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Chronic low back pain and insomnia: Understanding the experience and attributions made by out-patients about sleeplessness, pain, and their interaction.

Paul S McKenzie

Doctorate in Clinical Psychology

The University of Edinburgh

August 2012
Experiences of insomnia and chronic low back pain

Declaration

Name: Paul McKenzie

Assessed work: Thesis

Title of work: Chronic low back pain and insomnia: Understanding the experience and attributions made by out-patients about sleeplessness, pain, and their interaction.

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ii
Dedication

For Clare, Grace and baby Bella. For their tolerance, love and support.
Acknowledgements

I would like to thank my supervisors Professor Kevin Power (KP) and Dr David Gillanders (DG) for their crucial advice, guidance and feedback throughout this thesis. This has been fundamental in completing this piece of work.

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Finally, I would like to thank family and friends for supporting me throughout this venture, and for tolerating my focus on it for such a long time.
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Word count: 34,980
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Thesis Abstract

Systematic Review: Chronic pain and insomnia are highly comorbid, and evidence suggests a reciprocal relationship between these. CBT-I has been shown to improve sleep in those with chronic pain, therefore the potential of improved sleep leading to improvements in pain symptoms is a possibility. This led to the question: Does CBT-I improve pain symptoms in those with chronic pain and insomnia? A systematic review of the literature was conducted resulting in eight papers regarding six studies. Evidence was moderate that CBT-I improved sleep and pain related disability, but did not improve self reported pain levels. This discrepancy between improvements in pain related disability and no changes in self-reported pain levels led to the research question for the empirical element of the current thesis.

Empirical Element of Thesis

Objective: Chronic low back pain (CLBP) is a common form of chronic pain that affects a large population each year. Chronic pain and insomnia are highly comorbid conditions, yet knowledge about how patients perceive their interaction is limited. This qualitative study aims to inform our understanding of the patient experience with particular reference to beliefs and attributions surrounding pain, poor sleep and their interaction.

Methods: 11 outpatients from a chronic pain clinic were recruited who suffered CLBP as their main symptom, and who had subsequently developed insomnia as a result. Data were analysed using Interpretative Phenomenological Analysis (IPA).

Results: Qualitative analysis produced five super-ordinate themes: 1) the privacy of pain and solitude of sleep; 2) sleep/pain interaction; 3) night-time thinking; 4)
adjustment and acceptance; and 5) self-management.

**Discussion:** The first three themes combine to create the individual experience of CLBP: the visceral, emotional experience; the pre-existing and shifting beliefs; and the thought content. Once this is in place, the individual can reflect on what this means to them, and through acceptance, move through to adjustment. The individual accepts elements of their current experience, but where they see the opportunity to take control, these adjustments are translated into actions relating to self-management.

These themes suggest CBT-I should be adapted to include pain specific beliefs to form a CBT for Insomnia and Chronic Pain (‘CBT-CPI’).
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Systematic Review

Title

Does CBT-I improve pain symptoms in adults with insomnia and chronic pain? A systematic review.

Abbreviated Title for Running Head

Does CBT-I improve chronic pain symptoms?

Planned submission to Health Psychology journal (Appendix 12)
1.1 Abstract

Objectives: Chronic pain and insomnia are highly comorbid and the relationship between these conditions is considered to be reciprocal. Cognitive Behavioural Therapy for Insomnia (CBT-I) has been developed to improve sleep in this cohort. The purpose of this systematic review was to assess the quality of evidence for the efficacy of CBT-I in improving sleep in adults with chronic pain, and determine if this reduced pain symptoms. Methods: An electronic database search was performed to identify potentially relevant literature. Databases searched were: PsycINFO; MedLine; Embase as well as SIGN and NICE guidelines and Cochrane Reviews. SIGN quality assessment criteria were used to evaluate studies. Results: 1,353 articles were identified and screened to meet inclusion criteria and eight articles (relating to six studies) met this. Articles included were rated by three assessors using a standardised assessment tool: seven were of moderate quality, one was of poor quality. All studies showed some improvements in different aspects of sleep, although total sleep time did not usually improve. There was moderate quality evidence to show that improved sleep quality (through CBT-I treatment programme) does not sustainably improve pain severity, but does improve daytime functioning in those with chronic pain and insomnia. Discussion: This review provides evidence for the positive influence of CBT-I on pain related symptoms for those with chronic pain and insomnia (which are highly comorbid). This suggests that greater implementation of CBT-I in pain management programmes could have wide ranging benefits to patients.

Keywords: CBT, sleep, insomnia, chronic, pain (five keywords)

Abstract word count: 241.
1.2 Introduction

Poor sleep is often found in those suffering chronic pain. In a recent study by Tang, Wright and Salkovskis (2007), prevalence of clinical insomnia was found to be 53% in an outpatient group attending a pain clinic (n=70), compared with only 3% of matched-healthy controls. It is likely that the number suffering poor sleep at a sub-clinical level is far higher. Sleep is considered a crucial determinant of global quality of life (Kyle, Morgan & Espie, 2010); its disruption in individuals with primary insomnia leads to impaired occupational, social and relationship functioning, even in the absence of medical co-morbidity.

Poor sleep has been shown to be a highly significant predictor of pain frequency or intensity the following day (Affleck et al., 1996; Edwards et al., 2008; Tiede et al., 2010), but this relationship is considered to be reciprocal (Smith & Haythornthwaite, 2004; Edwards et al, 2008) with pain also relating to poor sleep the following night (although the relationship in this direction appears less strong in magnitude).

In healthy individuals, restricting sleep experimentally can impair emotional regulation, cognitive function and heighten pain perception by compromising optimistic outlook and psychosocial functioning (Haack & Mullington, 2005). Irwin et al. (2012) showed that when those with a chronic pain condition (Rheumatoid Arthritis) were partially sleep deprived, this exacerbated their levels of pain the following day. Tang et al. (2012) also found that sleep quality was a consistent predictor of pain the next day, and that there was a pain-relieving effect during the
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following morning.

This work implies that perturbed sleep exerts an influence over pain perception and, therefore, may be subject to modification in those with both chronic pain and sleep disturbance. From the insomnia literature, it is clear that Cognitive Behavioural Therapy for Insomnia (CBT-I) is an effective therapy for improving both core insomnia symptoms and daytime functioning (Morin & Espie, 2003; Riemann & Perlis, 2009; Kyle, Morgan & Espie, 2010). Indeed, CBT-I is the recommended treatment of first choice not only for Primary Insomnia, but also for insomnia co-morbid with additional medical and psychiatric co-morbidities (Morin et al., 2006).

CBT-I includes a sleep restriction programme and an element of cognitive therapy. The former involves structuring bed and rise times to stabilise the circadian clock, as well as time in bed restriction. This creates mild sleep loss in the initial phases helping to consolidate sleep into a concentrated block and squeeze out excessive wakefulness in bed. There is usually at least one session devoted to addressing dysfunctional beliefs about sleep and the racing mind. Other components include relaxation therapy, sleep hygiene and stimulus control. It is proposed that CBT-I improves sleep via three main routes: (1) through behavioural priming of the dysregulated sleep homeostat and internal biological clock (circadian clock); (2) correction of maladaptive beliefs and attitudes towards sleep; and (3) reducing physiological & cognitive over-arousal during the sleep period.

Given that we know sleep restriction can heighten pain perception, and better sleep is
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associated with reduced morning pain levels, it seems logical to consider improving sleep in those with insomnia and chronic pain, with a view to potentially reducing their pain symptoms. The mechanism of how to go about this would seem to be to apply the method most commonly applied to insomnia, and shown to be effective in reducing sleep problems in those with chronic pain. As mentioned, there is good evidence to show the efficacy of CBT-I in improving sleep problems in those with chronic pain. Therefore, this would seem the first choice mechanism to explore whether it is effective in also having a positive effect on reducing chronic pain symptoms. Therefore, the primary research question concerning this systematic review is:

“Does improvement in sleep (using CBT-I) for those with insomnia co-morbid with chronic pain have a positive influence in reducing pain symptoms?”

On examining the existing reviews, it is apparent there are four that have referred to this question to varying degrees.

Firstly, a review by Menefee et al. (2000) provides a general appraisal of the literature relating to sleep disturbance and chronic pain. This includes describing the frequency and comorbidity of sleep problems in different chronic pain conditions, comorbid mood disturbances, and hypotheses about how pain and sleep interrelate. It also covers treatment approaches (pharmacologic and non-pharmacologic) of which CBT-I is only one of several. Of the seven citations of original research studies in the section regarding non-pharmacologic interventions, only one article is relevant to the current
systematic review (Morin, Kowatch & Wade, 1989) and this was an exploratory study with only three participants. The other articles did not address our primary question, focussing on either sleep modification in *non-pain* participants, or other non-pharmacologic treatments (*not CBT-I or similar*) in pain participants. With regard to treatment, the authors conclude non-pharmacologic interventions can improve sleep, but they make no assertions relating to impact on pain.

In the review by Smith and Haythornthwaite (2004), the authors focussed on how poor sleep and chronic pain inter-related. To do this they referred to longitudinal and cognitive behavioural clinical trials literature. In their review, out of the 13 articles they identified as relevant to their purpose, three studies and two case studies related to cognitive and/or behavioural interventions for insomnia. The first of two case studies (Morin, Kowatch & Wade, 1989; Morin, Kowatch & O’Shanice 1990) was relevant to the current research question, although the second was not (participants did not have chronic pain). Of the three studies, one related to cancer pain patients (Cannici, Malcolm & Peek, 1983) and solely involved Progressive Muscle Relaxation techniques as the intervention (i.e. not a CBT-I programme) and was therefore not relevant to the current systematic review. Another study (Lichstein, Wilson & Johnson, 2000) included participants with either a psychiatric or medical condition considered to precipitate and aggravate their insomnia. Pain was not assessed as an outcome measure, therefore the study was again not relevant to the current review. The remaining study (Currie et al., 2000) is included in the current review. The Smith and Haythornthwaite (2004) review concluded that due to the small samples and restricted ranges for pain ratings, findings were limited, and nonspecific factors may
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account for changes identified in participant groups. It did not provide a search methodology, and the articles included did not provide sufficient breadth of evidence to adequately address the primary research question of the current review.

The third review identified was Smith, Huang and Manber (2005), and the author’s focus was on describing poor sleep and the use of CBT-I in a broad range of medical and psychiatric disorders. It included 15 articles regarding the efficacy of CBT-I in a range of disorders, two of which related to chronic pain conditions (Morin et al., 1989; Currie et al., 2000). Both of these are included in the current systematic review. The authors concluded that this provided some evidence for the efficacy of CBT-I in reducing chronic pain. No search methodology was provided, and provided insufficient breadth of evidence to adequately address our primary research question.

The most recent review was conducted by Roehrs (2009) and had the benefit of being undertaken in 2008, therefore being able to draw on more recent research. It questioned if effective management of sleep disorders using either pharmacological therapies or CBT-I improves pain symptoms in patients with pain. Considering this review, it was apparent there were potentially four reasons why it requires updating.

Firstly, the Roehrs (2009) review includes three studies relating to the efficacy of CBT-I, and only two additional studies were included over the previous reviews mentioned (Edinger et al., 2005; Vitiello et al., 2007) in addition to the Currie et al. (2000) study. The Edinger et al. (2005) study is comprehensive, but the Vitiello et al. (2007) study was reported in the form of abstract only, therefore the quality and
findings of this study could not be fully assessed by the review on this basis alone. The author is aware this abstract has since been developed into a published journal article (Vitiello et al., 2009), therefore is now possible to fully critique. All three articles mentioned are included in full in the current systematic review.

This brings us to the second reason: the review was conducted 4 years ago, and with the current high rate of publications in the area of chronic pain, it was considered prudent to conduct a search that would ensure that any new evidence was identified.

Thirdly, the review did not use a standardised measure to assess the quality of the studies it cites, and therefore may have been subject to reviewer bias (i.e. was a literature review rather than a systematic review). Systematic reviews are the preferred ‘gold standard’ method for assessing the available literature, to provide a structured, rigorous, replicable and transparent method of assessing not only the results of a study, but the quality of the methodology employed. From this, a clear picture of whether the literature supports a specific research question/hypothesis can be more completely assessed.

Finally, the Roehrs (2009) review concluded that it could not confidently answer the primary research question that is posed by the current review, recognising that evidence was limited. The authors reported that the three studies included showed improvements in sleep, and two showed improvements in chronic pain for those with various pain conditions (excluding fibromyalgia) and osteoarthritis. The study involving fibromyalgia participants did not show improvement in pain symptoms.
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Taking all these factors into account, this review provides insufficient evidence to confidently answer our primary research question, but sufficient evidence to warrant further investigation in this area.

Notably, a Cochrane review “Psychological therapies for the management of chronic pain (excluding headaches) in adults (Review)” (2009) did not include CBT-I as a treatment for those with comorbid insomnia and chronic pain.

SIGN 50: A Guideline Developer’s Handbook, (Scottish Intercollegiate Guidelines Network, 2011) uses the terminology of ‘considered opinion’ to conclude whether the existing reviews provide evidence that confidently addresses a primary research question. This is the national standard for developing health related guidelines for the National Health Service in Scotland. Therefore, in addition to assessing the quality of existing reviews, the author must consider the relevance of the reviews regarding the particular question that is being posed.

After assessing all the available reviews using SIGN 50 criteria (Methodology Checklist 1: Systematic Reviews & Meta- Analyses), it is the author’s considered opinion that they do not answer the primary research question posed by the current review with any certainty. This was primarily due to lack of evidence at the time of each review, lack of a transparent systematic methodology and lack of standardised quality assessment. It was therefore deemed essential to conduct a systematic review of the most up-to-date literature to adequately address the primary research question.
1.3 Method

1.3.1 Search strategy

An electronic database search was performed to identify potentially relevant literature. Databases searched were: PsycINFO; MedLine; Embase as well as SIGN and NICE guidelines and Cochrane Reviews. Limits set on the search were to include articles from 1989 onwards in English. This time limit was based on the first exploration of behavioural management of sleep problems concurrent with chronic pain (Morin, Kowatch & Wade, 1989). This study was also included in the review. The database searches used a strategy of searching keywords in text.

Keywords: ‘CBT’ or ‘cognitive’ or ‘behaviour’ or ‘behavioural’ and ‘pain’ and ‘sleep’ or ‘insomnia’.

After an initial screening of article titles, relevant abstracts were read and where necessary full text copies obtained to compare against inclusion criteria. In addition, the references of the retrieved papers were hand searched for previously not included and identified studies. Comparability of studies selected was assessed based on inclusion criteria below. Authors of selected studies were contacted by personal correspondence if further clarification of their work was required, or if they described relevant future research in their article.
1.3.2 Inclusion criteria

The criteria to retain original research studies for our systematic review were:

- Studies were published in English.
- Studies were original publications.
- Studies explicitly addressed the relationship between poor sleep and chronic, non-cancer pain, assessing these as outcomes.
- Studies were intervention studies including the use of Cognitive Behavioural Therapy for Insomnia (CBT-I). This in effect excluded other behavioural therapies for insomnia, such as hypnosis or sleep hygiene.
- Studies used patient populations with chronic pain.
- Studies included participants aged 18 years and over.

Note: studies assessing non-chronic pain or using participants who did not suffer chronic pain were excluded. Any ambiguities were resolved in discussions with collaborating researcher (KP).

1.3.3 Methodological quality criteria

To investigate the variability within the literature, the quality of reporting was evaluated using the SIGN 50 guideline. This is used by NHS Scotland when creating future health care guidance, and as part of this, provides specific guidelines to follow when undertaking a systematic review of available evidence. As part of this, it includes checklists to assess the quality of original intervention studies.
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To assess the quality of literature to be included in the current review, ‘Methodology Checklist 2: Randomised Controlled Trials’ from SIGN 50 was used (Appendix 1). The checklist is used to grade whether elements of a study met various standards in terms of addressing a clearly focussed and appropriate question, randomisation, concealment, blinding, treatment and control group similarities, intervention content, control group content, measures used, drop-out rates, follow-up period, intention to treat analysis, statistical analysis and multi-site consistencies (where relevant). The scoring criteria are also included (Appendix 2).

The author of this review (PM) coded the quality of reporting. Collaborating researchers (KP & JJ), who are familiar with SIGN 50, checked all included studies (n=8; with four studies allocated to each collaborating researcher) to ensure adherence to the coding criteria. Any emerging discrepancies were resolved in discussions.
1.4 Results

Figure 1 illustrates the outcome of the search path employed using a flowchart, regarding intervention studies of CBT-I in those with chronic pain. Common reasons for exclusion at the last stage were: 1) no measurement of pain at outcome despite participants having a chronic pain condition, and a focus on the efficacy of CBT-I regarding sleep in a chronic pain population; 2) participants not being chronic pain sufferers (often healthy subjects with artificial measurements of pain implemented); or 3) sleep problems being artificially controlled through experimental sleep deprivation i.e. participants did not have clinical insomnia.

![Flowchart of search pathway]

Figure 1. Original article search pathway

The following eight articles (relating to six studies) shown in Table 1 met the inclusion
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criteria: Morin, Kowatch and Wade (1989); Currie et al. (2000); Currie et al. (2002); Edinger et al. (2005); Rybarczyk et al. (2005); Vitiello et al. (2009); Jungquist et al. (2010); and Miro et al. (2011). These are briefly outlined below.
<table>
<thead>
<tr>
<th>Author/ Date/ Country</th>
<th>Participants</th>
<th>Treatment &amp; Controls</th>
<th>Measures</th>
<th>Follow Up</th>
<th>Drop-out &amp; intent to treat (ITT) analysis</th>
<th>Findings</th>
<th>Strengths</th>
<th>Limitations</th>
<th>Study Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morin, Kowatch &amp; Wade, (1989) USA</td>
<td>All had back pain with additional neck, shoulder or leg pain. n=3 35 -46 years old</td>
<td>6 weekly individual sessions: BT-I n=3</td>
<td>Sleep and pain diary; nocturnal PSG; BDI; STA; &amp; POMS.</td>
<td>6 months</td>
<td>BT-I n=0 (0%)</td>
<td>Improvements in sleep (diary TST, SOL, WASO &amp; EMA), anxiety &amp; depression. No average change in pain. Pt.1 stopped sleeping tablets; Pt.2- stopped pain medications; Pt.3- lower nocturnal pain (mirroring sleep improvements).</td>
<td>Follow-up timescale; PSG used pre-post; shows improvements and variability of individual responses.</td>
<td>Small number of participants; not ‘pure’ CBT-I.</td>
<td>-</td>
</tr>
<tr>
<td>Currie et al. (2000) Canada</td>
<td>Musculo-skeletal pain (excluding FM). n=60 29 -59 years old</td>
<td>7 weekly group sessions: CBT-I n=32 WLC n=28</td>
<td>Sleep diary; actigraphy; PSQI; MPI-PS; BDI; &amp; MQS.</td>
<td>3 months</td>
<td>CBT-I = 6/32 (18.8%) WLC = 3/28 (10.7%) (ITT used)</td>
<td>Sleep (diary SE, SOL, WASO, &amp; PSQI) improved in CBT-I v WLC (TST &amp; actigraphy movement was not). No group x time effects for pain severity.</td>
<td>First RCT comparing CBT-I with control; actigraphy used; reported clinical significance.</td>
<td>Sample size; WLC had different therapist exposure; not blinded/ randomised; ITT used for 9/60 (15%) results; no power reported.</td>
<td>+</td>
</tr>
<tr>
<td>Currie et al. (2002) Canada</td>
<td>Musculo-skeletal pain (excluding FM), n=51 29 -59 years old</td>
<td>7 weekly group sessions: CBT-I n=32 WLC/ CBT-I n=19</td>
<td>Sleep diary; MPI-PS; &amp; RMDQ.</td>
<td>12 months</td>
<td>CBT-I = 6/32 (18.8%) WLC = 3/28 (10.7%) (ITT used)</td>
<td>Within group changes: sleep (diary SE, SOL, WASO, &amp; PSQI) improved as did pain severity &amp; pain related disability. Improved v Unimproved groups – pain related disability improved but pain severity did not.</td>
<td>Good follow-up; control group used; clinically significant change analysed; PRD measure used.</td>
<td>Post hoc statistics based on Currie et al., (2000). No control group.</td>
<td>+</td>
</tr>
<tr>
<td>Edinger et al. (2005) USA</td>
<td>Fibromyalgia n=47 21 -65 years old</td>
<td>6 weekly individual sessions: CBT-I n=18 SH n=18 UC n=11</td>
<td>Sleep diary; ISQ; actigraphy; SF-36; MPQ; BPI; POMS</td>
<td>6 months</td>
<td>CBT-I = 12/18 (66.7%) SH = 11/18 (61.1%) UC = 4/11 (36.4%) (ITT used)</td>
<td>Sleep (diary SE, SOL, &amp; TWT) improved in CBT-I v WLC (WASO &amp; TST were not). SH+ group had reduced pain severity. No such effect for CBT-I or UC groups.</td>
<td>Polysomnography screening; control group used; follow - up; CONSORT statement; actigraphy used; treatment credibility assessed.</td>
<td>Small sample; Fibromyalgia only; high drop-out; SH not a clear control; not blinded/ randomised; no power calculations.</td>
<td>+</td>
</tr>
</tbody>
</table>
Experiences of insomnia and chronic low back pain

Table 1. Summary of Original Research (contd.)

<table>
<thead>
<tr>
<th>Author/ Date/ Country</th>
<th>Participants</th>
<th>Treatment &amp; Controls</th>
<th>Measures</th>
<th>Follow Up</th>
<th>Drop-out &amp; intent to treat (ITT analysis)</th>
<th>Findings</th>
<th>Strengths</th>
<th>Limitations</th>
<th>Study Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rybarczyk et al. (2005) USA</td>
<td>OA; COPD; CAD, n=92 &gt;54 years old</td>
<td>8 weekly group sessions: CBT-I n=46; SMW n=46</td>
<td>Sleep diary; PSQI; SII; DBAS; POMS; GDS; SF-36; SF-MPQ; SIP; ITEQ.</td>
<td>Pre-Post</td>
<td>CBT-I = 2/48 (4.2%) SMW = 2/48 (4.2%) (analysis based on n=92)</td>
<td>Sleep (diary SE, SOL, WASO, TTB &amp; PSQI) improved in CBT-I v SMW (TST was not). No group x time effect for pain severity, but reduced for sleep impairment (interference).</td>
<td>Low drop-out; better sample size; control group used; randomisation to treatment described.</td>
<td>Assessors not blinded; no follow-up/ randomisation/ power calculations; over 55s only.</td>
<td>+</td>
</tr>
<tr>
<td>Vitiello et al. (2009) USA</td>
<td>OA n=51 &gt;54 years old</td>
<td>8 weekly group sessions: CBT-I n=23; SMW &amp; CBT-I n=28</td>
<td>Sleep diary; SF-36; SF-MPQ; GDS.</td>
<td>12 months</td>
<td>CBT-I = 4/23 (17.4%) SMW &amp; CBT-I = 16/28 (57.1%) (ITT used)</td>
<td>Pre-post: sleep (diary SE, SOL, &amp; WASO) &amp; pain severity improved for CBT-I v SMW. Post: sleep, SE, SOL, WASO &amp; TST improved in combined CBT-I &amp; SMW crossovers (within group). Positive group x time effect for pain severity.</td>
<td>Good follow-up; control group used partially; cross-over participants used.</td>
<td>No control for 1 year follow-up; over 55s only; low ‘opt-in’ to combined treatment.</td>
<td>+</td>
</tr>
<tr>
<td>Jungquist et al. (2010) USA</td>
<td>Chronic pain originating from the spine. n=28 &gt;25 years old</td>
<td>8 weekly individual sessions: CBT-I n=19; PTC n=9</td>
<td>Sleep &amp; pain diary; MPI-PS/PI; PDI; MFI.</td>
<td>Pre-Post</td>
<td>CBT-I = 4/19 (21.1%) PTC = 3/9 (33.3%) (ITT used)</td>
<td>Sleep (diary SE, SOL, WASO, &amp; NWAK) improved in CBT-I v PTC (TST &amp; EMA were not). Pre-post pain severity improvement in CBT-I (not evident in SMW).</td>
<td>Detailed report of managing missing data; control group used; detail of CBT-I session content.</td>
<td>Randomisation not described; no blinding/power calculations; high drop-out; small sample size.</td>
<td>+</td>
</tr>
<tr>
<td>Miró et al. (2011) Spain</td>
<td>Fibromyalgia. n=44 females 25-60 years old</td>
<td>8 weekly group sessions: CBT-I n=22; SH n=22</td>
<td>ANT-I; Spanish versions of: PSQI; MPQ; HADS; FIQ.</td>
<td>Pre-Post</td>
<td>CBT-I = 2/22 (9.1%) SH = 2/22 (9.1%)</td>
<td>Sleep (PSQI) &amp; daily functioning (FIQ) improved CBT-I v SH. Pain severity not improved.</td>
<td>Blinding to group allocation; control group used.</td>
<td>Female only FM; treatment groups age difference; sample size.</td>
<td>+</td>
</tr>
</tbody>
</table>

**Interventions:** B-T-I (Behavioural Therapy for Insomnia – i.e. sleep restriction and stimulus control); CBT-I (Cognitive Behavioural Therapy for Insomnia); WLC (Waiting List Control); SH (Sleep Hygiene); PTC (Placebo Therapist Contact); UC (Usual Care); SMW (Stress Management & Wellness).  

**Measures & questionnaires:** MPI-PS/PI (Multidimensional Pain Inventory - Pain Severity Scale/Pain Interference Scales); RMDQ (Roland-Morris Disability Questionnaire); SF-36 (Medical Outcomes Survey 36-Item Short-Form Health Survey); STAI (State-Trait Anxiety Inventory); MPQ (McGill Pain Questionnaire); SF-MPQ (Short-Form McGill Pain Questionnaire); BPI (Brief Pain Inventory); SII (Sleep Impairment Index); GDS (Geriatric Depression Scale); SIP (Sickness Impact Profile); PDI (Pain Disability Index); PSQ (Pain Disability Index); MFI (Multidimensional Fatigue Index); MQS (Medication Quantification Scale); FIQ (Fibromyalgia Impact Questionnaire); PRD (Pain Related Disability); ANT-I (Attentional Network Test – Interactions); PSQI (Pittsburgh Sleep Quality Index).  

**Sleep and pain abbreviations:** PS (Self-reported pain severity); PRD (Pain Related Disability); SE (Sleep Efficiency – i.e. time asleep as a percentage of time spent in bed); SOL (Sleep Onset Latency – i.e. time taken to fall asleep); WASO (Waking After Sleep Onset – i.e. time awake during the night after having first fallen asleep); TST (Total Sleep Time in bed); TWT (Total Wake Time in bed); TTB (Total Time in Bed); NWAK (Number of Awakenings throughout the night); EMA (Early Morning Awakening – i.e. the time awake in the morning prior to planned awakening time).
1.4.1 Study characteristics

Morin, Kowatch and Wade (1989) conducted the first study to use a behavioural therapy approach with chronic pain participants. This was an exploratory study with three participants aimed at testing if the sleep restriction techniques used in a healthy insomnia population (Borkovec, 1982; Morin & Kwantus, 1988) would translate for those with a chronic pain condition. Although this study does not use a ‘pure’ CBT-I intervention, it forms the basis for the majority of content for all current CBT-I programmes, therefore this contribution was relevant enough for inclusion.

Currie et al. (2000) conducted an intervention study that implemented group CBT-I and a Waiting List Control (WLC) with a 3-month follow-up. Participants were adults with insomnia and chronic musculo-skeletal pain (excluding fibromyalgia). There were 60 participants at the outset, and 51 were followed up at 3 months.

The Currie et al. (2002) article analysed the data from the Currie et al. (2000) study, with key findings relating to pre-post change in group means, clinical improvement (and predictors), and comparison of improved and unimproved insomniacs. It did not focus on treatment group membership (i.e. efficacy of individual treatments), but instead on the relationship between changes in sleep compared with other variables. Results from the Roland and Morris (1983) Disability Questionnaire (RMDQ), which is a measure of pain-related disability was included - this was previously gathered but not analysed in Currie et al. (2000). This analysis used 51 of the original study’s
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participants, as this was the number who completed all three assessment time-points (pre-post, and 3-month follow-up).

The Edinger et al. (2005) study involved 47 adult participants with both fibromyalgia and insomnia. Participants were split into three groups where they received individual treatment: CBT-I; Sleep Hygiene; and Usual Care. These were assessed at baseline, post-treatment and 6 months later. 42 continued into the treatment phase and 20 continued to be assessed at 6-month follow-up.

The participants in the Rybarczyk et al. (2005) study were all 55 years or older, had insomnia, and had one or more of three health conditions: osteoarthritis (OA, n=51); chronic obstructive pulmonary disease (COPD, n=17); or coronary artery disease (CAD, n=38). Treatment was undertaken on a group basis, comparing CBT-I and a Stress Management and Wellness control. Measures were taken at pre-post treatment, and the study involved 92 participants initially, falling to 88 who were assessed at post-treatment.

In Vitiello et al. (2009) the authors re-analysed the data gathered for the 51 osteoarthritis participants from the Rybarczyk et al. (2005) study, and added to it data gathered at 12-month follow-up. The focus of this article was towards assessing if there was a link between improvements in pain and improvements in sleep quality. The Short Form 36 Health Survey (SF-36) Bodily Pain Subscale that was assessed but previously not analysed was also included in this article. In addition, the data from those in the Stress Management and Wellness control group who were later crossed
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over to CBT-I treatment was analysed alongside this. Where the Rybarczyk et al. (2005) study used analysis of variance; here the authors used within-subjects pre-post changes in each of the two groups due to small participant numbers.

Jungquist et al. (2010) recruited 28 participants who had insomnia and chronic back and/or neck pain. Participants underwent individual CBT-I or a control where therapist exposure was matched, and elements highlighted on the returned Beck Depression Inventory (BDI) were discussed. Measures were taken at baseline and post-treatment only, and from the original 28 assessed, 21 participants received treatment and were assessed post-treatment.

Finally, in Hiró et al. (2011), the study primarily focussed on a group of adult females with fibromyalgia, assessing the impact of CBT-I (n=20) versus Sleep Hygiene (n=20) on three attentional networks (alertness, orienting and executive function). Other outcome measures included were sleep, pain, depression, anxiety and daily functioning, and all measures were taken at baseline and post-treatment.

