no significant difference between the groups on measures of anxiety, or belief in personal control of their chest pain at follow-up. Completers analysis showed a similar pattern of results. There was evidence of the acceptability of the booklet (79% of intervention group read the booklet) and the majority of these (85%) reported that it was useful. Approximately half of those from the intervention condition returning follow-up measures reported use of cognitive behavioural strategies.

Conclusion: Cognitive behavioural therapy-based self-help is an acceptable treatment option for some patients with non-cardiac chest pain. Further research is needed to identify those who are most likely to benefit from such self-help intervention.

Keywords: Cognitive Behavioural Therapy, self-help, non-cardiac chest pain.

Introduction

Chest pain is a frequent presenting problem in healthcare settings (1). Rapid Access Chest Pain Clinics (RACPCs) are designed to assess for any cardiac explanation for chest pain. However, up to 70% of those attending these clinics are found to have chest pain of non-cardiac origin (2). Although these individuals have a favourable medical prognosis (3), many continue to experience chest pain and report high levels of distress and impaired quality of life (e.g. 4, 5). High healthcare utilisation costs have been associated with non-cardiac chest pain (NCCP), with this population identified as high frequency users of the healthcare system (e.g. 6).

Individual and group cognitive behavioural therapy (CBT) interventions have been found to be effective in this group. Improved outcome in terms of psychological morbidity, chest pain symptoms and quality of life following therapist-led CBT interventions has been reported (see Kisely *et al.* (7) for a review). However, low participation rates have been noted, which Mayou *et al.* (8) suggest may be because individuals are seeking intervention in a medical setting and explicitly psychological interventions may not be acceptable to them. The cost implications of therapist-led psychological therapy also mean that this intervention is available to only a minority of NCCP patients (7). A stepped care approach has therefore been advocated (7-8), with low intensity interventions provided which may be more acceptable to NCCP patients. Self-help interventions have been found to be acceptable and effective in a range of physical health settings, including for patients with angina (9), irritable bowel syndrome (10) and chronic pain (11). Therefore, CBT-based self-help intervention may also result in improved outcomes and be viewed as acceptable to NCCP patients. Given that previous CBT studies in this area have reported a reduction in anxiety post-intervention (7), it seems possible that a CBT-based self-help intervention may also result in a reduction in anxiety symptoms.

An individual's perceived understanding of their chest pain, and the associated strategies employed to cope with symptoms, appear key to understanding the impact of chest pain in terms of distress and functioning. In a qualitative study Price *et al.* (12) observed that RACPC clinic attendees wanted to increase their knowledge of what they could do to 'help themselves' regarding their chest pain. In an attempt to address this, Arnold *et al.* (4) conducted a randomised controlled trial comparing treatment as usual with those receiving an information leaflet containing possible causes of chest pain and signposting to CBT-based resources following attendance at RACPCs. They noted a decrease in symptoms of anxiety and depression and an increase in some components of quality of life, though it was unclear whether participants utilised the resources, and non-cardiac patients were not differentiated in the analysis from cardiac patients who received a different information sheet. This may have masked differences between the groups in terms of outcome. Thus it remains unclear whether the NCCP patients specifically benefitted.

Using the Illness Perceptions Questionnaire-revised (IPQ-R, 13) Robertson *et al.* (5) examined participant beliefs regarding chest pain in a sample experiencing NCCP. NCCP patients had lower belief in personal control of their chest pain and lower illness coherence (i.e. belief that they understand their symptoms) compared with cardiac patients following RACPC attendance. There has been little consideration of the impact of interventions on beliefs about chest pain in a NCCP population. Previous research with cardiac patients has reported an increase in personal control beliefs post-intervention (14, 15). A previous study by the current authors (Chapter 3) found a significant relationship between patient attribution of chest pain to psychological causes and measures of self-reported anxiety. It is unclear if this would translate into patients' engagement in an approach aiming to manage the impact of chest pain, using psychologically informed strategies such as relaxation techniques and management of unhelpful thoughts associated with chest pain.

Consequently, the aim of the current study was to explore the acceptability and effectiveness of a CBT-based self-help intervention for individuals diagnosed with NCCP following assessment at an RACPC. The following hypotheses were explored:

1. A CBT-based self-help intervention would reduce anxiety in a sample of NCCP patients compared to a treatment as usual group.
2. A CBT based self-help intervention would increase belief in personal control of symptoms in a sample of NCCP patients compared to a treatment as usual group.
3. A CBT based self-help intervention would be acceptable to NCCP participants.

Methodology

Design

A randomised, between-subjects, repeated-measures design with a treatment as usual control condition was used to explore the effectiveness of a CBT-based self-help intervention for NCCP.

Participants

All consecutive patients who attended a RACPC in three large Scottish NHS Hospitals over a one year period from August 2011 and who received a diagnosis of NCCP were considered for recruitment. Inclusion criteria were: diagnosis of NCCP following attendance at a RACPC; over 18 years of age; able to understand written English and give informed consent to participate. Exclusion criteria were: coronary artery disease or any other cardiac pathology; cognitive impairment; any obvious proximal cause of the chest pain (e.g. chest trauma, pneumonia, pulmonary embolism).

Recruitment

The project was mentioned to NCCP patients by their clinic facilitator and 2-6 weeks following clinic attendance, prospective participants were telephoned by the first author. Participants who expressed an interest in the study were randomly allocated to either the 'intervention plus treatment as usual' condition or the 'treatment as usual' condition based on a predetermined randomly generated number sequence (www.randomizer.org). The clinicians delivering the clinic were blind to the patient's treatment condition. A pack containing baseline questionnaire measures, consent form and participant information was posted to participants with a stamped addressed envelope for their return. Following return of the consent form and completed questionnaires, the intervention booklet and CD were posted to those in the intervention condition. Follow-up questionnaire packs were posted to both groups three months after the return of the initial questionnaires. It was anticipated that this would give sufficient time to allow intervention group participants to read through the materials and start to develop skills in the strategies introduced. Reminder letters with duplicate measures were sent two weeks after the initial pack was posted. After four weeks non-returners were telephoned to ensure that they had received the pack of measures.

Measures

Generalised Anxiety. The Hospital Anxiety and Depression Scale (HADS) anxiety subscale (16) comprises seven items rated on a four-point Likert scale and assesses symptoms of generalised anxiety over the past week. Higher scores indicate greater anxiety. This scale reduces the confounding impact of somatic items in medical populations (16). The HADS anxiety scale has good internal consistency (17) and has been used in previous NCCP CBT intervention studies (e.g. 18, 19). Previous research (e.g. Spinhoven *et al*. (20) with a NCCP population) also used only the anxiety subscale of the HADS.

Cardiac Anxiety. The Cardiac Anxiety Questionnaire (CAQ, 21) is an 18-item questionnaire measuring heart-focused anxiety. Each item is rated on a five-point Likert scale as to how frequently the behaviour typically occurs (from 'never' to 'always'), with higher scores indicating greater anxiety. A four-factor solution suggests domains of heart-focused attention, avoidance of activities that bring on symptoms, worry or fear regarding symptoms and reassurance seeking (22). A total score can be computed by summing responses to individual items. The CAQ has demonstrated sensitivity to change in previous intervention research with this population (20, 23).

Illness Beliefs. The personal control subscale of the Illness Perceptions Questionnaire – Revised (IPQ-R, 13) includes six statements assessing belief in personal control of chest pain, for example 'Nothing I do will affect my chest pain'. The participant was asked to rate the extent to which they agree or disagree with each item on a five-point Likert scale. Possible scores range from 6 to 30 with higher scores indicating greater belief in personal control. This measure assesses a specific component of illness representation as stated in Leventhal's Self-Regulatory Model (24, 25). The subscale has good psychometric properties (13). Factor analysis usually extracts the dimensions in Leventhal's model, providing evidence for their use as subscales (e.g. 26). The IPQ-R has previously been used in NCCP research (5).

Chest pain characteristics. Participants were asked to self-report their frequency of chest pain over the previous week on a four-point Likert scale from 'once a week or less' to 'more than once a day'. Participants were also asked to self-report the severity of their chest pain over the previous week on a five- point Likert scale from 'no pain' to 'severe' pain. This method of assessing chest pain frequency and severity was used by Dumville *et al.* (27) in their retrospective cohort study of patients who had attended a RACPC. Participants were also asked to rate the degree of impact of chest pain on activities (e.g. work, social life, hobbies or other daily activities) on a four-point Likert scale from 'most of the time' to 'not at all'. This method was adapted from Jonsbu *et al.* (28) who asked about the impact of chest

pain on family, social life and work in three separate questions on a four-point scale from 'high impact' to 'no impact'. These chest pain characteristics were collected for descriptive purposes and to allow comparison of the two groups post-randomisation.

Acceptability of intervention. At follow-up, the intervention group were asked if they had read the intervention booklet and how frequently they had practised specific components of the intervention over the previous two weeks using a five-point Likert scale. Free response sections provided the opportunity for qualitative comments.

Sample size

An *a priori* sample size calculation was conducted using G*Power 3.1.5 software (29). Previous therapist-led CBT interventions with this group have generally reported medium effect sizes on measures of anxiety (e.g. 20, 23). A self-help intervention would be expected to have a smaller treatment effect than a therapist-led intervention. An effect size of f=0.15, which represents a small effect according to Cohen's convention (33), was therefore assumed from a study that compared the effectiveness of individual CBT in reducing HADS anxiety relative to treatment as usual for patients with NCCP (18). Based on this study, with alpha at 0.05 and power at 0.80, 45 participants were required in each group. Allowing for 30% attrition, the study aimed to recruit 59 participants in each condition, giving a total target sample size of 118.

Intervention

A CBT-based self-help intervention booklet was designed by the authors. The intervention differed from previous information-based studies (e.g. 4) as the emphasis was to guide the reader through the process of actively trying out CBT-based strategies outlined in the booklet. The inclusion of quizzes, diaries to record the results of applying the techniques, and the provision of diaphragmatic breathing and progressive muscle relaxation exercises on a CD accompanying the booklet, aimed to emphasise the active nature of the intervention. The self-

help focus differentiates this study from previous therapist-led CBT interventions with this population (18-20, 23). The intervention was based on CBT protocols reported to be effective in the NCCP population such as those described by Potts *et al.* (19) and Van Peski-Oosterbaan *et al*. (18). It is also informed by CBT protocols developed for panic disorder (30), health anxiety (31) and unexplained physical symptoms (32). The booklet was divided into five sections providing information regarding chest pain causes, progressive muscle relaxation, diaphragmatic breathing, managing unhelpful thoughts and worry, and pacing activity. A 'cut-out and keep' summary of the contents was included, as was a reference list and suggestions for further reading. As part of the development of the booklet a qualitative review was undertaken with clinic attendees. A final version was produced on the basis of feedback provided.