1.4.2 Quality assessment

Table 2 summarises some of the key areas assessed by SIGN 50: Checklist 2 (Randomised Control Trials), as well as the assigned quality and relevance rating for each study. As in the assessment of existing reviews, this score relates not only to the quality of the study, but also to the extent that the study addresses the primary research question. Therefore, a study can be allocated a ‘-‘ score despite having a rigorous methodology if it was focussed on investigating a related, but different hypothesis. All
eight studies were firstly rated by PM, then, to ensure inter-rater reliability, JJ rated the first four whilst KP rated the second four. There were no discrepancies to the summary quality scores given.

One study was classified as ‘-‘ (poor) as this was a pilot study with only three participants (Morin et al., 1989), and conclusions from this were therefore difficult to generalise. The remaining seven articles reached a classification of ‘+‘ or of moderate quality, although it should be noted that had participant numbers been greater in four of these (Rybarczyk et al., 2005; Vitiello et al., 2009; Jungquist et al., 2010; Miró et al., 2011), they would have been allocated a ‘++‘ rating by assessors.
Table 2. SIGN 50 quality assessment of original research

<table>
<thead>
<tr>
<th>Author/ Date/ Country</th>
<th>1.1 Clear focus</th>
<th>1.2 Randomisation</th>
<th>1.3 Concealment</th>
<th>1.4 Blinding</th>
<th>1.5 Matched groups</th>
<th>1.6 Control of confounds</th>
<th>1.7 Measures</th>
<th>1.8 Attrition</th>
<th>1.9 ITT analysis</th>
<th>1.10 Multisite</th>
<th>Evidence rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morin, Kowatch &amp; Wade (1989), USA</td>
<td>Adequately addressed</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Poorly addressed</td>
<td>Poorly addressed</td>
<td>Adequately addressed</td>
<td>Not applicable</td>
<td>Morphine</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>-</td>
</tr>
<tr>
<td>Currie et al. (2000), Canada</td>
<td>Adequately addressed</td>
<td>Poorly addressed</td>
<td>Not applicable</td>
<td>Adequately addressed</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>CBT-I = 6/32 (18.8%) WLC = 3/28 (10.7%)</td>
<td>Adequately addressed</td>
<td>Not applicable</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Currie et al. (2002), Canada</td>
<td>Adequately addressed</td>
<td>Poorly addressed</td>
<td>Not applicable</td>
<td>Adequately addressed</td>
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<td>CBT-I = 6/32 (18.8%) WLC = 3/28 (10.7%)</td>
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<td>+</td>
<td></td>
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<tr>
<td>Edinger et al. (2005), USA</td>
<td>Adequately addressed</td>
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<td>Not applicable</td>
<td>Adequately addressed</td>
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<td>Not applicable</td>
<td>CBT-I = 12/18 (66.7%) SH = 11/18 (61.1%) UC = 4/11 (36.4%)</td>
<td>Adequately addressed</td>
<td>Not applicable</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Rybarczyk et al. (2005), USA</td>
<td>Adequately addressed</td>
<td>Poorly addressed</td>
<td>Not applicable</td>
<td>Adequately addressed</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>CBT-I = 12/18 (66.7%) SH = 11/18 (61.1%) UC = 4/11 (36.4%)</td>
<td>Adequately addressed</td>
<td>Not applicable</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Vitiello et al. (2009), USA</td>
<td>Adequately addressed</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Adequately addressed</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>CBT-I = 12/18 (66.7%) SH = 11/18 (61.1%) UC = 4/11 (36.4%)</td>
<td>Adequately addressed</td>
<td>Not applicable</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Jungquist et al. (2010), USA</td>
<td>Adequately addressed</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Adequately addressed</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>CBT-I = 12/18 (66.7%) SH = 11/18 (61.1%) UC = 4/11 (36.4%)</td>
<td>Adequately addressed</td>
<td>Not applicable</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Miro et al. (2011), Spain</td>
<td>Adequately addressed</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Adequately addressed</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>CBT-I = 2/22 (9.1%) SH = 2/22 (9.1%)</td>
<td>Adequately addressed</td>
<td>Not applicable</td>
<td>+</td>
<td></td>
</tr>
</tbody>
</table>

SIGN 50 Questions of internal validity

1.1 The study addresses an appropriate and clearly focussed question.
1.2 The assignment of subjects to treatment groups is randomised.
1.3 An adequate concealment method is used.
1.4 Subjects and investigators are kept ‘blind’ about treatment allocation.
1.5 The treatment and control groups are similar at the start of the trial.
1.6 The only difference between groups is the treatment under investigation.
1.7 All relevant outcomes are measured in a standard, valid and reliable way.
1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?
1.9 All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)
1.4.3 Key Findings

The key findings of each of the eight journal articles are briefly outlined below, with particular regard to outcomes of sleep quality and pain severity, amongst others.

It is difficult to draw conclusions based on such limited participant numbers as in the Morin, Kowatch and Wade (1989) study. Although there were improvements in self-reported pain severity, this was parallel to improvements that, had they occurred alone, may have increased pain severity. For instance, two participants stopped taking pain medications during the study—had they done so in isolation, one would usually expect pain severity to increase (as pain blocking decreased). No such response was shown and pain severity remained similar. This would indicate that reductions in pain severity may have been allowing participants to reduce their pain blocking medications without an increase in pain severity. This evidence was considered to be of poor standard in terms of answering the research question, therefore these results are not influential with respect to our conclusions in this systematic review.

In Currie et al. (2000), although some measures of sleep improved significantly in the CBT-I group, the measure of subjective pain severity did not match this suggests the improvements in sleep were either insufficient to impact on pain levels and therefore have no causal relationship.
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In Currie et al. (2002), a measure of pain related disability was included. When discounting treatment group membership, there were significant pre-post differences in pain severity as well as pain related disability. As both sleep and pain improved, this implies a link between improved sleep and reduced pain levels, but discounts a particular intervention as being responsible for this. This analysis created an artificial comparison grouping whereby intervention type became irrelevant, and rate of improvement, regardless of treatment, was the main focus alongside outcome measures.

The benefit of this is that any of the unsuccessful CBT-I treatments are effectively filtered out of the hypothesised relationship, and any of the positive placebo effects from the control group are included. We can see how improvements in sleep related to changes in pain severity. This study showed that self-reported improvements in sleep correlated with reductions in not only pain severity self-report, but also in reducing pain related disability. This suggests improving sleep in those with chronic pain may account for the improvements in these areas, but as this does not relate to a specific intervention, may be accounted for by other uncontrolled variables.

Edinger et al. (2005) showed when looking at the fibromyalgia population that again, CBT-I could be effective in improving some aspects of sleep in those with insomnia. There was some difficulty in directly bringing out a relationship between improved sleep and pain symptoms in this study. The CBT-I group did not significantly report improved pain severity scores, but the Sleep Hygiene group did. On analysis, a ‘Sleep Hygiene Plus’ subgroup seemed responsible for the pain improvements reported in the
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main Sleep Hygiene group. The authors deduced this subgroup was implementing some CBT-I strategies, particularly reducing the time spent in bed when unable to sleep (a key element of CBT-I). This Sleep Hygiene Plus subgroup (who had improved sleep efficiency, sleep onset latency and time awake after sleep onset) reported reductions in pain severity, which might indicate a positive relationship between these variables. Against this is the CBT-I group where no such improvements in pain severity were noted, therefore making the findings unclear.

In Rybarczyk et al. (2005), despite improvements in several areas of sleep, there were no improvements in self-reported levels of pain, although there was a significant improvement in the Sleep Impairment Index (SII) – Interference subscale. It is this latter result that highlights the lack of change in pain self-report. This indicates that pain related disability reduces, but pain is perceived to remain the same. We therefore see the data present a discrepancy between participant perceptions about chronic pain and the behaviours that participants assert a reduction in pain results in. One hypothesis might therefore be that real reductions in pain may be allowing participants to become more active, but when they reflect on their pain and try to score it, these ideas may be more fixed or entrenched leading to results that do not change. It is here that illness perceptions and expectations of how likely change is to occur, become important in our understanding. The benefits of reduced pain may be behaviourally demonstrated, but the perception may be that pain remains the same. This may also reflect on the content of CBT-I where most sessions relate to sleep reduction or change strategies, and often only one session relates to cognitive elements or reframing of the condition.
Vitiello et al. (2009) demonstrated that at pre-post treatment the CBT-I group showed significantly better improvement in sleep (for sleep efficiency, waking after sleep onset and sleep onset latency) and this was mirrored in the SF-36 bodily pain (BP) subcomponent, which was also significantly reduced. This indicates a link between improved sleep and pain severity, and is supported by results from the Short Form McGill Pain Questionnaire (SF-MPQ) that also reported improvements showing a non-significant trend in this direction. So at post-treatment at least, there was a significant difference between CBT-I and the Stress Management and Wellness control, supporting the hypothesis that improving sleep through CBT-I can improve pain severity.

Despite the small numbers etc., the results suggest a link between improving sleep and reducing pain. Further to this, the combined CBT-I and crossover group data showed significant within-participant improvements at 1-year in sleep efficiency, waking after sleep onset and sleep onset latency as well as total sleep time. Simultaneously, there was a significant within-participant reduction in pain levels as assessed by the SF-MPQ although not so with the SF-36 BP (although a non-significant trend of reducing levels of pain was apparent). It should be noted, there was no 1-year follow-up of Stress Management and Wellness participants that did not cross over to CBT-I, therefore we cannot tell if, for example, their sleep did not improve over the year, alongside a reduction in pain levels. We cannot confidently say that the sleep improvements are therefore responsible for pain reductions, but it does suggest the possibility of a strong link between the two.
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In the Jungquist et al. (2010) study, sleep was improved in terms of sleep onset latency, waking after sleep onset, number of night time awakenings and sleep efficiency with large effect sizes for the CBT-I group over the control, although showing no improvement in the total sleep time between groups. An important component of the insomnia definition is sleep efficiency, and the CBT-I group had several more that reached the >90% sleep efficiency rate. An improvement in sleep efficiency coupled with no significant change in total sleep time simply means less time spent in bed while awake (although there was a trend towards this, it was at a non-significant level). Although the author reported results that were “equal or better” than other previous studies, total sleep time is an important measure. If a good total sleep time allows for better mood regulation, (whether this be a physiological or psychological consequence) then this aspect of the various sleep measures may be a crucial one. Potentially it may be continuity of sleep, or some other aspect of sleep that is more important in its relationship with pain (see Smith et al., 2007, regarding discussions of sleep fragmentation versus sleep restriction).

Similar to Rybarczyk et al. (2005), Miró et al. (2011) found improvements in sleep as well as improvements in daily functioning despite no improvements in self-reported pain severity. This again raises the disparity between improvements in functioning occurring in a seeming contradiction with pain levels, and highlights that the cognitions and personal experience of the individual regarding pain and changes in sleep is complex. One hypothesis that might explain this is that the views held on the ability to make changes to chronic pain may be more rigid, whilst behaviours relating to associated disability are more malleable to change.
Therefore, although not conclusive at this stage, when combining these studies it would appear that where there are improvements in self-reported sleep (commonly sleep efficiency, time awake after sleep onset and sleep onset latency), there is often either an improvement in levels of self-reported pain and/or improvements of pain related disability. This does not always relate directly to the CBT-I treatment modality though, but there may be subgroups within the chronic pain population who may respond differently depending on their condition or baseline measures of pain and/or insomnia. The quality assessment of these studies has shown they have limitations when considered alone, but that on balance they provide a strong argument when their results are considered together. It seems more likely than not that there is a causal link between improving sleep (often by CBT-I), and subsequent improvement in pain related disability/daytime impairments in those with chronic pain conditions. There does not appear to be evidence for reducing pain severity by this mechanism.

1.4.4 Limitations of existing literature

As shown in the summary Table 2 there are several weaknesses to each of these studies. There was some variability in CBT-I treatments in terms of trainer expertise, number and content of sessions, and whether this was administered in a group or individual manner. These factors did not appear to affect the credibility of the intervention for any of the studies, and there were no significant differences between studies in terms of sleep improvements. Any differences in pain outcomes cannot be stated robustly due to the difficulty in comparing such diverse studies.
Vitiello et al. (2005) combined CBT-I and Stress Management and Wellness/CBT-I crossover groups and focussed on within-subjects changes. No control group was used for the one-year crossover element of analysis. There are other measures included in some studies such as mood and medications, but as these are inconsistent across studies, direct comparisons are difficult to make. Specifically, if medications are not controlled, we may see variations that counter the benefits of CBT-I treatment. The outcomes may be limited sleep improvements, but a reduced reliance on hypnotic medications. This makes a relationship between sleep and pain more difficult to establish. Several of the studies suffered high dropout rates, and in general these studies are likely to suffer from low power due to modest participant numbers. A weakness of the studies is also that power calculations were not reported, and this was reflected in their quality grading.

The studies vary in follow-up up length, which is potentially crucial if there are time delays in perceptual shifts about pain levels. Whereas clinically relevant changes in sleep were defined, no study defined clinically relevant changes in pain. All studies measured pain in terms of statistically significant change between baseline and either immediately post treatment and/or at follow-up. This means that some smaller improvements that have a real benefit to participants may not be highlighted. In Currie et al. (2000, 2002), pain statistics were done post hoc, meaning some bias may have been inadvertently involved in their implementation.
1.5 Discussion

1.5.1 Clinical implications

Regardless of mechanism, the studies included in this systematic review indicate positive benefits for those with chronic pain and insomnia who undertake a CBT-I treatment intervention. Existing Pain Management Programmes are based on behavioural principles, and as such, implementing more in-depth behavioural sleep work would be feasible with a CBT-I programme that is highly structured and well established, offering the additional aspect of cognitive reframing. Some clinical implications of CBT-I in those with chronic pain are:

1.5.1.1 Improvements in mental health

Even if improving sleep does not reduce pain levels significantly, we know that there are significant benefits to be gained from better sleep alone, such as improved mood (Morin & Espie, 2003; Edinger et al., 2005; Rybarczyk et al., 2005) and that benefits are maintained for some time after treatment (Riemann & Perlis, 2009). We also know that CBT-I has a growing field of literature in support of its efficacy in improving sleep in the chronic pain population (e.g. Vitiello et al., 2009; Jungquist et al., 2010; Miro et al., 2011). This in itself is an important area when we consider the importance of sleep in terms of reported quality of life (Kyle, Morgan & Espie, 2010), as well as the significant intercorrelations that insomnia has with depression and anxiety (Jansson-Fröjmark & Lindblom, 2008).
1.5.1.2  Improved daytime functioning and possible reductions in pain

The evidence from this systematic review indicates that improved sleep (via CBT-I programmes) has a positive relationship with pain related disability/daytime functioning and may also reduce pain severity (although the latter appears less likely). This could potentially have a great impact on the breadth of treatment options for those suffering chronic pain conditions. Often pain management through medication, acupuncture, physiotherapy, TENS or other interventions will only provide partial relief, with the patient still suffering distressing levels of pain. This is the key area where CBT-I can potentially have an important impact in Pain Management Programmes (PMPs).

Currently, The British Pain Society (The British Pain Society, 2007) advises strategies to improve sleep to be integrated into Pain Management Programmes, but the emphasis on improving sleep does not include a focussed sleep restriction programme. This is fair considering it has only been more recently that enough evidence has become available to reliably demonstrate benefits in the chronic pain population. Now, it is apparent that a programme of focussed CBT-I can improve levels of pain related disability and may also reduce pain severity.

1.5.1.3  Reduced medication

The impact on medication is twofold: there is medication aimed directly at improving sleep and that aimed at reducing pain. Firstly, sleep medication provides only temporary relief and efficacy is time limited (Riemann & Perlis, 2009). It is often used
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in the wider population to break a cycle of poor sleep habits or help a person through a stressful period. It is not a long-term solution, and those with chronic pain are faced with ongoing disruptive pain that will often reverse any improvements gained in the short-term. Other pain medication is often used to aid sleep due to its sedative effect, but the primary mode of action is to reduce pain (the side effect of the patient feeling sedated is used to help induce sleep). By improving sleep, the demand for these medications would be likely to be reduced. Secondly, any reduced pain levels experienced are likely to either reduce the demand/reliance on pain medications, or increase the cumulative effect of the pain management package. There is no evidence for sustained pain reduction, therefore less emphasis should be made of this point.

1.5.2 Study strengths and limitations

There are several strengths and limitations to this systematic review. The first author undertook a detailed and structured literature search using relevant electronic databases, referring to authors of published studies for details of follow-up studies where relevant. A robust set of quality assessment criteria was employed from the Scottish Intercollegiate Guidance Network (a consortium of academic and health care institutions in Scotland) health guideline; this is a standardised methodology used to systematically search and appraise all relevant literature prior to developing health guidelines. Quality assessment was undertaken by three authors independently, and good inter-rater agreement was found.

One of the key limitations is the small size of the current body of literature available for analysis. The SIGN 50 quality assessment criteria allows rigorous breakdown of
study quality and relevance, and the majority of the literature was of moderate quality despite some difficulties of low power and other features highlighted above. Combined, this places some limitations on how confident we can be in linking improved sleep through CBT-I with reduced chronic pain. The review excluded articles not in English, which may limit findings, but references were reviewed in the final tranche of studies and no studies in other languages were cited. Similarly, the search term ‘behavioural’ was used, which is the UK English spelling. Using ‘behav*’ with a wildcard ending may have been more robust, although studies from the USA and Canada were captured by the UK English spelling in our database searches. The review does not include any studies that are currently in press. By strict adherence to SIGN 50 criteria for systematically evaluating the quality of literature, there was less flexibility in assessing elements of the literature it does not cover e.g. treatment fidelity. Some elements included, such as blinding, were not always relevant as this is not possible for the recipient or provider of psychological treatment protocols.

1.5.3 Future research

Firstly, larger studies are required that replicate those included in this review to provide greater power to the statistical analysis. Secondly, the content of CBT-I programmes needs to be deconstructed to more accurately ascertain exactly what elements are key in improvement. Thirdly, our understanding of the impact CBT-I has on medication use is still somewhat sparse. With this, a more detailed health economics cost/benefit analysis should be assessed to determine the practical clinical and financial implications of a CBT-I programme for this population. Fourthly, an
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important consideration relates to the mode of action occurring through improvements in sleep architecture. Sleep improvements related to onset, continuity and waking, rather than the total amount of sleep being experienced. It is here where there should be considerations about the different *types* of sleep being improved, rather than just a gross measure of total sleep. Consolidated sleep may allow the appropriate expression of sleep stages and cycles, aiding recovery and repair of brain and bodily processes. Deep slow-wave sleep may be vulnerable to pain related disturbance and its recuperative functions are well documented (Dijk et al., 2010).

Finally, despite improvements in several aspects of sleep, most evidence showed no significant difference in pain severity across groups, although pain related disability/daytime impairment often improved. Further understanding of the dysfunctional beliefs about the nature of sleeplessness, chronic pain, and their interaction may help better understand this. Qualitative research is needed to explore the individual experience, attributions and beliefs about chronic pain and insomnia, in an effort to better explain the discrepancy between improved pain related disability and static levels of reported chronic pain.

1.5.4 Summary and Conclusions

All of the studies included provided a moderate or ‘+’ grading of quality, except the Morin et al. (1989) article which was rated as poor or ‘-‘ and was a preliminary study in this area including only three cases. The key common weakness in all of the studies was participant numbers, and therefore the threat of low power (which was not
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reported in any of the articles). The consistency of outcomes across the studies assigned moderate quality status does boost this reliability though. The question is:

“Does improvement in sleep (using CBT-I) for those with insomnia co-morbid with chronic pain have a positive influence in reducing pain symptoms?”

Two moderate quality studies that showed improvements in several sleep measures after the implementation of a CBT-I programme, also showed reduced pain severity (Rybarczyk et al., 2005; Vitiello et al., 2009; Jungquist et al., 2010). These pre-post improvements were not maintained at follow-up. Despite this, where daytime impairment was measured (Rybarczyk et al., 2005) this showed maintained improvements.

Three moderate studies showed no improvement in pain severity. One of these found that daytime impairment was improved (Miro et al., 2011) despite this giving some contradiction between this measure and pain severity. A second (Edinger et al., 2005) showed an improvement in pain severity in a control subgroup that was deemed to be implementing CBT-I techniques. The third (Currie et al., 2000, 2002) showed that when treatment type was replaced with ‘improved’ and ‘not improved’ regarding sleep changes, the improvers showed better pain related disability.

There is therefore moderate quality evidence to show that CBT-I does not sustainably improve pain severity but improved sleep quality (often through a CBT-I treatment
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programme) does improve daytime functioning in those with chronic pain and insomnia.
1.6 Systematic review references


Cochrane review. (2009). Psychological therapies for the management of chronic pain (excluding headaches) in adults *(Review).*


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2 Thesis aims

2.1 Bridging from systematic review to thesis

Considering the systematic review recently completed, there were key areas where further analysis was recommended. Cognitions were unexplored in all studies implementing Cognitive Behavioural Therapy for Insomnia (CBT-I) treatment, and this related to the highly subjective measures of sleep quality, sleep time estimates, impacts on daytime functioning and pain perception. The systematic review revealed common discrepancies between improvements in pain related disability and daily functioning when compared to self-reported pain severity, although no explanations as to why this was the case were uncovered.

Investigation into the attributions made by people regarding dysfunctional beliefs about poor sleep has been well explored in the insomnia population e.g. the Dysfunctional Beliefs and Attitudes about Sleep Scale-16 (DBAS-16) is a validated measure of sleep beliefs (Morin et al, 1993; Morin, Vallieres & Ivers, 2007). Cognitive behavioural models of sleep disturbance consider ‘correction’ of dysfunctional beliefs an important aspect of treatment, and these provide the basis for CBT-I (Espie, 1991; Harvey, 2002; Morin, 1993). Although ‘dysfunctional beliefs about sleep’ is a well-explored area in those with insomnia alone, little is known about the beliefs in those suffering insomnia comorbid with chronic pain. In effect, when CBT-I is implemented in the chronic pain population, we cannot be sure exactly what dysfunctional beliefs exist that may be unique to this population. These may or may
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not replicate those in the primary insomnia population. Currently, and to the best of the author's knowledge, only two papers exist that investigate dysfunctional beliefs about sleep in the context of chronic pain.

Firstly, Theadom and Cropley (2008) conducted a questionnaire-based quantitative study comparing 83 patients with fibromyalgia (FM) with 83 healthy, matched controls. Inclusion criteria did not define that participants had any sleep problems, therefore it was unknown if participants had good or bad sleep. They found that patients with FM (a condition predominantly defined by the presence of chronic pain and fatigue) scored higher on the DBAS-10 than healthy controls. Of note, the authors did not probe dysfunctional beliefs about sleep that relate to pain specifically. The DBAS-10 is a general questionnaire about sleep related beliefs, and has no component relating to chronic pain. Therefore, no assessment was made of the elements considered as possible maintaining factors in insomnia comorbid with chronic pain i.e. beliefs and attributions about pain and its relationship with sleep.

The second relevant study was conducted by Ashworth, Davidson and Espie (2010) and was again a questionnaire-based quantitative study. This work investigated the cognitive and behavioural factors associated with sleep quality in patients with chronic pain and poor sleep. They found three factors which had significant predictive value of sleep quality: 1) pain at night; 2) dysfunctional attitudes and beliefs about sleep and; 3) depression. Again, dysfunctional attitudes about sleep were generically covered, this time using the DBAS-16 that although very useful, was not developed as a pain related measure, and contains no questions about pain related beliefs.
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In addition to these, a third study has touched on dysfunctional beliefs about sleep linked with chronic pain (Theadom & Cropley, 2010). The authors recruited 16 FM patients and asked them about their quality of life with FM, sleep quality and management of symptoms. They found four overarching themes: 1) sleep disturbances; 2) inter-relationships between symptoms; 3) coping with disturbed sleep and; 4) impact on daily living. The above study did not qualitatively assess if participants had any sleep problems, and did not screen out any that may have been suffering depression, which is highly comorbid with primary insomnia (i.e. insomnia not related to another medical or psychological condition). Therefore, there is still no research related to those with clinical levels of insomnia (defined in inclusion/exclusion criteria) relating to a chronic pain condition.

Therefore, a number of topic areas remain poorly understood, ill-defined and under-researched in those with chronic pain and insomnia. Key questions remain unaddressed, such as how sufferers perceive pain and sleep interact with each other (e.g. do they feel one symptom exacerbates the other? and if so, how do they think this relationship works?); how they feel any perceived interaction has changed over time; the worries they have about sleep and future expectations about symptoms; what they believe others understand about their pain and sleep problems; or how the perceptions of others makes them feel. Importantly, there is no clear understanding of what those with insomnia and chronic pain think about when lying awake at night (if thoughts relate to pain, sleep or other issues) and how this experience makes them feel.
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When considering chronic pain populations, it is evident that chronic low back pain (CLBP) is one of the most common. Prevalence estimates vary between studies, although can be up to 46% percent of the population (based in 15 European countries and Israel) for point-in-time prevalence, with 18% living with disabling pain (Berivik et al., 2006). Each year, around 2.6 million people in the UK will consult their GP for advice about this (Arthritis Research Campaign, 2002). Sixty-two percent of people still have pain one year after their first episode of back pain, and 16% of those who were initially unable to work are still not working after one year (Hestbaek, Leboeuf-Yde & Manniche, 2003). It is the scale of this problem that is the primary reason that the current study has focused on this group.

No study to date has investigated the experience, beliefs and attributions about pain and sleeplessness in those with insomnia and chronic low back pain (CLBP). This has been shown as a key area relevant to current thinking about maintenance factors in insomnia, and currently remains unexplored.

2.2 Aims of current study

The current study aims to provide new insights into the individual experience of insomnia comorbid with CLBP, and subsequently inform models of insomnia comorbid with chronic pain, as well as clinical treatments such as CBT-I. The current study aims to achieve this by interviewing out-patients attending a chronic pain clinic who have a primary complaint of CLBP.
A novel aspect of this study is that all participants will be screened to ensure they reach the criteria for clinical insomnia, and therefore that the focus is purely on those with a defined sleep problem. Interviews will focus on areas which have not yet been explored by other studies, such as: the current beliefs held by participants regarding pain and sleep and any interaction; the development of these beliefs over time; the impact of pain and poor sleep on daytime functioning; relationships and work; what participants think about as they lay awake at night and expectations for the future.
3 Methodology

3.1 Design

The procedure outlined was adapted and developed from methodologies and qualitative analyses used in previous studies conducted with poor sleepers which were given ethical approval by local NHS ethics committees (cf. Wicklow & Espie, 2000; Harvey & Espie, 2004; Kyle, Espie & Morgan, 2010). The qualitative analytical framework was also used in a recent interview study by Theadom and Cropley (2010) to investigate sleep disturbance in fibromyalgia patients. Therefore, this study employed a qualitative design with participants being interviewed using a semi-structured format. These interviews were analysed using Interpretative Phenomenological Analysis (IPA) (Smith 1996; Smith & Osborn, 2003; Smith & Eatough, 2007) to generate super-ordinate themes and sub-themes. In addition to interviews, descriptive demographic data, measures of sleep, anxiety, depression and attributions were documented to help set the participants within some context.

3.2 Reflective prologue

This reflective prologue is written in the first person to better reflect my personal experience prior to conducting this research thesis. Working as Trainee Clinical Psychologist with a specialist placement in Health Psychology, I have experience working with many outpatient chronic pain referrals in relation to difficulties in symptom management and mood difficulties. Apparent in these cases were frequent difficulties experienced with sleeping in particular, and the various impacts this had on
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quality of life. This anecdotal experience is evidenced in Tang, Wright and Salkovskis (2007) where prevalence in a similar chronic pain out-patient group was identified as being extremely high (53% in CLBP outpatients versus 3% in a normal population sample).

In conjunction with this, I shared laboratory space in the Glasgow Sleep Centre (University of Glasgow, Scotland, UK) in a previous role as a Research Assistant working on another study. This awareness had led to links with the laboratory, and background knowledge concerning available treatments for ‘primary’ insomnia, including CBT-I. As part of this I was also aware of the strong correlation between insomnia and depression (Baglioni et al., 2011), and how improvements had been achieved in quality of life measures when insomnia symptoms had been reduced (Kyle et al., 2010; 2011).

Combining these elements led to curiosity in terms of the impact that improving sleep might have in those with a chronic pain condition (for example CLBP) and comorbid insomnia. It is from this point where my interest began, reflecting personal clinical experience, and some peripheral knowledge of insomnia and the impact this can have on quality of life and mood. I have never personally suffered from poor sleep except some reduction in quality on the brief occasion preceding and during a stressful event. Aware of my personal background, I undertook a reflexive journal as a means of recording my responses to the interview and research experience more broadly. I returned to this regularly during analysis of semi-structured interviews to increase my self-awareness of the experience. This can be extremely useful and highlight thoughts
as they appear and develop within the mind of the researcher. These are reflected upon as the study progresses, and can therefore help the development of the researcher’s perspectives through the research process.

Willig (2001) and Smith, Flowers and Larkin (2009) recommend transparency on the part of the researcher. Making the reader aware of the researcher’s own beliefs, attributions, experiences and personal identity allows them to view the interpretations made by the researcher in an open and transparent way. The reader can then judge if there has been bias or influence on the research, which is perhaps inevitable when conducting subjective interpretation of any data.

### 3.3 Choosing a qualitative approach

A qualitative approach was chosen in an effort to understand how the participants with CLBP and insomnia made sense of their experiences, and what these experiences mean to them. The stated aim of this study was to understand and explore the lived experience of those who had CLBP comorbid with insomnia. Of particular interest were perceptions and attributions held regarding the impact of chronic pain and poor sleep on each other, what influence participants felt they had on their symptoms, and expectations about how this might change in the future. To the researcher’s knowledge there are no validated questionnaires concerning this area. The DBAS (in its various guises) considers dysfunctional beliefs and attributions about sleep, but does not integrate or mention chronic pain. Tang (unpublished) has developed a preliminary ten question extension to the DBAS which focuses in this area, but this was developed in a ‘top-down’ manner, with assumptions (from her extensive research experience...
Experiences of insomnia and chronic low back pain nonetheless) applied to a sample cohort. It was decided that this study would try to approach the same issue from the ‘bottom-up’, allowing the participants to generate the issues and ideas that they felt were the most important to them, with the researcher then distilling them into relevant and cohesive themes. Participants would later be able to feedback how accurate these themes were after being able to review a summary of findings.

3.3.1 The underpinnings of interpretative phenomenological analysis (IPA)

Originally, phenomenological enquiry as we understand it today dates back to 1925 when Husserl started to approach the conscious reflection of a particular event. Like social constructionism, phenomenology puts forward the view that each individual holds a subjective interpretation of events. A phenomenological approach aims to understand the subjective reality experienced by the individual, and as such recognises that experiences of events may have different interpretations by different individuals (Willig, 2001). Smith, Flowers and Larkin (2009) state that IPA involves this along with hermeneutics and idiographic considerations.

Philosophical hermeneutics developed into the more familiar idea from Heidegger’s *Sein und Zeit* (1927): rather than it being purely the understanding of linguistic communication as it previously was, it became ontology – i.e. the nature of being itself, and a mode by which one can understand the world and apply meaning to it. In IPA this becomes double hermeneutics, whereby there is an attempt to understand the world of another individual, but recognising that doing so is a subjective exercise, and their interpretation of the world is being understood via our interpretation of the world
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(therefore double hermeneutics). Differing from quantitative approaches then, IPA acknowledges the experiences of the researcher, and how this can influence the interpretations made of the gathered material. Rather than objective statements being made about the world of the participant, the researcher makes subjective interpretations of how the participant experiences their world (Smith & Osborn, 2003). In addition to this, IPA is interested in the experience of the individual, reflecting an idiographic approach to analysis (Smith et al., 2009). It focuses on bringing together small groups of homogeneous ‘experts’ in a phenomenon (Smith, 1996) to aid understanding about their lived experiences, and the meanings they attribute to these.

IPA was the chosen framework that guided study design and proposed analysis. The associated methodology is well tested and explicitly detailed in guidance, meaning it is an accessible and practically useful tool in exploring the lived experience of the individual and the cognitions and attributions they hold. IPA has been shown to provide useful insights into health related topics for some time, including more recent studies aiming to improve understanding of those with sleep difficulties (Kyle et al., 2010) as well as those with chronic pain conditions (e.g. Theadom & Cropley, 2010; Snelgrove & Liossi, 2009). This demonstrates relevance to the subject matter being addressed in this particular study.

3.3.2 Other qualitative methodologies considered

Consideration was also given to the qualitative methods of grounded theory and discourse analysis that were both seen as valid alternative approaches in this context. Given the appropriateness of IPA discussed above, it was required that any alternatives
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would need to be: 1) more practical to implement; and 2) potentially derive greater value from the research data in terms of answering the research question, for them to be chosen over IPA.

3.3.2.1 Discourse analysis

Discourse analysis concerns itself with the shared, mutually agreed-on use of language, for it is this that is considered to assign language its meaning, rather than the language having an inherent meaning in itself. Evolving from semiotics and linguistic studies, discourse analysis breaks down language and how it is used by individuals to achieve personal, social or political goals. Language is considered to define social roles (as these are enacted through the use of language), but it is somewhat unclear as to whether discourse alone gives the full sense of personal identity. This approach focuses on the use of discourse in creating a reality, whereas the current study is interested in the meanings, experiences and attributions underlying the use of language. Therefore, when compared to grounded theory and IPA, it was felt that there was less of a match between the goals of discourse analysis and the aims of this study.

3.3.2.2 Grounded theory

Grounded theory’s goal is to develop an explanatory theory of basic social processes based on the data (Glaser & Strauss, 1967). The data gathering and analysis techniques are designed to allow theories to become self-evident from the data. Originally, the approach was considered positivist in terms of impartiality of the researcher allowing the true reality to be ‘discovered’, and Glaser (1990) identified this as realizing what is
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the reality held within the data, rather than a subjectively driven outcome. The researcher is perceived as a neutral witness whose role is to observe, collect, analyse and report. Their own being is secondary to the data itself, which does not sit well with critics of positivist approaches. It was therefore deemed that the lack of recognition of subjective interpretation was not in keeping with the approach of the author. Reflexivity is not emphasized in this approach, and it was the opinion of the author that to ignore this was not a true reflection of the experiential process of interpreting transcribed interviews.

Further to this, the methodological approach of Grounded Theory ideally aims at the researcher dealing with the subject matter in as much a naïve position as possible, with few prejudices or assumptions, and a limited knowledge of the existing literature in the area. This was not possible due to the author’s pre-existing research and clinical knowledge of the field. Undertaking the previous systematic review as part of the current thesis renders literature-naivety impossible.

In addition to this, as time has progressed, the positivist view of grounded theory has been challenged by those with a social constructionist interpretation (Charmaz, 1990). This recognises that what emerges from the data will have a subjective interpretation as the researcher is human and as such brings his or her own subjectivity when analysing the data. Therefore, theories are constructed by the researcher, and this partially addresses the subjective criticism levied above.
What still remains are discrepancies between the primary aims of grounded theory and the primary aims of this study. With particular regard to the research aims of this study, it was felt that these were less in line with Grounded Theory – this study aims to inform understanding of the experience, beliefs, attributions and expectations of sleep and pain that are held by patients with CLBP who have clinical insomnia. This study does not attempt to conclude with a theory or explanatory framework by which particular events happen, and as such, grounded theory was deemed to be less appropriate to the original aims of this study than IPA.

3.4 Sample size

Literature about the methodology was used to guide the sample size. Osborn and Smith (1998) who were fundamental in creating the IPA approach originally recommended approximately five participants or more when using this approach, and qualitative studies looking at sleep and pain commonly range in participant levels from 11 (Kyle et al, 2010) to 16 (Theadom & Cropley, 2010)). Using a larger group allows a broader spectrum of opinions and experiences to be explored, but the number is ideally one where the themes can be held in the mind of the researcher, therefore 11 was chosen to provide this balance.

3.5 Participants

3.5.1 Method of sampling and recruitment

In accordance with IPA methodology (Smith & Osborn, 2003) participants were purposively sampled. Participants were required to have CLBP as part of this focused ‘group of experts’, and were selected from an outpatient group attending a Chronic
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Pain Clinic (Ninewells Hospital, Dundee, Scotland). Those identified by pain clinic consultants to have CLBP were sent a pack about the study. This included an introductory cover letter from the lead consultant in the pain clinic, an information pack about the study and a consent form (see Appendices 4-6). In the pack, those who had a sleep problem in addition to their pain condition were invited take part in the study and contact the Chief Investigator. As shown in Tang, Wright and Salkovskis (2007), prevalence of insomnia in a similar out-patient group with chronic pain was found to be 53% in their study, therefore we predicted a similar ratio in the current study. A flow-chart detailing recruitment is shown in Figure 2.
Figure 2. CONSORT recruitment pathway

3.5.2 Inclusion and exclusion criteria

Inclusion and exclusion criteria were assessed in a screening interview held prior to the main qualitative semi-structured interview. Use of sleep medication was not an exclusion criterion, and allowed a more ecologically valid representation to be considered. Pain medication is often complex where sometimes the sedative effects of a pain medication may be used as a beneficial side effect to promote sleep. There can be ‘blurring of boundaries’ where pain medications have a sedative effect and have effects on sleep. Therefore, after discussions with pain clinic consultants, using this as an exclusion criterion was decided as being a somewhat artificial and unrealistic approach.

Inclusion criteria were defined as:

- Either difficulty initiating and maintaining sleep (or both) or non-restorative sleep on at least 3 nights per week in the last month.
- Sleep disturbance results in some form of daytime impairment, indicated by the presence of at least one associated daytime symptom, according to diagnostic criteria of: fatigue / malaise; attention, concentration or memory impairment; social / vocational dysfunction; mood disturbance / irritability; daytime sleepiness; motivation / energy / initiative reduction; proneness for errors / accidents at work or while driving; tension headaches and / or gastrointestinal
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symptoms in response to sleep loss and concerns or worries about sleep (Edinger et al., 2004).

• Pittsburgh Sleep Quality Index score (PSQI; Buysse, Reynolds, Monk, Berman, & Kupfer, 1989) of 6 or above.

• A score of 15 or above (clinical insomnia, moderate severity) on the Insomnia Severity Index (ISI; Morin, 1993).

• Sleep disturbance is not due to substance abuse, another mental or sleep disorder, or a general medical condition not related to their pain condition (adapted and assessed by structured interview, based on Morin & Espie, 2003).

• Outpatient at the Pain Clinic, Ninewells Hospital, Dundee.

• Non-cancer chronic low back pain.

• Participants aged 18 and over.

• Sleep disturbance was temporally related to initiation of pain i.e. the participant did not have pre-existing sleep problems prior to the development of their pain condition.

Exclusion criteria were defined as:

• Receiving treatment for sleeping difficulties outside Pain Clinic medication

• Suffering from a psychopathological disorder, based on self-report regarding any treatment from a mental health practitioner, or having been referred and not yet assessed.
3.6 Participant characteristics

Eleven participants were interviewed in the current study, of which 10 were female (Table 3). Participant ages ranged from 22 to 81 (mean=55.8, SD=15.8). 3 participants were employed full-time, 1 was employed part-time and 7 were not employed. Of the 4 who were employed, none worked shifts. The length of time that participants had their CLBP ranged from 1.6 to 49.0 years (mean= 19.4, SD= 17.4).
### Table 3. Demographic and descriptive data from 11 interviewed participants

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<th>Shift-work</th>
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Key: ISI (Insomnia Severity Index); PSQI (Pittsburgh Sleep Quality Index); Anxiety and depression scores taken from the HADS (Hospital Anxiety and Depression Scale) HADS scoring: 0-7 Normal; 8-10 Mild; 11-15 Moderate; 16-21 Severe. DBAS-16 (Dysfunctional Beliefs about Sleep). Validity analysis of DBAS-16 cut-off suggests >3.8 as level of unhelpful beliefs about sleep associated with insomnia (Carney et al., 2010).

### 3.7 Materials & Measures:

#### 3.7.1 Screening interview

Screening measures and criteria for insomnia were adapted from Harvey and Espie (2004) and Kyle, Espie and Morgan (2010). The Pittsburgh Sleep Quality Index (PSQI; Buysse, Reynolds, Monk, Berman, & Kupfer, 1989) and Insomnia Severity Index (ISI; Morin, 1993) were employed to this end. The screening interview included relevant questions to ensure whether inclusion or exclusion criteria were met.

#### 3.7.2 Second interview

Those participants who met the inclusion criteria assessed at the screening interview were requested to attend a second interview at a later date. This more in-depth session
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was broken into two elements: the semi-structured interview and completion of further questionnaires.

Firstly, a pilot interview protocol was developed by the Chief Investigator to address the key areas of the primary research question. This was reviewed by a thesis supervisor (KP), and academic supervisor (DG) with experience in qualitative research. The interview protocol outlined five key areas including relevant prompts (Appendix 8) and was to be used as a flexible guide (not an exclusive, directive list). This protocol was refined slightly after two initial pilot interviews to better focus questions. This revised protocol was then reviewed in conjunction with an experienced qualitative researcher (ZC) to ensure rigour and validity.

Questions were framed in an open way, to best elicit a broad and full response. These were aimed at being neutral in their content to avoiding leading the participant to respond with a particular answer. When the participant did not respond, they would be allowed time in which to gather their thoughts. If there was no response, non-directive prompts were given by the interviewer to initiate a starting point for the participant. When participants shared their thoughts, the interviewer would potentially ask them to expand, clarify or give an example of their point, explain how a particular event was like to experience (their feelings) or what thoughts it provoked in them. As part of this, the interviewer would reflect what the participant had been explaining, to allow for clarification or endorsement of this interpretation.
Questions were addressed in an order that was most naturally aligned to the flow of the interview, so that it was more discursive than a rigid question / response format. The purpose of this was to make the participant feel at ease, and in turn access richer quality responses through a conversational style. At the end of each interview, participants were asked how they found the experience of taking part in the interview, and to provide any more relevant detail they felt may have been omitted during the interview.

After the semi-structured interview, other quantitative measures were used to further improve the understanding of the participant group. These were undertaken afterwards so as not to influence the responses given in the semi-structured interview. Questionnaires included were the Dysfunctional Beliefs and Attitudes about Sleep (DBAS-16) and the Hospital Anxiety and Depression Scale (HADS).

Firstly, the DBAS-16 is a well validated measure of beliefs about sleep, and was used by Theadom and Cropley (2008) and Ashworth, Davidson and Espie (2010) in their studies of patients with chronic pain and sleep problems. The HADS was used to inform our understanding of participant mood that is considered a key component in maintaining insomnia (Morin, 1993). This is a well-validated measure of anxiety and depression, used in Tang, Wright and Salkovskis (2007) with participants with chronic pain and poor sleep. Due to small participant numbers, it was recognised that these quantitative measures were only used in an effort to help describe and understand the participants included in the study, and not in an effort to evidence any quantitative hypotheses.
3.8 Procedure

After recruitment, participants were allocated a convenient time to attend a screening interview at the Pain Clinic with the researcher. At this appointment, the researcher asked relevant screening questions and was available whilst the participant completed relevant questionnaires, should they have had any queries about these or anything else about the study. The decision on if they met inclusion criteria was made at the end of this screening appointment. If they were appropriate for the study, they were asked to attend a separate semi-structured interview (described below). Inclusion criteria required participants to be fluent in English, therefore arrangements were not required regarding translation or the provision of interpreters.

The first two semi-structured interviews to take place were considered as pilot interviews, used to refine the interview schedule, and these were included in the final analysis. All of the following nine interviews used a slightly amended interview schedule, and all interviews were conducted from 5\textsuperscript{th} January 2012 until 31\textsuperscript{st} May 2012. Interviews ranged in duration from 31 minutes in length to 62 minutes, with a mean duration of 41 minutes (SD= 12.2). All interviews were conducted on a one-to-one basis, except one when the participant’s partner and young child were also present. These were undertaken in individual therapy rooms at Ninewells Hospital, Dundee, Scotland, UK, and were recorded using a digital voice recorder. Following guidance from Smith and Osborn (2003), the audio recordings were transcribed verbatim.

The interviewer was aware that participants would have different preferences regarding appointment times based on health needs and when they usually felt most
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alert (often a particular time of day). A common symptom in this client group is fatigue, which can impact both physically and cognitively, and these factors were taken into consideration when collaboratively organising appointments.

Interview transcripts were analysed using Interpretative Phenomenological Analysis, and once complete, participants were sent a summary on which they were invited to comment by ‘phone call, written response or in person. Contact was made with four participants, and feedback was summarised and included in the thesis write-up.

3.9 Research context

As part of a qualitative approach, it is considered important to set the research context for the reader, so as to lead to better understanding of participant responses, and limit bias of interpretation. The two important areas to be covered in this study relate to the background of the researcher and the Pain Clinic from which participants were recruited.

Firstly, the researcher was a Trainee Clinical Psychologist undertaking this research as part of their qualification of Doctorate in Clinical Psychology. They specialised in Health Psychology and as part of this training, had worked clinically for approximately three years with a client group that included patients with various conditions such as CLBP, chronic regional pain syndrome (CRPS), fibromyalgia (FM), chronic fatigue syndrome (CFS), Ehler’s Danlos syndrome, irritable bowel syndrome (IBS), rheumatoid arthritis and Crohn’s disease. These patients would
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usually be involved with the Pain Clinic on a longer term basis for treatment, with which the Health psychology clinic shared its clinic rooms.

The Pain Clinic treats patients who have long-term pain conditions that have proved treatment-refractory. As a result of this, many patients receive treatment that is designed to manage their pain, but may not significantly reduce or eliminate it. Treatment options available include medication delivered through outpatient appointments (with the potential for inpatient treatments when relevant), the supply and monitoring of transcutaneous electrical nerve stimulation (TENS) machines to patients, acupuncture, and physiotherapy (aimed at maintaining mobility and pain management rather than a traditional injury recovery model). This clinic uses a multi-disciplinary team model including Anaesthetic Consultants, junior Doctors, nurses (with specialist training in acupuncture and TENS), clinical psychologists and a specialist pain physiotherapist.

3.10 Ethical considerations

Risks and burdens on participants were considered as part of the ethics process in order to best protect individuals recruited into the study, and these are discussed below. This study was formally reviewed and passed by a Local Research Ethics Committee i.e. NHS Tayside Committee on Medical Research Ethics A (Appendix 3).

3.10.1 Time demands on participants

The initial screening session took approximately 30 minutes and semi-structured interview approximately 45-60 minutes based on similar qualitative studies. Overall,
participants were involved in the study for a maximum of approximately 2 months depending on when screening and interview sessions were arranged that suited the participant. The participants therefore attended a maximum of two appointments at the Pain Clinic, Ninewells Hospital. Every effort was made to accommodate participants by arranging appointments that coincided with routine review appointments or other hospital appointments, thus minimising travel wherever possible.

3.10.2 Emotional demands on participants

Considerations were made regarding whether participants may find discussing their experiences of chronic pain and/or sleep distressing. All participants had access to referral to Clinical Health Psychology through the Pain Clinic from which they are to be recruited. It was planned that if this was deemed necessary, the researcher who was conducting the interviews (and who was a Trainee Clinical Psychologist specialising in Health Psychology) would discuss potential referrals with the lead consultant of the clinic, and a referral be made if deemed appropriate. Participants were aware that this research was aimed at contributing to the increased understanding of chronic pain and insomnia. It was anticipated that some participants may derive some positive therapeutic benefit from sharing their experiences, and this was highlighted by several participants at the end of the semi-structured interviews.

3.10.3 Data security and participant confidentiality

Paper files were stored in a locked filing cabinet in a secured office on NHS property. Electronic files were held on an NHS computer and were password protected. These
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were accessible only by the researcher and clinical supervisor (KP). All data was anonymised by attributing a number to each set of records. A list of participants was held (securely on a password protected NHS computer in a secured office on NHS property) to allow them to receive a summary of findings, and provide them with the opportunity to provide feedback. Participant records were initially identified by a sequential number allocated on the order that participants were interviewed, beginning with ‘1’. Anonymised transcripts of interviews were also held on the home computer of the researcher so these could be analysed, therefore no personally identifiable data was held outside NHS property.

3.10.4 Gaining informed consent:

Potential participants were sent a cover letter from the lead clinician at the pain Clinic, an Information Sheet about the study along with a consent form and stamped and return addressed envelope. The Information Sheet included contact details of the researcher so they could ask for further information or answers to any specific questions prior to returning the Consent Form. In addition to this, contact details were provided for an independent contact at Edinburgh University (who could provide general information about research studies), the lead clinician at the Pain Clinic (who could be contacted for any concerns or queries about the specific study), and the Head of Psychological Services, NHS Tayside, (should they have any queries they wished to address in this area).

If potential participants did not return a consent form, they were not contacted again, and this was ensured by the maintenance of a record of all those who had been sent
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information packs. All participants were informed both verbally and in writing that they could withdraw from the study at any time without providing a reason, and that this would in no way interfere with their treatment at the Pain Clinic. Only returning patients to the Pain Clinic were approached about this study. The reasoning behind this was that it was anticipated new patients may be less confident on their first visit to the clinic than returning patients, and therefore be more likely to acquiesce to a request to participate in a study that they were unsure of. We aimed to make this an open and voluntary choice, and did not wish the first-time attender to feel under any undue pressure.

3.10.5 Vulnerability of the participant sample

If the researcher became aware of clinical levels of anxiety or depression whilst partaking in this study, they were offered relevant psychological input, as would be the case for all patients that attended the Pain Clinic.

3.10.6 Emotional impact on researcher

Reflective consideration was made prior to undertaking this research in terms of the emotional impact conducting these interviews might have on the researcher. Therefore, even though the researcher had experience in conducting similar interviews as part of clinical practice, regular supervision was sought with a qualified Clinical Health Psychologist. This provided a forum in which reflections or concerns could be discussed in a supportive manner, as well as positive encouragement to explore thoughts and ideas developed throughout the study.
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In addition to this, the researcher was in regular contact with both an allocated academic thesis supervisor (DG) and clinical thesis supervisor (KP).

### 3.11 Data management

Initial screening interviews entailed the employment of several standardised questionnaires as well as questions relating to inclusion and exclusion criteria. These records were held in a locked filing cabinet on NHS premises. For those participants who were invited and accepted the offer of attending the second interview, further questionnaires were administered after the semi-structured interview was complete. Interviews were recorded on an NHS digital voice recorder, and deleted after analysis of the transcript was complete. Transcripts were held electronically on an NHS password protected computer, and a participant number was allocated to each file and all identifiable material removed. Transcripts were hand coded by the researcher with these being entered into an Excel spreadsheet for organisation, analysis and manipulation of data.

### 3.12 Data analysis

The data from the semi-structured interviews was analysed using the approach outlined by Smith et al. (2009) where each transcript is analysed individually before moving onto the next transcript, as a gradual process of developing shared themes develops. Initially, the transcript was read then re-read before initial noting takes place. Emergent themes were developed and connections made across these themes. Once the case was complete, the researcher moved onto the next case whilst looking for patterns developing across the cases. When new themes became apparent, the
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The digital voice recordings of participants were transcribed and the means to become experientially re-engaged with them was to listen to original recordings whilst simultaneously reading then re-reading the transcripts. This was to reinforce the subtle nuances of speech that can be missed when reviewing even by detailed verbatim transcription, and improve appropriate hermeneutics implied by tone or pace of speech in doing so. An element outside of this was to note any thoughts, ideas or emotions evoked by the experience, so these could be reviewed later when considering interpretation.

Comments were broken down into three types to aid analysis, and help clarity of approach: 1) descriptive comments to explain the particular area being discussed; 2) linguistic comments concerning the use of language and tone; and 3) conceptual comments to provide some meaning and interpretation to the area being discussed. These were initially made in pen in the right hand margin, each distinguished by being underlined, circled or boxed around respectively.

On reviewing these initial notes, themes were identified and noted in the left hand margin. These were based on moving from phrases in the transcript that were then taken to a deeper level of subjectively interpreted meaning by the researcher. These attempt to explain the reflective experience of the individual and the sense that they make from those experiences. Using a combination of note taking and spreadsheets,
clusters of themes from the interview were drawn together to form super-ordinate themes, under which common threads could be drawn together. From this, a summary table for each participant was produced (e.g. Appendix 13). Nvivo analysis software was considered, but an efficient and intuitive system of note-taking and spreadsheets was created by the researcher that met analytical needs, therefore this was not required. Once this procedure was completed for a participant, it was repeated for the next participant, and so on until all interviews were analysed. Summary tables for each participant were drawn together to identify common cross-participant themes, as well as themes that stood out as being unique to only one or two participants. These tables were integrated to form a table of super-ordinate themes.

3.13 Demonstrating quality

Based on guidance on ensuring academic rigour in qualitative research from Yardley (2000, 2008), some recommended principles were applied: sensitivity to context; commitment and rigour; coherence and transparency; and impact and importance.

3.13.1 Sensitivity to context

The researcher was sensitive to the context of chronic pain and poor sleep through two avenues: firstly, clinical experience in dealing with this client group and; secondly, through researching the available literature in this field. This allowed a synthesis of understanding between the pertinent and evidence based issues current in this field, along with the emotional experience of dealing with clients who face such difficulties. This provided sensitivity to context.
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3.13.2 Commitment and rigour

By undertaking 11 semi-structured interviews (with a mean length 42 minutes) including two pilot interviews, a commitment and rigour in trying to provide a broad sample of experience was demonstrated by the researcher. To ensure a focussed, relevant sample, screening interviews assessed participant suitability, and ruled out those not matching strict evidence-based inclusion criteria, providing a rigorous selection procedure. All interviews were read at least four times with voice recordings being used in tandem on two of the four readings showing commitment to immerse the researcher in the data. Themes were cross-checked by three other researchers (ZC, DG and KP) to verify the significance of themes and corroborate their validity. Feedback from these was taken on-board and themes revisited where necessary. Finally, after analysis was complete, a summary was sent to participants who had the opportunity to feedback, showing rigour in making sure results honestly reflected those of the participants.

3.13.3 Coherence and transparency

Coherence of this study with existing literature ensured relevance and was presented in a manner that was pertinent to the field. Summary tables and diagrams served to elucidate results in a clear and accessible way providing transparency. Regular reviews and supervision with qualified and experienced academic and clinical staff ensured work produced met this aim. Coherence with existing literature was evidenced by the employment of a standardised methodology, and this was reported in a detailed and transparent manner with clarity as a key focus to allow this study to be replicated if
necessary. Details of all procedures were provided in a step-by-step manner, with recruitment processes, screening questionnaires, inclusion / exclusion criteria and interview materials all provided for review and examination to ensure transparency.

### 3.13.4 Impact and importance

Considering finally the impact and importance of this research, the introduction of this study and previous systematic review are cited. The latter indicated a gap of knowledge in trying to tease out the relationship between reported levels of chronic pain severity after CBT-I treatment with improvements in pain related disability. This lack of understanding underpins this study. Further to this, when attempting to assess the literature that would help answer these questions, there are only three studies that the researcher is aware of that are partially relevant to this. None of these fully address the aims of the current study. This sparse knowledge indicates that a fuller understanding and analysis of this patient group would improve the limited knowledge held regarding the cognitions and attributions that are a key focus of CBT-I treatments. Ultimately this may inform future CBT-I programmes with particular regard to those with chronic pain.
4 Results

4.1 Introduction

The aim of the current study was to better understand the experience, beliefs and attributions of those with chronic low back pain and comorbid insomnia. Sub-ordinate themes were arrived at after analysing each interview and considering the frequency and ‘weight’ of topics that developed into cogent ideas (Appendix 13). The reflexive journal was used to explore these ideas as they developed from initial ‘sense-making’ into more solid themes. Themes were discussed in supervision with the Clinical Supervisor (KP) and an experienced qualitative researcher (ZC). The first three interviews were given to ZC for thoughts on themes and coding advice. The themes recognised by ZC were compared to those of the lead author in order to determine some convergence and assurance that qualitative techniques were being applied correctly. The resulting convergence of some of the themes highlighted that this was the case. The recurrent sub-themes were grouped into coherent super-ordinate themes and synthesised across participants. Later, other interview samples and provisional themes were passed to ZC and DG to assess thoroughness of analysis. Finally, all 11 participants were sent a summary of the super-ordinate and sub-ordinate themes (Appendix 11). Four were contacted by telephone to assess how accurate interpretation had been in terms of the participant’s perspective. Feedback demonstrated agreement from participants on the themes identified. Super-ordinate and sub-ordinate themes are described below and summarised in Table 4.

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<th>Super-ordinate themes</th>
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Experiences of insomnia and chronic low back pain

| The privacy of pain and solitude of sleep | Invisible illness  
Keeping it to myself  
Isolation  
Relationships affected |
| Night-time thinking | More thinking time at night  
Not worried about sleep…but what about everything else?  
Next day coping  
Thought control |
| Sleep/pain interaction | The significance of sleep  
Sleep impacting pain and daytime functioning  
Pain impacting sleep |
| Adjustment and acceptance | Loss and grieving  
Acceptance  
Adjustment  
Not coming to terms with it – superficial acceptance  
The future |
| Self-management | Controlling the bedroom environment  
Sleep strategies |

4.2 Overview of themes

4.2.1 The Privacy of Pain & Solitude of Sleep

Pain and sleep problems were often perceived as being ‘invisible’ to others. Participants described poor understanding of symptoms by others, keeping symptoms to themselves, as well as the isolation that this could lead to.

4.2.1.1 Invisible illness

The experience of chronic pain, insomnia and associated low mood was identified as something that other people really could not understand. For both examples given, there was an associated tone of irritation in the recording, implying latent frustration at the person they were talking about.
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“What she (friend) has, she can’t sleep just because she can’t sleep, it’s not because of the pain she can’t sleep sometimes, but I think well, if you had all these years of pain then you would understand.” (Participant 6).

“Well my very good pal (name), she keeps saying that she’s depressed and she doesn’t sleep and I’m just thinking in the background... ‘you might be talking about it, you know, but I’m feeling it but I’m not talking about it’. ” (Participant 3).

One aspect of this was the ‘invisibility’ of chronic pain and insomnia. Several Participants highlighted that their condition, although extremely debilitating, was not obvious for others to see, and that this influenced how people perceived them.

“It’s difficult. I think because you look well and that you’re in a normal way that they think there’s not much wrong with you. I think there’s a lot of that. And perhaps maybe I was like that in my day, I don’t know but it’s difficult to not bore people.” (Participant 8).

There was a sense of an undercurrent frustration at how others might perceive them, in that they might not have a condition as serious as they claim, or that somehow other people either could not, or would not understand the experience they were going through, and were resigned to this.

4.2.1.2 Keeping it to myself

One reason that participants will ‘keep it to themselves’ was that they feel that people in general were not interested in listening to them.

“...She says ‘right, you’ve had your moan, I’m supposed to be working’. ” (Participant 2).
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If they did share their feelings, it was usually only with a specific other very near to them, usually a family member, close friend or partner.

“Well my good friends, they will be interested to know how I’m feeling. I don’t really expect people to want to know how I’m feeling.” (Participant 3).

It was common for this experience not to be passed on to certain people.

“Well I don’t make an issue of it. I don’t tell my sons or my daughter. I don’t tell anybody else...Just my wife but I don’t tell her too much.” (Participant 7).

“This is the first time I’ve ever spoke about it, about sleep and pain.” (Participant 10).

When probed further as to why they did not share their anxieties or experience, there was an indication that these might be dismissed.

“Well I know what they would say. They’d say ‘don’t fuss yourself’ you know, but it’s there nevertheless.” (Participant 7).

Following on from this, participants would therefore try to avoid genuinely answering the question.

“I try to kind of say to them, I’m fine, you know I try not to let them worry about it...and I’ll say to him ‘but I’m fine’.” (Participant 4).

“They’ll say, ‘how are you?’, and you want to say ‘awful’, you say ‘och, I’m fine’. ” (Participant 8).

This was not always the case, and those closest might be privy to the negative experience.
“She’ll (participant’s mother) say, ‘you look really tired’, and I say ‘I’m exhausted. I just feel totally drained’.” (Participant 1).

4.2.1.3 Isolation

Participants, as part of holding back on whom they talked to, felt others did not understand their symptoms and that their experience went unnoticed, and with this came associated feelings of isolation. For instance, the solitude and isolation of insomnia:

“I used to text her during the night and she used to say dinnae text me during the night cos my phone goes of...Ken, when you’re sitting there during the night and you’re looking out the window and there’s nothing moving.” (Participant 2).

This was followed by the restrictive aspects of being awake during the night, particularly as the participant lived in a flat.

“It’s boring really. You cannæ do your ironing ‘cos that’s standing up and you’re sore. You cannæ do this, you cannæ do that, you cannæ even shove some washing in the machine and put it on ‘cos you’re annoying your neighbours then. You cannæ do nothing.” (Participant 2).