Statistical analysis

Descriptive statistics were used to summarise the participants' demographic characteristics. The assumptions required for the use of parametric statistics were met for continuous data. *T*-tests for continuous variables and Chi-squared tests for categorical variables were used in order to determine whether the intervention and control groups were suitably matched on key variables after randomisation. An alpha level of 0.05 was used for all statistical tests. Item level missing data on the HADS and IPQ-R were managed according to the scale manuals. Missing data on the CAQ was managed using expectation maximisation when the frequency of missing values was less than 20% per participant and 10% per variable. This method imputes values by maximum-likelihood estimation using the observed data in an iterative process (34). In order to evaluate if the intervention condition varied from the treatment as usual condition, changes over time on scores on the HADS, CAQ and the personal control subscale of the IPQ-R were examined using a 2 (group) x 2 (time) split-plot analysis of variance (ANOVA). Partial eta squared (η^2) was used to examine effect sizes and interpreted using Cohen's scales of magnitude (33). Analyses were conducted on an intent-to-treat (ITT)

basis, with the last available observation (baseline score) carried forward to serve as follow-up score where follow-up data was unavailable. This included all participants randomised and allowed a conservative assessment of the effectiveness of the self-help booklet. In addition completer analyses were conducted.

Results

A total of 294 patients met inclusion criteria, of whom 237 were contacted by telephone; the remaining 57 (19%) were uncontactable within six weeks following their clinic attendance. Following the telephone call, 195 potential participants consented to have the study pack posted to them, with 119 (61%) returning the baseline questionnaire pack and entering the study (66 randomised to the intervention; 53 to treatment-as-usual). Demographic characteristics of those included in the statistical analyses are shown in Table 4.1. There were no significant baseline differences between the groups on any of the demographic variables.

Table 4.1. Demographic characteristics of study participants.

		Intervention **Total n (%)** **(n=66)**	**Treatment-as-usual** **Total n (%)** **(n= 53)**	**Total N (%)** **(N=119)**
Gender Male		37 (56%)	25 (47%)	62 (52%)
Mean Age		54 years (10.4 S.D.)	56.7 years (9.1 S.D.)	55.2 years (9.9 S.D.)
Work status	Full-time Part-time Voluntary No	32 (49%) 6 (9%) 2 (3%) 26 (39%)	23 (43%) 10 (19%) 3 (6%) 16 (30%) (n=52)	55 (46%) 16 (13%) 5 (4%) 42 (35%) (n=118)
Education	None S'/ O' Grade SVQ/NVQ Highers HNC/ HND Degree Post graduate qualification Other	18 (27%) 11 (17%) 4 (6%) 6 (9%) 8 (12%) 4 (6%) 8 (12%) 7 (11%)	13 (25%) 10 (19%) 4 (8%) 5 (9%) 5 (10%) 7 (13%) 3 (6%) 3 (6%) (n=50)	31 (26%) 21 (18%) 8 (7%) 11 (9%) 13 (11%) 11 (9%) 11 (9%) 10 (8%) (n=116)

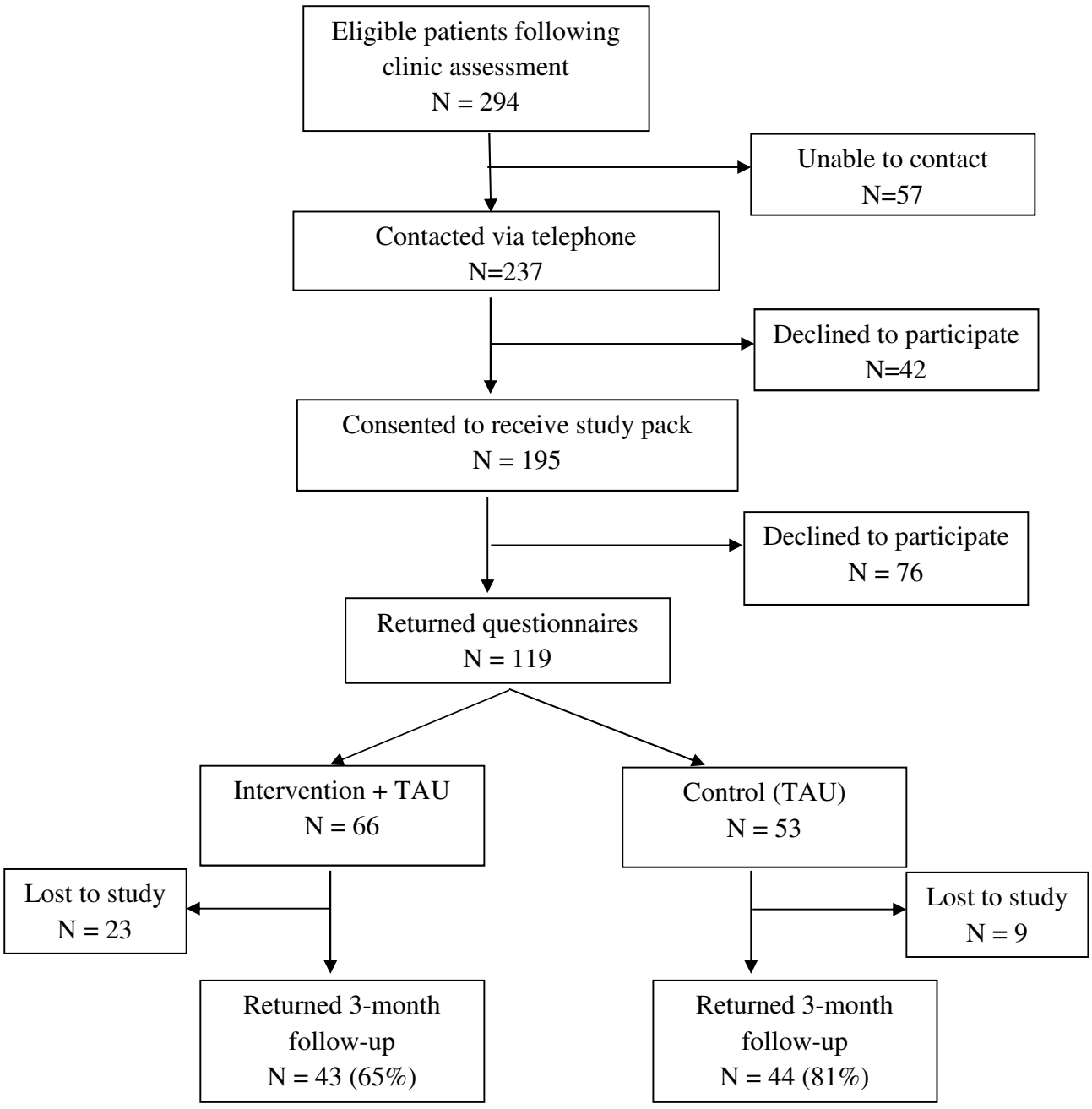
There were no significant differences at baseline between the groups on the frequency or severity of chest pain or self-reported impact of chest pain on activities (Table 4.2).

Table 4.2: Chest pain characteristics of study participants.

		Intervention group (%)	**Treatment as usual group (%)**	**Total N (%)**
		(n= 66)	**(n= 53)**	**(N=119)**
Severity of chest pain at baseline	No pain	19 (29%)	19 (36%)	38 (32%)
	Very mild pain	23 (35%)	11 (21%)	34 (29%)
	Mild pain	10 (15%)	13 (25%)	23 (19%)
	Moderate pain	10 (15%)	7 (13%)	17 (14%)
	Severe pain	3 (5%)	3 (6%)	6 (5%)
		(n= 65)	(n=53)	(n=118)
Frequency of chest pain at baseline	Once a week or less	40 (61%)	34 (64%)	74 (62%)
	Not every day but more than once a week	20 (30%)	13 (25%)	33 (28%)
	Every day	3 (5%)	5 (9%)	8 (7%)
	More than once a day	2 (3%)	1 (2%)	3 (3%)
		(n=65)	(n=53)	(n=118)
Activities affected by chest pain	Not at all	37 (56%)	35 (66%)	72 (61%)
	Time to time, occasionally	22 (33%)	13 (25%)	35 (29%)
	A lot of the time	3 (5%)	1 (2%)	4 (3%)
	Most of the time	3 (5%)	3 (6%)	6 (5%)
		(n= 65)	(n= 52)	(n= 117)

Eighty-seven participants (73% of sample) completed 3-month follow-up, i.e. post intervention, questionnaires. There were no significant differences on any of the demographic variables, clinical characteristics of chest pain or baseline outcome measures between those who were lost to the study and those who returned follow-up measures. Figure 4.1 summarises participant throughput in the study.

Figure 4.1. Flow of participants



TAU: Treatment as Usual

Treatment effects on anxiety

Table 4.3 shows mean anxiety scores at baseline and follow-up. Analysing HADS anxiety, a 2 (group) x 2 (time) ANOVA found no significant interaction between time and treatment group ($F(1,115)= 0.52$, $p= 0.819$, $\eta^2 <.01$.) Degrees of freedom were corrected using Huynh-Feldt estimates of sphericity (epsilon = 1). This suggests that there was no difference between the HADS anxiety scores between the groups over time. Analysing CAQ total scores, a 2 x 2 ANOVA found no significant interaction between time and treatment group ($F(1,112)= 1.185$, $p= 0.279$, $\eta^2= .01$.). This is a small effect size (33). Degrees of freedom were corrected using Huynh-Feldt estimates of sphericity (epsilon = 1). This suggests that there were no difference between the groups over time on CAQ total scores. Thus HADS and CAQ anxiety scores decreased modestly in both groups between baseline and follow-up, but there was no meaningful difference between the groups.

Table 4.3: Outcome measure summary statistics at baseline and follow-up (intent-to-treat).

Measure	**Time point**	**Intervention group mean (*S.D*)**	**TAU group mean (*S.D.*)**
HADS anxiety	Baseline	7.73 (4.33)	7.75 (4.65)
	Follow up	7.08 (4.45)	7.19 (4.45)
	n	66	51
CAQ total score	Baseline	1.23 (0.51)	1.25 (0.57)
	Follow up	1.13 (0.56)	1.08 (0.60)
	n	66	51
IPQ-R personal control subscale	Baseline	18.72 (4.07)	19.78 (4.59)
	Follow up	19.69 (4.22)	19.47 (4.78)
	n	64	50

Treatment effects on personal control belief

Table 4.3 reports the means and standard deviations, of the personal control subscale of the IPQ-R. A 2 x 2 ANOVA identified a statistically significant time by treatment group interaction ($F(1,111)= 5.764$, $p= 0.018$, $\eta^2= 0.049$). This is a small to medium effect size (33). Degrees of freedom were corrected using Huynh-Feldt estimates of sphericity (epsilon = 1). There was an increase in belief in the personal control of chest pain in the intervention group at follow-up compared to baseline, and a decrease in the treatment as usual group scores on this measure over time. However, as can be seen in Table 4.3, the intervention group had a lower score at baseline than the control group. This difference was not statistically significant at baseline but contributes to the statistically significant interaction effect observed. T-tests were completed to further examine the statistically significant interaction effect. Independent t-tests showed non-significant differences between intervention and treatment as usual groups at baseline ($t(112)= 1.31$, $p= 0.19$) and follow up ($t(112)= 2.55$, $p= 0.79$) and a dependent t-test showed a non-significant difference between baseline and follow-up scores for the treatment as usual group ($t(49)= 0.94$, $p= 0.35$). A dependent t-test revealed a statistically significant difference between baseline and follow-up scores in the intervention group ($t(62)= 2.52$, $p= 0.014$). However the mean score in the intervention group increases by just under one point where the range of scores is 6-30 and the standard deviation is approximately 4. Therefore the statistically significant interaction found on this measure cannot be taken as evidence that the intervention led to greater belief in personal control of chest pain in the intervention group.

Completer analysis

Overall, the results of the completers analysis (n=87) of baseline and follow-up treatment changes yielded a similar pattern of results (Table 4.4). More specifically, a 2 x 2 ANOVA of HADS anxiety scores revealed a non-significant time by treatment condition interaction ($F(1,84)= 0.207$, $p= 0.650$, $\eta^2= 002$). A 2 x 2 ANOVA of CAQ total scores revealed a non-

significant time by treatment condition interaction ($F(1,81)= 0.867$, $p= 0.355$, $\eta^2= 0.011$). A 2 x 2 ANOVA of personal control scores showed a significant interaction ($F(1,82)= 6.282$, $p= 0.014$, $\eta^2= 0.071$). These results indicate that in the participants who completed baseline and follow-up measures, there was no significant effect of the intervention booklet on anxiety scores in completers. As in the ITT analyses, the statistically significant interaction observed on belief in personal control of chest pain scores should be interpreted with caution and it cannot be concluded that the intervention results in increased belief in control of chest pain.

Table 4.4. Outcome measure summary statistics at baseline and follow-up (completers).

Measure	**Time point**	**Intervention group mean (*S.D*)**	**TAU group mean (*S.D.*)**
HADS anxiety	Baseline	7.7 (4.3)	7.9 (4.9)
	Follow up	6.4 (3.4)	7.2 (4.6)
	n	45	41
CAQ total score	Baseline	1.16 (0.44)	1.22 (0.59)
	Follow up	1.03 (0.50)	1.0 (0.61)
	n	45	41
IPQ-R personal control subscale	Baseline	18.9 (4.0)	19.8 (5.0)
	Follow up	20.3 (4.1)	19.4 (5.2)
	n	44	40

A sub-analysis of completers showed that 38 (19 intervention; 19 TAU) had clinically significant HADS anxiety scores at baseline i.e. a score greater than or equal to 8. At follow up, 38 completers had clinically significant HADS anxiety scores (18 intervention; 20 TAU) indicating that there was no change over time in the proportion with clinically significant anxiety.

Acceptability of intervention

Thirty-four (79%) of intervention condition completers reported reading the intervention booklet. The remainder (21%) did not read the booklet. Four of these reported that this was because they were no longer experiencing chest pain, two indicated that this was because they had previously tried something similar which did not help, and the remaining three did not report their reasoning.

Of those who read the intervention booklet, 85% (n=29) reported finding it useful. Qualitative comments highlighted that participants found it helpful to gain information and learn more about possible causes of chest pain, e.g. "*It made me focus on alternative causes for my chest pain other than heart problems*." Or they found specific strategies useful, e.g. "*It provided some helpful advice on relaxation and breathing techniques*." Some comments related to participants having a sense of uncertainty and finding reassurance in the booklet contents e.g. "*Anything is a help when you don't know*." Others comments related to the booklet encouraging time to reflect on their chest pain, for example "*The booklet was informative and easy to understand. It made me think*."

When asked how frequently they had practised the strategies introduced in the intervention booklet, 47% of those who had read the booklet stated that they had used progressive muscle relaxation, 50% reported that they had used the diaphragmatic breathing exercise and 49% reported that they had managed their unhelpful thoughts in the preceding two weeks.

The five participants who reported reading the booklet but not finding it useful indicated that it did not provide new information, e.g. "*I do this (relaxation, breathing, thoughts) anyway as a way of coping with crazy modern life.",* or seemed irrelevant to them e.g. "*It was interesting but very little seemed to apply to me*."

Discussion

This study aimed to explore the clinical effectiveness and acceptability of a CBT-based self-help intervention for those with chest pain of non-cardiac origin. The hypotheses were partly supported. As hypothesised, there was evidence that the intervention was acceptable to most NCCP participants, with 79% reporting having read the booklet and the majority of these (85%) reporting that it was useful. Approximately half of those reading the booklet reported that they had used coping strategies outlined in the booklet in the two weeks prior to completion of follow-up measures. The hypotheses that the intervention would reduce anxiety and increase personal control beliefs was not supported, with no differences found between the groups on these variables.

Anxiety

The prevalence of anxiety at baseline in the current study was similar to that found in previous research (5, 18-20, 23). The finding that anxiety did not reduce in the intervention booklet group compared to the control group was unexpected, as previous studies have shown improvement on measures of anxiety following therapist-led CBT (18-20, 23). It is possible that a pure self-help intervention is insufficient in treating anxiety in some NCCP patients. The studies reporting a significant effect of CBT on anxiety have varied in terms of the characteristics of treatment delivered, however they have all involved at least a one hour individual session to introduce the approach (18-20, 23). It is possible that guided self-help, in which participants meet with a facilitator (such as a trained nurse) to receive an introduction to the self-help materials and receive short-term guidance on the development of

strategies, would be effective for individuals with NCCP. Future research should explore whether guided self-help impacts on generalised, and cardiac specific, anxiety.

It is also possible that current study's method of recruiting all consecutive attenders regardless of their current chest pain characteristics is relevant in explaining the lack of effect of the intervention on anxiety. Previous studies reporting an effect of CBT include those recruiting participants who experienced a specified minimum frequency of chest pain (18-20). Esler *et al.* (23) recruited consecutive attenders regardless of current symptoms and found an effect of CBT on cardiac anxiety. However their sample experienced more frequent episodes of chest pain than the current study's sample, which found that approximately one third of patients had not experienced chest pain in the week preceding completion of baseline measures. Given that both groups in the current study were found to show modest improvements over time on measures of anxiety this may reflect a 'regression to the mean' phenomenon, observed because consecutive clinic attendees were recruited regardless of current chest pain status or level of anxiety.

A sub-analysis on completers observed no change in the proportion with clinically significant generalised anxiety at baseline and follow-up measured using the HADS. A similar sub-analysis was not possible on the cardiac anxiety construct measured using the CAQ as this is a relatively new measure with no suggested cut-off values for scores indicating clinical significance published. It would appear useful for future research to include a measure of cardiac anxiety such as the CAQ, and to establish the sensitivity and specificity of cut-off scores on this measure which identify clinically significant symptoms in the NCCP population. This would add to future research into the effectiveness of interventions.

Illness Beliefs

This is the first study, known to the author, to examine the impact of CBT-based self-help on individuals' belief in personal control of their chest pain in a NCCP sample. At baseline,

participants tended to have low belief in their personal control of symptoms. This finding is similar to previous NCCP research (5), and scores in this population are lower than those found in cardiac samples (35, 36). The lack of effect of the intervention booklet on personal control beliefs was unexpected. There was a trend to increased scores in the intervention condition, with decreased scores in the control condition and this would appear worthy of further investigation. It is possible that the sampling method chosen is relevant in explaining the lack of effect of the booklet and future research should explore evidence for effectiveness in a sample reporting on-going difficulties following clinic attendance.

Illness beliefs are important targets for intervention according to Leventhal's (24, 25) model of illness representations. This states that the impact of symptoms on an individual is related to the beliefs held about their symptoms. Belief that there is something that the individual can do to manage their chest pain appears important in this population, who often do not receive a definitive diagnosis to explain their symptoms (8). Perceived controllability of symptoms has been associated with coping in the health psychology literature, whereby symptoms perceived to be controllable are linked to the use of active coping strategies, whereas those perceived to be uncontrollable are linked to less adaptive coping strategies such as denial and avoidance (37). It therefore appears vital to include a measure of illness beliefs, such as belief in personal control of symptoms, in NCCP intervention studies.

Acceptability

Forty per cent of those eligible to participate in the current study did so. This is a comparable level of recruitment to other intervention studies in this area (e.g.18, 20). Mayou *et al*. (8) advocated the use of a stepped care intervention approach for NCCP and purported that low intensity interventions such as self-help may be more acceptable to these patients than individual psychological therapy. The current study's participation rate was comparable to those studies investigating individual therapy, which may indicate that self-help is not more

acceptable to this group that therapist-led CBT. However it is important to note that 40% of consecutive attenders participated in this study, whereas previous research has targeted recruitment at individuals who might be predicted to be more motivated to participate given that they have a specified frequency of symptoms.

At follow-up the retention rate was better for those in the control condition compared to the treatment condition (65% of the intervention group retained; 81% of the control group). This may relate to the fact that control group participants were aware that they would receive the intervention booklet after their return of follow-up measures. The booklet was broadly acceptable to those allocated to receive it as the majority reported finding it useful. Approximately half of those allocated to receive the booklet reported using the strategies introduced in the two weeks preceding completion of the follow-up measures. The acceptability statistics must be interpreted with caution, given that those returning measures may have been more likely to believe that psychological factors were relevant to them and therefore agree to participate in the study. Potential participants were aware that the primary investigator was a psychologist and questionnaires were returned to a psychology department. It will be important for future research to explore participation rates in self-help studies in this area delivered by medical personnel in order to determine if greater participation rates are found. Nevertheless, the results suggest that CBT-based self-help is an acceptable intervention for many NCCP patients.

Strengths and limitations

Previous studies reporting an effect of CBT have often specified a minimum chest pain frequency and/or duration of symptoms for eligibility to participate (e.g. 18-20). This allows specific analysis of the impact of the intervention on chest pain symptoms. It has been suggested that chest pain indices such as frequency and duration of chest pain are inappropriate intervention outcome measures as these variables can be unreliable predictors

of pain related disability and distress (38). Therefore, the current research did not seek to examine the impact of the intervention on chest pain. However, it would have strengthened the study to measure the duration that participants had experienced chest pain as this would have allowed comparison of these results with other studies. Anecdotally participants reported a variety of prior experiences of chest pain, with some stating that they had experienced only one episode prior to attending the clinic. Others reported a longer duration of symptoms with multiple prior investigations. The current study asked participants to report on the frequency and severity of chest pain over the preceding week. However this time frame may be insufficient to obtain an accurate overview of the chest pain experienced and future research should assess symptoms over a longer timeframe. Given that the minimum frequency of pain experience assessed was 'once a week or less' this limits the ability to distinguish those who experienced no pain from those experiencing pain once per week. In addition, the impact of comorbid conditions was not measured or controlled for which limits the interpretation of the results.