4.2.1.4 Relationships affected

Being in a relationship and sharing a bed was affected by chronic pain and insomnia in several respects. A great deal of comments in interviews related to how their relationships were affected, and related to areas such as disturbing partners, or being more sensitive, and how this could make them feel guilty or a burden on others. One example was the assumption of a participant that their husband must be an ‘angel’ to tolerate her, when discussing how she was disturbed by her condition during the night:
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“...my husband is blessed with a very good nature and he is an angel really. He’s very good. I do my very best to keep him in a good amiable mood and happy so we can both manage between us.” (Participant 3).

Although the participant is describing her partner as ‘an angel’, there was a distinct tone during the interview that she felt she was ‘walking on eggshells’ in trying not to annoy him. Following this, participants described that when lying in bed awake, they were anxious to avoid disturbing their partner, or express concern about the impact this had on them.

“I try to move slowly so it doesn’t affect him because he does shift work and if he is on a day shift he is up at 6 in the morning and so you know if I’m up at like 2, 3 or 4 in the morning I do know it has on occasions woken him up and I feel, ‘oh golly!’ then he has difficulty in getting back to sleep and he’s got to get up in the morning to do a 12 hour shift and I feel oh, so I am conscious of that.” (Participant 4).

Alternatively, because the participants were sensitive to waking, and treated their sleep as a precious commodity, they would try to ensure that they were not disturbed.

“Most nights we sleep in separate rooms. My husband, if he snores then I will get less sleep that way as well.” (Participant 3).

There was also a negative impact that the pain, associated fatigue and frustration that came with insomnia seemed to generate.

“Yeh, I’m frustrated because I can’t sleep and I’m shouting at my mum on the texts and then I have to say I shouldn’t have said that so I say ‘sorry’ and she says ‘that’s okay, am your mum’ but I feel terrible and I shouldn’t be doing that.” (Participant 1).
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“I says, I’ve got no quality of life, I feel like a total burden to everybody…” (Participant 9).

Therefore, along with the expressed frustration to others that the participants care about, there was also evidence of feelings of guilt about the situation, and this can be read into the statements above concerning the kindness and tolerance of partners who ‘put up’ with the behaviours driven by their chronic pain and insomnia. Some participants were more fortunate in this respect, although this was the exception rather than the rule.

4.2.2 Night–time thinking

The cognitions that participants had about their symptoms, both in terms of emotional regulation and the impact these had on their life were prevalent throughout the interviews. Night-time in particular provided a space for rumination, and participants discussed what they thought about, and how emotive or otherwise this could be. Sleep itself was not so much of a focus, rather, the impact of poor sleep and what this meant to the participant the following day with regard to their ability to cope.

4.2.2.1 More thinking time at night

The space for thought and restrictions on distraction were influences on night-time being a time where more reflection would occur.

“It’s night-times (that I worry)...It’s not quite so bad during the day because I can do things, my crosswords, I can read, I can go on my laptop, speak to my grand-daughter.” (Participant 6).
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This overlaps with the elements of isolation previously identified; the solitude and restrictions on activity and reduced competing stimuli. As previously quoted in the sub-theme ‘isolation’, but just as relevant to this theme was the comment of Participant 2 regarding being bored during the night: unable to iron or do some washing for fear of waking a neighbour.

4.2.2.2 Not worried about sleep...but what about everything else?

When reviewing what participants thought about not being able to sleep, and if this was something they thought about, answers were variable, and some seemed initially counter-intuitive.

“(I think about poor sleep) All the time.” (Participant 1).

“No I don’t worry about it (sleep). One thing I think about I would say about 2 o’clock, I’ve got 8 hour left or 6 hours left you know. I often say that to myself or I say I’ve got 2 hours left. Whether that’s a worry or not, I wouldn’t class it as ...” (Participant 7).

Other participants would tend to give more general responses, recognising sleep was not the only thing they thought about when lying awake at night.

“Just things that happened during the day and things that you’ve done, things that you’re going to do...” (Participant 8)

“Everything. You know, my family...because they don’t get on. My husband; I worry about him...Yeh. Everything just...” (Participant 6).

For most participants, although they thought about sleep, they did not always seem to worry about the sleep itself, and this linked to their levels of acceptance.
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“Well, I’ve stopped worrying about not sleeping now because I thought what’s the point in worrying about it, there’s no point in worrying about it.” (Participant 8).

The participants thought about sleep, but were not necessarily worried about it excessively.

“I don’t actually worry about it. I mean, I know I’m going to be exhausted the next day and it will be more difficult.” (Participant 3).

This introduces concerns about symptoms that poor sleep is perceived to generate, which is covered in the following sub-theme, as well as worries about how the symptoms related to activities and daily functioning the next day.

“…I’ll only really worry about it (sleep) as I say if I’ve got a big day the next day. Normally I won’t worry about it because the next day, if I’m not going anywhere, I’ll have a quieter day.” (Participant 3).

4.2.2.3 Next day coping

As mentioned previously, concerns lay less with direct worries about not being able to sleep per se, but more to do with coping and impact on daytime functioning. Those were the more specific, concrete worries that related to the consequence of not sleeping. This was exemplified when asked the main thoughts they have when unable to sleep.

“How I’m going to cope the next day with...I’ll be more aware of pain the following day if I haven’t had a good night.” (Participant 3).

“it (lack of sleep) affects my speech pattern, my co-ordination, ability to cope with things from the point of view as very much
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to do with coping in my life. Things that I could do standing on my head suddenly become a big mission.” (Participant 5).

Following on from the concerns about how they might struggle to cope the following day, some participants highlighted what this would mean in relation to working. When one who stated they were not worried about sleep was asked if they would feel differently if they had to get up to go to work, they had quite a different perspective.

“Oh yes, I don’t think I would be able to go to work. I certainly wouldn’t I don’t think.”

4.2.2.4 Thought control

There was a strong element of participants being aware of unpleasant thoughts entering their minds, although these were always described in general terms and were usually followed by explanations about trying to manage what they thought about.

“I try not to think about work and I’ve become quite adept at being able to - as thoughts jump into my head about what the next day brings and what work I have to do…” (Participant 5).

In addition to managing what were potentially negative ruminations, some participants focussed on other more positive aspects of their lives.

“There is various things I might have to do, you know my plans, I’ll start thinking about things, as I would during the day...Maybe even thinking about holidays you know away in a months time and...” (Participant 3).

In discussion there was recognition of this, what appeared to be unconscious, thinking strategy. This links to the ‘self-management’ sub-theme below.
“Trying to replace the experience of pain with something more pleasurable maybe. I like to paint, you know, so I’ll maybe be thinking about my painting and planning things like that.” (Participant 3).

4.2.3 Sleep/pain interaction

A key element for understanding relevant dysfunctional beliefs was to understand the attributions and perceived relationship between pain and poor sleep.

4.2.3.1 The significance of sleep

Highlighted in all interviews was the perceived importance of sleep, whether in relation to next day functioning, pain severity, general well-being or coping. This is reflected in the terms by which sleep was described, and gives context to how the poor sleep was seen as crucial to how participants lived their life, or perceive it might be changed by better sleep.

“See when you have a really good sleep it’s almost like you shut the world out, you don’t feel nothing, you don’t feel pain, you don’t feel worry, you don’t feel anxiety.” (Participant 10).

“if only I could get a decent nights sleep; what a difference it would make to how I felt…it would make life so much easier.” (Participant 5).

This is further shown when considering in more detail the different perceptions of how both pain and poor sleep interact.
4.2.3.2 Sleep impacting pain and daytime functioning

Most participants felt that better sleep had a positive impact on their pain. If they had a good sleep, it was perceived to have a positive effect.

“It’s probably easier to cope with because you’re physically and mentally not so tired.” (Participant 5).

“If I have a good night, I have a fairly good day.” (Participant 3).

The converse was also generally accepted, and if they had a particularly bad nights sleep, this could affect the individual on different levels. Firstly, this could negatively impact on the individual’s pain perception.

“I think it (sleep) does (impact on pain). I think when I get less of a peaceful sleep I think the pain is in the higher. It’s maybe even a difference between a 7 and a 9.” (Participant 10).

“Definitely. Much worse pain the next day if I’ve had a particularly bad night. Yes it really does.” (Participant 3).

Not only was there a perceived physical impact on pain severity, there was also perceived influence on the emotional ability to cope with pain, impact on mood, and cognition.

“...you’re that tired and then you know the pain is there anyway but it just seems to be more unable to cope with the pain.” (Participant 4).

“When you ask how it impacts I think it is about mood more than anything.” (Participant 10).

Although this was not always the case, and some participants did not think there was any link between pain and poor sleep.
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“I don’t know the answer to that. I don’t think a bad sleep influences the quality of the pain.” (Participant 7).

4.2.3.3 Pain impacting sleep

All participants had sleep problems that developed after their chronic pain condition began, and this was part of the inclusion criteria and was clarified in the screening interview. In the second interview, when trying to determine perceptions about the impact of pain upon sleep, a concrete example of pain increasing over the years beside worsening sleep was given by Participant 3.

“...I cannot really remember how long I’ve been having trouble with my sleep. I just cannot remember but I do feel that it (sleep) has been worse since my operation. I am much worse since having the operations.” (Participant 3).

This cannot be assumed to be a reversible relationship, as another participant explained. Their pain had improved for a short while, and they were asked if their sleep changed at all as a result of this. Their reply indicated that there was an established pattern of sleep that meant that they would wake up just the same regardless of their improved pain levels.

“I’ve now got into this pattern, this habit and I can’t get out of it.” (Participant 8).

Despite this experience, the beliefs and attributions of others are quite contradictory when considering the impact that reduced pain would have on their sleep.

“I think it (reduced pain) would affect it (sleep) greatly. I think I would sleep no problem.” (Participant 6).
4.2.4 Adjustment and acceptance

One of the prevalent issues faced by participants was their experience of encountering their pain condition and the impacts this had on their lives. The first part of this was recognising a difference in their often-reduced abilities compared to those pre-chronic pain, and grieving for those. Following on from this there appeared to be a progression onto coming to terms with the reality of the ‘loss’ of their old self, and acceptance of their new self. From this, some participants appeared to come to terms with these losses, and from this adopt an attitude of coping in order to describe how they were getting on with their lives. This could be translated into a soundbite of ‘just getting on with it’ (or similar) that reflected how the person thought they were dealing with it. This did not always match up to undercurrent feelings of not coming to terms with the loss, despite vocalising positive statements in other parts of the interview.

4.2.4.1 Loss and grieving

When participants discussed the development of their pain, or how they felt about it, this came across as similar to a person grieving a loss. The arrival of pain often displaced part of their old self as the pain stopped them engaging in activities the way they had once done. There was a feeling of ‘now’ and ‘then’ comparing before and after the pain and insomnia began, with feelings of loss and reflections on the past – what is no longer there that was before.
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“...we went into John Lewis and we had something to eat and then I would have a walk around the lady’s department well I couldn’t do it because my back was so painful I had to just come down and sit at the shoe department... I thought ‘I think we’ll just need to go home’ so we just had to get the bus home because that was as much as we could do. We used to do that quite a lot. It’s things like that that really upset me. Really upset me.” (Participant 8).

This related not only to activity levels, but also to mood and perspective, where there was a distinct picture of what the individual was like and how they treated life.

“You would never see me sitting still for two minutes, it’s just the type of person I was, but I had to learn to cut my life accordingly.” (Participant 5).

4.2.4.2 Acceptance

Acceptance of the pain seemed to be the next step in the narrative several participants shared. They recognised that their pain condition was chronic and unlikely to change in the short to medium term, and explained how they had become accepting over time of their current levels of ability, and of their poorer quality sleep.

“It has become the norm you see now. It’s not as if my life is not sleeping very well but I do not give it an awful lot of thought. I’ve just come to accept that’s me and that’s the way I live...I don’t worry about it. If it (the pain) wakes me up, it wakes me up.” (Participant 3).

Participants tended to recognise this change in perspective when it occurred. Some admitted they used to become frustrated or angry, and would take their feelings out on others near to them. Others acknowledged that they perhaps used to feel sorry for themselves, or worry excessively about their situation.
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“I used to be a big worrier. I used to be years and years ago. You know, I have learned to adapt that over the years.” (Participant 4).

As part of coming to terms with their condition, some participants used social comparison to aid a reduction of perceived severity of their own symptoms.

“I keep thinking ‘there’s always somebody worse than yourself’ and you’ll get there.” (Participant 2).

The comparison with others allows the participant to minimise their symptoms and help gain perspective on their life. By somehow acknowledging they are not the only one experiencing their symptoms, this puts them on a scale where they are not at the extreme end.

4.2.4.3 Adjustment to the new situation

When participants had come to a stage where they vocalised they had accepted their symptoms, and that they might not be able to change these significantly, views about the future related to ‘managing’ it and ‘getting on with it’. They would reflect on what had been, and when probed about how they managed would often use stock phrases that seemed well used and almost automated when dealing with this issue.

“...you’ve just got to get on with it.” (Participant 6).

“...I’ve got to get up but because I’m a coper and get on with it...” (Participant 5).

When discussing work:

“It's the bit that I just get on with.” (Participant 10).
As well as these stock responses was a deeper reflection on how the condition had led them to re-evaluate their life, and take a new approach to it. There is the view that plans might need to be brought forward as the condition changes, and also that this will change the plans that participants had for their longer-term future. Within this lie anxieties, despite the pro-active plans.

“...I thought if I leave it another three, four, five years, you know, how am I going to be then? Am I going to be able to do physically the things that I want to do?” (Participant 5).

4.2.4.4 Not coming to terms with it…superficial acceptance

For some participants there was a conflict of feelings suggesting they were not fully adjusting or accepting of their health situation, despite initial statements that they were. As an example, one participant initially expresses that they are accepting of the difficulties, and becomes emotional:

“I accept that I’m really disabled and that is emotional. That is very emotional. I haven’t accepted that very easily. (Participant starts crying) I wasn’t going to cry again.” (Participant 8).

There then comes further affirmation of acceptance, before admission that this process is not wholly complete (and possibly may never be), and can be very difficult for them to deal with.

“It’s taken a long time to accept and perhaps I haven’t fully accepted the fact that I’m not going to be the person what was, and I’ve just got to do that and it’s difficult. Very difficult.” (Participant 8).
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After previously talking about how they have accepted their condition, participants would typically go on to discuss how difficult their condition was to cope with. Often the descriptions could become quite emotive, and although the language used may seem innocuous, the tempo or tone could increase, indicating rising distress when talking about the subject. Beginning with a positive statement:

“...I always look for a silver lining...” (Participant 4).

The participant then went on to provide a description of what happens during the night with their partner in terms of trying not to disturb him and take her medication. This was a detailed ‘blow-by-blow’ account that increased in pace with little breathing space, and indicated they were becoming exasperated as they partially relived the experience during the interview.

“I have tried putting medication at the bedside so I can just reach over and get it and things like that but one of them is an Oramorph bottle it has one of they lids that ... and with having arthritis it is difficult at times and I keep saying I’m going to move into another box. My children are all grown up now and there is no risk of a child taking it because otherwise at night I could be doing click, click, click and he’s saying ‘Give me it, I’ll do it’. Usually he’s saying that and I hear that and there’s a wee nudge and I say speak up, you know and he’s like shouting ‘I’LL DO IT!’”. (Participant 4).

When asked how that made her feel:

“I just think another day, more pain....well you just hope that when you get up it eases (sobs). Sorry.” (Participant 4).

This was representative of when participants recounted their experiences, as well as feelings of resignation that although tied in with their statements of acceptance,
implied this acceptance had somehow been ‘forced upon them’, and they had no choice but to cope. These statements did not always sit well with how they expressed their situations, and could contradict their global coping statements of earlier.

4.2.4.5 The future

Exploring expectations about the future led to participants focussing on disparate areas. Here, there was not a cohesive theme, but a variety of expectations, assumptions, levels of acceptance and coping, as well as uncertainty. Some had not thought about the future and what it might hold in terms of their health in general or pain and poor sleep in particular.

“I don’t know, I’ve never really thought about it. I’ve never thought to myself will get this get worse, will it ever get better. I’ve never thought of that sort of thing, I’ve just accepted it and eh you know...No, I don’t reflect on it at all.” (Participant 7).

Some had thought about it, and expected no changes to occur. The pain, in one case, is expected to be there forever (described as a ‘fact’), and attitude is one of managing the condition rather than trying to change it.

“It’s been that long and I’ve lived that long with pain it’s almost like I can’t envisage what a sleep would be like with it not being there.” (Participant 10).

Following this, the outlook of some participants had been modified by their condition. Despite feeling the condition was not going to change, or potentially might worsen, they had taken this into consideration when thinking how this might impact their life in the future. The first considers how they might change their career, the second how
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their outlook will shift to focussing more on the moment, with less planning for the future.

“...I’ve a lot of plans and I look to the future when I retire...Am I going to be able to do physically the things that I want to?...it has made me re-evaluate life.” (Participant 5).

4.2.5 Self-management

This related to the areas where the participants perceived they could control their environment, and possibly, symptoms. The first area was that of the bedroom environment, and the second was sleep strategies.

4.2.5.1 Controlling the bedroom environment

One of the key areas to be repeatedly highlighted was the bedroom environment. Not only was this frequently mentioned, but participants would often go into great detail about exactly how their bedroom was laid out, what types of mattress, pillows or duvet they used (and previous experiences with different variations). The environment would have been well thought out, with variations and ‘tweaks’ made over time including temperature, colour schemes, and smells (using e.g. lavender on their pillow). From this, there is a strong feeling of searching for a solution; a means by which they can improve their sleep. Again, this would seem to contradict the belief that only pain can improve sleep, and suggest that although this is a clear belief, they will search for alternative strategies.

“I redecorated my bedroom, I bought more bedding, I tried to get more fluffy things, I try to make it soft, I get the soft colours, I get the scented candles, I make sure there’s no TV in...
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*my room, there’s no activity, cos I’ve read all sorts of things about sleep.* (Participant 10).

The bedroom might be shared with a partner, but they could have a second room that they used sometimes. This overlaps with, and is covered in quotations in the sub-theme of ‘impact on relationships’ discussed above.

### 4.2.5.1 Sleep strategies

In addition to the descriptions given about their bedroom environment, the routines and strategies employed during the night were discussed in several interviews. This included doing mathematical problems in their head, ‘offloading’ thoughts or concerns into a notebook to deal with the next day, and simply getting out of bed to have a biscuit or drink.

> “I used to lie sometimes and factorise numbers in my head or multiply long numbers together.” (Participant 7).

Despite the majority of these adhering to the ethos of basic sleep hygiene principles, not all strategies are what could be described as positive.

> “Sometimes I get up and go and get a cup of coffee and just sit there for a wee while.” (Participant 2).

And some strategies that used to be employed were more difficult to implement due to either pain, fatigue or a feeling that they don’t work.

> “I used to knit but I cannae knit now. I can’t follow a pattern or anything. If I could maybe do something, ken? If there was something that you could do that’s quiet...I cannae read; I’ve no concentration. If I’m watching the television, if it’s a film I’ll tape it.” (Participant 2).
4.2.6 Relationship between super-ordinate themes

As part of an analysis of a larger sample of participants, it is advised (Smith et al., 2009) that a diagrammatic representation of how super-ordinate themes interrelate, and this is shown in Figure 3. Considering how themes relate to each other allows a process where we can evaluate the significance and influence each might have on the other, and possible temporal relationships.

As a starting point it seemed that three themes interacted with each other in a bidirectional relationships: The privacy of pain and solitude of sleep; night-time thinking; and pain/sleep interaction. Through the interaction of these three elements, a cohesive lived experience emerges and translates into the acceptance and adjustment process of managing the condition. Following this, the adjustment and acceptance translates into actions in the form of self-management strategies.

Firstly, considering how the first 3 elements interact, we can see that: Private pain and the solitude of sleep, relates to the fundamental visceral experience of chronic pain and insomnia; Sleep and pain interaction relates to the beliefs held about how these factors might affect each other and; Night-time thinking relates to the cognitions that go through the mind of the individual – it is their thinking. When combining the visceral experience with beliefs (both pre-existing and subsequently reshaped) and thoughts, the result is a multi-dimensional lived experience. Once this is in place, the individual can reflect on what this means to them, and through acceptance, move through to adjustment. The individual accepts their current experience, but where they
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see the opportunity to take control, these adjustments are translated into actions relating to self-management.
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The lived experience of chronic pain & insomnia:
Learning what pain and insomnia mean to the person

Adjustment & acceptance
- Loss & grieving
- Acceptance & adjustment
- Coping & ‘getting on’

Translated into actions:
Controlling what can be controlled

Self-management
- Controlling the bedroom environment
- Sleep strategies

Figure 3. Model illustrating integration of super-ordinate themes
4.3 Reflections on findings

As mentioned previously, both Willig (2001) and Smith et al. (2009) both recommend transparency on the part of the researcher. Making the reader aware of the researcher’s own beliefs, attributions, experiences and personal identity allows them to digest the interpretations made by the researcher in an open and transparent way. The reader can then themselves judge if there has been bias or influence on the research. In addition to this, the journal can highlight these to the researcher themselves, and therefore help their development through the research process.

To facilitate this transparency, the researcher undertook a reflexive diary where thoughts, emotions and experiences could be expressed. This diary was reviewed post-interviews and elements of it are given below, expressed in the first person so as to better reflect the personal experience to the reader.

4.3.1 Personal Reflections

The first elements that I noted just prior to undertaking the qualitative interviews with participants expressed some of the anxieties I felt at that time. I had conducted semi-structured interviews before, but never for a qualitative study, so I was unsure how this experience might differ.

“Not sure what this will be like today. Will questions be relevant? Will the discussion dry up? Not sure how I’ll balance probing questions with empathy – don’t want them to think I’m being pushy...” (Extract 1).
In addition to this there was the weight that this related to my doctoral thesis, and that the outcomes could have a significant impact on my qualification as a Clinical Psychologist. There was an element of guilt mixed in with this too.

“Feeling the pressure to get ‘good material’. Feels a bit mercenary prying like this for what feels like my own gain. What do they get out of it?” (Extract 2).

After my first two interviews I was feeling better about the interviews in terms of having gotten some of them ‘under my belt’ and a bit of experience. Later, when reading through the transcripts of these, which were my ‘pilot’ interviews (on the basis of which I was planning to tweak my interview protocol) I began to have some doubts about the richness of data I was garnering.

“Not sure how good my follow-up questioning has been, and if I’m getting enough information out of the interviews. Struggling to pull together themes at this stage after reviewing a couple of interview. A bit worried I won’t get enough data to analyse.” (Extract 3).

I felt I could have been more probing or used better follow-up questions to get more information, but was wary about being too ‘pushy’ at the same time.

In addition to this, as the interviews progressed, I noticed an urge to help the participants; providing guidance or asking questions that would normally relate more to a therapeutic role to which I am accustomed to working. When hearing about participants using poor basic sleep hygiene, it was difficult to maintain focus on maintaining the role of an enquirer, rather than a therapist.
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“I keep on wanting to tell people that what they’re doing isn’t helping themselves! It’s hard not to turn the interview into some kind of treatment session... I must resist the urge!” (Extract 4).

As interviews progressed, I began to feel more comfortable with the fundamental purpose of the research. Although initially it felt that I had been doing this for my own gain, through participant responses, I began to see that taking part in the research was itself giving participants a positive feeling. This came through particularly when wrapping up interviews with the final question about how they found the interview experience and talking about these issues.

“Feeling that interviews are giving people a chance to talk about something they normally bottle up and keep to themselves. They can feel pretty lonely when it comes to their symptoms. They seem to feel better just by my listening and showing interest. Talking about them as a ‘whole’ rather than just being seen as constituent parts. Some say that’s how they feel when they see medics, which makes me feel sad for them. If only medics could have the chance to talk to them the way I have it might help things...” (Extract 5).

Because of this, my ‘urge to help’ perspective changed. Instead, I began to realise that by giving the participants the opportunity to talk about their symptoms in a safe environment, and feel this is contained, seemed to have a positive effect in itself. I reflected on this, thinking I should be mindful of this element when going back to my therapeutic work.

My confidence in ‘getting enough data’ began to grow, and I realised that the information would come by itself, if people were given the space to bring their thoughts. My attitude eased off with this confidence, allowing the data to come through itself, with less anxiety about asking the ‘right questions’.
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Feeling better about interviews the more I do. Realising that each one will contribute a little bit more, and that each interview will not have ALL the answers.” (Extract 6).

This reduced anxiety helped address my feelings of doubt surrounding how much I could probe in certain topics. The pressure to gain better information reduced, and I allowed more space; as I allowed more space, the participants filled this with what was relevant to them. This also helped any concerns about agenda setting, with the participant having a greater role in choosing the course that the interview would take.

In summary, as the interviews progressed, my urge to ‘fix’ was replaced by my recognition that the interviews themselves were providing a safe space for people who may not have had the opportunity to talk about this subject. In addition, as my confidence grew, I became more relaxed about allowing the participant the space to choose the direction of the interview, and that by doing so, this naturally brought rich data in most cases.

4.3.2 Participant reflections

Participants were asked at the end of their interview how they found the experience. Commonly this would bring them to comment on the themes previously mentioned, such as keeping their experiences to themselves, and how it was rare of them to share these. Often this would be followed with some reflection on how the sharing process itself had been good, and something of a relief when having ‘bottled up’ their feelings for such a long time.
Participants also became aware that some of the questions asked had made them think about topics they had not done so before, such as the future or more deeply about the relationship between their pain and sleep. Was stated in a reflective, thoughtful manner, as participants seemed to be thinking about our discussion as they spoke. Sometimes this could be quite melancholy.

“At least you’re very reflective and realise how some people let you down. (laugh) It makes you feel emotional and you realise that this is the way life is however long any of us have got, nobody knows.” (Participant 5).

After analysis was complete, each participant was sent a summary of the results section where themes were collated and explained (Appendix 15). Contact was made with 4/11 (36%) of participants (Participants 4, 6, 8, and 11), and their feedback was discussed.

Participants re-emphasised the theme of ‘keeping it to myself’, and expanded that it may depend on how long you had suffered pain and poor sleep. Two suggested that if you had symptoms for many years, you would be more likely to keep these to yourself, as you would become sensitive not to bore people with complaints.

One of the strongest messages that came across was that others could not understand what the experience was like. This came through on all feedback discussions, and
participants felt strongly that unless you experienced it yourself, you could not know what pain and insomnia combined was like, and the impact it could have on your life.

One participant highlighted the relationship between pain and sleeplessness, emphasising how pain became worse with lack of sleep, and how this pain/fatigue combination reduced their motivation to engage in activities. Their exhaustion would mean they were less likely to undertake the advice of doctors and physiotherapists in particular. They had been recommended to go swimming but due to the fatigue, found it difficult to leave the house to implement this advice. This highlights the peripheral effects of sleeplessness and fatigue, whereby it results in patients finding difficulty in actively engaging in their recovery/maintenance programmes. This in turn feeds back into the cycle of continuing pain and poor sleep.

The ‘acceptance’ theme was highlighted by two participants as being important, but for different reasons. Firstly, one described struggling to accept their situation, but despite this repeated some of the stock phrases explored earlier, such as:

“You’ve no option. You’re stuck with it. You just have to do the best you can and get on with it.” (Participant 4).

The other described recognising that it probably was not going to improve, but that retirement from her job would hopefully improve things. She added that this would reduce the pressure she felt under at work, and that she would often worry about returning back to work, and what her manager would say. This would usually be unsympathetic and anxiety provoking.
One participant disagreed with the theme that the insomnia and pain could cause difficulties in relationships. She described her relationship with her husband being fine. The theme was then explained in terms of it being about how symptoms could change how participants related to partners, friends and family. The participant said that it was only her and her husband, and that their relationship was not affected by these symptoms.

Overall there was good agreement with themes, and it was expected that some themes may not have been pertinent to all participants. Feedback was positive about the subjective interpretation of interviews, describing the identified themes as a good way of ‘telling the story’ of what they went through on a daily basis and how it felt for the individual.
5 Discussion

This chapter will firstly summarise the findings from the current study before providing reflections on individual super-ordinate themes in the context of existing literature, including relevant studies previously reviewed in the earlier systematic review. How current findings translate into implications to existing theory and clinical practice will then be discussed, followed by methodological strengths and limitations of the study. Finally, suggested areas for future research shall be discussed.

5.1 Summary of results

The aim of this study was to explore the experience of chronic pain and insomnia. In particular, enquire about the beliefs, thoughts and feelings in relation to pain, insomnia, functioning, and how these relate to each other. 11 outpatients were recruited who were attending a chronic pain clinic with CLBP as their main symptom, and who had subsequently developed insomnia as a result.

Participants were interviewed about their sleep and pain experiences, attributions and beliefs and transcripts of interviews analysed. Using Interpretative Phenomenological Analysis (IPA) five super-ordinate themes were generated. The first theme was ‘The privacy of pain and solitude of sleep’ and this represented the experiential and emotional element of having chronic pain and insomnia. The symptoms are often invisible to others and this could make participants feel isolated and misunderstood. The ‘Sleep/pain interaction’ theme indicates the bi-directional nature of these
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symptoms and associated beliefs and attributions. They were both perceived to drive each other in a negative cycle (although poor sleep was commonly thought to reduce coping with pain by increasing fatigue, rather than increasing pain directly). ‘Night-time thinking’ covers the range of night-time rumination that was prevalent throughout all participants. Thoughts were not necessarily worries - some thoughts were positive strategies to avoid thinking about pain. Following this, acceptance levels of their condition appeared to moderate the anxiety associated with night-time thinking. These three themes are linked in terms of representing the experience, thoughts and beliefs of living with chronic pain and insomnia. Combining these led on to the fourth theme of ‘Adjustment and acceptance’. This relates to the process through which participants moved from initially grieving the loss of their old self, through varied levels of adjustment and acceptance, and the need to feel they had to ‘just get on with it’. This links with the next theme of ‘Self-management’. Here, for both those that come to some form of acceptance as well as those that do not, self-management was an important factor in participants exerting some sort of control over their environment. This was the behavioural outcome of the previous themes combining, and where they felt it was possible, participants would implement self-management strategies to minimize symptoms where they could.

Linking all of these master themes together is the influence of control. This can be exemplified in recognising the loss of functioning (and hence inability to control symptoms), accepting limited levels of control, recognising that there are still some areas that might be controlled, and trying to influence these through self-management where possible. For those not accepting their pain symptoms as relatively fixed, this
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was an ongoing area of testing what could and could not be controlled, and may account for the frustrations and distress. For others, the grieving process seemed to still be with them as they became upset at the loss of ability and impact of symptoms.