Other brief intervention studies have recruited all attendees regardless of their current, or past, history of chest pain and co-morbid health status (e.g. 23). The treatment effects might have been maximised by recruiting only those continuing to report symptoms after attending the clinic, and by excluding those with significant co-morbidities. However the current methodology allowed an analysis of the clinical effectiveness of the intervention in a way that maximised the external validity and 'real life' application of the results.

It must also be borne in mind that participants were not blind to treatment condition and therefore there was potential for expectation bias to influence their responses to measures. It was believed to be ethically unfeasible to withhold treatment condition from participants. Future research should seek to complete trials comparing self-help to therapist-led intervention to minimise this potential bias.

It would have strengthened the scientific rigour of the study if the time spent reading the intervention booklet and developing skills in the strategies introduced had been measured. The intervention booklet did not have the expected effect in terms of the outcome measures assessed. This may be related to the degree to which participants completed the self-help treatment outlined in the booklet which was not assessed in the study. However, a strength of the current study compared to previous self-help research (4) is that participants' use of the key strategies introduced in the booklet was assessed at follow-up.

Conclusion

Despite a number of limitations, the findings from this study suggest that CBT-based self-help intervention is acceptable, at least to some with NCCP. It is unclear from the current study whether provision of a pure self-help intervention is ineffective in reducing anxiety and increasing belief in personal control of chest pain for those with NCCP, or whether the lack of effect is due to the limitations of the study. The finding that the intervention resulted in a trend to increased belief in personal control of symptoms is worthy of further investigation. These findings are relevant for healthcare professionals involved in the care of NCCP patients. They provide support for the potential utility of a stepped care approach including self-help as a low intensity intervention. Future research is needed to ascertain who is most likely to benefit from such self-help approaches.

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Chapter 5: Additional Methodology

This chapter aims to provide additional information regarding the methodology of the two studies reported in Chapters 3 and 4 that formed the thesis research. This includes ethical considerations, additional information regarding the development of the intervention booklet and further information regarding data analyses. It is also prudent to note that the research project will be continued beyond the thesis with participants also completing follow-up questionnaires at 6- and 12-months. Following completion of 12-month measures the intervention booklet will be posted to the treatment as usual group.

Ethical Considerations

Ethical approval was sought from the South East Scotland NHS Research Ethics Committee Two and the local health board's Research and Development department (see Appendix IV, p.127 for consent letters). Participant information sheets and consent forms (Appendix V, p.133) were enclosed in the questionnaire packs distributed at the initial baseline time point. Participant's General Practitioners were informed of their participation in the study (see Appendix VI, p.137) but were blind to the intervention condition in order to minimise potential bias in the treatments they themselves offered patients.

Additional information regarding development of intervention booklet

A CBT-based self-help intervention booklet was designed specifically for the study with input from a clinical psychologist working in cardiac rehabilitation and a health psychologist. The content of the booklet was developed in an iterative process between the authors. A draft was piloted (see Appendix VII, p.139 for the method and results of the pilot study) and a final draft was then constructed.

The booklet includes a brief introductory page aiming to introduce the purpose of the booklet, followed by three patient quotes from a qualitative study of RACPC attendees when informed

that the results of the assessment indicated that their chest pain was non-cardiac in origin (Price *et al*., 2005). These quotes illustrated the uncertainty experienced by some NCCP patients regarding the cause of their chest pain and their desire to do something to manage the pain. The booklet then included education and instruction in CBT-based techniques. This intervention differs from those delivered in previous studies (e.g. Arnold *et al.,* 2009) in that there was an emphasis on not only reading the information but also actively trying out strategies which were introduced and explained in the booklet. The inclusion of quizzes, diaries to record the results of applying the techniques and the provision of diaphragmatic breathing and progressive muscle relaxation exercises on a CD accompanying the booklet, aimed to emphasise the self-help, active nature of the intervention. The pure self-help focus differentiates this study from existing studies demonstrating the effectiveness of therapist-led CBT in this population when delivered on an individual (e.g. Esler *et al*., 2003; Spinhoven *et al.,* 2010) or group (e.g. Potts *et al*., 1999) basis.

The intervention was based on CBT protocols found to be effective in the NCCP population such as that described by Van Peski-Oosterbaan *et al.* (1999) for therapist-led interventions. It was informed by CBT protocols developed for panic disorder (Clark, 1986), health anxiety (Warwick & Salkovskis, 1990) and unexplained physical symptoms (Speckens *et al*., 1995). The booklet was divided into 5 sections, outlined below:

*Section 1: "*Information about Non-Cardiac Chest Pain". This section included definitions of non-cardiac chest pain and coronary artery disease. Some possible causes of non-cardiac chest pain were discussed and it was emphasised that these are not medically serious (i.e. life threatening). The rationale for the self-help guide was outlined and it was explained that the strategies covered in the guide may help the individual to cope with non-cardiac chest pain. An explanation of how to use the guide (either working through each section trying all techniques or reading and trying the techniques from one section at a time) was given.

Section 2 "Tension and Relaxation" began with a quiz in which six statements were presented and the individual was asked to agree or disagree. These statements were developed from questionnaires aiming to assess anxiety and stress (HADS, Zigmond & Snaith, 1983) and Depression, Anxiety and Stress Scale (DASS, Lovibond & Lovibond, 1995). If the individual agreed with any of the statements in the quiz they were encouraged to read and try the strategies discussed in the section. An activity diary was introduced in order to assist participants to monitor the inclusion of relaxing activities and breaks into their daily life. They were asked to record activities and rate them in terms of how relaxing they were.

The rationale for progressive muscle relaxation (PMR) was outlined and instructions for the completion of the PMR exercise on the CD given. Common difficulties were listed and strategies to manage these suggested. A 'relaxation record' to record the completion of the PMR exercise and rate the level of relaxation pre- and post-completion was provided. PMR techniques were included as several interventions found to be effective for NCCP incorporated instruction in PMR (e.g. Klimes *et al.,* 1990, van Peski-Oosterbaan *et al.*, 1999).

Section 3 "Impact of Breathing" outlined the rationale for, and provided instruction in, diaphragmatic breathing. This technique has been included in other interventions for NCCP (e.g. Esler *et al*., 2003; van Peski-Oosterbaan *et al*., 1999 and Spinhoven *et al*. 2010). This section ended with a 'true or false' quiz designed to reinforce the section contents..

Section 4 "Unhelpful Worrying Thoughts" aimed to normalise the occurrence of worrying thoughts following RACPC attendance and provide education on the role of thoughts in distress and chest pain. CBT techniques to manage unhelpful thoughts (dropping selective attention to bodily sensations, distraction and thought challenging using thought diaries) were explained with examples. A focus on identifying and challenging unhelpful thoughts has been used in other CBT intervention studies for NCCP (e.g. Esler *et al*., 2003 and Spinhoven *et al.* 2010). Section 4 also focussed on the process of worry as adapted with permission from the Henderson *et al.* (2005) self-help booklet titled: "Dealing with worry". This was informed by

the cognitive conceptualisation of generalised anxiety disorder (e.g. Wells, 1997) with the concept of helpful versus unhelpful worry discussed and strategies to manage unhelpful worry via problem solving explained.

Section 5 "Increasing Activities, Pacing and the Impact of Avoidance." This section explained unhelpful activity patterns that can hinder individuals with NCCP (informed by Price *et al*., 2005 and studies of chronic pain samples e.g. Harding & Watson, 2000). The concept of pacing and goal setting was introduced and explained in relation to a case vignette. The active nature of the intervention continued in this section with participants encouraged to use a paced approach to return to an activity. Jonsbu *et al.* (2010) emphasised the importance of physical activity in their CBT intervention for NCCP and benign palpitations and aimed to encourage participants to test the theory that physical activity would not harm their hearts. Van Peski-Oosterbaan *et al.* (1999) described the inclusion of behavioural experiments to test individuals' fears regarding exerting themselves, as in Clark's (1986) CBT panic model.

A section with a 'cut-out and keep' summary of the contents was included, as was a reference list and suggestions for further reading if the participant felt that stress and/or low mood were relevant. This included CBT self-help books 'Manage Your Mind' (Butler & Hope, 2006) and 'Overcoming Stress' (Brosnan and Todd, 2009) and a Mindfulness book 'Mindfulness: A Practical Guide to Finding Peace in a Modern World' (William & Penman, 2011). The address for the CBT 'life skills' website 'Living Life to the Full' (http://www.llttf.com/) was included. An appendix provided additional copies of the diaries ("activity sheets") used in the booklet.

The Flesch reading ease score of the final version is 71.9. The Scottish Executive (2006) recommended that self-help interventions for anxiety and depression have a Flesch reading ease score over 60 (the maximum score is 100 with the higher the score the easier it is to understand the document).

Additional information regarding data analysis

Preliminary Statistics

As recommended (e.g. Tabachnick & Fidell, 2007) the data were screened using box plots, frequencies and histograms. This allowed an analysis of any possible data entry errors.

Missing Values

Data was examined for any missing values. Table 5.1 outlines the proportion of missing data for each variable assessed, at each time point. This does not include those lost to the study (*n*=32).

Table 5.1: Extent of missing data for each variable at each time point assessed.

Variable	**Missing data (*n*)**	**Proportion of sample (%)**
Educational status	3/119	2.5
Work status	1/119	0.8
Pain severity baseline	1/119	0.8
Pain frequency baseline	1/119	0.8
Activities affected baseline	2/119	1.7
GP visits baseline	1/119	0.8
Other healthcare professional contact baseline	2/119	1.7
HADS A baseline	2/119	1.7
CAQ total score baseline	6/119	5
CAQ total score follow-up	8/87	9
IPQ-R personal control subscale baseline	10/119	8.4
IPQ-R personal control subscale follow-up	6/87	6.9
IPQ-R illness coherence subscale baseline	8/119	6.7
IPQ-R illness coherence subscale follow-up	2/119	1.7
IPQ-R psychological cause	9/119	7.6

The extent of missing data for each variable was less than 10%. Cohen and Cohen (1983) suggest that when up to 10% of participants have missing data on a variable, the variable should be retained and the missing data treated. Tabachnick and Fidell (2007) suggest that the choice of treatment technique is insignificant provided that the amount of missing data is low (less than 5%). They recommend exploration of the patterns of missing data, which was completed in the case of this study. Little MCAR test was statistically non-significant (X^2= 23.933, *df*= 26, *p*= 0.580) indicating that it can be inferred that data were missing completely at random. Each measure also provides guidance regarding the management of missing data and this was borne in mind when considering how to manage missing data.

HADS Anxiety Subscale: As recommended (Zigmond & Snaith, 1994) if more than one item was missing then the subscale was judged invalid. This applied to data from two participants at baseline (who were excluded from HADS analyses) and no participants at three month follow-up. Graham (2009) suggested that if the loss of cases due to missing data is small (defined as less than 5%) bias and loss of power from excluding these from the analysis is minimal.