5.2 Reflections on master-themes

5.2.1 Reflections on ‘the privacy of pain and solitude of sleep’

As discussed in the introduction, the breadth of literature examining the combined experience of pain and insomnia is extremely limited, therefore much of the existing context that this study is set within relates to literature exploring either chronic pain or insomnia. The privacy of pain and solitude of sleep is an example of this, and these are identified individually within the literature for pain and the literature for insomnia. These factors are combined in the current study (potentially increasing the effect), and describe an experiential element of chronic pain and insomnia.

Firstly, the ‘invisible illness’ sub-theme is identified in chronic pain literature and Snelgrove and Liossi (2009) recognise this in their qualitative study on living with chronic back pain. Their subtheme of ‘not being believed’ was underpinned by the lack of visibility of the condition, and Clarke and Iphofen (2005) identified those with CLBP feeling vulnerable to accusations of malingering. Following this, one participant discussed how coping with the lack of sympathy was upsetting, and that this was down to the hidden nature of the condition - it was differentiated from a cut on your hand that is seen by others. The lack of understanding ties in with the feelings of isolation that the current study also showed affected participants.
In the qualitative study by Kyle, Espie and Morgan (2010), three superordinate themes were identified in those with insomnia: 1) ‘Just struggle through’, 2) ‘isolated, feeling like an outsider’ and 3) ‘insomnia is an obstruction to the desired self’. The second theme in particular was picked out in the current study, marking out isolation and how relationships between the individual and others was affected by their unique experience of solitude caused by insomnia.

5.2.2 Reflections on ‘night-time thinking’

This cognitive element of experiencing chronic pain and insomnia is recognised in other literature particularly relating to the night-time experience of lying awake. Despite the content of thoughts often relating to pain, the type of thoughts are strongly reflected in the insomnia literature, and suggested models of maintenance of insomnia symptoms.

In the study by Wicklow and Espie (2000), insomniacs used voice activated recording devices to record their pre-sleep thoughts when experiencing delayed sleep onset (n=21 over 63 subject nights). In this study they found that 43% of thoughts related to ‘rehearsing/planning, problem solving’ (past day, experiences, next day, things to do, planning things, forthcoming events; work-related and social issues; friends and family); 20% related to sleep and its consequences; 12% reflections on quality of thoughts (‘thinking about thinking’, mind buzzing, thoughts rushing); 9% about arousal status (thinking about feeling exhausted, experiencing sleepiness, preoccupation with physical tiredness). Remaining thoughts related to external noise
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(6%), autonomic experiences (6%), procedural factors to do with research (3%), and getting up/ putting the light on (1%).

Firstly it can be seen that the second most common topic is mirrored by this study’s highlighting about concerns of the impact of sleep, and consequences on next day coping. The most common topic overlaps with ‘Not worried about sleep’, although recognises some distinct differences. As the majority of the participants in our study acknowledged, this was not an area they focussed on, and that their thoughts were more general in nature (what happened during the day, things they had done, things they were planning to do, family etc.) This matches the Wicklow and Espie (2000) study. What seems quite different is that there was more concern about not only next day consequences and coping, but the element of falling asleep itself. It is recognised that the current qualitative study did not measure thoughts in a quantitative way, so this is interpreted with caution. Despite this, there seemed to be a qualitative difference in anxiety about sleep, which was an affect-laden cognition in the Wicklow and Espie (2000) study, but was not reported as such in the current study. This is an area to be discussed in suggested future research below. This is a very interesting study in that it, despite the lack of chronic pain being a part of this experience, the affect related to the thoughts was also assessed. As noted above, the largest element of pre-sleep cognitive activity related to ‘rehearsing, planning and problem solving’ thoughts, and this percentage may not be the same for those with chronic pain. The authors highlighted that the most commonly thought about subject was not necessarily causing the participants worry or delaying sleep onset.
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Through statistical analysis Wicklow and Espie (2000) demonstrated that ‘active problem solving’ was the sole category that did not show a significant correlation with ratings of emotional tone assigned to recordings. The authors therefore conclude this implies that this area (representing the majority of pre-sleep cognition) is less affect-laden. This links strongly with the aspect noted in the current study that participants did not necessarily worry about things (and were keen to point this out), more that they thought about things (a less affect-laden implication being given). This differentiates thinking from worrying, an assumption that can intuitively be made about insomniac thought content during sleepless night-time periods. Here, a link can be made to the model proposed by Espie and Wicklow (1999), where pre-sleep mental arousal (being a factor inhibiting sleep-onset) corresponds to the cognitive demands on the individual. They describe this is as the ‘load’ or ‘business’ of the mind.

Watts, Coyle and East (1994) studied (non-pain) pre-sleep mental activity, and concluded there were two types of insomniacs: worried insomniacs think about work-related issues and general mental activity; in contrast ‘non-worried insomniacs’ tended to focus on problems they were having with sleep process itself. This indicates that we cannot globalise insomnia and thinking styles or patterns. Predispositions also need to be considered. In the Wicklow and Espie (2000) study, self-awareness and self-monitoring was found to inversely correlate with what they described as ‘emotional tone’. From this they conclude that more monitoring of the autonomic state of the individual, the greater the perceived unpleasant emotions. Although both ‘sleep and its consequences’ and ‘rehearsing, planning and problem solving’ were shown to delay sleep onset, it was the former that showed greater negative associated affect. Therefore
the current study builds on this nascent but growing body of research, highlighting the needs to challenge assumptions that all night-time thinking is necessarily worrisome. This is important when considering how focussed CBT-I should be, and what areas it should concern itself with.

5.2.3 Reflections on ‘sleep/pain interaction’

The impact of poor sleep is widely recognised and its impact on quality of life well documented (Kyle, Espie & Morgan, 2010) and this is highlighted in the current study. The breadth of impact extends into the next day for the participants, and this matches the diagnostic definition of insomnia as a ‘24 hour disorder’. Snelgrove and Liossi (2009) recognised the psychological impact of the pain as well as the physical with participants reporting feeling ‘crabby’ and short-tempered resulting in quarrels, upset and feelings of being ‘down in the dumps’.

Another important element of this was the impact sleep had on pain and daytime functioning. Affleck, Urrows, Tennen, Higgins and Abeles (1996) studied 50 females with fibromyalgia and reported that the poorer sleepers tended to report significantly more pain. Temporal analysis showed that a comparatively bad nights sleep correlated with a following day of significantly greater pain levels. As discussed in this introduction, poor sleep has been shown as a highly significant predictor of pain frequency or intensity the following day (e.g. Irwin et al., 2012; Tang et al., 2012). The recent study by Irwin et al. (2012) showed that when those with a chronic pain condition (Rheumatoid Arthritis) were partially sleep deprived, this exacerbated their levels of pain the following day. This was the first study to experimentally restrict
sleep in a genuine chronic pain population (previous studies had artificially induced pain), which gives this research good credence. All this research is consistent with the reports given by participants in the current study.

When considering the impact pain has on sleep, things become more complex. Studies have demonstrated pain relates to poor sleep the following night (Edwards et al, 2008; Nicassio, Moxham, Schuman & Gevirtz, 2002; Smith & Haythornthwaite, 2004), but this evidence has been challenged. Affelck, et al. (1996) reported that a more painful day was followed by a night of poorer sleep (self-reported). Their study showed that when analysing across participants, the attention paid to pain was unrelated to sleep, but within-person analysis showed a significant bi-directional relationship between these factors that was not correlated with varying levels of pain intensity. This challenges the attribution that the participants in the current study make that pain severity itself is the driver of poor sleep. It would seem that evidence begins to point to it being the attention paid to pain that may have some influence. This research is furthered by work from Tang, Wright and Salkovskis (2007) who studied chronic back pain & insomnia. They found that health anxiety and emotionally loaded pain ratings best predicted severity of sleep problems in their sample. This accounted for 30% of the total variance when current pain severity was controlled for. What was described as ‘affective pain’ was still a significant predictor of insomnia severity when additional factors of anxiety and depression were controlled for alongside pain intensity. Further research by Tang, Goodchild, Sanborn, Howard and Salkovskis (2012) assessed pain at different time points throughout the day. They found that pre-
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sleep cognitive arousal rather than pain severity, was a more reliable predictor of sleep.

It is evident that cognitions and attributions about sleep are important in the impact they have on sleep quality; the current study shows that there are strong attributions about the influence of pain on sleep, but that research demonstrates that it may be the attributions themselves, rather than the pain severity, that is disrupting sleep. An example of this is shown in Wilson, Watson and Currie (1998) where subjects with musculoskeletal pain who experienced greater pain severity reported more sleep impairment than those with low pain severity – actigraphy measuring sleep showed that this perception was incorrect. Therefore, it was the perception of pain that correlated with their perception of their sleep rather than pain severity itself, which showed no correlation.

When considering the relationship between insomnia and chronic pain, it is worth revisiting one of the key models of primary insomnia (Figure 4) by Morin (1993). This provides some context within which to reflect upon the attributions made by the participants in the current study. By using this, we can assess how the model might account for, or accommodate chronic pain symptoms. Figure 4 illustrates how the different factors interplay, and although this model is some years old, it is still relevant in translating the findings of affect laden pain perceptions over pain severity scores.
Although pain can be added into the ‘Arousal’ element of Morin’s model, what emerges from the literature and the findings from the current study is the importance of the attributions made about pain. Previously this model had focussed on the dysfunctional attributions and beliefs surrounding sleep, and these would often be maintaining factors driving insomnia in the longer term. The responses from the participants in the current study emphasise the importance of pain on their sleep could just as easily be added into the Dysfunctional Cognitions segment of Morin’s model, as these appear to be just as powerful in predicting severity of insomnia symptoms.

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Just as Morin and Espie (2003) put it in their book Insomnia – A clinical guide to assessment and treatment’:

“a person may experience sleep disturbances because of real stressful events, but such difficulties are typically exacerbated because of the person’s appraisal of insomnia and its consequences.”

This could easily be transposed onto the findings from the current study with relation to attributions about the interaction between pain and insomnia.

5.2.4 Reflections on ‘adjustment and acceptance’

After the above three super-ordinate themes that explore the lived experience, adjustment and acceptance covers the product of combining these: it represents the process and outcome of what an individual goes through as they experience chronic pain, and assign some practical meaning to this in their life. As with the participants in the current study, Snelgrove and Liossi (2009) identified what they described as ‘secondary losses’ such as loss of independence, social roles, spontaneity and mobility. Their qualitative study investigating living with CLBP and participants often referred to their ‘old self’ and what they were like prior to the chronic pain starting. This reflects the experience of the participants in the current study, where loss and grieving for the old self was a part that seemed to co-exist with adjustment and coping strategies. It was still present in the thinking of participants in both studies, with references made back to the ‘old self’ compared to the new, seemingly less valued self.
Snelgrove and Liossi (2009) identify an increasing loss of faith in physical treatments, and the current study again reflects a move away from expecting change to occur in the future, and towards an acceptance of the status quo. Notably, this theme is less prevalent in the insomnia literature, possibly indicating the attribution in the chronic pain / insomnia population that pain is the key driver to insomnia, as shown in above themes. For instance, it does not feature in the theoretical model of insomnia by Morin (1993) shown in Figure 4, nor does it appear in the qualitative analysis of Kyle, Espie and Morgan (2010) where the three superordinate themes recognised in their primary insomnia participants were: Just struggle through; Isolated, feeling like an outsider; Insomnia is an obstruction to the desired self.

Osborn and Smith (2006) highlight the model suggested by Pincus and Morley (2001) with regard to how pain is assimilated into a meaning or view of the self. As well as a self-schema, they propose individuals also hold one or more illness-schemas, as well as a pain schema. This seems rather limiting, but none-the-less accounts for the internal conflict exemplified in the current study. These schemas, they suggest, are activated individually and accessed accordingly – but if they become frequently activated simultaneously, can lead to enmeshment. This means that what were views of the self that existed to form a cogent picture, become disrupted with affective distress the outcome. This may represent the element found in the current study where there is conflict between the statements of adjusting to the situation / coping with the losses of functionality, and the underlying distress which contradicted this in terms of distressed tone / tempo of speech or crying. This inner conflict is represented most clearly with statements by participants that they ‘just got on with it’ being expressed at
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the same time as distress (exemplified through increased tone, tempo of speech, wavering voice or crying). This seems to evidence an affect management strategy that was evident not only within in the interview, but also in other everyday settings they recounted in interview. These are distracting statements that avoid the key issues and ‘cover’ a lack of acceptance.

5.2.5 Reflections on ‘self-management’

Following on from Adjustment and acceptance, and in relation to the model proposed linking the super-ordinate themes together in the current study, participants showed they would try to intervene and improve any elements that they thought were under their control. This was the result of the assessments made through adjustment and acceptance, and related more directly to cognitive and behavioural self-management strategies. Participants, through evaluating their situation, began to reach conclusions of what they could and could not control in their condition, or would be involved in a process of testing out where these boundaries were. In the current study, two key areas where they felt they could somehow influence their symptoms related to managing the bedroom environment and employing strategies to reduce negative nocturnal rumination.

The strategies from the current study reflect a component within the Fichten et al. (1998) study, who go on to propose a theory of how these are applied. Fichten et al. (1998) studied older adults during periods of wakefulness in bed (both good and poor sleepers), and their analysis concluded a three factor model of thinking categories: 1). generalised positive thinking; 2). generalised negative thinking; and 3). thoughts
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related to sleep. Our participant group was different in terms of having a chronic pain condition, but there are similarities evident nonetheless. They suggest that insomniacs may use positive thinking as a ‘buffer’ in an attempt to combat more negative emotions, and this would relate to the ‘thought control’ sub-theme.

In the qualitative Snelgrove and Liossi (2009) study concerning living with CLBP, ‘managing the pain’ was one of the three super-ordinate themes. Coping strategies were physically focussed e.g. changing bodily position to alleviate pain, use of heat and avoidance strategies. This was despite the recognition that the physical pain had emotional impact on themselves – the physical element remained the focus of attempting to control the symptoms, potentially reflecting it being seen as the driver to emotional difficulties. In the current study, there was a large emphasis on trying to control the bedroom environment and associated activities in order to address the pain, which was also seen as the driver of the insomnia. What was also evident was the application of cognitive strategies that were amiss in the CLBP focussed study.

There was similar recognition in both studies of the impact of pain, but it was only in the current study where there seemed to be recognition of the value of using cognitive strategies – even if participants did not reflect on them as ‘strategies’ until they were questioned about what they thought about at night and why. This may reflect the different experience of insomnia, and indicates there may be a large element of rumination involved, possibly encouraged by the time spent awake during the night with little else to do. The cognitive challenges appear to be more apparent in the insomnia literature in terms of excessive rumination, despite both conditions (chronic
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pain and insomnia) evidencing strong challenges to adjustment within the individual. This is evidenced by the plethora of cognitive therapy techniques relating to dysfunctional beliefs about sleep (Espie, Inglis, Harvey & Tessier, 1999; Morin, 1993; Morin et al., 1993), as well as Cognitive Behavioural Therapy for Insomnia (CBT-I) studies and reviews demonstrating its effectiveness in the primary insomnia population (e.g. Morin & Espie, 2003; Riemann & Perlis, 2009) as well as comorbid with chronic pain (e.g. Rybarczyk et al., 2005; and Vitiello, Rybarczyk, Von Korff & Stepanski, 2009; Jungquist et al., 2010).

5.3 Implications for clinical practice

A number of recommendations can be made for clinical practice and service provision based on the themes identified in the current study. It was deemed likely that recommendations appropriate for those with CLBP and insomnia, could also be generalised for those with other chronic pain conditions. This was based on the premise that the underlying experiences of CLBP were recognised in literature investigating other chronic pain conditions (Nicasio, Moxham, Schuman & Gevirtz, 2002; Theadom, Cropley & Humphrey, 2007; Theadom & Cropley, 2010; Tang et al., 2012; Irwin et al., 2012). Based on findings from the systematic review above in conjunction with the current study, it is recommended that different areas of assessment, formulation, and treatment are tailored in line with a stepped-care model.

5.3.1 Accurate assessment

There should be effective assessment of dysfunctional beliefs about chronic pain, sleep and their interaction. Finding an efficient screening tool such as an adaptation of the
DBAS may provide the answer to this, and this is discussed in ‘Further research’ below. It is only upon high quality assessment that a thorough formulation can be built. It is therefore crucial to ensure that assessment is accurately identifying the factors that research has shown best predict insomnia and chronic pain symptoms. Key elements of these have been evidenced above as dysfunctional beliefs about the chronic pain and insomnia interaction.

In addition to this, gender differences were highlighted in the current study with regard to response rate. For males this was 2/37 (5.4%) and for females this was 18/64 (28.1%). This indicates that males are much less likely to volunteer to engage in this type of study, and by implication may be less likely to share their personal experiences about chronic pain and insomnia. This should be noted by the chronic pain practitioner, as unless this area is probed, then the patient may be inclined to keep these concerns to themselves.

5.3.2 Thorough formulation

Simply being aware of the impact that misattributions about chronic pain and sleep can have, can bring them into the consciousness of the practitioner dealing with this population. This in turn will allow consideration when developing a formulation based, for example, on the model of Morin (1993). Following a cohesive and thoughtful formulation, more appropriate treatment allocation can be undertaken based on a stepped care model. This will ideally result in providing the best use of resources as well as providing the patient with the most effective potential route to improving their symptoms.
5.3.3 Improving Treatment

5.3.3.1 Implementing CBT-I in PMPs

Current Pain Management Programmes (PMPs) acknowledge poor sleep as an area of importance to those with chronic pain. The emphasis is often on sleep hygiene rather than a targeted programme of CBT-I, and this would potentially demand an increase in resources (staffing, training, accommodation overheads, integration into the existing PMP– potentially increasing their length, or a reduction in other parts of the PMP to accommodate). Edinger et al. (2007) has conducted some research identifying four fortnightly sessions as being an effective treatment exposure to a CBT-I programme for this with primary insomnia (although this may need to be further assessed in terms of the chronic pain population).

A benefit of this type of intervention is that there is good evidence that it can be put into a structured protocol and delivered by appropriately trained staff. This means that a range of health professionals can be involved potentially creating efficiencies and improving feasibility. Espie et al. (2012) demonstrated an effective ‘online’ CBT-I treatment delivered by a ‘media-rich’ web application. This was shown to improve sleep and associated daytime functioning of adults with insomnia. This might be applied to a chronic pain population (see further research).

5.3.3.2 Tailoring a CBT-I programme for chronic pain

Tang (2009) highlights the need to improve the efficacy of existing CBT-I programmes when treating pain-related insomnia. After treatment ended and
improvements were made, remission rates of 57% (Edinger et al., 2004) to 16% (Currie et al., 2000, 2002) indicate a large proportion of participants lose benefits gained in treatment.

None of the CBT-I programmes that have been employed in studies with chronic pain participants with insomnia had been modified specifically to target those with a chronic pain condition (see above Systematic review). All were based on standard CBT-I programmes for primary insomnia. Most of these programmes focus on the behavioural elements of insomnia (usually 6-8 sessions), with only one session directed towards challenging dysfunctional beliefs. Morin, Blais and Savard (2002) showed the importance in addressing dysfunctional beliefs and attitudes about sleep, when a reduction in these through a treatment programme showed a significant correlation with better treatment outcomes and maintenance of gains. This was in a primary insomnia population so this should be noted as a difference, but potential indicator of relevance.

The current study found particular areas of thinking that could be used to inform changes of the cognitive element of existing CBT-I programmes. Firstly, some group work might be useful in terms of evidence from the theme ‘The privacy of pain and solitude of sleep’. Exploring this experience jointly would be aimed at gaining a shared experience across individuals - the significance of isolation was evidenced in the current study and a group-format would facilitate an opportunity to address this. Possibly allowing some informal meeting time at the end or beginning of group sessions might also be an indirect way of addressing this.
The assumption that nighttime thinking was usually laden with negative affect appeared not to be the case in the current study. This was evidenced in the ‘Nighttime thinking’ theme, where participants used strategies to distract from pain or to spend their time awake in a positive way (potentially reducing the negative affect experienced). Therefore, using nighttime thinking in a positive way could form part of the programme – an example being positive planning of enjoyable activities.

The super-ordinate theme of ‘Pain / sleep interaction’ links with recent research where the emotional affect associated with the pain is more significant in determining perceived sleep quality than the pain severity itself (Tang et al., 2012) Some psycho-education regarding this may be useful in shifting such beliefs about how these factors influence each other. This would have the aim of reducing pain related affect and therefore improving perceptions of sleep quality.

These three areas provide the foundation for the experience of the individual, and go to shape how they perceive their experiences. By intervening here and challenging the beliefs identified in the current study as unhelpful, the opportunity presents where the resulting experience can be modified in a positive way. This is emphasising the influence cognitions have in the insomnia / chronic pain experience, and adding this to the existing CBT-I protocol. The other themes recognised (‘Acceptance and adjustment’ and ‘Self management’) are discussed in terms of how they relate to ACT principles and this is explored below.
5.3.3.3 Acceptance and Commitment Therapy (ACT)

There has been some work in applying ACT to insomnia, although it is used more commonly with chronic pain. Incorporating ACT principles into CBT-I was the focus of a study by Dalrymple, Fiorentino, Politi and Posner (2010). This work reflects the elements in the current study relating to adjustment and acceptance, as well as participants trying to influence parts of their life that they believed could be controlled. These are aspects that are found in ACT, and indicate there is the potential to draw on this technique to address elements of chronic pain and insomnia, also explored by Espie et al. (2010).

Key ACT principles include the ability to recognise in a situation the elements that should be accepted, and are outwith the means of control of the individual. This reflects the super-ordinate theme of ‘Adjustment and acceptance’ from the current study and therefore the relevance of an ACT approach. The relative permanence of chronic pain and its ongoing disruption to sleep was a difficult aspect for participants in the current study to accept. With this were associated negative emotions, and ACT allows the individual to be less dominated by these through the use of metaphor and mindfulness techniques.

In addition to this, the super-ordinate theme of ‘Self-management’ relates to the element of ACT that is concerned with living to one’s values. In a limited way, participants were trying to live to their values by e.g. protecting their relationships by occasionally sleeping in adjacent rooms or getting out of bed and reading. Although not always enjoyable, they were trying to exert some control and protect that which
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yay valued most. This aspect could be broadened by an ACT approach to relate to other, more general aspects of life. Reflecting on the values of an individual is a component in ACT which allows the individual to review what it is in life they really value, and whether the actions they take are aimed at making this come true (where possible). This allows a prioritising of actions which is particularly useful for those with reduced capacity for activity, such as those with chronic pain conditions and fatigue which is exacerbated by insomnia.

5.4 Methodological critique

5.4.1 Limitations

The current study has methodological limitations. Firstly, participants were recruited from a single outpatient pain clinic. The sample was 91% female despite recruiting from a gender mix of 63% female, which indicates a gender bias. Much of the existing literature shows a tendency for women to be involved in research studies of chronic pain, although this does not necessarily reflect the balance of those experiencing chronic pain and insomnia. The experience and thoughts of females and males may be different, and referring to the age of the only male involved, he was 81 years old, and the oldest participant in the study. This may introduce some bias to results. Males and females may self-refer in different quantities, and as the response rate to recruitment shows, females appear more willing to talk about this than their male counterparts.

Following this, response rates previously cited appear low, particularly for males 2/37 (5.4%). Response rates for females was 18/64 (28%). To put this in context, we must consider the prevalence rates of insomnia in the chronic pain population as a whole:
Tang, Wright and Salkovskis (2007) quote this as 53% in their chronic pain outpatient sample. Therefore, only a predicted 53% of the 101 would have relevant symptoms, and it was from this limited pool that participants were drawn. This lower response rate for males in itself tells us something about potential gender differences. It is a useful indicator that we should be more inquisitive when dealing with men as they are less likely to provide such information, particularly if unsolicited.

Recruitment was made on the basis of staff referrals, and although they were encouraged to put forward anyone with chronic low back pain, they may have displayed selection bias, for instance, based on who seemed more likely in their view to respond, the emotional content of the ongoing consultation (which could be distressing for some patients) or for other reasons.

By selecting only chronic low back pain patients, the current study may be highlighting difficulties that are not experienced by all chronic pain sufferers. This is acknowledged and should be remembered when considering results. It is also acknowledged that the symptoms of CLBP can translate across to other chronic pain conditions, and that this was the primary chronic pain symptom of the participants, although most had other areas of pain to a lesser degree, some of which were extremely complex or had no known diagnosis (medically unexplained symptoms).

Participants had experienced CLBP for differing periods of time, which may have influenced their perspective. The more complicated comorbid symptoms of other
conditions were not discussed due to limited relevance, and the specific scope of the current study.

Those receiving treatment for a psychopathological disorder were excluded from the study in order to reduce confounding variables and heterogeneity in the sample. This may therefore not be representative of the ‘real’ population of those with chronic pain and insomnia.

As the transcripts were reviewed one after the other, there was a potential influence of sequential analysis. As themes were identified, there is the possibility that these become sought out by the researcher, and others potentially overlooked as a results. In an effort to reduce this, earlier interviews were reviewed later to reassess if other themes had been missed, and results were passed to selected participants to assess for agreement. The researcher acknowledges that this is a subjective exercise, therefore themes and interpretations will be subjective as a result. The results of the current study should be considered in this context.

5.4.2 Strengths

This is the first study to explore the experiences of chronic pain (CLBP) and its relationship with insomnia. The author is aware of only three studies that study areas similar to this: two of these were quantitative, questionnaire based studies, and the other was a qualitative study. The first (Theadom & Cropley, 2008) used the DBAS questionnaire alone to assess dysfunctional beliefs about sleep in fibromyalgia sufferers. The second (Ashworth, Davidson & Espie, 2010) studied the predictive
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quality of variables (including chronic pain and dysfunctional beliefs about sleep) to predict sleep. Neither of these included any questionnaires relating to beliefs about pain or the interaction of pain and sleep. Finally, a third study (Theadom & Cropley, 2010) where they focused on coping and the impact of chronic pain with no reference to how participants felt or what they thought about chronic pain, sleep or any interaction. Therefore, the current study is unique in terms of population and results.

Rather than standing alone as a set of results, this study has been shown in context of current research and existing models (such as the insomnia model of Morin, 1993), and as such provides useful information in terms of how results can be applied to clinical applications. The qualitative approach has provided a depth of analysis that is not possible with deductive quantitative research, which can be hypothesis driven. The current study is inductive in the findings generated, assisting in building broader understanding in an area little understood.

Following on from this, and in addition to standard demographic information, quantitative data was taken from participants to allow comparisons with the ‘typical’ chronic pain population. This provides additional insight, and although numbers are too small for any statistical comment, the availability to the reader of quantified scores of anxiety, depression and beliefs about sleep allows a broader context within in which to set the current study and its participants.

The current study demonstrated methodological quality by showing: sensitivity to context; commitment and rigour; coherence and transparency; and impact and
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importance. Ethical considerations were paramount, choice of analysis was defined and justified, methodology itself detailed.

By using a CLBP population (some with other comorbid chronic pain conditions) the results are more readily generalised to other chronic pain conditions. The current study also applied a strict criterion of clinical insomnia, meaning those selected had to undergo rigorous but sensitive screening interview to assess insomnia severity. This was not the case in the Theadom and Cropley (2008, 2010) studies, whose focus lay elsewhere.

5.5 Possibilities for future research

5.5.1 Improved assessment tools

Firstly, to assess the significance of chronic pain to insomnia, more efficient measures should be developed. Currently there are no well-validated questionnaires that assess the level of significance of dysfunctional chronic pain and sleep beliefs. The DBAS questionnaire assesses dysfunctional beliefs about sleep but not those related to chronic pain, and this is a key element as these can be predictive of sleep quality, and therefore next day fatigue and reduced coping. In a poster presentation by Nicole Tang (unpublished) she proposed an extension to the existing DBAS in the form of a ten question supplement focussing on pain attributions and beliefs. This questionnaire is in its formative stages and no cut-off scores or deeper meaning has yet been derived from preliminary results as yet.
5.5.2 Quantitatively assess night-time thought content in real time

In the Wicklow and Espie (2000) study, voice activated recorders were used to assess thought content of poor sleepers prior to sleep onset. If this was replicated involving participants with chronic pain and insomnia, this ‘real-time’ thought content would compliment the work of the current study. This would mean we could better understand the affect associated with thoughts, and determine if these are similar to those held during the daytime. As was shown in Tang, Wright and (2007), health anxiety and pain appraisal accounted for 30% of the variance in insomnia severity, despite present pain severity being controlled. Therefore, analysing pain appraisal and health anxiety should form part of the analysis of future research.

5.5.3 Beliefs about pain as predictors of sleep

As discussed, we know that the associated affect of thoughts related to pain better predict sleep quality than pain severity. Work by Crombez, Vlaeven, Heuts and Lysens (1999) showed pain-related fear was more disabling than pain itself, and it is along such lines as this that research for pain and insomnia might progress. To better understand this we need to study the importance of fear-related beliefs about pain, and the impact these have on insomnia severity. Comparing the predictive strength of these beliefs compared to e.g. self-reported pain severity would potentially change how sufferers think about self-management, and inform future CBT-I approaches.
5.5.4 CBT-I and ACT focussed research

By adapting a CBT-I programme to incorporate elements addressing the dysfunctional beliefs about sleep and pain, research could focus on assessing the efficacy of a tailored treatment programme of CBT for those with chronic pain and insomnia (e.g. ‘CBT-CPI’). In addition to this, work by Dalrymple et al., (2010) and Espie, Barry and Forgan (2012) recognise the compatibility of ACT with CBT-I principles, and this relates to the current study in terms of the importance of adjustment and acceptance themes. Ideally this would be a randomised control trial, which would then consider outcomes such as: sleep variables; pain severity (across time points over 24 hours); illness beliefs and health anxiety. The DBAS and an adaptation including chronic pain and insomnia (and their interaction) beliefs would also be informative to further understanding about cognitions and how treatment influenced them.

5.6 Conclusions

The current study has provided an insight into the lived experience of those with chronic low back pain and insomnia. The findings suggest 3 elements combine to create the lived experience: beliefs about pain and sleep (‘pain/sleep interaction’); thoughts and worries at night (‘night-time thinking’); and the experience of being awake at night whilst in pain (‘the privacy of pain and solitude of sleep’). These underpin a process of grieving, adjustment and acceptance (‘adjustment and acceptance’). Acceptance can be transient, with superficial acceptance masking undercurrent struggles, and it is here that consideration of ACT principles become relevant to treatment, based on the research of the current study. From this comes an ongoing development of how the individual feels they can control their symptoms.
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(‘self-management’). This changes over time and develops as adjustment and acceptance changes over time. These findings have repercussions in terms of existing research that shows negative pre-sleep cognitive affect relating to pain predicts insomnia severity. This would suggest that existing CBT-I treatment models should be tailored for chronic pain, possibly including relevant ACT principles, where a ‘CBT-CPI’ treatment approach would better address the dysfunctional beliefs surrounding the relationship between chronic pain and insomnia severity, as well as the adjustment process.
6 Journal Article

Title

Chronic low back pain and insomnia: Understanding the experience and attributions made by out-patients about sleeplessness, pain, and their interaction.

Abbreviated Title for Running Head

Experiences and attributions about chronic low back pain, insomnia and their interaction.

Planned submission to Health Psychology journal (Appendix 12)
6.1 ABSTRACT

Objective: Chronic low back pain (CLBP) is a common form of chronic pain that affects a large population each year. Chronic pain and insomnia are highly comorbid conditions, yet knowledge about how patients perceive their interaction is limited. This qualitative study aims to inform our understanding of the patient experience with particular reference to beliefs and attributions surrounding pain, poor sleep and their interaction.

Methods: 11 outpatients from a chronic pain clinic were recruited who suffered CLBP as their main symptom, and who had subsequently developed insomnia as a result. Data were analysed using Interpretative Phenomenological Analysis (IPA).

Results: Qualitative analysis produced 5 super-ordinate themes: 1) the privacy of pain and solitude of sleep; 2) sleep/pain interaction; 3) night-time thinking; 4) adjustment and acceptance; and 5) self-management.

Discussion: The first 3 themes combine to create the individual experience of CLBP: the visceral, emotional experience; the pre-existing and shifting beliefs; and the thought content. Once this is in place, the individual can reflect on what this means to them, and through acceptance, move through to adjustment. The individual accepts elements of their current experience, but where they see the opportunity to take control, these adjustments are translated into actions relating to self-management. These themes suggest CBT-I should be adapted to include pain specific beliefs to form a CBT for Insomnia and Chronic Pain (‘CBT-CPI’).

Keywords: sleep, insomnia, chronic, back, pain, CLBP (six keywords)

Abstract word count: 223
Journal word count: 7,769
6.2 INTRODUCTION

Prevalence estimates of low back pain vary between studies, although can be up to 46% percent of the population (based in 15 European countries and Israel) for point-in-time prevalence, with 18% living with disabling pain (Breivik et al., 2006). In the year 2000, around 2.6 million people in the UK consulted their GP for advice about this (Office for National Statistics, 2002). Sixty-two percent of people still have pain one year after their first episode of back pain, and 16% of those who were initially unable to work are still not working after one year (Hestbaek, Leboeuf-Yde & Manniche, 2003).

The cost implications of this for both health care systems and the economy are significant - cost of illness estimates (Maniadakis & Gray, 2000) were £1.6 billion for health care and range from £3.4 billion to £9.1 billion (depending on estimate method used) for indirect costs due to lost production. NICE suggests the current costs of these are likely to be substantially greater than these figures, with the retail price index increasing by 28.8% in the following 10 years to July 2008.

A frequent co-morbid symptom of chronic pain is poor sleep. In a recent study by Tang, Wright & Salkovskis (2007), prevalence of clinical insomnia was found to be 53% in an outpatient group attending a pain clinic (n=70), compared with only 3% of matched-healthy controls. It is likely that the number suffering poor sleep at a sub-clinical level is far higher.
Some studies have shown poor sleep to be a highly significant predictor of pain frequency or intensity the following day (Affleck et al., 1996; Edwards et al., 2008; Tiede et al., 2010; Irwin et al., 2012), but this relationship is considered to be reciprocal (Edwards et al., 2008; Smith & Haythornthwaite, 2004); with pain also relating to poor sleep the following night (although the relationship in this direction appears less strong in magnitude). This view has been challenged more recently by Tang et al. (2012) who showed that levels of bedtime anxiety were more important in predicting quality of sleep than previous day pain levels – which showed no predictive effect in their study of 119 participants with chronic pain conditions.

This highlights that as well as the potential contributory physiological impact of poor sleep on pain perception (e.g. dysregulation of the descending pain inhibitory control system; for a review, see Lautenbacher et al., 2006), the cognitive elements of this interaction are also fertile ground for investigation. In healthy individuals, restricting sleep experimentally can impair emotional regulation, cognitive function and heighten pain perception by compromising optimistic outlook and psychosocial functioning (Haack & Mullington, 2005). Irwin et al. (2012) showed that when those with a chronic pain condition (Rheumatoid Arthritis) were partially sleep deprived, this exacerbated their levels of pain the following day. Tang et al. (2012) also found that sleep quality was a consistent predictor of pain the next day, and that better sleep correlated to a pain-relieving effect the following morning.

Investigation into the attributions made by people regarding dysfunctional beliefs about poor sleep has been well explored in the insomnia population e.g. the
Dysfunctional Beliefs and Attitudes about Sleep Scale-16 (DBAS-16) is a validated measure of sleep beliefs (Morin, 1994; Morin, Vallieres & Ivers, 2007). Cognitive behavioural models of sleep disturbance consider ‘correction’ of dysfunctional beliefs an important aspect of treatment, and these provide the basis for CBT-I (Espie, 1991; Harvey, Inglis & Espie, 2002; Morin, 1993). Although ‘dysfunctional beliefs and attitudes about sleep’ is a well-explored area in those with insomnia alone, little is known about such beliefs in those suffering insomnia comorbid with chronic pain. In effect, when CBT-I is implemented in the chronic pain population, we cannot be sure exactly what dysfunctional beliefs exist in the first place. These may or may not replicate those in the primary insomnia population. Currently, and to the best of the author's knowledge, only three papers exist that investigate dysfunctional beliefs about sleep in the context of chronic pain.

Firstly, Theadom and Cropley (2008) conducted a questionnaire-based quantitative study comparing 83 patients with fibromyalgia (FM) with 83 healthy, matched controls. Inclusion criteria did not define that participants had any sleep problems, therefore it was unknown if participants had good or bad sleep. They found that patients with FM (a condition predominantly defined by the presence of chronic pain and fatigue) scored higher on the DBAS-10 than healthy controls. Of note, the authors did not probe dysfunctional beliefs about sleep that relate to pain specifically. The DBAS-10 is a general questionnaire about sleep related beliefs, and has no component relating to chronic pain. Therefore, no assessment was made of the elements considered as possible maintaining factors in insomnia in those with chronic pain i.e. beliefs and attributions about pain and its relationship with sleep.
The second relevant study was conducted by Ashworth, Davidson and Espie (2010) and was again a questionnaire-based quantitative study. This work investigated the cognitive and behavioural factors associated with sleep quality in patients with chronic pain and poor sleep. They found three factors which had significant predictive value of sleep quality: 1) pain at night; 2) dysfunctional attitudes and beliefs about sleep and; 3) depression. Again, dysfunctional attitudes about sleep were generically covered using the DBAS-16 that although very useful, was not developed as a pain related measure, and contains no questions about pain beliefs.

In addition to these, a third study has touched on dysfunctional beliefs about sleep linked with chronic pain (Theadom & Cropley, 2010). The authors recruited 16 FM patients and asked them about their quality of life with FM, sleep quality and management of symptoms. They found four overarching themes: 1) sleep disturbances; 2) inter-relationships between symptoms; 3) coping with disturbed sleep and; 4) impact on daily living. The above study did not quantitatively assess if participants had any sleep problems, and did not screen out any that may have been suffering depression, which is highly comorbid with primary insomnia (i.e. insomnia not related to another medical or psychological condition). Therefore, there is still no research related to those with clinical levels of insomnia (defined in inclusion/exclusion criteria) relating to a chronic pain condition.

Reflecting on the existing research, a number of topic areas remain poorly understood and under-researched in those with chronic pain and insomnia. Key questions remain unaddressed, such as how sufferers perceive pain and sleep interact with each other
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(e.g. do they feel one symptom exacerbates the other? and if so, how do they think this relationship works?); how they feel any perceived interaction has changed over time; the worries they have about sleep and future expectations about symptoms; what they believe others understand about their pain and sleep problems; or how the perceptions of others makes them feel. Importantly, there is no clear understanding of what those with chronic pain and insomnia think about when they are lying awake at night (if thoughts relate to pain, sleep or other issues), and how this experience makes them feel.

No study to date has investigated the experience, beliefs and attributions about pain and sleeplessness in those with insomnia and chronic low back pain. This has been shown as a key area relevant to current thinking about maintenance factors in insomnia, and remains unexplored. The current study aims to address this by interviewing out-patients attending a chronic pain clinic who have a primary complaint of CLBP. A novel aspect of this study is that all participants will be screened to ensure they reach the criteria for clinical insomnia, and therefore that the focus is purely on those with a defined sleep problem. Interviews will focus on areas which have not yet been explored by other studies, such as: the current beliefs held by participants regarding pain and sleep and any interaction; the development of these beliefs over time; the impact of pain and poor sleep on daytime functioning; relationships and work; what participants think about as they lay awake at night and expectations for the future.
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This study aims to provide new insights into the individual experience of insomnia comorbid with CLBP, and subsequently inform models of insomnia comorbid with chronic pain, as well as clinical treatments such as CBT-I.
6.3 METHOD

6.3.1 Participants

101 outpatients at a Chronic Pain Clinic were identified with CLBP and sent an information pack about the study and consent form. A CONSORT diagram (Figure 1) shows the recruitment procedure. 15 volunteers attended an initial screening interview and 11 went on to attend the final qualitative interview.

Inclusion criteria were defined as:

Figure 1. CONSORT recruitment pathway
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- Either difficulty initiating and maintaining sleep (or both) or non-restorative sleep on at least 3 nights per week in the last month.

- Sleep disturbance results in some form of daytime impairment, indicated by the presence of at least one associated daytime symptom, according to diagnostic criteria of: fatigue / malaise; attention, concentration or memory impairment; social / vocational dysfunction; mood disturbance / irritability; daytime sleepiness; motivation / energy / initiative reduction; proneness for errors / accidents at work or while driving; tension headaches and / or gastrointestinal symptoms in response to sleep loss and concerns or worries about sleep (Edinger et al., 2004).

- Pittsburgh Sleep Quality Index score (PSQI; Buysse, Reynolds, Monk, Berman, & Kupfer, 1989) of 6 or above.

- A score of 15 or above (clinical insomnia, moderate severity) on the Insomnia Severity Index (ISI; Morin, 1993).

- Sleep disturbance is not due to substance abuse, another mental or sleep disorder, or a general medical condition not related to their pain condition (adapted and assessed by structured interview, based on Morin & Espie, 2003).

- Outpatient at the Pain Clinic, Ninewells Hospital, Dundee.

- Non-cancer chronic low back pain.

- Participants aged 18 and over.

- Sleep disturbance was temporally related to initiation of pain i.e. the participant did not have pre-existing sleep problems prior to the development of their pain condition.
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Exclusion criteria were defined as:

- Receiving treatment for sleeping difficulties outside Pain Clinic medication
- Suffering from a psychopathological disorder based on self report regarding any treatment from a mental health practitioner, or having been referred and not yet assessed.

Of the remaining 11 participants (Table 1), 10 were female, and ages ranged from 22 to 81 (mean=55.8, SD=15.8). Three participants were employed full-time, one was employed part-time and seven were not employed. None worked shifts. The length of time that participants had CLBP ranged from 1.6 to 49 years (mean= 19.4, SD= 17.4).

<table>
<thead>
<tr>
<th>Participant ID</th>
<th>Gender</th>
<th>Age at interview</th>
<th>Years with CLBP</th>
<th>Bed partner</th>
<th>Alcohol units / week</th>
<th>Employed</th>
<th>Part-time</th>
<th>Shift work</th>
<th>Anxiety</th>
<th>Depression</th>
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<th>PSQI</th>
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</tr>
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<td></td>
</tr>
<tr>
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<td>6.6</td>
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</tr>
<tr>
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<td>11</td>
<td>5</td>
<td>23</td>
<td>16</td>
<td>6.8</td>
<td></td>
</tr>
</tbody>
</table>

Key: ISI (Insomnia Severity Index); PSQI (Pittsburgh Sleep Quality Index); Anxiety and depression scores taken from the HADS (Hospital Anxiety and Depression Scale) HADS scoring: 0-7 Normal; 8-10 Mild; 11-15 Moderate; 16-21 Severe, DBAS-16 (Dysfunctional Beliefs about Sleep). Validity analysis of DBAS-16 cut-off suggests >3.8 as level of unhelpful beliefs about sleep associated with insomnia (Carney et al., 2010).
6.3.2 Procedure

The recruitment procedure was developed in collaboration with the staff of the Chronic Pain Clinic. Medical staff identified patients with CLBP who were then sent an information pack and consent form about the study. Written consent was obtained from participants prior to interview, and the local NHS Medical Research Ethics Committee approved the study. Participants were advised that their participation in the study would not impact their clinical treatment; and that they could withdraw at any time without needing to provide any explanation. All interviews were digitally recorded and transcribed verbatim. Participant identifying numbers replaced personal identifiers to ensure anonymity.

The screening interview employed relevant questionnaires detailed in the inclusion criteria, as well as demographic information and questions to determine inclusion compatibility. Those who were appropriate for the study were invited back for the second, qualitative interview. The semi-structured interview schedule for the second interview was developed following a review of literature pertaining to both chronic pain conditions as well as that of insomnia, and relevant models (e.g. Morin 1993). The interview protocol outlined five key areas including relevant prompts and was to be used as a flexible guide (not an exclusive, directive list). This protocol was refined slightly after two initial pilot interviews to better focus questions. Questions were framed in an open way, to best elicit a broad and full response, and when the participant did not respond, they would be allowed time in which to gather their
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thoughts. If there was no response, non-directive prompts were given by the interviewer to initiate a starting point for the participant.

<table>
<thead>
<tr>
<th>Interview Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Relationship between poor sleep and pain</strong></td>
</tr>
<tr>
<td>1.1 How, if at all, does pain impact on your sleep (and vice versa)? (probes: daytime/night-time pain influencing sleep; poor sleep influencing pain)</td>
</tr>
<tr>
<td><strong>2. Worries about sleep</strong></td>
</tr>
<tr>
<td>2.1 What do you think or worry about when you can’t sleep? (probes: work, family, pain, money etc)</td>
</tr>
<tr>
<td>2.2 When and how often do you worry about poor sleep?</td>
</tr>
<tr>
<td><strong>3. Sleep changes over time</strong></td>
</tr>
<tr>
<td>3.1 Why do you feel your sleep problems developed?</td>
</tr>
<tr>
<td>3.2 What are your expectations about sleep in the future?</td>
</tr>
<tr>
<td>3.3 How has your pain affected your sleeping patterns?</td>
</tr>
<tr>
<td><strong>4. Influence over symptoms</strong></td>
</tr>
<tr>
<td>4.1 How do you try and improve your symptoms?</td>
</tr>
<tr>
<td>4.2 What would make your sleep/pain better?</td>
</tr>
<tr>
<td><strong>5. Experience impacting identity</strong></td>
</tr>
<tr>
<td>5.1 What do other people understand about your pain and poor sleep?</td>
</tr>
<tr>
<td>5.2 How does this make you feel?</td>
</tr>
</tbody>
</table>

*Figure 2. Interview Schedule used in qualitative interviews*

In order to help describe the participant sample, and put this in some context with the existing literature, two quantitative measures were administered after the interview (so as not to influence the responses given in the semi-structured interview). Questionnaires included were the Dysfunctional Beliefs and Attitudes about Sleep (DBAS-16) and the Hospital Anxiety and Depression Scale (HADS). It was recognised that these quantitative measures were only used in an effort to help describe and understand the participants included in the study, and not in an effort to evidence any quantitative hypotheses.
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6.3.3 Data Analysis

To analyse the transcripts, Interpretative Phenomenological Analysis (IPA) was employed based on the guidance of Smith and Osborn (2003). The technique of IPA is used to study the lived experience of the individual and recognise its significance i.e. how the individual makes sense of their experiences. The data from the semi-structured interviews was analysed using the approach outlined by Smith, Flowers and Larkin (2009) where each transcript is analysed individually before moving onto the next transcript, as a gradual process of developing shared themes develops. Initially, the transcript was read then re-read before initial noting takes place. Emergent themes were developed and connections made across these themes. Once each case was complete, the researcher moved onto the next case whilst looking for patterns developing across cases. When new themes became apparent, the researcher later revisited the earlier transcripts to check if new themes had been apparent but missed on first inspection.

The digital voice recordings of participants were transcribed and to aid re-engaging with them, these were listened to whilst simultaneously reading then re-reading the transcripts. Comments were broken down into three types to aid analysis, and help clarity of approach: 1) descriptive comments to explain the particular area being discussed; 2) linguistic comments concerning the use of language and tone; and 3) conceptual comments to provide some meaning and interpretation to the area being discussed. On reviewing these initial notes, themes were identified and noted in the left hand margin. Clusters of themes from the interview were drawn together to form
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super-ordinate themes, under which common threads could be drawn together. From this, a summary table for each participant was produced. Once this procedure was completed for a participant, it was repeated for the next participant, and so on until all interviews were analysed. Summary tables for each participant were drawn together to identify common cross-participant themes, as well as themes that stood out as being unique to only one or two participants. These tables were integrated to form a table of master themes, where these were present in over one third of participants (Smith et al., 2009).
6.4 RESULTS

Analysing the interviews lead to five recurrent super-ordinate themes (Table 1), each covering a group of related sub-ordinate themes.

Table 2. Overview of super-ordinate and sub-ordinate themes.

<table>
<thead>
<tr>
<th>Super-ordinate themes</th>
<th>Sub-ordinate themes</th>
</tr>
</thead>
<tbody>
<tr>
<td>The privacy of pain and solitude of sleep</td>
<td>• Invisible illness</td>
</tr>
<tr>
<td></td>
<td>• Keeping it to myself</td>
</tr>
<tr>
<td></td>
<td>• Isolation</td>
</tr>
<tr>
<td></td>
<td>• Relationships affected</td>
</tr>
<tr>
<td>Night-time thinking</td>
<td>• More thinking time at night</td>
</tr>
<tr>
<td></td>
<td>• Not worried about sleep…but what about everything else?</td>
</tr>
<tr>
<td></td>
<td>• Next day coping</td>
</tr>
<tr>
<td></td>
<td>• Thought control</td>
</tr>
<tr>
<td>Sleep/Pain interaction</td>
<td>• The significance of sleep</td>
</tr>
<tr>
<td></td>
<td>• Sleep impacting pain and daytime functioning</td>
</tr>
<tr>
<td></td>
<td>• Pain impacting sleep</td>
</tr>
<tr>
<td>Adjustment and acceptance</td>
<td>• Loss and grieving</td>
</tr>
<tr>
<td></td>
<td>• Acceptance</td>
</tr>
<tr>
<td></td>
<td>• Adjustment</td>
</tr>
<tr>
<td></td>
<td>• Not coming to terms with it – superficial acceptance</td>
</tr>
<tr>
<td></td>
<td>• The future</td>
</tr>
<tr>
<td>Self-management</td>
<td>• Controlling the bedroom environment</td>
</tr>
<tr>
<td></td>
<td>• Sleep strategies</td>
</tr>
</tbody>
</table>

Extracts were selected on the basis that they best represented the thoughts and emotions of the broader group of participants (shown in italics). Names have been replaced with a participant number to protect anonymity, and other personal identifying information removed.
6.4.1 Theme 1: The privacy of pain & solitude of sleep

Pain and sleeplessness had an emotional effect on participants. The ‘invisibility’ of the symptoms meant that they tended to keep the experience to themselves, leading to isolation and impact on relationships.

6.4.1.1 Invisible illness

The experience of chronic pain, insomnia and associated low mood was identified as something that other people really could not understand. One aspect of this was the ‘invisibility’ of chronic pain and insomnia. Several participants highlighted that their condition, although extremely debilitating, was not obvious for others to see, and that this influenced how people perceived them.

“Well I’m very private and don’t talk about my pain or lack of sleep at all...except to my husband. Well they’re (other people) just ignorant and it’s okay lets just, you know, that’s fine, we’ll just go along like that...” (Participant 3).

There was a sense of an undercurrent frustration at how others might perceive them, in that they might not have a condition as serious as they claim, or that somehow other people either could not, or would not understand the experience they were going through, and were resigned to this.

6.4.1.2 Keeping it to myself

One reason that participants kept things to themselves was that they feel people in general were not interested in listening to them. If they did share their feelings, it was
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usually only with a specific other very near to them, usually a family member, close
friend or partner.

“Well my good friends, they will be interested to know how I’m
feeling. I don’t really expect people to want to know how I’m
feeling.” (Participant 3).

It was common for this experience not to be passed on, but in interview, there was the
sense that they would like to be able to do so..

“This is the first time I’ve ever spoke about it, about sleep and
pain. And this is really, even when I think about friends I
haven’t spoke about that in connection with pain…I don’t find
it easy to speak to just everybody.” (Participant 10).

6.4.1.3 Isolation

Participants, as part of holding back on whom they talked to, felt others did not
understand their symptoms and that their experience went unnoticed, and with this
came associated feelings of isolation.

“I used to text her during the night and she used to say ‘dinnae
text me during the night cos my phone goes off’...” (Participant
2).

This was followed by the restrictive aspects of being awake during the night,
particularly as the participant lived in a flat.

“It’s boring really. You cannae do your ironing ‘cos that’s
standing up and you’re sore. You cannae do this, you cannae
do that, you cannae even shove some washing in the machine
and put it on ‘cos you’re annoying your neighbours then. You
cannae do nothing.” (Participant 2).
6.4.1.4 Relationships affected

Being in a relationship and sharing a bed was affected by chronic pain and insomnia in several respects, such as disturbing partners, or being more sensitive, and how this could make them feel guilty or a burden on others. One example was the assumption of a participant that their husband must be an ‘angel’ to tolerate her, when discussing how she was disturbed by her condition during the night:

“…my husband is blessed with a very good nature and he is an angel really. He’s very good. I do my very best to keep him in a good amiable mood and happy so we can both manage between us.” (Participant 3).

Although the participant is describing her partner as an ‘angel’, there was a distinct tone during the interview that she felt she was ‘walking on eggshells’ in trying not to annoy him. There was also a negative impact on interactions with others due to the pain, associated fatigue and frustration that came with insomnia.

“Yeh, I’m frustrated because I can’t sleep and I’m shouting at my mum on the texts and then I have to say I shouldn’t have said that so I say ‘sorry’ and she says ‘that’s okay, am your mum’ but I feel terrible and I shouldn’t be doing that.” (Participant 1).

6.4.2 Theme 2 - Night-time thinking

Night-time in particular provided a space for rumination, and participants discussed what they thought about, and how emotive or otherwise this could be. Sleep itself was not a primary focus, rather, the impact of poor sleep and what this meant to the participant the following day with regard to their ability to cope.
6.4.2.1 More thinking time at night

The space for thought and restrictions on distraction were influences on night-time being a time where more reflection would occur.

“It’s night-times (that I worry)…It’s not quite so bad during the day because I can do things, my crosswords, I can read, I can go on my laptop, speak to my grand-daughter.” (Participant 6).

This overlaps with the elements of isolation previously identified; the solitude and restrictions on activity and reduced competing stimuli.

6.4.2.2 Not worried about sleep...but what about everything else?

When reviewing what participants thought about not being able to sleep, and if this was something they thought about, answers were variable.

“(I think about poor sleep) All the time.” (Participant 1).

“No I don’t worry about it (sleep).” (Participant 7).

Other participants would tend to give more general responses, recognising sleep was not the only thing they thought about when lying awake at night.

“Everything. You know, my family…because they don’t get on. My husband; I worry about him…Yeh. Everything, just.” (Participant 6).

For most participants, although they thought about sleep, they did not always seem to worry about the sleep itself, and this linked to their levels of acceptance.
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“Well, I’ve stopped worrying about not sleeping now because I thought what’s the point in worrying about it, there’s no point in worrying about it...I certainly don’t think, ‘oh, I canna (cannot) sleep.’” (Participant 8).

6.4.2.3 Next day coping

As mentioned previously, concerns lay less with direct worries about not being able to sleep per se, but more to do with coping and impact on the following day’s functioning. This was exemplified when asked the main thoughts participants had when unable to sleep.

“How I’m going to cope the next day with, there might be something in particular I have to do, I might have to go somewhere and I worry that my experience of this outing or whatever I’m going to do is going to be impaired by lack of sleep...I’ll be more aware of pain the following day if I haven’t had a good night.” (Participant 3).

6.4.2.4 Thought control

There was a strong element of participants being aware of unpleasant thoughts entering their minds, although these were usually followed by explanations about trying to manage what they thought about.

“I try not to think about work and I’ve become quite adept at being able to - as thoughts jump into my head about what the next day brings and what work I have to do...” (Participant 5).

In discussion there was recognition of what appeared to be unconscious, thinking strategies. This links to the self-management sub-theme below.

“Trying to replace the experience of pain with something more pleasurable maybe. I like to paint, you know, so I’ll maybe be
thinking about my painting and planning things like that…” (Participant 3).

6.4.3 Theme 3 – Sleep/pain interaction

Participants discussed symptoms of pain and sleep, and as part of this it became apparent that there were strong perceived links between these.

6.4.3.1 The significance of sleep

Highlighted in all interviews was the perceived importance of sleep, whether in relation to next day functioning, pain severity, general well-being or coping. This is reflected in the terms by which sleep was described, and gives context to how the poor sleep was seen as crucial to how participants lived their life, or perceive it might be changed by better sleep.

“See when you have a really good sleep it’s almost like you shut the world out, you don’t feel nothing, you don’t feel pain, you don’t feel worry, you don’t feel anxiety.” (Participant 10).

“…if only I could get a decent nights sleep; what a difference it would make to how I felt…it would make life so much easier.” (Participant 5).

This is further shown below when considering in more detail the different perceptions of how both pain and poor sleep interact.
6.4.3.2 Sleep impacting pain and daytime functioning

Most participants felt that better sleep had a positive impact on their pain. If they had a good sleep, it was perceived to have a positive effect, with the opposite also being true.

“If I have a good night, I have a fairly good day.” (Participant 3).

“Definitely. Much worse pain the next day if I’ve had a particularly bad night. Yes it really does.” (Participant 3).

Not only was there a perceived physical impact on pain severity, there was also perceived influence on the emotional ability to cope with pain, impact on mood, and cognition.

“...if you’ve not had enough sleep...it just seems to be more unable to cope with the pain.” (Participant 4).

6.4.3.3 Pain impacting sleep

The beliefs and attributions about the impact of pain on sleep were generally very definite in their content as well as in the manner in which these statements were made.

“If I’d no pain I would have no trouble in getting to sleep. I would say it is crucial.” (Participant 7).

“...until this pain is under control I’m never going to sleep...” (Participant 9).
6.4.4 Theme 4 - Adjustment and acceptance

One of the prevalent issues faced by participants was their experience of their pain condition and the impact this had on their lives. This process was made up of moving on from a process of grieving, through adjustment and acceptance of their new self.

6.4.4.1 Loss and grieving

When participants discussed the development of their pain, or how they felt about it, this came across as similar to a person grieving a loss. The arrival of pain often displaced part of their ‘old self’ as the pain stopped them engaging in activities the way they had once done. There was a feeling of ‘now’ and ‘then’ comparing before and after the pain and insomnia began, with feelings of loss and reflections on the past – what is no longer there that was before.

“...we went into John Lewis and we had something to eat and then I would have a walk around the lady’s department well I couldn’t do it because my back was so painful I had to just come down and sit at the shoe department... I thought ‘I think we’ll just need to go home’ so we just had to get the bus home because that was as much as we could do. We used to do that quite a lot. It’s things like that that really upset me. Really upset me.” (Participant 8).

6.4.4.2 Acceptance

Acceptance of the pain seemed to be the next step in the narrative several participants shared. They recognised that their pain condition was chronic and unlikely to change in the short to medium term, and explained how they had become accepting over time of their current levels of ability, and of their poorer quality sleep.
“It has become the norm you see now. It’s not as if my life is not sleeping very well but I do not give it an awful lot of thought. I’ve just come to accept that’s me and that’s the way I live…I don’t worry about it. If it (the pain) wakes me up, it wakes me up.” (Participant 3).

6.4.4.3 Adjustment

When participants had come to a stage where they vocalised they had accepted their symptoms, and that they might not be able to change these significantly, views about the future related to ‘managing it’ and ‘getting on with it’. They would reflect on what had been, and when probed about how they managed would often use stock phrases that seemed well used and almost automated when dealing with this issue.

“…you’ve just got to get on with it.” (Participant 6).

As well as these stock responses was a deeper reflection on how the condition had led them to re-evaluate their life, and take a new approach to it. There is the view that plans might need to be brought forward as the condition changes, and also that this will change the plans that participants had for their longer-term future. Within this lie anxieties, despite the pro-active plans.

“...I thought if I leave it another three, four, five years, you know, how am I going to be then? Am I going to be able to do physically the things that I want to do? So that has concerns for the future and I am not working full-time any longer but have plans of things that I want to do with my life, and I think ‘well, is that going to be feasible now?’” (Participant 5).
6.4.4  Not coming to terms with it…superficial acceptance

For some participants there was a conflict of feelings suggesting they were not fully adjusting or accepting of their health situation, despite initial statements that they were. As an example, one participant initially expresses that they are accepting of the difficulties, and becomes emotional:

“I accept that I’m really disabled and that is emotional. That is very emotional. I haven’t accepted that very easily. (Participant starts crying) I wasn’t going to cry again.” (Participant 8).

There then comes further affirmation of acceptance, before admission that this process is not wholly complete (and possibly may never be), and can be very difficult for them to deal with.

“It’s taken a long time to accept and perhaps I haven’t fully accepted the fact that I’m not going to be the person what was, and I’ve just got to do that and it’s difficult. Very difficult.” (Participant 8).

6.4.4.5  The future

Exploring expectations about the future led to participants focussing on disparate areas. Here, there was not a cohesive theme, but a variety of expectations, assumptions, levels of acceptance and coping, as well as uncertainty. Some had not thought about the future and what it might hold in terms of their health in general or pain and poor sleep in particular.

“I don’t know, I’ve never really thought about it. I’ve never thought to myself will this get worse, will it ever get better.
I’ve never thought of that sort of thing, I’ve just accepted it and eh you know…No, I don’t reflect on it at all.” (Participant 7).

Others had definite ideas of how their condition would change.

“I think it will get worse. I just think it will get worse because it doesn’t matter what I do.” (Participant 6).

Following this, the outlook of some participants had been modified by their condition. Despite feeling the condition was not going to change, or potentially might worsen, they had taken this into consideration when thinking how this might impact their life in the future.