IPQ-R: The guidance for missing data in the IPQ-R was followed, with the individual mean replacement method used if missing data met the criteria of only one item missing on the five item illness coherence scale, and up to two items missing on the six item personal control subscale (Moss-Morris, 2005). The IPQ-R guidance states that the scale is not valid if more than two items were missing from one subscale. Data from participants where this was the case were therefore excluded from the IPQ-R analyses.

Personal control: Five out of ten participants (4% of total sample) at baseline had more than two items missing on the personal control subscale, one out of six participants had more than two items missing on the items that make up this subscale at follow-up. These participants were therefore excluded from the analysis.

Illness coherence: Five out of eight participants with missing values at baseline had more than one item missing on the illness coherence scale and were therefore excluded from the analysis. This represents exclusion of 4% of the sample and therefore minimal bias and loss of power (Graham, 2009).

Psychological attribution: This score was calculated as the mean of the items specified as targeting psychological attributions as stated in the IPQ-R development paper (Moss-Morris *et al*., 2002). Mean replacement was used to account for missing data if up to two items were missing. Five participants (4%) had greater than 2 missing data points at baseline and were therefore excluded from the analysis..

CAQ: There is no agreed method to manage missing data on the CAQ therefore expectation maximisation was used when the frequency of missing values on the CAQ was less than 20% per participant and less than 10% per variable. Two participants were excluded from baseline analyses and none from follow-up analyses following missing data management. Graham (2009) advocated the use of expectation maximisation to manage missing data in order to preserve the characteristics of the data set as a whole thus minimising potential bias.

Outliers:

Examination of boxplots revealed that there were no outliers for HADS data. At baseline there was one outlier for the CAQ total score and multiple outliers on three of the four CAQ subscales. At baseline the IPQ-R personal control subscale had 4 outliers and the illness coherence subscale 2 outliers. Outliers were examined in order to ascertain that they were not the result of data entry error. It appeared that, as stated by Tabachnick and Fidell (2007), outliers were from the intended population but the distribution for the variable had more extreme values than a normal distribution. Cases were therefore retained and the decision made to examine descriptive statistics only for CAQ subscales and complete inferential statistics on the CAQ total scores.

Assumptions for parametric statistics

These were checked by initial exploration of histograms, and skewness and kurtosis values. Kolmogorov-Smirnov tests were computed and the Levene statistic for the homogeneity of variance examined. Parametric assumptions were met for the HADS analyses, with the exception that the Levene statistic was significant (p= 0.043) for the completers analysis. ANOVA tests are known to handle moderate violations of the assumption of equal variance if there are equal or nearly equal factors and levels (Field, 2009). This was the case in the current study. For the CAQ total score analysis, the presence of one outlier was the only violation of the assumptions for parametric analyses. The analysis was re-run with this outlier deleted. Table 5.2 shows that this resulted in minimal impact on the mean scores. A 2 (group) x 2 (time) ANOVA revealed a similar non-significant interaction (F(1,111)= 1.124, p= 0.291, η^2= 0.01). For the IPQ-R personal control subscale analysis, there were four outliers (2 intervention, 2 control group) at baseline and two in the control group at follow-up. Significant Kolmogorov-Smirnov statistics indicated a violation of the normal distribution assumption. Given that Field (2009) described ANOVA to be robust to violations of the normality assumption in large sample sizes (greater than 30); the analysis was re-run with the outliers deleted. Table 5.3 shows that this resulted in minimal impact on mean scores on this measure. A 2 (group) x 2 (time) ANOVA revealed a similar significant interaction (F(1,107)= 5.085, p= 0.026, η^2= 0.045).

Table 5.2 Comparison of CAQ mean scores with outlier included and excluded.

		Intervention mean score (S.D.)	**Treatment as usual mean score (S.D.)**
CAQ total score with outlier included	Baseline Follow up	1.23 (0.51) 1.13 (0.56)	1.25 (0.57) 1.08 (0.60)
CAQ total score with outlier deleted	Baseline Follow up	1.20 (0.47) 1.11 (0.52)	1.25 (0.57) 1.08 (0.60)

Table 5.3 Comparison of personal control mean scores with outliers included and excluded.

		Intervention mean score (S.D.)	**Treatment as usual mean score (S.D.)**
Personal control mean score with outliers included	Baseline Follow up n	18.72 (4.07) 19.69 (4.22) 64	19.78 (4.59) 19.47 (4.78) 50
Personal control mean score with outliers deleted	Baseline Follow up n	18.70 (3.62) 19.43 (4.01) 62	20.35 (3.68) 20.00 (4.06) 48

Attrition:

Drop outs were managed with intent-to-treat (ITT) with the baseline score carried forward. In addition a completers analysis was conducted. This method has been used in previous studies in this area (e.g. Spinhoven *et al*., 2010). The treatment of missing data is problematic with no universally agreed management method. ITT is a conservative method as it assumes that those who drop out remain unchanged from baseline. It is considered preferable to excluding participants from the analysis, particularly in randomised trials where participants

should be analysed in the groups to which they were randomised (e.g. Streiner & Geddes, 2001). Consideration was given to alternative methods to manage attrition such as multiple imputation, however it was decided that a conservative estimate of the effect of the intervention was warranted given the fact that the study examined the effectiveness of an intervention.

Equivalence of groups following randomisation:

Differences at baseline between intervention and control groups were analysed using Chi-square tests for categorical variables (demographic variables and clinical characteristics of chest pain) and a two-tailed *t*–test for age (the only continuous demographic variable). Groups were collapsed when expected cell frequencies were less than five to ensure the validity of results (Field, 2009). No significant between group differences were observed (Table 5.4).

Table 5.4: Equivalence between groups at baseline

Variable	Intervention	Treatment as usual	Test statistic	*p* value
Gender	37 Male	25 Male	Chi-square = 0.931	0.335
Age Mean (S.D.)	54.0 (10.42)	56.7 (9.1)	t= 1.505	0.135
Work status	Yes full-time 32 Yes part-time or voluntary 8 No 26	Yes full-time 23 Yes part-time or voluntary 13 No 16	Chi-square = 3.431	0.180
Education	None 18 School exams/ SVQ 21 HNC/ HND/ degree or post graduate 27	None 13 School exams/ SVQ 19 HNC/ HND/ degree or post graduate 18	Chi-square = 0.509	0.775
Severity of chest pain	No pain 19 Very mild pain 23 Mild pain 10 Moderate or severe pain 13	No pain 19 Very mild pain 11 Mild pain 13 Moderate or severe pain 10	Chi-square = 3.837	0.280
Frequency of chest	Once/week or less 40 Not every day but more than once/week 20 At least once per day 5	Once/week or less 34 Not every day but more than once/week 13 At least once per day 6	Chi-square = 0.851	0.654
Activities affected by chest pain	Not at all 37 Time to time, occasionally 22 A lot of the time or most of the time 6	Not at all 35 Time to time, occasionally 13 A lot of the time or most of the time 4	Chi-square = 1.342	0.511

Completers (87) and those lost to follow up (32) were also compared in relation to demographics and clinical characteristics of chest pain at baseline. No significant differences emerged between these two groups. No significant differences were revealed between completers and those lost to follow up for baseline HADS anxiety scores (two-tailed t-test), or for baseline CAQ total scores (two-tailed t-test). Mann-Whitney tests were carried out for non-normally distributed continuous variables (CAQ subscale scores, IPQ-R personal control and IPQ-R illness coherence), with no significant differences emerging between completers and those lost to the study (see Table 5.5).

Table 5.5: Comparison of completer and drop out scores on baseline outcome measures.

Variable	**Completers** Mean (SD)	**Drop outs** Mean (SD)	**Test statistic**	**P value**
HADS Anxiety	7.59 (4.55)	8.13 (4.21)	t= 0.573	0.568
CAQ total score	1.19 (0.51)	1.37 (0.57)	t= 1.658	0.100
IPQ-R personal control subscale	19.33 (4.48)	18.74 (3.82)	U= 1,327	0.537
IPQ-R illness coherence subscale	11.75 (4.52)	12.45 (4.52)	U= 1,110.500	0.424

Inferential statistics

In journal article two all explorations of outcome measure variables used 2 (group) x 2 (time) split-plot ANOVA analyses. The Huynh-Feldt epsilon correction procedure was used in order to control for the inflated Type I error rate associated with the mixed-model univariate ANOVA when the sphericity assumption is not met (Field, 2009). The partial eta-squared

statistics were reported as a measure of effect size. These are a measure of the proportion of variance that a variable explains, that is not explained by the other variables in the analysis (Field, 2009). Effect sizes are one method to quantify the effect of the variables of interest in the population of interest. Cohen (1988) suggests that a partial eta squared value of .01 = small effect, .06 = moderate effect and .14 large effect. Given that effect sizes complement reporting of *p* values (Field, 2009) the decision was made to report both statistics in journal article two.

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Appendices

List of appendices:

Appendix I: Author guidelines for Psychosomatic Medicine.

Psychosomatic Medicine Instructions for Authors

Manuscripts for review should be submitted over the World Wide Web at http://psymed.editorialmanager.com. They should be addressed to the attention of Willem J. Kop, PhD, Editor-in-Chief, *Psychosomatic Medicine*. Postal correspondence may be sent to the *Psychosomatic Medicine* Editorial Office at 1120 E. Kennedy Blvd. #1410, Tampa, FL 33602, USA. The editorial office telephone number is (813) 525-0098. The e-mail address is:PsychosomaticMedicine@gmail.com.

The Journal welcomes original research articles, meta analyses and systematic literature reviews, articles on methodology and statistics, and letters to the editor. The Journal publishes special series on selected topics in psychosomatic medicine and the Methods and Statistics series. Authors submitting to these series are encouraged to send a detailed query to the Editorial Office to gauge interest in the particular manuscript or topic. Original data manuscripts may be considered for Rapid Communication if the text including references and tables is no longer than 3,200 words and the manuscript does not require major revision. If a major revision is required, the manuscript will be processed as a regular submission. Note that this category is for succinct manuscripts of unusual interest, not for pilot data or work in progress.

Manuscripts are reviewed with the understanding that they are original, have not been published other than in an abstract form, and are not under simultaneous review elsewhere. All authors must approve of the submission, and before publication, the corresponding author should secure permission to name anyone listed under acknowledgments. Most manuscripts are sent to outside peer reviewers, but a significant percentage are evaluated only in-house and may be rejected if they are not suitable for the journal or up to the journal's quality standards. *Psychosomatic Medicine* requests authors to adhere to the journal's statistical guidelines, available on the Web at:http://www.psychosomaticmedicine.org/site/misc/stat.xhtml. The journal endorses several statements developed to improve the quality of medical research reports. Authors are encouraged to consult the CONSORT, MOOSE, and PRISMA statements, available on the World Wide Web at: http://www.consort-statement.org or http://www.equator-network.org.

Manuscript formatting: Electronic manuscripts should be formatted so text is double-spaced (including references and tables) on 8 1/2"x 11" paper size. When submitting a manuscript, describe in a brief cover letter the paper's objectives and significance. The editor welcomes, but is not bound by, suggestions for possible peer reviewers.

On the title page, include the title, full names of author(s), with highest academic degrees and academic or professional affiliations, and the complete address, telephone number, fax number, and e-mail address of the author to whom proofs and correspondence should be sent. Indicate the total number of words contained in the manuscript, and the number of tables and figures; the word count should include the body of the paper, the references and the tables. If the title exceeds 45 characters, supply an abbreviated running title of fewer than 46 spaces. Please also include a section on the title page labeled "Conflicts of Interest and Source of Funding." (Further instructions are below.) Number pages consecutively beginning with the abstract page. **Manuscripts should be no longer than 6,500 words.**

Abstract: All papers should include a brief initial abstract of not more than 250 words followed by up to 6 key words for indexing. Abstracts should be submitted in outline format, using the bolded headings of Objective, Methods, Results, Conclusions, and, if applicable, Trial Registration. Precise results for main findings should be presented. After the keywords, list all acronyms used in text, e.g., DBP = diastolic blood pressure; BMI = body mass index.

P value style: If $p < .10$, then it should be expressed to 3 digits after the decimal point. If the value is .10 through .99, then it should be expressed to 2 digits. Values of .000 and 1.0 should be reported as $< .001$ and $> .99$, respectively.
Tables and Illustrations: Tables should be double-spaced, including all headings, and should have a concise descriptive title. Each table should be numbered sequentially in Arabic numerals and begin on a new page. When preparing tables, if appropriate to the data, include the number of participants or observations, the statistical tests or estimation techniques used, exact p values, and some measure of variability (standard deviations, standard errors or confidence intervals) for any estimates (e.g., means, differences, proportions) presented. For figures, please do not use three-dimensional graphs for two-dimensional data.

For manuscripts accepted for publication, authors are strongly encouraged to provide scalable vector files in formats such as EPS, PowerPoint, or PDF. Line artwork created in Microsoft Word and Excel is acceptable provided the text and objects within the artwork can be formatted and edited without loss of image clarity. Preferred fonts include Arial and Helvetica. A separate sheet of legends for illustrations should be included. Authors wishing to use color figures will incur a fee to defray the associated printing costs; in the online edition, color figures may be included at no cost.

References and Footnotes: In the text, citation of references is by full-sized numbers in parentheses. Footnotes to the text are indicated by Arabic numeral superscripts numbered consecutively throughout the paper and placed at the foot of each page on which they are cited. List references in the order cited in the text. Number references consecutively, using Arabic numerals. References should be typed double-spaced and placed at the end of the text beginning on a separate page. **List all authors; do not use "et al."** The reference list should not include personal communications or manuscripts submitted but not accepted for publication. References should be styled as follows:
Book: Tomb DA. Psychiatry. 5th ed. Baltimore: Williams & Wilkins; 1994.
Edited Book: Gorman JR, Locke SE. Neural, endocrine, and immune interactions. In: Kaplan HI, Sadock BJ, editors. Comprehensive textbook of psychiatry. vol 1. 5th ed. Baltimore: Williams & Wilkins; 1989. p. 111-25.
Journals: Irvine J, Baker B, Smith J, Jandciu S, Paquette M, Cairns J, Connolly S, Roberts R, Gent M, Dorian P. Poor adherence to placebo or amiodarone therapy predicts mortality: results from the CAMIAT study. Psychosom Med 1999;61:566-75.
Periodical abbreviations should follow those given by Index Medicus. Correct journal abbreviations can be found by searching at: http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=journals

Appendix II: Systematic review quality assessment sheet.

Quality criteria assessment data collection sheet			
AUTHORS (S):			
DATE:			
TITLE:			
1. Sample			
1.1.	The sampling method ensures that the sample selected is representative of a general clinical sample	Well covered... 2 Adequately addressed... 1 Poorly addressed... 0 Not addressed (i.e. not mentioned, or indicates that this aspect of study design was ignored)...0 Not reported (i.e. mentioned but insufficient detail to allow assessment to be made)...0 Not applicable...0	Well covered= the sampling method ensures that minimal bias is introduced by ensuring that probability sampling is used. Appropriate and not unduly rigorous inclusion/exclusion criteria applied and 70% or more of those eligible to participate do so. Adequately addressed= the sampling method may introduce an element of bias. Only between 60-69% of those eligible to participate in study do so or inclusion/ exclusion criteria applied limit the generalizability of results. Poorly addressed = the sample is highly selected e.g. volunteers or only 59% or less of those eligible to participate do so.
1.2	The study clearly states attrition rates for each group compared and this is similar for each group	Well covered... 2 Adequately addressed ... 1 Poorly addressed... 0 Not addressed...0 Not reported...0 Not applicable...0	Well covered = details given regarding drop out for both groups and similar for each group (from pre- post intervention within 10% of each other and 20% of total participants). Adequately addressed = drop out somewhat alike between groups (within 20% of each other and less than 30% of total

			participants from pre- to post-intervention). Poorly addressed = high drop out in general or uneven drop out.
1.3	Participants in each group are sufficiently alike at baseline in terms of key variables that may impact on intervention outcome (clinical characteristics of chest pain, psychological distress, educational status). Any differences controlled for appropriately.	Well covered... 2 Adequately addressed ... 1 Poorly addressed... 0 Not addressed...0 Not reported...0 Not applicable...0	Well covered = differences are assessed between treatment and control groups and they are sufficiently alike at the start of the trial on anxiety and other key variables that may affect outcome (educational status, severity, intensity and duration of chest pain, severity of psychological distress). Alternatively differences on these variables are controlled for in the analysis (e.g. added as a covariate). Adequately addressed= no difference between groups on measures of anxiety, or any differences controlled for in the analysis. Poorly addressed= no comparison between treatment and control groups at baseline
Total section 1			/6
2. Study design			
2.1	A rigorous research design is applied to address the study question	Well covered... 2 Adequately addressed ... 1 Poorly addressed... 0 Not addressed...0 Not reported...0 Not applicable...0	Well covered = RCT Adequately addressed =non-randomised controlled trial, quasi-experimental design, or a well-designed, multiple subject design. Poorly addressed =poorly-designed multiple subject design
2.2	If RCT assignment to the groups should be	Well covered... 2	Well covered= clear information is given regarding the method of

	randomised	Adequately addressed ... 1 Poorly addressed... 0 Not addressed...0 Not reported...0 Not applicable...0	randomisation and this is appropriate to study design (e.g. random number generator) Adequately addressed= randomisation occurred although insufficient information given regarding methods used Poorly addressed =assignment to groups is not adequately described and may be non-randomised. Methods in which researcher could work out which group patient assigned (e.g. allocation by date of birth).
2.3	Assignment to the groups should be adequately concealed on participant entry into the study and to those scoring results	Well covered... 2 Adequately addressed ... 1 Poorly addressed... 0 Not addressed...0 Not reported...0 Not applicable...0	Well covered= researchers are unaware which group participants are being allocated to at the time they enter the study. Centralised allocation, computerised allocation or use of coded identical containers/ envelopes used to allocate to group. Those scoring the results should <u>also</u> be blind to treatment condition. Adequately addressed = researchers are unaware which group participants are being allocated to at the time they enter the study <u>or</u> those scoring the results are blind to treatment condition. Poorly addressed = poor method of concealment used or an easy to subvert method used to allocate to group <u>and</u> those scoring the results not blind to treatment condition.
2.4	Follow-up assessment at a suitable time period completed and	Well covered... 2 Adequately addressed ... 1	Well covered= a FU following post-treatment of 6 months or more completed and at least 80% of participants completing

	acceptable attrition rate	Poorly addressed... 0 Not addressed...0 Not reported...0 Not applicable...0	pre measures retained for follow-up Adequately addressed= a 3 to <6 month FU post treatment completed. At least 60% of participants completing pre measures retained. Poorly addressed =no FU or short (<3month) FU or less than 60% of those completing pre measures retained.
2.5	Sample size adequate	Well covered... 2 Adequately addressed ... 1 Poorly addressed... 0 Not addressed...0 Not reported...0 Not applicable...0	Well covered= sample size for those completing pre and post measures well covered if 51 or more in each group. (1 tailed t-test with alpha 0.05, power 0.80 and medium effect size (Cohen's d = 0.5) needs 51 participants per group) Adequately addressed= sample size adequate - participants completing pre and post measures at least 39 per condition (power 0.70). Poorly addressed= low sample size (less than 39) and hence low power (less than 0.70).
Total section 2			/10
3. Intervention			
3.1	Fidelity/compliance check regarding well specified intervention	Well covered... 2 Adequately addressed... 1 Poorly addressed... 0 Not addressed...0 Not reported...0 Not applicable...0	Well covered= treatment operationalized (e.g. treatment manual) and check on treatment fidelity. Both conducted thoroughly (e.g. rating of audio recorded sessions). Adequately addressed= if operationalized treatment but no check on treatment fidelity or adequate check on intervention (e.g. audio recordings listened to

			by supervisor) but treatment not operationalized. Poorly addressed= intervention not operationalized and no fidelity checks completed. If supervision only (with no more rigorous check on fidelity) consider poorly addressed.
Total section 3:			/2
4. Outcomes			
4.1	Anxiety measured in a standard, valid, reliable way	Well covered... 2 Adequately addressed... 1 Poorly addressed... 0 Not addressed...0 Not reported...0 Not applicable...0	Well covered= standardised outcome measure(s) used with well reported psychometric properties (i.e. valid and reliable) in non-cardiac chest pain population (e.g. HADS, CAQ). Anxiety measured pre- and post-intervention and measure used allows severity of anxiety to be assessed. Adequately addressed= standardised outcome measure(s) pre- and post-intervention with adequate psychometric properties but little or no evidence of reliability and validity in non-cardiac chest pain population. Or diagnostic interview (e.g. ADIS-IV) alone. Poorly addressed= non-standardised outcome measure(s) used. Anxiety measured at only one time point.
Total section 4:			/2
5. Statistical Analysis			
5.1	The analysis is appropriate to the design and type of outcome measure	Well covered... 2 Adequately addressed... 1 Poorly addressed... 0	Well covered= analysis appropriate to design. All subjects analysed in the groups to which they were allocated. Appropriate statistical method

		Not addressed...0 Not reported...0 Not applicable...0	used to deal with missing data (e.g. ITT with baseline score carried forward in order to minimise bias). Adequately addressed= analysis appropriate to design. No statistical management of missing data (e.g. ITT) but proportion of participants excluded from analysis reported and less than 20% Poorly addressed=Poor method used to deal with missing data (e.g. if ITT last score carried forward used hence potential for bias if e.g. post intervention score carried forward to FU)
Total section 5			/2
Overall total: /22			

Appendix III: List of the number of articles examined and excluded from systematic review, with reasons for exclusion.