“...I’ve a lot of plans and I look to the future when I retire...Am I going to be able to do physically the things that I want to do? It has made me re-evaluate life.” (Participant 5).

6.4.5 Theme 5 – Self-management

All participants made comment to some extent on controlling their environment or cognitions. This was an area they felt could somehow improve their situation.

6.4.5.1 Controlling the bedroom environment

One of the key areas to be repeatedly highlighted was the bedroom environment. Not only was this frequently mentioned, but participants would often go into great detail about exactly how their bedroom was laid out, what types of mattress, pillows or duvet they used (and previous experiences with different variations).

“I’ve tried all the different pillows. And now I’m on the memory foam one and they’re supposed to go back to their
normal...It’s like it’s this way and that way one night and another way another night.” (Participant 2).

“I would probably say I have had this system kinda in place probably for the last four or five months now.” (Participant 4).

The bedroom would sometimes be shared with a partner, but they might have a second room that was used on occasion. This overlaps with, and is covered in quotations in the sub-theme of ‘impact on relationships’ discussed above.

6.4.5.2 Sleep strategies

In addition to the descriptions given about their bedroom environment, the routines and strategies employed during the night were discussed in several interviews. This included participants doing mathematical problems in their head, ‘offloading’ thoughts or concerns into a notebook to deal with the next day, and simply getting out of bed to have a biscuit or drink.

“figures were always were important to me and I used to lie sometimes and factorise numbers in my head or multiply long numbers together.” (Participant 7).

Some strategies that used to be employed were more difficult to implement due to either pain, fatigue or a feeling that they don’t work.

“I used to knit but I cannae knit now. I can’t follow a pattern or anything. If I could maybe do something, ken? If there was something that you could do that’s quiet...I cannae read; I’ve no concentration.” (Participant 2).
6.4.6 Relationship between super-ordinate themes

As part of an analysis of a larger sample of participants, it is advised (Smith et al., 2009) that a diagrammatic representation of how master-themes interrelate, and this is shown in Figure 3. Considering how themes relate to each other allows a process where we can evaluate the significance and influence each might have on the other, and possible temporal relationships. As a starting point it seemed that three themes interacted with each other in bidirectional relationships (pain/sleep interaction; night-time thinking; and the privacy of pain and solitude of sleep). Through the interaction of these three elements, a cohesive lived experience emerges and translates into the acceptance and adjustment process of managing the condition. Following this, the adjustment and acceptance translates into actions in the form of self-management strategies.

Firstly, considering how the first three elements interact, we can see that: Private pain and the solitude of sleep, relates to the fundamental visceral experience of chronic pain and insomnia; Sleep and pain interaction relates to the beliefs held about how these factors might affect each other and; Night-time thinking relates to the cognitions that go through the mind of the individual – it is their thinking. When combining the visceral experience, with beliefs (both pre-existing and subsequently reshaped) and thoughts, the result is a multi-dimensional lived experience. Once this is in place, the individual can reflect on what this means to them, and through acceptance, move through to adjustment. The individual accepts their current experience, but where they
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see the opportunity to take control, these adjustments are translated into actions relating to self-management.
Figure 2. Model illustrating integration of super-ordinate themes

- Adjustment & acceptance
  - Loss & grieving
  - Acceptance
  - Being a coper / getting on

  Translated into actions:
  - Controlling what can be controlled

- Self-management
  - Controlling the bedroom environment
  - Sleep strategies
6.5 Discussion

The current study provides a novel insight into the lived experience of those with chronic low back pain and insomnia. It explains key beliefs and attributions surrounding chronic pain and sleeplessness, and suggests a model of how the themes generated link together to form an adjustment process to chronic symptoms. Analysis of interviews revealed five super-ordinate themes: the privacy of pain and solitude of sleep; sleep/pain interaction; night-time thinking; adjustment and acceptance; and self-management.

Firstly, ‘the privacy of pain and solitude of sleep’ is identified in chronic pain literature and Snelgrove and Liossi (2009) recognise this in their qualitative study on living with chronic back pain. Their subtheme of ‘not being believed’ was underpinned by the lack of visibility of the condition, and Clarke and Iphofen (2005) identified those with CLBP feeling vulnerable to accusations of malingering. In the qualitative study by Kyle, Espie and Morgan (2010), one of three superordinate themes was picked out in the current study (“isolated, feeling like an outsider”), marking out isolation and how relationships between the individual and others was affected by their unique experience of solitude caused by insomnia. This was also an experience for those with fibromyalgia in the Theadom and Cropley (2010) study.

The current study highlighted the importance of pain, sleep and their interaction. The impact of poor sleep is widely recognised and its impact on quality of life well documented (Kyle, Espie & Morgan, 2010; Theadom & Cropley, 2010) and this was also highlighted in the current study. Snelgrove and Liossi (2009) recognised the
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psychological impact of the pain as well as the physical with participants reporting feeling ‘crabby’ and short-tempered resulting in quarrels, upset and feelings of being ‘down in the dumps’. Another important element of this was the impact sleep had on pain and daytime functioning, which was again a theme in Theadom and Cropley (2010). Poor sleep has been shown as a highly significant predictor of pain frequency or intensity the following day (e.g. Edwards et al., 2008; Tiede et al., 2010; Irwin et al., 2012) and this was consistent with the reports given by participants in the current study.

In a study by Wicklow and Espie (2000), pre-sleep cognitions were measured using voice activated recorders. The second most common pre-sleep topic of thought that they found (concerns of the impact of sleep, and consequences on next day coping) is mirrored by the current study. The primary topic reported (rehearsing, planning and problem solving) overlaps with ‘Not worried about sleep…but what about everything else?’.

As with the participants in the current study, Snelgrove and Liossi (2009) identified what they described as ‘secondary losses’ such as loss of independence, social roles, spontaneity (a sub-ordinate theme in Theadom and Cropley, 2010) and mobility. Their qualitative study investigating living with CLBP and participants often referred to their ‘old self’ and what they were like prior to the chronic pain starting. This reflects the experience of the participants in the current study, where loss and grieving for the old self was a part that seemed to co-exist with adjustment and coping strategies.
Snelgrove and Liossi (2009) identify an increasing loss of faith in physical treatments, and the current study again reflects a move away from expecting change to occur in the future, and towards an acceptance of the status quo. Notably, this theme is less prevalent in the insomnia literature, possibly indicating the attribution in the chronic pain/insomnia population that pain is the key driver to insomnia, as shown in the above themes. For instance, it does not feature in the theoretical model of insomnia by Morin (1993), nor does it appear in the qualitative analysis of Kyle, Espie and Morgan (2010). Despite this, it does feature in two recent studies amongst others: the work of Dalrymple, Fiorentino, Politi and Posner (2010) looked at introducing ACT principles to CBT-I, and the Espie, Barrie and Forgan (2012) study assessing patient’s preferred treatment approaches to insomnia (comparing CBT-I and ACT principles).

The cognitive strategies from the current study reflect a component within the Fichten et al. (1998) study, who go on to propose a theory of how these are applied. Fichten et al. (1998) studied older adults during periods of wakefulness in bed (both good and poor sleepers), and their analysis concluded a three factor model of thinking categories: 1) generalised positive thinking; 2) generalised negative thinking; 3) and thoughts related to sleep. Our participant group was different in terms of having a chronic pain condition, but there are similarities evident nonetheless. They suggest that insomniacs may use positive thinking as a ‘buffer’ in an attempt to combat more negative emotions, and this would relate to the ‘thought control’ sub-theme. This model is useful but can perhaps be criticised as relatively simplistic, and the current study highlights the breadth of thoughts, some of which are contradictory, concerning beliefs and attributions about sleep and pain.
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Therefore, based on the themes identified in the current study, a number of recommendations can be made for clinical practice and service provision. This was split into aspects of assessment, formulation and treatment.

Firstly, it is recommended that there should be effective assessment of dysfunctional beliefs about chronic pain, sleep and their interaction. Finding an efficient screening tool such as an adaptation of the DBAS may provide the answer to this, and this is discussed in ‘Further research’ below. It is only upon high quality assessment that a thorough formulation can be built. In addition to this, gender differences were highlighted in the current study with regard to response rate. This indicates that males are much less likely to volunteer to engage in this type of study, and by implication may be less likely to share their personal experiences about chronic pain and insomnia. Thorough formulation follows this. Simply being aware of the impact that misattributions about chronic pain and sleep can have, can bring them into the consciousness of the practitioner dealing with this population.

Finally, improving treatment in two areas is recommended: CBT-I should be routinely implemented as part of Pain Management Programmes, and CBT-I should be tailored for those with chronic pain i.e. ‘CBT-CPI’ so that it relates to the findings in the current study. Firstly, some group work might be useful in terms of evidence from the theme ‘The privacy of pain and solitude of sleep’. Exploring this experience jointly would be aimed at gaining a shared experience across individuals - the significance of isolation was evidenced in the current study and a group-format would facilitate an opportunity to address this. Secondly, the assumption that nighttime thinking was
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usually laden with negative affect appeared not to be the case in the current study. This was evidenced in the ‘Night-time thinking’ theme, where participants used strategies to distract from pain or to spend their time awake in a positive way (thus reducing the negative affect experienced). Therefore, using night-time thinking in a positive way could form part of the programme – an example being positive planning of enjoyable activities.

The theme of ‘Pain / sleep interaction’ links with recent research where the emotional affect associated with the pain is more significant in determining perceived sleep quality than the pain severity itself (Tang et al., 2012). Some psycho-education regarding this may be useful in shifting such beliefs about how these factors influence each other. This would have the aim of reducing pain related affect and therefore improving perceptions of sleep quality.

These three areas provide the foundation for the experience of the individual, and go to shape how they perceive their experiences. By intervening here and challenging the beliefs identified in the current study as unhelpful, the opportunity presents where the resulting experience can be modified in a positive way. This is emphasising the influence cognitions have in the insomnia / chronic pain experience, and adding this to the existing CBT-I protocol. The other themes recognised (‘Acceptance and adjustment’ and ‘Self management’) are suited to ACT principles and this is discussed below.
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Including ACT principles as part of this reflects the themes generated in the current study relating to adjustment, acceptance, and living to values by controlling their environment where possible. Key ACT principles include the ability to recognise in a situation the elements that should be accepted, and are outwith the means of control of the individual. This reflects the super-ordinate theme of ‘Adjustment and acceptance’ from the current study and therefore the relevance of an ACT approach. The relative permanence of chronic pain and its ongoing disruption to sleep was a difficult aspect for participants in the current study to accept. With this were associated negative emotions, and ACT allows the individual to be less dominated by these through the use of metaphor and mindfulness techniques.

In addition to this, the super-ordinate theme of ‘Self-management’ relates to the element of ACT that is concerned with living to one’s values. In a limited way, participants were trying to live to their values by e.g. protecting their relationships by occasionally sleeping in adjacent rooms or getting out of bed and reading. Although not always enjoyable, they were trying to exert some control and protect that which they valued most. This aspect could be broadened by an ACT approach to relate to other, more general aspects of life. Reflecting on the values of an individual is a component in ACT which is useful for the individual to review what it is in life they really value, and whether the actions they take are aimed at making this come true (where possible). This allows a prioritising of actions which is particularly useful for those with reduced capacity for activity such as those with chronic pain conditions and fatigue which is exacerbated by insomnia.
The current study has methodological limitations. Firstly, participants were recruited from a single outpatient pain clinic. The sample was 91% female despite recruiting from a gender mix of 63% female, which indicates a gender bias, and is reflected in lower response rates particularly for males. Recruitment was made on the basis of staff referrals and this may involve selection bias. Excluding those with psychopathological disorder may reduce the generalizability of findings. As the transcripts were reviewed one after the other, there was a potential influence of sequential analysis. In an effort to reduce this, earlier interviews were reviewed later to reassess if other themes had been missed, and results were passed to selected participants to assess for agreement.

The current study demonstrated methodological quality by showing: sensitivity to context; commitment and rigour; coherence and transparency; and impact and importance. Ethical considerations were paramount and the methodology is replicable.

This is the first study to explore the experiences of those with chronic pain (CLBP) and its relationship with insomnia. In addition to standard demographic information, quantitative data was taken from participants to allow comparisons with the ‘typical’ chronic pain population.

There are several potential areas for future research. Firstly, improving assessment tools tailored to dysfunctional beliefs about chronic pain and the relationship with sleep would greatly help assessment and formulation. Secondly, quantitatively assessing night-time thought content in real time for those with insomnia and chronic pain (similar to Wicklow & Espie, 2000) would compliment the work of the current study. Analysing pain appraisal and health anxiety should form part of the analysis of this future research. Following this, research on beliefs about pain as predictors of
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sleep would help inform future CBT-I approaches. Finally, the efficacy of a tailored CBT programme for chronic pain and insomnia (‘CBT-CPI’) should be assessed, ideally including ACT principles relating to acceptance, adjustment and living to values.

The current study has provided an insight into the lived experience of those with chronic low back pain and insomnia. The findings suggest 3 elements combine to create the lived experience: beliefs about pain and sleep (‘pain/sleep interaction’); thoughts and worries at night (‘night-time thinking’); and the experience of being awake at night whilst in pain (‘the privacy of pain and solitude of sleep’). These underpin a process of grieving, adjustment and acceptance (‘adjustment and acceptance’). Acceptance can be transient, with superficial acceptance masking undercurrent struggles, and it is here that consideration of ACT principles become relevant to treatment, based on the research of the current study. From this comes an ongoing development of how the individual feels they can control their symptoms (‘self-management’). This changes over time and develops as adjustment and acceptance changes over time. These findings have repercussions in terms of existing research that shows negative pre-sleep cognitive affect relating to pain predicts insomnia severity. This would suggest that existing CBT-I treatment models should be tailored for chronic pain, possibly including relevant ACT principles, where a ‘CBT-CPI’ treatment approach would better address the dysfunctional beliefs surrounding the relationship between chronic pain and insomnia severity, as well as the adjustment process.
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6.6 Journal article references


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7 References


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Cochrane review. (2009). Psychological therapies for the management of chronic pain (excluding headaches) in adults *(Review).*


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8 Appendices
8.1 Appendix 1: SIGN 50 Methodology Checklist 2: Randomised Control Trials
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**METHODOLOGY CHECKLIST 2: RANDOMISED CONTROLLED TRIALS**

<table>
<thead>
<tr>
<th>Study identification</th>
<th>(Include author, title, year of publication, journal title, pages)</th>
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<td>Guideline topic:</td>
<td>Key Question No:</td>
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**Before** completing this checklist, consider:

1. **Is the paper a randomized controlled trial** or a controlled clinical trial? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a controlled clinical trial questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+.

2. **Is the paper relevant to key question?** Analyze using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

**Reason for rejection:** Reason for rejection: 1. Paper not relevant to key question □ 2. Other reason □ (please specify):

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### Section 1: Internal validity

**In a well conducted RCT study...**

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<th>In this study this criterion is:</th>
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<td>1.1</td>
<td>The study addresses an appropriate and clearly focused question.</td>
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**Well covered; Adequately addressed; Poorly addressed; Not addressed; Not reported; Not applicable**

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<td>1.2</td>
<td>The assignment of subjects to treatment groups is randomised</td>
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**Well covered; Adequately addressed; Poorly addressed; Not addressed; Not reported; Not applicable**

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<td>1.3</td>
<td>An adequate concealment method is used</td>
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**Well covered; Adequately addressed; Poorly addressed; Not addressed; Not reported; Not applicable**

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<td>1.4</td>
<td>Subjects and investigators are kept ‘blind’ about treatment allocation</td>
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**Well covered; Adequately addressed; Poorly addressed; Not addressed; Not reported; Not applicable**
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<td>1.5</td>
<td>The treatment and control groups are similar at the start of the trial</td>
<td>Well covered; Adequately addressed; Poorly addressed; Not addressed; Not reported; Not applicable</td>
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<td>1.6</td>
<td>The only difference between groups is the treatment under investigation</td>
<td>Well covered; Adequately addressed; Poorly addressed; Not addressed; Not reported; Not applicable</td>
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<td>1.7</td>
<td>All relevant outcomes are measured in a standard, valid and reliable way</td>
<td>Well covered; Adequately addressed; Poorly addressed; Not addressed; Not reported; Not applicable</td>
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<td>1.8</td>
<td>What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
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<td>1.9</td>
<td>All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)</td>
<td>Well covered; Adequately addressed; Poorly addressed; Not addressed; Not reported; Not applicable</td>
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<td>1.10</td>
<td>Where the study is carried out at more than one site, results are comparable for all sites</td>
<td>Well covered; Adequately addressed; Poorly addressed; Not addressed; Not reported; Not applicable</td>
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**Section 2: OVERALL ASSESSMENT OF THE STUDY**

| 2.1     | How well was the study done to minimise bias? Code ++, +, or - | |
| 2.2     | Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention? | |
| 2.3     | Are the results of this study directly applicable to the patient group targeted by this guideline? | |
## Notes
Summarise the authors conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question.

### Section 3: Description of the Study

#### 3.1 Do we know who the study was funded by?
- [ ] Academic Institution
- [ ] Healthcare Industry
- [ ] Government
- [ ] NGO
- [ ] Public funds
- [ ] Other

#### 3.2 How many centres are patients recruited from?

#### 3.3 From which countries are patients selected?
(Select all those involved. Note additional countries after "Other")
- [ ] Scotland
- [ ] UK
- [ ] USA
- [ ] Canada
- [ ] Australia
- [ ] New Zealand
- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Netherlands
- [ ] Scandinavia
- [ ] Spain
- [ ] Other

#### 3.4 What is the social setting (ie type of environment in which they live) of patients in the study?
- [ ] Urban
- [ ] Rural
- [ ] Mixed

#### 3.5 What criteria are used to decide who should be included in the study?

#### 3.6 What criteria are used to decide who should be excluded from the study?

#### 3.7 What intervention or risk factor is investigated in the study? (Include dosage where appropriate)

#### 3.8 What comparisons are made in the study (ie what alternative treatments are used to compare the intervention with). Include dosage where appropriate.
| 3.9 | **What methods were used to randomize patients, blind patients or investigators, and to conceal the randomization process from investigators?** |
| 3.10 | **How long did the active phase of the study last?** |
| 3.11 | **How long were patients followed-up for, during and after the study?** |
| 3.12 | **List the key characteristics of the patient population. Note if there are any significant differences between different arms of the trial.** |
| 3.13 | **Record the basic data for each arm of the study. If there are more than four arms, note data for subsequent arms at the bottom of the page.** |
| 3.14 | **Record the basic data for each IMPORTANT outcome in the study. If there are more than four, note data for additional outcomes at the bottom of the page.** |
| 3.15 | **Notes. Summarise the authors conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question. (Much of this is likely to be contributed by GDG members).** |
8.2 Appendix 2: Notes on the use of SIGN 50 Methodology Checklist 2: Randomised Control Trials
Notes on the use of Methodology Checklist 2: Randomised Controlled Trials

Section 1 identifies the study, the reviewer, the guideline for which the paper is being considered as evidence, and the key question(s) it is expected to address. The reviewer is asked to consider a series of aspects of RCT design and to make a judgement as to how well the current study meets this criterion. Each relates to an aspect of methodology that research has shown makes a significant difference to the conclusions of a study.

For each question in this section you should use one of the following to indicate how well it has been addressed in the study:

- Well covered
- Adequately addressed
- Poorly addressed
- Not addressed (i.e. not mentioned, or indicates that this aspect of study design was ignored)
- Not reported (i.e. mentioned, but insufficient detail to allow assessment to be made)
- Not applicable.

1.1 The study addresses an appropriate and clearly focused question

Unless a clear and well defined question is specified, it will be difficult to assess how well the study has met its objectives or how relevant it is to the question you are trying to answer on the basis of its conclusions.

1.2 The assignment of subjects to treatment groups randomised

Random allocation of patients to receive one or other of the treatments under investigation, or to receive either treatment or placebo, is fundamental to this type of study. If there is no indication of randomisation, the study should be rejected. If the description of randomisation is poor, the study should be given a lower quality rating. Processes such as alternate allocation, allocation by date of birth, or day of the week attending a clinic are not true randomisation processes and it is easy for a researcher to work out which patients received which treatment. These studies should therefore be classed as Controlled Clinical Trials rather than RCTs.

1.3 An adequate concealment method is used

Allocation concealment refers to the process used to ensure that researchers are unaware which group patients are being allocated to at the time they enter the study. Research has shown that where allocation concealment is inadequate, investigators can overestimate the effect of interventions by up to 40%. Centralised allocation, computerised allocation systems, or the use of coded identical containers would all be regarded as adequate methods of concealment, and may be taken as indicators of a well conducted study. If the method of concealment used is regarded as poor, or relatively easy to subvert, the study must be given a lower quality rating, and can be rejected if the concealment method is seen as inadequate.

1.4 Subjects and investigators are kept 'blind' to treatment allocation

Blinding refers to the process whereby people are kept unaware of which treatment an individual patient has been receiving when they are assessing the outcome for that patient. It can be carried out up to three levels. Single blinding is where patients are unaware of which treatment they are receiving. In double blind studies neither the doctor nor the patient knows which treatment is being given. In very rare cases studies may be triple blinded, where neither patients, doctors, nor those conducting the analysis are aware of which patients received which treatment. The higher the level of blinding, the lower the risk of bias in the study.

1.5 The treatment and control groups were similar at the start of the trial

Patients selected for inclusion in a trial must be as similar as possible. The study should report
Experiences of insomnia and chronic low back pain

any significant differences in the composition of the study groups in relation to gender mix, age, stage of disease (if appropriate), social background, ethnic origin, or comorbid conditions. These factors may be covered by inclusion and exclusion criteria, rather than being reported directly. Failure to address this question, or the use of inappropriate groups, should lead to the study being downgraded.

1.6 The only difference between the groups is the treatment under investigation
If some patients received additional treatment, even if of a minor nature or consisting of advice and counselling rather than a physical intervention, this treatment is a potential confounding factor that may invalidate the results. If groups were not treated equally, the study should be rejected unless no other evidence is available. If the study is used as evidence it should be treated with caution.

1.7 All relevant outcomes measured in a standard, valid and reliable way
The primary outcome measures used should be clearly stated in the study. If the outcome measures are not stated, or the study bases its main conclusions on secondary outcomes, the study should be rejected. Where outcome measures require any degree of subjectivity, some evidence should be provided that the measures used are reliable and have been validated prior to their use in the study.

1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?
The number of patients that drop out of a study should give concern if the number is very high. Conventionally, a 20% drop out rate is regarded as acceptable, but this may vary. Some regard should be paid to why patients dropped out, as well as how many. It should be noted that the drop out rate may be expected to be higher in studies conducted over a long period of time. A higher drop out rate will normally lead to downgrading, rather than rejection of a study.

1.9 All the subjects are analysed in the groups to which they were randomly allocate (intention to treat analysis)
In practice, it is rarely the case that all patients allocated to the intervention group receive the intervention throughout the trial, or that all those in the comparison group do not. Patients may refuse treatment, or contra-indications arise that lead them to be switched to the other group. If the comparability of groups through randomisation is to be maintained, however, patient outcomes must be analysed according to the group to which they were originally allocated irrespective of the treatment they actually received. (This is known as intention to treat analysis.) If it is clear that analysis was not on an intention to treat basis, the study may be rejected. If there is little other evidence available, the study may be included but should be evaluated as if it were a non-randomised cohort study.

1.10 Where the study is carried out at more than one site, results are comparable for all sites
In multi-site studies, confidence in the results should be increased if it can be shown that similar results were obtained at the different participating centres.

Section 2 relates to the overall assessment of the paper. It starts by rating the methodological quality of the study, based on your responses in Section 1 and using the following coding system:

+++ All or most of the criteria have been fulfilled. Where they have not been fulfilled the conclusions of the study or review are thought very unlikely to alter.

++ Some of the criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are thought unlikely to alter the conclusions.

+ Few or no criteria fulfilled. The conclusions of the study are thought likely or very likely to
The code allocated here, coupled with the study type, will decide the level of evidence that this study provides.

The aim of the other questions in this section is to summarise your view of the quality of this study and its applicability to the patient group targeted by the guideline you are working on.

Section 3 asks you to summarise key points about the study that will be added to an evidence table at the next stage of the process. It is important that you complete this section as fully as possible, and include actual data from the study wherever relevant.
8.3 Appendix 3: Letter of NHS Research Ethics Committee approval
Dear Mr McKenzie,

Study title: Chronic low back pain and insomnia: Understanding the experience and attributions made by patients about sleeplessness, pain, and their interaction.

Thank you for your letter of 14 September 2011, responding to the Committee’s request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Co-ordinator by delegated authority.

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.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see “Conditions of the favourable opinion” 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 the start of the study at the site concerned.
Experiences of insomnia and chronic low back pain

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Other conditions specified by the REC

- The letter from Dr Bannister should include a version number and full date. Please submit a revised version for our records.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Confirmation should also be provided to host organisations together with relevant documentation.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evidence of insurance or indemnity</td>
<td></td>
<td>22 July 2011</td>
</tr>
<tr>
<td>Interview Schedules/Topic Guides</td>
<td>1.0</td>
<td>15 July 2011</td>
</tr>
<tr>
<td>Investigator CV</td>
<td></td>
<td>12 August 2011</td>
</tr>
<tr>
<td>Letter of invitation to participant</td>
<td></td>
<td>02 March 2011</td>
</tr>
<tr>
<td>Other: CV - Dr David Gillanders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other: CV - Professor Kevin Power</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other: Letter from Mrs Anne Femon</td>
<td></td>
<td>28 June 2011</td>
</tr>
<tr>
<td>Participant Consent Form</td>
<td>2.0</td>
<td>06 September 2011</td>
</tr>
<tr>
<td>Participant Information Sheet</td>
<td>2.0</td>
<td>06 September 2011</td>
</tr>
<tr>
<td>Protocol</td>
<td>1.0</td>
<td>01 July 2011</td>
</tr>
<tr>
<td>Questionnaire: Dysfunctional Beliefs and Attitudes About Sleep</td>
<td></td>
<td>14 January 2008</td>
</tr>
<tr>
<td>Questionnaire: ISI</td>
<td></td>
<td></td>
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<tr>
<td>Questionnaire: Pittsburgh Sleep Quality Index</td>
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<tr>
<td>Questionnaire: HADS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Questionnaire: 10 Items reflecting pain-related sleep beliefs</td>
<td>1.0</td>
<td>01 August 2011</td>
</tr>
<tr>
<td>REC application</td>
<td></td>
<td>17 June 2011</td>
</tr>
<tr>
<td>Response to Request for Further Information</td>
<td></td>
<td>14 September 2011</td>
</tr>
</tbody>
</table>
Experiences of insomnia and chronic low back pain

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.

After ethical review

Reporting requirements

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

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- 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.

Feedback

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.

Further information is available at National Research Ethics Service website > After Review

11/ES/0020 Please quote this number on all correspondence

Yours sincerely

Mr Carlos Wigderowitz
Chair

Email: fionabain@nhs.net

Enclosures: “After ethical review – guidance for researchers”

Copy to: Professor Kevin Power
Gemma Watson, University of Edinburgh
TASC R&D
8.4 Appendix 4: Introductory letter from Pain Clinic lead consultant
Dear Patient

Please find enclosed some information about a voluntary research study we are running here at the Pain Clinic in Ninewells Hospital. The lead researcher for this study is Paul McKenzie, who is a Trainee Clinical Psychologist, and is running this study as part of his doctoral thesis with the University of Edinburgh.

We are interested in hearing about the experiences of people who have chronic low back pain and difficulty sleeping.

We invite you to take part in this study, but you do not have to and any decision you make will not affect your treatment, care or your relationship with staff in any way.

Yours sincerely

Jonathan Bannister
Signed Electronically

Dr Jonathan Bannister
Consultant in Pain Medicine
Clinical Leader, Tayside Pain Service

Enc
8.5 Appendix 5: Participant Information Sheet
Participant Information Sheet

Title of Project- “The relationship between chronic pain and poor sleep: A qualitative study of patient beliefs”

You are being invited to take part in a research study that is being conducted in part fulfillment of Doctorate in Clinical Psychology degree at the University of Edinburgh. Before you take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Please contact the lead researcher (Paul McKenzie, Trainee Clinical Psychologist) on 01382 740 406 if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

What is the purpose of the study?
The aim of the study is to help us understand the experiences and beliefs of people who have chronic low back pain and clinical insomnia. These two symptoms often happen alongside each other, but what patients feel about these together has not been evaluated.

In this study I would like to ask you about your beliefs about chronic pain and sleep, and how you feel these relate to daily activities.

Am I eligible to volunteer?
To volunteer for this study you must fulfill the following criteria:

- Attend the Pain Clinic with chronic low back pain as a main symptom
- Have sleep problems that began after your pain condition began (or at the same time)
- Either difficulty initiating and maintaining sleep (or both) or non-restorative sleep on at least 3 nights per week in the last month
- Sleep disturbance resulting in some form of daytime impairment or difficulties

How to volunteer,
If you are willing to take part in this study you can arrange for the lead researcher (Paul McKenzie, Trainee Clinical Psychologist) to contact you to arrange an appointment. To do this:

- Phone us here at the Pain Clinic on 01382 740 406
  or
- Post the consent form back (address is on the form)
  or
- Speak to a member of staff when you next attend an appointment here at the Pain Clinic

Do I have to take part?
No. Your decision will not affect your treatment or care or your relationship with staff in any way. If you decide to take part you are still free to withdraw at any time without giving a reason. If you withdraw, all identifiable data will be destroyed. A decision to withdraw at any time will not interfere in any way with your treatment or care.

What will happen to me if I take part? What do I have to do?
If you decide to take part, you will need to sign a consent form to make sure that you have understood the information on the form.

I will arrange with you to have a half hour appointment with me (Paul McKenzie) at the Pain Clinic. I will ask some questions about your sleep and medications, and you will be asked to complete some questionnaires to assess your sleep quality. If you have levels of poor sleep that can be classified as ‘clinical insomnia’ you shall be invited back for a second session to discuss if these affect you on a day to day basis, and what you think of how pain and sleep interact for you (if at all). This will be conducted by me and should take about 45-60 minutes, and will be recorded so it can be transcribed later.

You will be sent out a summary of the study findings, and have the opportunity to comment on these if you wish. You will be able to speak to the lead researcher (Paul McKenzie), or send in your comments, but you are not obliged to do so.
What are the possible advantages/disadvantages of taking part?
We hope these findings will contribute to future treatments for people with chronic pain and sleep problems. By participating, you will be helping in this process. The experience of discussing these issues may be upsetting in some instances. If you do feel upset, I will be happy to stop the interview for a break or to reschedule. You may decide that you wish to withdraw from the study, and can do so without having to provide a reason. Additional support can be provided through the Pain Clinic who can refer you to the relevant clinician.