Stage of review	Number of studies excluded	Reason(s) for exclusion
Abstract review	88 excluded	Discursive articles or literature reviews not reporting original research
	18 excluded	Sampled conditions other than non-cardiac chest pain (cardiac (n=11); cardiac syndrome X (2); gastrointestinal (n=3); cancer (n = 1), chronic fatigue syndrome (n=1)).
	12 excluded	Study designs did not meet inclusion criteria (7 case studies; 5 non-comparative designs).
	7 excluded	Non-English language
	6 excluded	Non-CBT intervention.
	3 excluded	Book chapters not reporting original research.
	1 excluded	Dissertation abstract - the same author later published an article which is included in the review
	1 excluded	Conference proceeding -on reviewing title it is clear that a non-intervention study is reported.
Full article review	2 excluded	Non-CBT intervention
	2 excluded	Study designs did not meet inclusion criteria
	2 excluded	Participant groups the same as those reported in other, included studies.
	1 excluded	No measure of anxiety

	1 excluded	Data for NCCP patients pooled with other participant data and an attempt to contact author to obtain NCCP data was unsuccessful.
Review of articles obtained from reference lists of full articles examined	5 excluded	Study design did not meet inclusion criteria (2 case studies; 3 non-comparative designs).
	4 excluded	Reviewed CBT for 'somatoform disorder', 'somatisation disorder' or 'medically unexplained symptoms' but did not differentiate in terms of presenting symptoms.
	3 excluded	Discursive articles or literature reviews not reporting original research
	1 excluded	No measure of anxiety
	1 excluded	Sampled condition other than non-cardiac chest pain (unexplained headache).

Appendix IV: Ethical approval correspondence

Lothian NHS Board

South East Scotland Research Ethics Committee 2
Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Telephone 0131 536 9000
Fax 0131 536 9068

www.nhslothian.scot.nhs.uk

NHS Lothian

Miss Shona L Brown
Trainee Clinical Psychologist
NHS Lothian
Department of Clinical Psychology
Astley Ainslie Hospital
Edinburgh
EH9 2HL

Date 01 April 2011
Your Ref
Our Ref

Enquiries to Lyndsey Baird
Extension 35673
Direct Line 0131 465 5673
Email lyndsey.Baird@nhslothian.scot.nhs.uk

Dear Miss Brown

Study title: **CBT (Cognitive Behaviour Therapy) based self help intervention for noncardiac chest pain: A pilot study to examine clinical efficacy and acceptability.**
REC reference: **11/S1102/5**
Protocol number: **N/A**

Thank you for your letter of 25 March 2011, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a sub committee of the REC

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

NHS
Lothian

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

11/S1102/5	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

Mr Thomas Russell
Chair

Email: lyndsay.baird@nhslothian.scot.nhs.uk

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

"After ethical review – guidance for researchers"

Copy to: *Gemma Watson*

Lothian NHS Board

South East Scotland Research Ethics Committee 2
Waverley Gate
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NHS Lothian

Miss Shona L Brown
Trainee Clinical Psychologist
NHS Lothian
Department of Clinical Psychology
Astley Ainslie Hospital
Edinburgh
EH9 2HL

Date 27 May 2011
Your Ref
Our Ref

Enquiries to Lyndsay Baird
Extension 35673
Direct Line 0131 465 5673
Email lyndsay.Baird@nhslothian.scot.nhs.uk

Dear Miss Brown

Study title: **CBT (Cognitive Behaviour Therapy) based self help intervention for noncardiac chest pain: A pilot study to examine clinical efficacy and acceptability.**
REC reference: **11/S1102/5**
Protocol number: **N/A**
Amendment number: **1**
Amendment date: **19 May 2011**

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review 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:

Document	Version	Date
Participant Consent Form	4	19 May 2033
Participant Information Sheet	4	19 May 2011
Protocol	3	19 May 2011
Notice of Substantial Amendment (non-CTIMPs)	1	19 May 2011
Covering Letter		19 May 2011

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

NHS
Lothian

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

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

11/S1102/5:	**Please quote this number on all correspondence**

Yours sincerely

Mr Thomas Russell

Chair

E-mail: lyndsay.baird@nhslothian.scot.nhs.uk

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Gemma Watson*

South East Scotland Research Ethics Committee 02

Attendance at Sub-Committee of the REC meeting

Name	*Profession*	*Capacity*
Mr Thomas Russell	Consultant Neurosurgeon	Expert
Professor Lindsay Sawyer	Retired	Lay

University Hospitals Division

NHS Lothian

Queen's Medical Research Institute
47 Little France Crescent, Edinburgh, EH16 4TJ

Research & Development
Room E1.12
Tel: 0131 242 3330
Fax: 0131 242 3343

Email: R&DOffice@luht.scot.nhs.uk

Director: Professor David E Newby

DEN/KB/approval

05/05/2011

Miss Shona L Brown
Department of Clinical Psychology
Astley Ainslie Hospital
Edinburgh
EH9 2HL

Dear Miss Brown

Lothian R&D Project No: **2011/R/CAR/09**

Title of Research: CBT (Cognitive Behaviour Therapy) based self help intervention for noncardiac chest pain: A pilot study to examine clinical efficacy and acceptability.

REC No: 11/S1102/5

CTA No: N/A **Eudract:** N/A

PIS: Version 3, dated 03 March 2011 **Consent:** Version 3, dated 03 March 2011

Protocol No: Version 2, dated 01 March 2011

I am pleased to inform you that this study has been approved for NHS Lothian and you may proceed with your research subject to the conditions below. This letter provides Site Specific approval for NHS Lothian.

Please note that the NHS Lothian R&D Office must be informed if there are any changes to the study such as amendments to the protocol, recruitment, funding, personnel or resource input required of NHS Lothian. This includes any changes made subsequent to management approval and prior to favourable opinion from the REC.

Substantial amendments to the protocol will require approval from the ethics committee which approved your study and the MHRA where applicable.

Please inform this office when recruitment has closed and when the study has been completed.

I wish you every success with your study.

Yours sincerely

Professor David E Newby
R&D Director

enc Tissue Policy (if applicable)

University Hospitals Division

NHS Lothian

Queen's Medical Research Institute
47 Little France Crescent, Edinburgh, EH16 4TJ

RESEARCH & DEVELOPMENT
Room E1.12
Tel: 0131 242 3330
Fax: 0131 242 3343
Email: R&DOffice@nhslothian.scot.nhs.uk

Director:
Professor David E Newby

CPP/JK/app mrecamend

1 July 2011

Miss Shona L Brown
Department of Clinical Psychology
Astley Ainslie Hospital
Edinburgh
EH9 2HL

Dear Miss Brown

REC No: **11/S1102/5**
R&D Project ID No: **2011/R/CAR/09**
Title of Research *CBT (Cognitive Behaviour Therapy) based self help intervention for noncardiac chest pain: A pilot study to examine clinical efficacy and acceptability.*

I am writing in reply to recent correspondence in relation to the following amendment(s) to the above project.

Amendment: **No.1 dated 19 May 2011**

- **As an additional study is recruiting from the Rapid Access Chest Pain clinic, the protocol has been amended in order to minimise potential confusion for participants. Instead of being given information on this study at their clinic visit, patients will now be advised to expect a telephone call at a later stage from the researchers to discuss this study and invite them to participate.**
  - **Protocol, version 3 dated 19 May 2011**
  - **Patient Information sheet, version 4 dated 19 May 2011**

We have now received a copy of the amendment(s) and assessed any consequential changes in NHS Lothian resource use. I confirm that NHS Lothian management approval is extended to cover the specific changes intimated. You should be aware that approval for this amendment should be sought from REC before it is implemented

Yours sincerely

C Phillips

Dr Christine P Phillips
Deputy R&D Director

Appendix V: Participant information sheet and consent form

Information about the research

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. 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.

Study title: Self-help intervention for non-cardiac chest pain

What is the purpose of the study?
Some people who attend the Rapid Access Chest Pain clinic are told that their chest pain is not related to their heart. We would like to explore how this affects them, for example how they make sense of their chest pain and if it affects how they feel and their quality of life. This study aims to explore a treatment that might be helpful for people with non-cardiac chest pain after they have attended a Rapid Access Chest Pain Clinic.

Why have I been invited?
You have been invited to take part because you have attended a Rapid Access Chest Pain Clinic and been told that your chest pain is non-cardiac (not coming from your heart). Many people with chest pain who attend the clinic and have tests are found to have no evidence of heart disease. We hope to learn more about the outcomes of those with non-cardiac chest pain after they have been to the clinic.

What are the possible benefits of taking part?
If you agree to take part in the research you will receive a self-help intervention aiming to provide you with information and strategies that may help you to cope with the impact of non-cardiac chest pain. You will receive this following your appointment at the Rapid Access Chest Pain Clinic or after 12 months. It is hoped that by taking part you may help us to better understand how non-cardiac chest pain affects people and what strategies and information could help them to cope with it.

Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign and return a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason.

We are aware that you have been asked to participate in another study recruiting people who have attended the Rapid Access Chest Pain Clinic. It is important that you are aware that can participate in both of these studies, just one of these studies or neither. This decision will not affect your subsequent care.

What will happen to me if I take part?
If you agree to take part, we would first like you to complete some short questionnaires about yourself. This may take up to 30 minutes. We would then like you to contact you in the future (in 3 months time, again in 6 months and finally in 12 months time) and ask you to complete the same questionnaires again.

Following attending the clinic some people who agree to participate in the study will be sent an information booklet right away. This includes some information about non-cardiac chest pain and advice on how to practice some behaviours that that might help you to deal with it. These have been proven to help some patients with non-cardiac chest pain (e.g. Kisely, Campbell & Skerritt, 2005).

Some people will be randomly assigned to receive the treatment booklet 12 months after attending the clinic. If you are one of these people Shona Brown (Trainee Clinical Psychologist) will inform you of this.

All the information collected will be kept in the strictest of confidence by the study investigators. Anonymous data will be saved securely to allow us to report the results of the study. Information you submit to the study will not be passed to other professionals involved in your care, unless you request this or there is a significant risk of harm to yourself or others. Your GP will be informed of your participation in the study. Please contact your GP if you feel that you would like further support.

What do I have to do?
If you decide to take part we would like you to complete and return the questionnaires that you have been given at the end of your clinic appointment. A stamped addressed envelop is provided for this. You will be posted another pack of questionnaires 3 months, 6 months and then again at 12 months after attending the clinic.

What happens when the research study stops?
At the end of the research we will write to you in person and let you know what we have learnt from the research project. If you would prefer to speak to the principal investigator individually about the study, or not to receive any further information at all, we will of course respect your wishes.

Will my taking part in this study be kept confidential?
All information collected about you during the course of the research will be kept strictly confidential. Any information about you will have your name and address removed as soon as possible so that you cannot be recognised from it. Limited information will be kept on record so that we can get back in touch with you later if necessary.

What will happen to the results of the research study?
We will write up the results from the study as a publication. This will probably be in a specialist psychology or medical journal. Your personal details will not appear in any report or publication arising from the research.

Who has reviewed the study?
The study has been reviewed by the Ethics Committee and by senior members of staff within the University of Edinburgh.

Contact for Further Information
You should feel free to think about taking part for as long as you want. Should you wish to speak to someone about the study, you can speak to the principle investigator (Shona Brown, Telephone number: 0131 536 9128).

Many thanks for your consideration

Shona Brown (Trainee Clinical Psychologist)
Address: Department of Clinical Psychology, Astley Ainslie Hospital, Edinburgh
Tel: 0131 537 9128
Email: shonabrown2@nhs.net

Frances Divers (Cardiology Nurse Consultant)
Address: Ward 24, 2nd Floor, St John's Hospital
Tel: 01506 523 882

Rapid Access Chest Pain Clinic
Ward 24, 2nd Floor
St Johns Hospital

CONSENT FORM

Patient Identification Number :

Project: Self-help intervention for non-cardiac chest pain **Principal Researcher: Shona Brown**

Please tick box

1. I confirm that I have read and understand the information sheet dated 19/5/11 (version 4) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

4. I agree that my GP can be informed of my participation in this study. ☐

5. I agree that anonymous data (without my name or any identifying features) can be saved by the study researchers to allow the results to be reported. ☐

6. I understand that the Principal Researcher will have access to my name and contact details (address and telephone number) to allow the researcher to telephone me to answer any questions I might have and to allow the questionnaires and the self-help booklet to be posted to me. This information will be stored securely and destroyed as soon as it is no longer required. ☐

7. I understand that data collected during the study may be looked at by the study researchers and individuals from the University of Edinburgh, regulatory authorities or from NHS Lothian, where it is relevant to my taking part in this research. I give permission for these individuals to have access to this data which will not contain names or other identifying information. ☐

8. I agree to take part in the study. ☐

_____ _____ _____

Signature Date Name

Appendix VI: GP Information Sheet

GP Information Sheet

We would like to inform you that a patient registered with your practice is participating in our research study.

Patient name:
Address:
Date of birth:

Study title: Self-help intervention for non-cardiac chest pain

What is the purpose of the study?
To explore how receiving a diagnosis of non-cardiac chest pain following attendance at a Rapid Access Chest Pain Clinic affects individuals, for example how they make sense of their chest pain and how it impacts on how they feel and their quality of life. This study aims to explore if a Cognitive Behaviour Therapy (CBT) based self-help treatment for people with non-cardiac chest pain is effective in reducing anxiety and if it impacts on how people make sense of their chest pain. We would also like to explore if this kind of intervention is acceptable to these patients.

Your patient has been invited to take part because they have attended a Rapid Access Chest Pain Clinic and been told that their chest pain is non-cardiac.

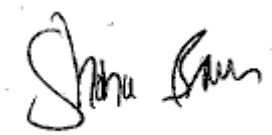
What will happen during the study?
Patients will be asked to complete questionnaires following their attendance at the Rapid Access Chest Pain Clinic. Following this some people who agree to participate in the study will be sent a cognitive behavioural therapy based self-help intervention immediately. Others will be randomised to receive the treatment booklet 12 months after attending the clinic. Patients will be informed when they will receive the intervention via a telephone call from Shona Brown (Principle Researcher and Trainee Clinical Psychologist). This phone call will provide patients with the opportunity to ask questions about the study.

We will then contact them by post and ask them to complete questionnaires in 3 months time, again in 6 months and finally in 12 months time.

Patients have been advised to contact their GP if they feel that they would like further help with any of the issues raised in the questionnaires or the treatment booklet.

Who has reviewed the study?
The study has been reviewed by the Ethics Committee and by senior members of staff within the University of Edinburgh.

Contact for Further Information
Should you wish to speak to someone about the study, you can speak to the principle investigator (Shona Brown, Telephone number: 0131 536 9128).



Shona Brown (Trainee Clinical Psychologist)
Address: Department of Clinical Psychology, Astley Ainslie Hospital, Edinburgh
Tel: 0131 537 9128
Email: shonabrown2@nhs.net

Appendix VII: Method and results of pilot study to develop intervention booklet.

It was decided that a pilot study to obtain the views on the intervention booklet of non-cardiac chest pain (NCCP) patients who have attended the Rapid Access Chest Pain Clinic (RACPC) would be advantageous. We aimed to recruit six individuals from the RACPC at a large Scottish hospital.

Method

The nurse delivering the clinic invited those with NCCP following clinic attendance to participate in a pilot study to evaluate a self-help booklet written for patients with NCCP. They were informed that this booklet was shortly to be evaluated in a research study. It was emphasised that participation was voluntary. If in agreement to participate the booklet and CD were given at the end of the clinic appointment and the participant informed that a researcher would be in touch via telephone in approximately one week to ask their views on the booklet. A4 and A5 copies of the booklet were included as we wished to ascertain which size participants preferred. A letter was included in the pack containing the booklet and the CD which thanked the individuals for agreeing to review the booklet and stated that we were particularly interested in their views on the following:

- The size of the booklet – did they prefer the large (A4) or the small (A5) version?
- What did they think of the name of the booklet "Non-Cardiac Chest Pain: What Can I do to Help Myself?"
- What did they think of the picture on the front of the booklet?
- What did they think of the different sections in the booklet?
- What did they think of the CD that comes with the booklet?

Two individuals agreed to participate. Due to the small numbers an additional participant from Cardiac Rehabilitation was therefore approached to participate. This individual had

previously experienced a cardiac event (a Myocardial Infarction) however had been seen by the service in relation to non-cardiac chest pain.

Results

Female, 53 years old, teacher.

- Preferred A5 format (A4 "too text heavy")
- Suggested that the title could be "snappier" and "more appealing". She felt that the original title of "Non-Cardiac Chest Pain" was "a bit dry". She was unsure what she would prefer but stated she believed that the first line should not read 'non-cardiac chest pain'. She wondered if something about getting on with life was preferable.
- She stated she thought the content was helpful and liked the pictures that were used, including the picture on the front cover.
- She thought that the exercises were a relevant inclusion and helpful for non-cardiac chest pain individuals. She thought the language used was "good".
- She stated that the '8 rules to help you cope 'was a good and helpful summary. She wondered if the importance of this could be emphasised.
- The original title of the appendix was 'Worksheets' which she felt has connotations of school and things being 'hard' work. She suggested that this section could be renamed "Activity sheets to help you"
- Where questions were used in the text she suggested using bullet points to help these stand out more.

Male, 48 years old, works in Information Technology.

- Preferred A4 format to read through but thought the A5 format was preferable given the inclusion of the diaries. He felt that the A5 format would be easier to transport and this would make it easier to complete the diaries.
- In relation to the title of the booklet he stated that this did not "jar" with him but that he thought the shorter the title, the better.
- He did not see the benefit of picture on the front page of the person holding their chest – he found this "silly". He suggested that just the university and NHS logos on the front cover would be preferable.
- He did not feel that the content was relevant to him. For example given that his chest pain could occur when he feels relaxed he did not view relaxation as relevant to him. He could see how this would be helpful for others. He felt that some of the content was patronising in tone, particularly the section regarding managing unhelpful thoughts. He viewed the underlying message in this section as "try not to think unhelpful thoughts" but stated that "it is not that easy".
- Overall message he took from the booklet was "we can't find what is wrong with you, therefore it must be you that is at fault". However he stated that not everyone would necessarily share this view and that perhaps the booklet was "better than nothing".

  He reported that he liked that the booklet was separated into different sections so that he could "dip" into those that seemed relevant.
- He thought that it would be particularly helpful for someone experiencing panic attacks.
- He commented on repetition of content in relation to written information and then inclusion of the same information in a diagram in the thoughts section in relation to the Jane vignette. He found this frustrating but stated that he the diagram may help others to understand the content.
- He commented that he liked the "bit at the back giving sources of further information".
- He wondered if the number of pictures could be reduced to make booklet shorter.

Male, 58, works in clinical research for a pharmaceutical company. Cardiac patient who also experiences medically unexplained chest pain.

- He liked the CD and the exercises on it.
- He stated that he thought the use of the term "non-cardiac" should be used less in the booklet as he thought it would be beneficial to reduce the use of jargon. He suggested the term "non-heart", or "chest pain". He liked the explanation of "non-cardiac" on the second page of the booklet.
- He queried the use of words like "outcomes", "strategies" and "tools" and wondered if people would understand what these mean. He suggested the use the words "ways" or "techniques" where possible. He also advocated the use of one term as much as possible as he felt that the alternation between different terms could potentially confuse those reading the booklet.
- He pointed out a typo error in the booklet.
- He liked the pictures used and stated that he thought the inclusion of pictures was important otherwise it would be too text heavy.
- He stated that the start of booklet could provide more guidance on how to use booklet. He suggested that instructions could be added on page three.
- He believed that people at the start of investigations are looking for a reason for pain. He felt that the different approach taken by the booklet (which he stated he took to be that there may not be a medical solution to pain but the important thing is that it is not life threatening) was important and potentially helpful.
- He stated that he himself is now accepting that his chest pain is there and that nothing "horrendous" is happening to him but that it took time to get to that point. When asked what had helped him to get to that point he reported that challenging his thoughts, and

using relaxation and mindfulness techniques had helped. He thought it was useful to have lots of the things he has used in a handy summary booklet and planned to keep the booklet to refer to.

- He felt that the booklet contained a useful message – there is something that can help.
- In relation to the section entitled "Further help for stress and low mood" he suggested changing the title to "Further Help" or "Other resources that may be helpful in managing non-cardiac chest pain" as the inclusion of stress and low mood may lead some to feel that the booklet aims to suggest that the pain is related to a mental health problem.
- He liked the '8 rules to help you cope' summary as felt it was a useful "cut out and keep" section.

Discussion

On the basis of this pilot study several amendments were made to the booklet. These are listed below:

- The error pointed out was amended.
- The title of the booklet was changed to "Managing Chest Pain".
- Instructions regarding how to use the booklet were added to page three.
- The terms "things you can do" or "strategies" were used as much as possible in relation to the techniques introduced in order to avoid the use of many different terms which may be confusing.
- Bullet points were used in the text when questions were used aiming to encourage participants to reflect on their own experience. This was suggested by one individual in order to help these questions "stand out more".
- The title of the "Further help for stress and low mood" section was changed to "Further Help". A sentence "Chest pain can lead to distress and is often stressful. If you feel you would like further help with stress and/or low mood the following resources may be

helpful" was added before then listing the references and the fact they can be obtained from local libraries, bookshops or online.

- The title of the appendix was changed from "Worksheets" to "Activity Sheets".

A limitation of this pilot study is that the views of only three individuals were sought. Given time constraints it was not practical to extend the recruitment period of the pilot study and delay recruitment of the major study. A further limitation was the potential bias introduced in terms of those who agreed to participate in the pilot – these individuals were highly educated and all in the 40-60 years age bracket. It would have strengthened the study to recruit individuals with a variety of educational experience and from different age ranges.