Will my information be kept confidential?
Yes. Your name will be replaced by a participant number so you cannot be identified. All information gathered in the study shall be stored in a locked cabinet, until the final report is written and recordings and transcripts shall be destroyed. The only time confidentiality will be breached is if we become concerned that you or someone else is at risk of harm.

The Tayside Committee on Medical Ethics A/B, which has a responsibility for scrutinising proposals for research on humans, has examined this proposal and raised no objections from the point of view of medical ethics. The study has also been reviewed by appropriate groups from the Pain Clinic and University of Edinburgh. Sometimes, to make sure researchers are doing what they said they would, information from the study is available for scrutiny by monitors from NHS Tayside and the University of Edinburgh.

What will happen to the results of the study?
The results of the study will be submitted to the University of Edinburgh for review and may be published for report, scientific journal and/or presented in conferences. All direct quotes used will be anonymised and identifying details removed.

What if there is a problem?
Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you decide to take part in the research and are not happy with any aspect of the study, you can speak to:

- Professor Kevin Power, Psychological Services, 7 Dudhope Terrace, Dundee, DD3 6HG. Tel: 01382 306150.

As a patient of the NHS, you have the right to pursue a complaint through the usual NHS process. To do so, you can submit a written complaint to the:

- Patient Liaison Manager, Complaints Office, Ninewells Hospital, DD1 9SY. Freephone 0800 027 5507.

If you believe that you have been harmed in any way by taking part in this study, you have the right to pursue a complaint and any resulting compensation through the University of Edinburgh who are acting as the research sponsor. Details about this are available from the research team. Note that the NHS has no legal liability for non-negligent harm. However, if you are harmed and this is due to someone's negligence, you may have grounds for a legal action against NHS Tayside but you may have to pay your legal costs.

Independent advice
If you want to speak to someone independent from the study about research and what it involves, you can contact:

- Dr Heather Wilkinson, Research Director, School of Health in Social Science, University of Edinburgh, Teviot Place, Edinburgh, EH8 9AG.

Contact for further information
Should you have any further questions about the study, please contact:

- Mr Paul McKenzie, Trainee Clinical Psychologist, Clinical Health Psychology, South Block, Level 6, Ninewells Hospital, Dundee, DD1 9SY, Tel: 01382 740406

Thank you for taking the time to read this information sheet and considering taking part
Paul McKenzie

Version 2.0 Page 2 06/09/11
8.6 Appendix 6: Participant Consent Form
Experiences of insomnia and chronic low back pain

Consent Form

Title of Project: The relationship between chronic pain and poor sleep: A qualitative study of patient beliefs

Name of Research Leader: Mr Paul McKenzie, Trainee Clinical Psychologist

I confirm that I have read and understand the Information Sheet (v2.0 dated 6/9/11) for the above study. I have had the opportunity to ask questions and have these answered.

I understand that my participation is voluntary and that I have the right to withdraw from the study at any stage without giving a reason, and without my medical care or rights being affected.

I agree to information being audio recorded and transcribed.

I understand that small segments of my interview may be used for publication in reports. I understand that should this happen, I will not be identified from any of the information.

I agree to the research leader asking my consultant to provide a list of my current medications.

I agree to participate in the study.

Your Contact Phone Number: ____________________________

Name of Patient ____________________________ Signature ____________________________ Date ____________

Name of Interviewer ____________________________ Signature ____________________________ Date ____________

Please phone Paul McKenzie on 01382 740406 to arrange an appointment or post this form and he will call you back:

Paul McKenzie, Clinical Health Psychology, South Block, Level 6, Ninewells Hospital, Dundee, DD1 9SY.

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8.7 Appendix 7: General screening and demographic questions
## Screening: Sleep and Chronic Pain Study

**Name:**

**DoB:**

- Chronic lower back pain.
- Either difficulty initiating and maintaining sleep (or both) or non-restorative sleep on at least 3 nights per week in the last month.
- Sleep disturbance is not due to substance abuse, another mental or sleep disorder, or a general medical condition not related to their pain condition (adapted and assessed by structured interview, based on Morin & Espie, 2003).
- Sleep disturbance results in some form of daytime impairment, indicated by the presence of at least one associated daytime symptom, according to diagnostic criteria (Edinger et al., 2004).
- PSQI score of 6 or above.
- ISI score of 16 or above.
- Outpatient at the Pain Clinic, Ninewells Hospital, Dundee.
- Non-cancer pain.
- Aged 18 and over.
- Sleep disturbance is temporally related to initiation of pain
- Not receiving treatment for sleeping difficulties outside the Pain Clinic
- Not suffering from a psychopathological disorder.

**Is participant eligible to be included in study? Yes / No**

**Did participant agree to return for interview? Yes / No**
Screening: Sleep and pain Study

Name: ______________________________ Date: __________________
DoB: ___________ Participant Id: ___________
Gender: ______
Chronic lower back pain: Yes / No
Other medical conditions:

Mental health conditions:

Receiving treatment for sleeping difficulties outside the Pain Clinic: Yes / No

Current medications:

Start of pain symptoms (year): ______
Start of sleep problems (year): ______
Employment: No / Full time / Part time
Does participant work shifts: Yes / No
Alcohol consumption per week:
Caffeine consumption:

PSQI completed: Yes / No
ISI completed: Yes / No
Other sleep disorders screen completed: Yes / No
8.8 Appendix 8: Interview Schedule
Experiences of insomnia and chronic low back pain

Interview Schedule

The interview will focus on the current beliefs held by the participant regarding pain and sleep and any interaction, the development of these beliefs over time, and the impact they perceive pain and poor sleep has on them.

Key areas which inform the scope of this study and questions

1. Relationship between poor sleep and pain
2. Worries about sleep
3. Sleep changes over time
4. Influence over symptoms
5. Experience impacting identity

1. Relationship between poor sleep and pain
   1.1 How, if at all, does pain impact on your sleep (and vice versa)? (probes: daytime/nighttime pain influencing sleep; poor sleep influencing pain)

2. Worries about sleep
   2.1 What do you think or worry about when you can't sleep? (probes: work, family, pain, money etc)
   2.2 When and how often do you worry about poor sleep?

3. Sleep changes over time
   3.1 Why do you feel your sleep problems developed?
   3.2 What are your expectations about sleep in the future?
   3.3 How has your pain affected your sleeping patterns?

4. Influence over symptoms
   4.1 How do you try and improve your symptoms?
   4.2 What would make your sleep/pain better?

5. Experience impacting identity
   5.1 What do other people understand about your pain and poor sleep?
   5.2 How does this make you feel?

How did you find this interview?
8.9 Appendix 9: Excerpt from Participant 10 coded transcript
### Experiences of insomnia and chronic low back pain

<table>
<thead>
<tr>
<th>Thematic Coding</th>
<th>Interview – Participant 8</th>
<th>Exploratory codes: Underlined = Description / Content; Italics = Language; Bold = Conceptual / Interrogative.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>I:</strong> What about changes in pain?</td>
<td><strong>P:</strong> That’s interesting because I hadn’t even thought about that because it’s like that pain is there that much that it’s almost like just a part of me and I hadn’t even thought about it.</td>
<td>Reflective pose</td>
</tr>
<tr>
<td><strong>I:</strong> People answer that question differently, your focus was on what I can do and what I’ve done and trying to improve that, so what can I control. Rather than what can other people or things, what other things could change.</td>
<td><strong>P:</strong> It’s been that long and I’ve lived that long with pain it’s almost like I can’t envisage what a sleep would be like with it not being there. When you asked me what would make me have a better sleep, I think I’ve actually accepted the fact that pain is there and all I can do is try and do things to make it less of a discomfort but I can’t do anything to take it away. That’s what I feel. I feel I have to find a way to cope with it, manage it, live with it but I can’t do anything to change it. I can’t change that in itself, it’s there.</td>
<td>Acceptance; Reflective storytelling exploration.</td>
</tr>
<tr>
<td><strong>I:</strong> Yes, it’s fixed or relatively fixed.</td>
<td><strong>P:</strong> That’s what it feels like, it feels like I’ll have it for the rest of my life and I feel I’ll never get rid of it.</td>
<td>Has she accepted it? Is this reluctant ‘superficial’ acceptance?</td>
</tr>
</tbody>
</table>
| **I:** That was actually one of things I was going to ask you about because when we were going through the questionnaires you indicated that it’s been like thirty years or something that the pain really | }
| Self-management | started through work and heavy lifting and stuff and then the sleep started getting worse after that started. But then thinking about how you anticipate it being in the future. It sounds from what you’re saying that you think it might be quite fixed. |
| Future expectations about pain - acceptance | P: I think so, I mean I’ve done all sorts of things, I’ve seen chiropractors and different people with different treatments and paid a fortune for alternative therapies, you know, reflexology, Indian head massage and Shiatsu, the whole lot. I’ve gone through the whole of them and sports physios and all sorts. I’ve even had x-rays done where apparently the bottom vertebraes are practically touching each other so I feel like if it’s in my spine and I’ve already went down the route of trying to do myself what I could with the help of certain other approaches. |
|  | I: So maximise the potential of what you can do. So in the future you see pain pretty much the same. Is that ....? |
|  | P: I would love to waken up one day and it’s not there. I would love to. All I can think of is that certain days I will waken up and it’ll be a little bit less than the day before. Or I might get a week when it’s not too bad and then I might get a couple of weeks when it’s just horrendous and I have to be glad for the weeks or the days when it is not at it’s worst and that’s how I feel. Do I ever think that it won’t ever by there though, to be able to just take away, no I don’t think that because I don’t think that’ll happen. I’m only getting older and degenerative whichever is just going to get worse. So what can you do. I think by being physically active, I’m doing what I can to try and slow the degenerative side of things down because they say that is a good thing to be in motion or whatever. I try various things. |

Symptoms feel ‘fixed’ and immovable.

Explaining the different methods of managing symptoms herself.

“I would love to” emphasising the significance to the individual of sleep.

Almost trying to
<table>
<thead>
<tr>
<th>Future expectations about sleep (more positive than about pain)</th>
<th>I: The pain seems quite fixed. Obviously you’re doing your best to keep it as limited as possible with what you do and what do you think about sleep in the future?</th>
</tr>
</thead>
<tbody>
<tr>
<td>P: I often think I hope I’ll get more sleep, I hope I will allow myself to sleep more but then would I allow myself even if I could. Would I allow myself to sleep ten hours? I don’t think I could sleep that long because you get to the point even on a Saturday or Sunday when you could sleep longer and you don’t need to get up early for work you begin to feel uncomfortable in the bed anyway and feel it’s time to get up and start moving around.</td>
<td></td>
</tr>
<tr>
<td>I: So actually the movement is important.</td>
<td></td>
</tr>
<tr>
<td>P: Yeh, because I feel the pain is worse when I’m static, when I’m sitting, especially when I’m sitting. Sitting in the car driving, sitting, and whey you’re lying down as well, even lying on the sofa sometimes I lie on the sofa and watch TV and I sit up because again I’m sitting. I try and change positions. I even got one of those exercise blow up balls that you get.</td>
<td></td>
</tr>
<tr>
<td>I: I’ve seen that, these Swiss balls.</td>
<td></td>
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<tr>
<td>P: I use that watching TV because I feel that might take the pressure off a bit. But I try various things and …</td>
<td></td>
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<tr>
<td>I: It sounds like you’ve been really quite proactive in trying to think about all these different things that you’ve been doing and I mean talk about how you said to some extent you have accepted it. Do you worry about your sleep because you work?</td>
<td></td>
</tr>
<tr>
<td>“Sitting” repeated several times – perhaps she feels she is forced to do more sitting in her life than she would like?</td>
<td></td>
</tr>
<tr>
<td>convince that she does lots to try and make pain better.</td>
<td></td>
</tr>
<tr>
<td>Doesn’t actually want to sleep too long, even though she has sleep problems.</td>
<td></td>
</tr>
</tbody>
</table>
Experiences of insomnia and chronic low back pain

| Daytime consequences of poor sleep | P: I do worry about the fact about concentration because it affects my concentration, it affects my memory. I’m sitting here just now and I feel like my heads really heavy, I feel my eyes are really heavy. I feel like my eyes are half open, they might not look like they’re half open but they feel that way. My eyes always feel tired and they feel heavy. My head can feel heavy although I don’t get headaches but I can feel like a heavy head from lack of sleep or. I say lack of sleep but I think well I’ve slept seven hours wasn’t that enough. |
| Not accepting – or ‘giving in’ | I: Do you worry about sleep then during the day? |
| | P: I won’t give into it. I’m one of these people, I think that if I allowed myself. Sometimes I won’t give into it and I’ll think to myself no I’ve got to go do this or I should be able to meet up with friends or I should try and be more sociable or I should go to the gym or I should go and do something instead of going to work and the minute I get home I want to lie on the sofa just because I’m in pain or I’m tired or I feel tired. |
| | I: Do you? |
| | P: I did it last night and there’s times when I just feel I need to. Most of the time I try and fight it because I want to be active. |
| | I: How often does it pop into your head that you’re thinking about sleep? |
| | P: I don’t sort of go around thinking oh god I need to lie down. |
| | I: Is it only when you get home? |
| Don’t think about sleep – | P: I don’t so much think about sleep, I think I’m tired. I don’t even think sleep, I |

Language – repetition of really, really heavy.

‘Determined’ not to give in. Trying to come up with solutions to the problem that cannot be solved, but only managed, at best.

‘Fight’ the pain.
<table>
<thead>
<tr>
<th>next day consequences</th>
<th>...think I’m tired and two days ago I felt extremely tired I thought god what is it, is it the weather or there is something that I ate, or something to get a boost of energy. ...</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thinking of the future</td>
<td>...So you were saying that it’s not really worry about sleep but in some ways the idea about fatigue and not getting a proper sleep is always there or thereabouts. ...</td>
</tr>
<tr>
<td></td>
<td>...It worries me how tired I feel these last few years, how tired I feel. In some ways I am going to be 50 this year, a lot of people don’t think I look that age but on the other hand I feel like, some days I feel like I’m 70 years of age just with the pain that I’m feeling. ...</td>
</tr>
<tr>
<td></td>
<td>...Do you know that’s interesting because that brings us on to one of the questions that is quite key in this area and it’s about you understand what your symptoms are like from what you’ve described, both the pain and the fatigue and the poor sleep. What do other people understand about your sleep problems? ...</td>
</tr>
<tr>
<td></td>
<td>...I don’t think they even know there is a problem. You talk about personality types about these things. I’m the kind of person I’m older and I won’t go around complaining about it, I won’t moan about it and I probably won’t mention it. ...</td>
</tr>
<tr>
<td>Keeping it to myself</td>
<td>...Questioning what other factors might be determining her symptoms. Searching for answers. ...</td>
</tr>
<tr>
<td></td>
<td>...Explaining worries and concerns that develop over time. ...</td>
</tr>
<tr>
<td></td>
<td>...Describing how she doesn’t complain about her symptoms much now. ...</td>
</tr>
</tbody>
</table>
8.10 Appendix 10: Summary table of themes for all participants
### Experiences of insomnia and chronic low back pain

<table>
<thead>
<tr>
<th>Super-ordinate themes</th>
<th>Sub-ordinate themes</th>
<th>Distribution of recurrent super-ordinate themes for each participant</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>The privacy of pain and solitude of sleep</strong></td>
<td>Invisible illness</td>
<td>✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓</td>
</tr>
<tr>
<td></td>
<td>Keeping it to myself</td>
<td>✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓</td>
</tr>
<tr>
<td></td>
<td>Isolation</td>
<td>✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓</td>
</tr>
<tr>
<td></td>
<td>Relationships affected</td>
<td>✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓</td>
</tr>
<tr>
<td><strong>Night-time thinking</strong></td>
<td>More thinking time at night</td>
<td>✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓</td>
</tr>
<tr>
<td></td>
<td>Not worried about sleep...but what about everything else?</td>
<td>✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓</td>
</tr>
<tr>
<td></td>
<td>Next day coping</td>
<td>✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓</td>
</tr>
<tr>
<td></td>
<td>Thought control</td>
<td>✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓</td>
</tr>
<tr>
<td><strong>Sleep/pain interaction</strong></td>
<td>The significance of sleep</td>
<td>✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓</td>
</tr>
<tr>
<td></td>
<td>Sleep impacting pain and daytime functioning</td>
<td>✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓</td>
</tr>
<tr>
<td></td>
<td>Pain impacting sleep</td>
<td>✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓</td>
</tr>
<tr>
<td><strong>Adjustment &amp; acceptance</strong></td>
<td>Loss and grieving</td>
<td>✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓</td>
</tr>
<tr>
<td></td>
<td>Acceptance</td>
<td>✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓</td>
</tr>
<tr>
<td></td>
<td>Adjustment</td>
<td>✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓</td>
</tr>
<tr>
<td></td>
<td>Not coming to terms with it - superficial acceptance</td>
<td>✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓</td>
</tr>
<tr>
<td></td>
<td>The future</td>
<td>✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓</td>
</tr>
<tr>
<td><strong>Self-management</strong></td>
<td>Controlling the bedroom environment</td>
<td>✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓  ✓</td>
</tr>
</tbody>
</table>
Experiences of insomnia and chronic

8.11 Appendix 11: Participant feedback letter and summary themes
Dear Ms X

Thank you for participating in the recent study about poor sleep and chronic back pain. I have now completed my analysis of 11 interviews with participants with similar symptoms. I have enclosed a summary of the common themes that people talked about for your information.

I shall call you this week to ask for your feedback on this: are these similar / different to your own experiences? Have I covered areas important to you or have I missed any?

We can talk over the phone, or if you prefer you can come in to the department to discuss this. If I cannot reach you by telephone, please feel free to post any comments to me. Your feedback will be greatly appreciated.

Yours sincerely

Paul McKenzie
Trainee Clinical Psychologist
Participant Feedback

Key themes from interviews:

1. The privacy of pain and solitude of sleep
   - *Invisible illness:* other people can’t see what you’re going through
   - *Keeping it to myself:* I tend to not talk about symptoms to others
   - *Isolation:* this can make me feel isolated sometimes
   - *Relationships affected:* this can affect my relationships with others

2. Night-time thinking
   - *More thinking time at night:* I think about things more when I’m lying awake at night
   - *Not worried about sleep...but what about everything else?* I don’t worry about sleep too much; I just accept that’s the way it is. I think about lots of other things (e.g. family, work, events from during the day, planning what’s happening tomorrow).
   - *Next day coping:* I can worry about how the poor sleep will affect me the next day
   - *Thought control:* I try to think about other things when I’m awake during the night (e.g. pleasant things, nice memories or planning activities)

3. Sleep, pain and interaction
   - *The significance of sleep:* it would make a big difference if I could get a good nights sleep
   - *Sleep and next day coping:* a bad nights sleep will really affect how I cope the next day (e.g. suffering worse fatigue and/or emotional stress)
Experiences of insomnia and chronic low back pain

- **Pain impacting sleep**: if I’m in worse pain it will mean I have a worse nights sleep

4. Adjustment and acceptance

- **Loss and grieving**: I sometimes look back and compare myself now to how I was before I had this back pain and insomnia; this can make me feel a bit down (or used to)

- **Acceptance**: I recognise that my back pain and poor sleep is here for at least the short to medium term future

- **Adjustment**: I have changed the things I do to accommodate my difficulty sleeping and back pain

- **Not coming to terms with it - superficial acceptance**: sometimes I feel that although I try to get on with things, I’m still unhappy with my pain and sleep, and don’t really accept it

5. Self-management/ Magic potions

- **Controlling the bedroom environment**: I try different pillows, mattresses, or quilts to help me get comfy. I might sleep in a separate room some nights to help sleep (for those with partners).

- **Sleep strategies**: I will try to think about positive things to help me sleep, or to keep negative thoughts at bay. I will think about pleasant events, holidays, family gatherings or activities or I’ll plan the next day. I have routines that I follow to help me sleep.
8.12 Appendix 12: Journal scope and author guidelines

It is planned to submit both articles to Health Psychology journal.
Health Psychology journal scope and submission guidelines

Submission

The main emphasis of Health Psychology is on original research in health psychology. Analytical reviews of research and brief scientific reports are also considered for publication. Submissions are welcomed from authors in psychology and other health-related disciplines.

Submit manuscripts electronically (.rtf, PDF, or .doc) to
Anne E. Kazak  The Children's Hospital of Philadelphia  34th and Civic Center Blvd.  Room 1486 CHOP North  Philadelphia, PA 19104-4399

Keep a copy of the manuscript to guard against loss. Do not submit manuscripts via mail or email.

In recognition of the reality that institutional spam filters may capture files from the APA and the Journals Back Office, please take the following steps to facilitate communication with our editorial office:

3. Provide an alternative email address which we can use to contact you in the event of technical difficulties with email communication using your primary address;

4. Add "apa.org" to your list of "safe" addresses and consider asking your IT administrators to add it to their "white list;" and

5. Contact Jessica Karp if you do not receive confirmation of your submission within three business days or an editorial decision letter within three months.

General correspondence may be directed to the Editor's Office.

Information About Submissions

The page limit for research manuscripts is 25–30 pages. The page limit is inclusive of all parts of the manuscript, including the cover page, abstract, text, references, tables and figures.

Authors may request consideration of longer papers, in advance of submission, when there is clear justification for additional length (e.g., the paper reports on two or more studies or has an unusual or complex methodology).

Scholarly reviews and meta-analyses should not exceed 25 pages, but tables and references may be outside this page limit.

Brief reports are encouraged for innovative work that may be premature for publication as a full research report because of small sample size, novel methodologies, etc. Brief reports should be designated as such and should not exceed a total of 12 pages, inclusive of all parts of the manuscript, including the cover page, abstract, text, references, tables and figures.

All manuscripts should be double-spaced, with margins of at least 1 inch on all sides and a standard font (e.g., Times New Roman) of 12 points (no smaller).

Health Psychology considers letters concerning previously published articles. Letters should be no more than 500 words and have a maximum of five references.

Authors also have the option of placing supplemental materials online.
Submissions that exceed the page limits will be returned to the author for shortening prior to the initiation of peer review.

Submission Letter

The cover letter should indicate that the authors have read and followed the Health Psychology Instructions for Authors. It should also include a statement indicating that the paper has been seen and approved by all authors. The cover letter should describe how the paper advances research in health psychology, referring to the journal mission to assure that the submission fits with the types of papers published in Health Psychology.

The full mailing address, telephone, fax, and email address for the corresponding author should be included in the cover letter, along with the names and affiliations of all co-authors.

The cover letter must confirm that the manuscript has not been published, is not currently submitted elsewhere, and that it does not contain data that is currently submitted or published elsewhere.

When a manuscript contains data that is part of a larger study, authors should describe the larger study and provide references for other study papers. Authors must be prepared to provide copies of related manuscripts when requested as part of the editorial review process. Authors should clarify the relationship between their paper, including detailed specification of the overlap in participants, measures, and analysis, and others from the study. The value-added scientific contribution of their study must be clearly stated in the cover letter.

Authors of brief reports should indicate in the cover letter that the full report is not under consideration for publication elsewhere and similarly address potential overlap with other papers.

Manuscripts

The manuscript title should be accurate, fully explanatory, and no longer than 12 words. The title should reflect the content and population studied. If the paper reports a randomized clinical trial, this should be indicated in the title. The title of brief reports should start with the words "Brief Report”.

The title page should include the names of all authors and their affiliations at the time the research was done. This information will be masked to ensure a blind peer review process by the editorial office. Authors should make sure that all other identifying information in the text of the paper is masked/removed prior to submission.

All manuscripts must include a structured abstract containing a maximum of 250 words with the following sections:

1. Objective (brief statement of the purpose of the study);
Experiences of insomnia and chronic low back pain

2 Methods (summary of the participants, design, measures, procedure);  
3 Results (primary findings); and  
4 Conclusions (specific statement of the implications of the data).

Please supply up to five keywords or brief phrases after the abstract. The Introduction should typically not exceed 3-4 pages in length. The paper should be referenced appropriately but excessive citations should be avoided. 
All research involving human participants must describe oversight of the research process by the relevant Institutional Review Boards and should describe consent and assent procedures briefly in the Methods section.
All statistical tests should include effect size whenever possible.

First person language ("I", "we") should be avoided. Terminology should be sensitive to the individual who has a disease or disability. The journal endorses the concept of "people first, not their disability." Terminology should reflect the "person with a disability" (e.g., children with diabetes, persons with HIV infection, families of people with cancer) rather than the condition as an adjective (e.g., diabetic children, HIV patients, cancer families). Nonsexist language should be used.

It is important to highlight the significance and novel contribution of the work. The translation of research into practice must be evidenced in all manuscripts. Authors should incorporate a meaningful discussion of the clinical and/or policy implications of their work throughout the manuscript, rather than simply providing a separate section for this material.

*Health Psychology* publishes a broad array of types of papers. Authors of qualitative and measure development papers should read the guidelines for these types of papers, noted below.

**Qualitative Research**

Research papers that utilize qualitative methods should follow the general instructions to authors for style and format. We ask that authors of qualitative papers review the additional guidance below to assure that papers meet the following criteria utilized by *Health Psychology*.

The introduction should make a compelling case for the significance of the study and clearly identify if the study is a stand-alone study or if it fits into a larger study. For example, qualitative manuscripts may inform the development of a survey, use small-incident samples, or establish feasibility. The specific qualitative paradigm should be specified (e.g., grounded theory, qualitative descriptive approach, interpretive phenomenology) with a rationale as to why it was selected to address the research question.

At the same time, authors are encouraged to avoid methodological tutorials and cite appropriate references for the methodology. Describe your sampling frame clearly and how the sample was selected, justifying the type and size of your sample using
Experiences of insomnia and chronic low back pain

While many qualitative studies may not use a conceptual model, if you have done so, explain how the model may have shaped the design, data collection, analysis and interpretation. Explain carefully how you strengthened and insured rigor in your study e.g., data analysis protocols (including how coders were trained), audit procedures, and demonstration of data saturation. Describe the data analysis and how it relates to your overall approach or paradigm. Present rich and compelling results with data that have been analyzed and interpreted appropriately for your method (e.g., discourse analytic results would be presented differently than those of a grounded theory).

The paper should convey how this research fills an important gap in the science and promises to change the way we approach future studies.

Scale Development

Empirical papers related to the development of new instruments related to health psychology should follow the general guidelines for style and format of this journal. Authors should make a convincing case for the need and rationale for the new instrument, particularly with respect to new and innovative constructs. Included in this rationale should be the theoretical foundation on which their new instrument rests along with presentation of other, related scales currently in use.

It is important that the research have a degree of generalizability across populations and settings. Instruments that are more narrow in scope or of limited clinical utility may be better suited for subspeciality journals. Authors should clearly articulate the specifics of the study design and of the analytical techniques used. There should be strong consistency among the purpose statements, methods, and the manner in which findings are presented.

An increasing number of studies are incorporating mixed-methods designs in their research. The specifics of these designs should be equally well-detailed without being excessive. Attention should be given to the nature of the items, the basis for their creation, and the rationale for the response options. The underlying theoretical structure of the approach should be evident, for example, whether one is premising their study on classical or modern theory (IRT, Rasch) techniques. The characteristics of the research will be in part dictated by the nature of the scale. For instance, large, nationally-normed tests may have a much different make-up than that of small, more narrowly-defined measures. Research involving both types of instruments will be considered.

Finally, all instrument development papers should convey how the literature base will be strengthened with the addition of the particular instrument along with a clear and convincing case for the clinical relevance of the information that it provides.

Letters to the Editor

*Health Psychology* will, at the discretion of the Editor-in-Chief, publish Letters to the
Editor on the journal website.

Letters should be prepared in direct response to articles published in the journal, should include reference to the published paper in the letter, and should be received through the Manuscript Submission portal within 60 days of the date when the relevant article is published in hard copy. The text of the letter, excluding the title, references and author(s) name, title, affiliation and email, may not exceed 400 words.

In a separate cover letter, the author should indicate that the submission is a Letter to the Editor for consideration of posting on the Health Psychology website and provide the full citation of the original article to which the letter refers. The cover letter should also indicate if the letter writer(s) have any conflicts of interest related to the article or correspondence.

Masked Review Policy
Masked review is used. Do not include author information (addresses, phone numbers, electronic mail addresses, and fax numbers) in the manuscript. Please ensure that the final version for production includes a byline and full author note for typesetting.

Use of CONSORT Reporting Standards
All randomized controlled trials must include a diagram indicating participant flow into the study and a completed CONSORT checklist. CONSORT diagrams (and adaptations) should be included whenever possible to clarify the flow of participants through a study.

Manuscript Preparation
Prepare manuscripts according to the Publication Manual of the American Psychological Association (6th edition). Manuscripts may be copyedited for bias-free language (see Chapter 3 of the Publication Manual).

Review APA's Checklist for Manuscript Submission before submitting your article.

Double-space all copy. Other formatting instructions, as well as instructions on preparing tables, figures, references, metrics, and abstracts, appear in the Manual.

Below are additional instructions regarding the preparation of display equations and tables.

Display Equations
We strongly encourage you to use MathType (third-party software) or Equation Editor 3.0 (built into pre-2007 versions of Word) to construct your equations, rather than the equation support that is built into Word 2007 and Word 2010. Equations composed
Experiences of insomnia and chronic low back pain

with the built-in Word 2007/Word 2010 equation support are converted to low resolution graphics when they enter the production process and must be rekeyed by the typesetter, which may introduce errors.

To construct your equations with MathType or Equation Editor 3.0:

← Go to the Text section of the Insert tab and select Object.
← Select Math Type or Equation Editor 3.0 in the drop-down menu.

If you have an equation that has already been produced using Microsoft Word 2007 or 2010 and you have access to the full version of MathType 6.5 or later, you can convert this equation to MathType by clicking on MathType Insert Equation. Copy the equation from Microsoft Word and paste it into the MathType box. Verify that your equation is correct, click File, and then click Update. Your equation has now been inserted into your Word file as a MathType Equation.

Use Equation Editor 3.0 or MathType only for equations or for formulas that cannot be produced as Word text using the Times or Symbol font.

Tables

Use Word's Insert Table function when you create tables. Using spaces or tabs in your table will create problems when the table is typeset and may result in errors.

Submitting Supplemental Materials

APA can now place supplementary materials online, available via the published article in the PsycARTICLES® database. Please see Supplementing Your Article With Online Material for more details.

References

List references in alphabetical order. Each listed reference should be cited in text, and each text citation should be listed in the References section.

Examples of basic reference formats:

