Sleep in Chronic Health Conditions and Inflammatory Bowel Disease

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A thesis submitted in partial fulfilment of the requirements for the Doctorate in Clinical Psychology

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Declaration

This thesis has not been submitted for any other qualification at the University of Sheffield or any other institution.

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Structure and Word Counts

Section One: Literature Review

Excluding references and tables	7963
Including references and tables	14,791

Section Two: Research Report

Excluding references and tables	8015
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Total Word Count

Excluding references and tables	15,978
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Overall Abstract

Inflammatory Bowel Disease (IBD), referring primarily to Crohn's Disease and Ulcerative Colitis is an incurable, relapsing and remitting disease in which the immune system attacks the digestive system, causing inflammation and ulceration. It affects around 6 people per 100,000 with symptoms including abdominal pain, diarrhoea, fatigue and rectal bleeding. As with other chronic illnesses, sleep disturbance is relatively common, and has been linked physiologically to IBD through inflammation. Emerging evidence also suggests psychological links between sleep disturbance and IBD. Little is currently known about the experience of sleep for people with IBD.

This thesis aims to broaden knowledge about sleep and sleep disturbance for people with IBD. First, research evaluating the most commonly used psychological insomnia intervention (Cognitive Behavioural Therapy for Insomnia; CBT-I) for people with chronic health conditions (CHCs) is reviewed through meta-analysis. Following this, the experience of sleep for people with IBD is explored in the research study.

CBT-I has demonstrated effectiveness for people with CHCs, but it is not clear how well CBT-I works if people have a CHC without a mental health problem (MHP), as previous research mixes these groups. This analysis reviews CBT-I research where participants have *only* a CHC alongside insomnia. Effects on secondary outcomes of pain, fatigue and quality of life, and potential moderators of effectiveness were also examined.

Results suggest that CBT-I is effective for this population, though slightly less so than for people with both CHCs and MHPs. Medium to large summary effect sizes are reported for subjectively measured insomnia symptoms and small to medium effects for pain, fatigue and quality of life. However, CBT-I did not improve most objective measures of sleep. Potential explanations for this are discussed. Moderator analysis suggested that CBT-I is most effective if provided one-to-one. Thus, it is recommended that one-to-one CBT-I is

offered to people with CHCs (with or without MHPs). However, the analysis was small, and some outcomes were heterogenous or affected by publication bias, thus more research is needed.

In the research study, eight adults with IBD were interviewed about their sleep. Data was analysed with Interpretative Phenomenological Analysis and four super-ordinate themes emerged: 'Frustration, worry and flare – night-time struggles'; 'My self changed – variations in feeling ok about the way things are'; 'Reinforcing cycles: IBD, stress and sleep' and 'Seeking control of sleep and IBD'. Disturbed sleep was common, disrupted by pain and toileting during flare, and by anxiety, arousal and coping habits (e.g. napping) in disease remission. Participants appeared in various stages of accepting (or not) the changes to their sleep. They offered theories of cyclical relationships between sleep, IBD, fatigue and anxiety, and attempted to control this through distraction from worry at night, or strict routines of food, exercise and energy usage during the day. Participants reported feeling dismissed or invalidated by clinicians whilst seeking IBD diagnosis (and beyond). Findings highlight the potential benefit of CBT-I for this population, as well as the importance of collaborative and respectful work to people with IBD.

Acknowledgements

Firstly, I wish to express thanks to those who gave up their time to take part in the research and for giving me access to their experiences. I sincerely hope that this research contributes to improving sleep for people with Inflammatory Bowel Disease.

I would like to offer thanks to my research supervisor Dr Georgina Rowse for her encouragement and guidance on this project. Thank you also to Dr Alex Scott whose insight into the meta-analytic process and sleep research was immensely valuable whilst I found my way through the literature. Further, I'd like to thank my supervisors Dr Katherine Hildyard and Dr Shona Goodall for showing patience, respect and kindness during my final year.

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Section One: Literature Review

The Effectiveness of Cognitive Behavioural Therapy for Insomnia, with Insomnia Comorbid to Chronic Health Conditions: A Meta-Analysis

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Abstract

Objective

Insomnia may be considered a public health concern, is frequently comorbid with chronic health conditions (CHCs) and may worsen pain, fatigue and quality of life (QoL). Meta-analyses suggest cognitive behavioural therapy for insomnia (CBT-I) is effective for people with CHCs, and more effective when participants have diagnosed mental health problems (MHPs). This analysis therefore aims to examine CBT-I for people with insomnia and CHCs, without an MHP.

Method

Five databases (PsycINFO, PubMed, Scopus, The Cochrane Library, and Web of Science) were systematically searched in October 2018. Randomised controlled trials comparing CBT-I to control conditions for the target population were extracted. Random effects meta-analysis was used to estimate summary effects of CBT-I on insomnia and secondary outcomes (pain, fatigue, and QoL). Moderator, heterogeneity and publication bias analyses were performed.

Results

Eighteen studies were included (1406 participants). Sample-weighted mean summary effect sizes comparing CBT-I to controls suggest small to medium effects on subjective measures: QoL (g = 0.30), pain (g = 0.32), fatigue (g = 0.46), time taken to fall asleep (g = 0.49) and early waking (g = 0.55), and large effects for insomnia severity (g = 0.92) and sleep quality (g = 0.83). Objective insomnia measures showed no significant improvement (except early waking; g = 0.38).

Conclusion

CBT-I appears effective for people who have a CHC and insomnia, without diagnosed MHPs. Moderator analysis suggests individual interventions are most effective. Further research is needed, however, due to the small number of studies, heterogeneity in some outcomes and publication bias.

Practitioner points

- CBT-I appears to be effective for people with insomnia and a chronic health problem, without a mental health problem.
- CBT-I may be more effective when provided one-to-one, than group or self-help approaches.

Limitations

- Heterogeneity was significant for three outcomes, and publication bias possibly affected four. This may indicate some results are not robust.
- Other moderators, particularly specific CHC diagnosis may be important, but were not reviewed due to lack of studies.

Introduction

Insomnia broadly refers to difficulty falling asleep, and/or difficulty maintaining sleep (e.g. waking after sleep onset, or waking earlier than desired), and can be experienced with or without subsequent daytime sleepiness, often accompanied by mood disturbance, reduced quality of life, fatigue and functional impairment (American Psychiatric Association, 2000; 2013; Krystal, 2007; Slater & Steier, 2012). Global epidemiological data estimates approximately 30-35% of adults report at least one insomnia symptom (varied by country), with an average of 10% meeting criteria for a clinical diagnosis (Morin et al., 2015). Further, insomnia is commonly a chronic condition, with a median duration of three years (Morin et al., 2009). Insomnia has been described as a public health concern (Moloney, Konrad, & Zimmer, 2011; Robotham, 2011), with evidence suggesting that insomnia is predictive of mental health difficulties such as anxiety, depression and psychosis (Hertenstein et al., 2019; Li, Wu, Gan, Qu, & Lu, 2016). Furthermore, insomnia demonstrates considerable comorbidity with both physical (Taylor et al., 2007; Geiger-brown, Rogers, Liu, Ludeman, & Downton, 2015), and mental health difficulties (Khurshid, 2018; Pearson, Johnson, & Nahin, 2006).

Improving insomnia

One of the most widely used and effective approaches to improving insomnia is Cognitive Behavioural Therapy (CBT) adapted to address insomnia symptoms (i.e. CBT-I; Morin et al., 1999). CBT-I incorporates behavioural techniques with cognitive components (Morin et al., 1999) that aim to address the maintaining mechanisms of insomnia, namely by reducing cognitive and autonomic arousal, by addressing maladaptive thoughts and beliefs about sleep (e.g. ‘if I don’t get eight hours sleep I will be unable to function tomorrow’), by correcting dysfunctional sleep behaviours (e.g. daytime napping, or lying in bed when awake), and

providing psychoeducation about sleep. Meta-analytic reviews of CBT-I not only suggest that CBT-I can have a medium-to-large sized effect on insomnia outcomes (Koffel, Koffel, & Gehrman, 2015; Okajima, Komada, & Inoue, 2011), but that the effects are equal or superior to pharmacological approaches (Sivertsen et al., 2006; Smith et al., 2002), may be preferred by patients (Schutte-Rodin, Broch, Buysse, Dorsey, & Sateia, 2008; Vincent & Lionberg, 2001), and can be delivered effectively in face-to-face (van Straten et al., 2018), or computerised formats via the internet (Cheng & Dizon, 2012; Espie et al., 2019).

Insomnia in Chronic Health Conditions and Mental Health Problems[1]

Insomnia frequently accompanies various chronic health conditions (CHCs) such as cancer, chronic pain, rheumatoid and osteoarthritis, stable heart failure, chronic kidney disease, chronic obstructive pulmonary disorder and others (prevalence rates vary between 19 and 64%; Geiger-brown et al., 2015). Insomnia accompanying mental health problems (MHPs) such as anxiety, depression, psychosis or trauma is more prevalent (Stepanski & Rybarczyk, 2006), with prevalence estimated between 32 and 93% (Baglioni et al., 2011; Soehner, Kaplan, & Harvey, 2013; Spiegelhalder, Regen, Nanovska, Baglioni, & Riemann, 2013; Staner, 2010).

Meta-analyses examining the use of CBT-I where people have insomnia and both CHCs and MHPs has demonstrated effectiveness in reducing insomnia outcomes (Geiger-brown et al., 2015; Okajima & Inoue, 2018; Wu, Appleman, Salazar, & Ong, 2015). Improvement on important disease-related outcomes such as pain and quality of life has also been demonstrated (Wu et al., 2015; Okajima & Inoue, 2018).

[1] 'Mental health problems' is commonly adopted as an acceptable label for difficulties with mental health and is recommended for use by prominent mental health campaigning charities (Time to Change, 2019). It is used here to replace terms more common in the literature such as "psychiatric disorders".

Separating insomnia comorbidity with CHCs and MHPs

Other meta-analyses have examined the effectiveness of CBT-I for people with CHCs (Wu et al., 2015; Okajima &Inoue, 2018), but have not examined the effectiveness of CBT-I on samples where insomnia is comorbid to *only* a CHC, in studies that specifically exclude MHPs. Studies included in these reviews have sometimes featured mixed comorbidities (i.e. both MHPs and CHCs) even where analysis labels them as 'medically comorbid', or included samples where up to half of the participants do not have a condition other than insomnia. Further, these meta-analyses have included studies where patients are diagnosed with fibromyalgia, the medical status of which is currently debated (Wolfe, 2015). Thus, we cannot generalise from these results to assume that CBT-I is effective where only a CHC is present with insomnia. It may be that CBT-I is more effective where an MHP is present, and less effective where physiological insomnia maintenance is prominent, discussed below.

CBT-I may be more effective for people with MHPs

Evidence suggests psychologically-maintained insomnia ('primary' or 'comorbid' insomnia; Lichstein, 2006) shares similar underpinning mechanisms to various MHPs. Cognitive-behavioural models of insomnia suggest it is maintained by arousal resulting from worry and rumination (about sleep, mostly at night), negatively biased or catastrophic beliefs and thinking (about sleep and potential consequences of getting too little) and avoidant or safety-seeking behaviours (Harvey, 2002). As acknowledged by Harvey (2002), this is very similar to cognitive models of anxiety and depression (except that problematic worry, thinking, beliefs and behaviours may concern subjects other than sleep; Beck, Rush, Shaw, & Emery, 1979; Borkovec, Wilkinson, Folensbee, & Lerman, 1983; Borkovec, Alcaine, & Behar, 2004; Dugas et al., 2004). Accordingly, evidence suggests common underlying traits may unite psychologically-

maintained insomnia and MHPs such as tendency to worry or ruminate, holding polarised or catastrophic beliefs and tendency towards use of avoidant or safety-seeking behaviours (Beck & Dozois, 2011.; Espie, 2002; Harvey, 2005; Morin, Stone, Trinkle, Mercer, & Remsberg, 1993; Nolen-Hoeksema & Susan, 2000; Olatunji, Naragon-Gainey, & Wolitzky-Taylor, 2013). CBT-I targets precisely these mechanisms, similarly to CBT for anxiety or depression (Kennerley, Kirk, & Westbrook, 2011; Morin, Savard, & Ouellet, 2012). Therefore, it may be that CBT-I is more effective when insomnia is present alongside an MHP, as its mechanisms of action may address both psychologically-maintained insomnia and (indirectly) accompanying MHPs which also disturb sleep. Previous meta-analyses have suggested CBT-I is more effective where people are known to have been diagnosed with an MHP, than where they are only known to have been diagnosed with a CHC (Okajima & Inoue, 2018; Wu et al., 2015), though these distinctions may not be robust (see above). Further, limited evidence suggests that targeting MHP symptoms where insomnia and an MHP are jointly present improves sleep more than targeting the insomnia directly (Belleville, Ivers, Bélanger, Blais, & Morin, 2016).

Physiological maintenance may be more important where only a CHC is present

Some authors have argued that the majority of insomnia occurring alongside CHCs is psychologically-maintained (e.g. Lichstein, 2006). However, evidence is emerging of physiological mechanisms of insomnia maintenance across various CHCs. Physiological insomnia maintenance models are proposed between: insomnia and musculoskeletal pain (Doufas, Panagiotou, & Ioannidis, 2012); insomnia and chronic pain (Finan, Goodin, & Smith, 2013); insomnia contributing to wakefulness-promoting cytokine[2] release in inflammatory conditions (such as osteoarthritis and inflammatory bowel disease; Ali, Choe, Awab, Wagener,

[2] Cytokines are messenger proteins similar to hormones, implicated in the (dys)regulation of inflammatory response (Neurath, 2014).

& Orr, 2013; Krueger, 2008; Moldofsky, 2010; Parekh, Oldfield IV, Challapallisri, Ware, & Johnson, 2015); and similarly linked to inflammation in cancer (Bower et al., 2011; Liu et al., 2017); and insomnia linked to chronic nervous system activation in diabetes and renal diseases (Chen et al., 2008; Vgontzas, Liao, Pejovic, et al., 2009; Vgontzas, Liao, Bixler, Chrousos, & Vela-Bueno, 2009). Thus, it may be that for people with CHCs, psychologically-maintained insomnia is less prevalent than physiologically-maintained insomnia, so CBT-I may be less effective.

This study therefore aims to review the effectiveness of CBT-I for people with *only* a CHC and insomnia, and explicitly not an MHP, to investigate any differences in effectiveness.

What factors might influence the effectiveness of CBT-I on insomnia comorbid to CHCs?

Intervention characteristics

Fidelity to the model

Sticking closely to proven effective components of a model may be important in preserving the usefulness of any psychological intervention, though it may also be argued that adaptation may improve effectiveness (McHugh, Murray, & Barlow, 2009). Some researchers have experimented with adapted versions of CBT-I (e.g. adding pain-specific CBT intervention components; Pigeon et al., 2012; Vitiello et al., 2013), or with abridged versions of CBT-I (Casault, Savard, Ivers, & Savard, 2015), whilst preserving the 'core' elements that have demonstrated individual effectiveness (Epstein, Sidani, Bootzin, & Belyea, 2012).

Modality of treatment delivery

Whether an intervention is administered individually, via group or self-help may impact on effectiveness (e.g. Covin, Ouimet, Seeds, & Dozois, 2008), though evidence suggests effects are often comparable (Cuijpers, Donker, van Straten, Li, & Andersson, 2010). Evidence within

CBT-I is conflicted suggesting both superiority for individual interventions over self-help and group (Geiger-brown et al., 2015; Yamadera et al., 2013) and equivalence (Bastien, Morin, Ouellet, Blais, & Bouchard, 2004).

Intervention dose (length)

Intervention length has been demonstrated to produce a dose effect for CBT-I, with approximately 6 hours (4 x 90 minute sessions) suggested as optimal (Edinger, Wohlgemuth, Radtke, Coffman, & Carney, 2007). Some studies report very limited intervention with patients ranging from 90 minutes (3 x 30 minute sessions; Smitherman et al., 2016), to 16 hours of therapeutic contact (Rybarczyk et al., 2005). Whilst shorter sessions do not necessarily indicate less instruction or practice, they may indicate less exposure to other known moderators of clinical effects such as clinician contact time (Hubble, Duncan, & Miller, 1999).

Study design variables

Control group type

In randomised controlled trials (RCTs), the nature of the control group may impact on the observed effects (Furukawa et al., 2014). Compared to passive control conditions like wait-list control (WLC), interventions are likely to return stronger effect sizes than when compared to treatment as usual (TAU), or active controls such as placebos (in approximate order; Lambert, 2012). In well-designed studies with believable psychological sham interventions, placebo effect sizes approach that of the intervention (Wampold, Minami, Tierney, Baskin, & Bhati, 2005).

Study quality

It is recommended to account for study quality influence on effect size (Conn & Rantz, 2003). All studies included in this review are RCTs, generally recognised as the highest quality evidence (Burns, Rohrich, & Chung, 2011). However, RCTs vary in their stringency of

randomisation, sampling, measurement and analysis (amongst other factors). Lower quality studies are more at risk of bias, and produce less reliable results (Higgins, Altman & Sterne, 2011).

Study publication year

As research data accumulates, reported intervention efficacy appears to diminish over time, with large effect sizes in earlier research mitigated as additional data is added to the meta-analytic pool (Trikalinos et al., 2004). Outcomes of CBT interventions for depression, for example, have been demonstrated to be significantly moderated by publication year (Johnsen & Friborg, 2015). The studies included in this review span a 16-year period, and thus may exhibit similar effects.

The present review

This review aimed to examine the effectiveness of CBT-I in addressing insomnia for people with a comorbid CHC only. Additionally, this paper examines if CBT-I is associated with improvement of related health difficulties, including pain, fatigue and quality of life.

Method

Literature search strategy

A systematic search of five bibliographic databases was conducted in October 2018, including PsycINFO, PubMed, Scopus, The Cochrane Library, and Web of Science. Databases were searched using terms in the title, abstracts, and/or keyword fields that aimed to identify studies where participants with insomnia comorbid to a CHC took part in a CBT-I intervention and were compared to similar participants in a control condition (see Table 1). Search terms were based on extant literature and previous systematic reviews (Geiger-brown et al., 2015; Okajima & Inoue, 2018; Wu et al., 2015).

Table 1.

Search engine terms

Intervention	Target difficulty	Target population
CBT OR CBT* OR “CBT for Insomnia” OR Cognitive behav* OR Cognitive-behav* OR “sleep restriction” OR “stimulus control”	sleep* OR sleep problem OR sleep disorder OR insomnia	comorbi* OR co-morbi* OR "long term" OR “long-term” OR "LTC" OR "chronic medical" OR "chronic conditio*" OR "chronic diseas*" OR "chronic health"

Each database was searched from first included records to present day. Grey literature was additionally searched (via Opengrey) and only English language papers were reviewed due to practical constraints of translation. To ensure the highest quality evidence and maximise study similarity for comparison purposes, only RCTs were extracted. Where a study was described across multiple papers (i.e. secondary analysis), the paper most relevant to the research question was included and the other papers excluded to prevent double-counting of results. Backwards and forwards ancestry searches were conducted within extracted papers and previous reviews.

Inclusion/exclusion criteria

Included papers needed to satisfy the criteria below (Table 2). The criteria aim to increase effect size homogeneity by ensuring the papers compared are as similar as possible. MHP comorbidity was determined based upon explicit declaration within the study regarding participant MHP diagnosis. If this information was absent from the study, but baseline measures of mental health symptoms were taken (i.e. anxiety and depression assessment instruments), studies were included if baseline scores fell below clinical ranges or in the very mild ranges for that instrument. If MHP comorbidity was not discussed, and no baseline measures were taken, the study was excluded.

Table 2.

Inclusion and exclusion criteria for meta-analysis

Inclusion criteria	Exclusion criteria
Studies must state that participants have diagnosed chronic health condition comorbid to insomnia (excluding fibromyalgia as medical status is currently disputed; Wolfe, 2015).	Studies must state that participants are not diagnosed with active mental health problems (i.e. severe anxiety, depression, psychosis).
Where comorbidity with mental health problems is not specified in study: Any included baseline measures of mental health symptom constructs (i.e. anxiety, depression) must not suggest significant active mental health problem (i.e. below clinical cut-offs, or in very mild range)	Participants have comorbid sleep condition that better explains sleep problems than insomnia (i.e. Periodic Limb Movement Disorder, parasomnias, REM Sleep Behaviour Disorder, Circadian Rhythm Sleep Disorders, Shift-work Sleep Disorder, Narcolepsy, (unmanaged) Sleep Apnoea.
Research must include at least two groups in randomised controlled design.	Conference abstracts without full text articles.
Intervention group (CBT-I based) must be compared to control condition (waitlist, treatment as usual, placebo or intervention defined as ineffective).	Non-inferiority trials, i.e. CBT-I intervention is not compared to a control condition (passive or active).
Research report must be available in English.	
At least one group in the research must engage in intervention based upon CBT-I.	
Identified target for research is to improve sleep.	
Full text version of article must be accessible after all reasonable attempts (including contacting the authors directly) to obtain it.	
Research must report enough data to calculate Cohen's d_{ppc2} (standardised mean difference, pre-post between groups) effect size either within paper, or after reasonable attempts to obtain it from the authors.	

Study selection and data extraction

Initial searches across all databases returned 3834 results, and another 2 were discovered by ancestry search (one of which was included in the final review). After comparison to identify duplicates, 2209 studies were removed and the remaining 1625 were screened. Studies were screened first by title and then abstract if required. Following this, 1543 records were excluded as incompatible and the remaining 82 articles were assessed in full-text form for eligibility. Where appropriate, full-text papers were reviewed and included or excluded with supportive reasoning recorded as per PRISMA group guidelines (Moher, Liberati, Tetzlaff, Altman, & PRISMA Group, 2009; Figure 1). Sixty-four of these articles were excluded at review, details of exclusion are outlined in Figure 1.

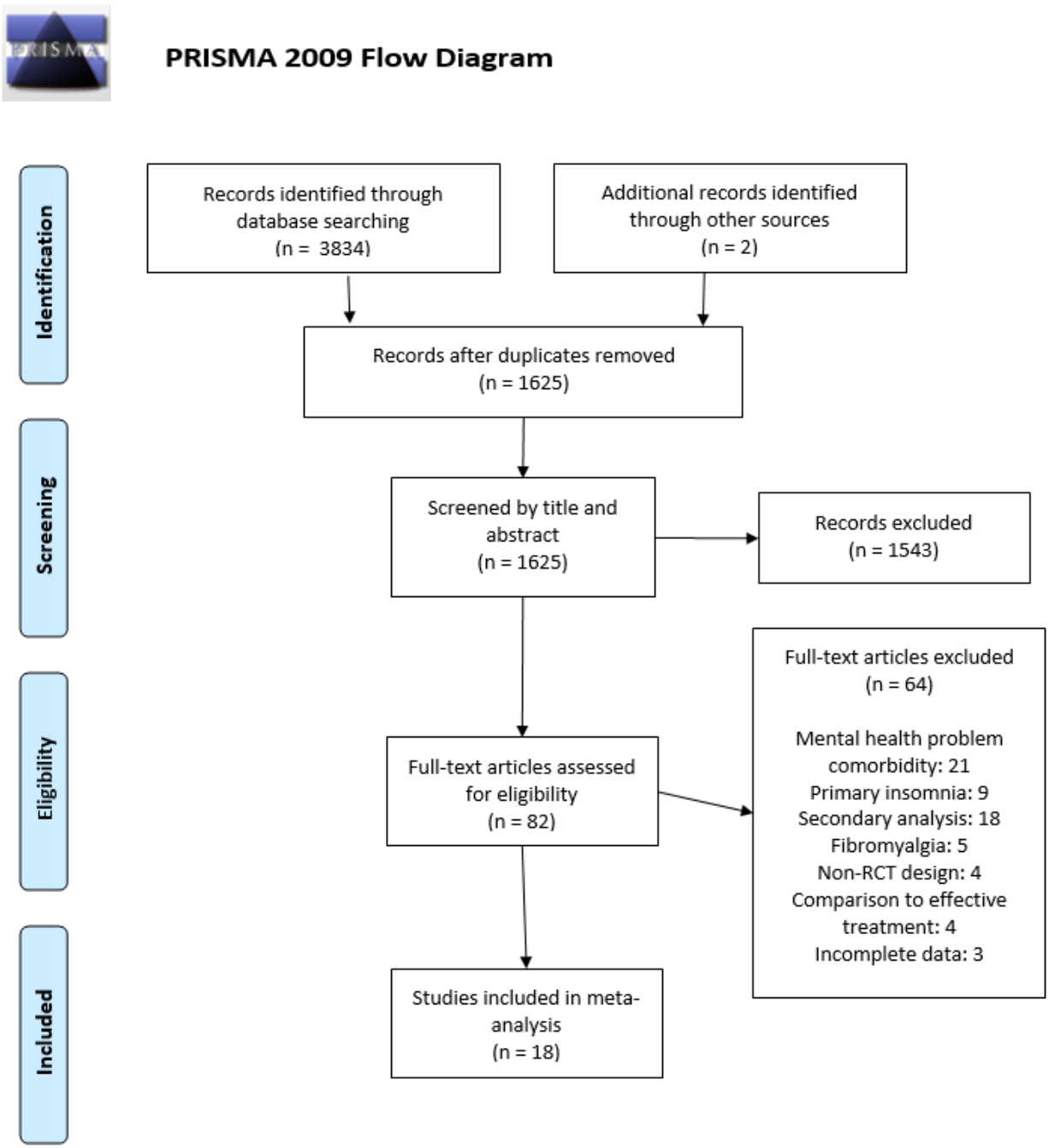

Figure 1: PRISMA flow diagram

Data extraction

Following data extraction table templates (Appendix A), each paper was reviewed for sleep, pain, fatigue and quality of life relevant outcome data, and coded for fidelity to the CBT-I model (i.e. whether the authors state they adapted the model or shortened it), control group type

(waitlist control, treatment as usual or active control), intervention length (in hours), intervention delivery modality (individual, group or self-help), study quality (as rated via a quality assessment tool; Downs & Black, 1998) and year of publication. Papers predominantly reported subjective sleep diary measures, objective sleep measures (from actigraphy, see below), a global measure of insomnia severity or sleep quality (or both), and a measure of pain, quality of life or fatigue.

Sleep diary measures

Following previous meta-analytic convention (i.e. Geiger-brown et al., 2015; Okajima et al., 2011), sleep diary items are reported separately to global insomnia or sleep quality questionnaires. Sleep diary items include Sleep Onset Latency (SOL; time taken to initially fall asleep) and Wake After Sleep Onset (WASO; time spent awake after initially reaching sleep). Subjective measures of Total Sleep Time (TST; total minutes spent asleep) and Sleep Efficiency (SE; ratio of total time spent in bed asleep relative to time spent in bed) are excluded from this meta-analysis for parsimony, as there are questions surrounding the accuracy of their reporting in the literature, as well as their usefulness as measures of insomnia (Morin et al., 2012; Reed & Sacco, 2016)[3]. However, despite these caveats, both SE and TST are analysed as objective sleep measures primarily due to the paucity of other reported objective data within the studies, but their limitations are acknowledged.

Global sleep questionnaires

Global measures include the Insomnia Severity Index (ISI; Morin, 1993) a checklist of insomnia symptoms and the Pittsburgh Sleep Quality Index; (PSQI; Buysse, Reynolds, Monk, Berman, & Kupfer, 1989), a measure of sleep quality, often used in research as measures of

[3] Both TST and SE are directly affected by the *practice* of CBT-I, as it requires specifically reducing time spent in bed awake as part of the protocol, which would increase SE and reduce TST initially, though may not indicate better sleep. These effects may particularly bias reviews considering only post-intervention and not follow-up data, as this review does.

insomnia severity and remission. Although there is overlap between sleep diary variables and these questionnaires, it is recommended to consider several together as insomnia is a subjective problem that may consist of different problem symptoms per individual (Smith & Wegener, 2003).

Objective sleep measures

Although polysomnography[4] is identified as the 'gold standard' objective sleep measure (van de Water, Holmes, & Hurley, 2011), only one of the included papers reported this and thus all objective data is actigraphy[5]-derived. Actigraphy-derived SE, WASO and TST reflect the most commonly reported objective sleep measures in included papers, with too few papers reporting other objective variables for analysis.

Secondary measures

Papers report a variety of measures for fatigue, pain and quality of life. Following meta-analytic convention (Okajima & Inoue, 2018; Wu et al., 2015), summary effect sizes were calculated for each of these secondary outcome constructs by combining effect size data from each paper (thus between a variety of instruments measuring the same construct). It is beyond the scope of this review to detail these measures individually, but all papers reported outcomes from standardised validated instruments, and reliability and validity was examined to ensure bespoke or unreliable measures were not included. All instruments from which effect sizes were extracted demonstrated correlation with other validated instruments measuring that same construct, increasing the likelihood the summary effect represents a single construct (Card & Little, 2016).

[4] Polysomnography is the study of sleep through monitoring or brain waves, blood oxygen, heart rate, breathing, eye movements and limb movements (Lichstein et al., 2006).

[5] Devices that record movements, typically worn on the wrist.

Coding fidelity to the model

Interventions were categorised as either pure CBT-I or adapted CBT-I. To be classified as pure CBT-I, the intervention used must be described and must include the key behavioural components of CBT-I (Epstein et al., 2012): Stimulus Control[6] (correcting conditioned associations between bed and wakefulness) and Sleep Restriction[7] (a reduction of total time in bed and rigid wake time to provide build-up of 'sleep pressure' throughout the day, without napping). Typically, CBT-I interventions also included cognitive components addressing dysfunctional beliefs and thoughts about sleep and worries about sleep. Categorisation as 'adapted' CBT-I required that studies made some attempt to modify the core components of CBT-I by introducing non-traditional elements (e.g. hybridised with CBT for Pain; Pigeon et al., 2012; Vitiello et al., 2013), or by providing a minimised version of typical components (Casault et al., 2015).

Coding of intervention modality

Intervention modality was coded as individual, group or self-help. Individual interventions were coded where participants had direct one-to-one, face-to-face contact with a facilitator where verbal instruction and discussion was present (e.g. Jungquist, O'Brien, et al., 2010). Group interventions were coded where several participants received an intervention at once (even if potentially supportive contacts such as brief phone calls may later occur). Studies were coded as self-help if the predominant method of intervention involved personal review of

[6] Lying in bed awake (and worrying) at night is cognitively and physiologically arousing, and people with insomnia may therefore develop a conditioned association between bed and this aroused state (Bootzin, Epstein, & Wood, 1991).

[7] Sleep restriction aims to 'compress' the time spent in bed so that more of it is spent asleep. This involves reducing the amount of time allowed in bed (to a minimum of 5 hours) until sleep efficiency is above 85%. Extra time is added to the 'sleep window' in 15 minute increments until sleep efficiency drops below 85% once more (Glovinsky & Spielman, 1991)

materials away from clinician contact including where minimal contact was offered (i.e. follow-up phone calls promoting adherence; Casault et al., 2015).

Coding control group type

Control conditions were coded as either treatment as usual (TAU), waitlist control (WLC) or active controls. TAU coding required that the study explicitly stated that participants were continuing to receive ongoing medical care from another source. WLC coding required participants were not declared as receiving ongoing treatment for sleep, and expected to receive the intervention of interest after a waiting period. Active coding required that a sham psychological placebo intervention was engaged with by the control group, or that a significant attention component (i.e. extensive sleep diary review and discussion; Jungquist, Brien, et al., 2010) was present to mimic common factor influences. Sleep hygiene is often included within CBT-I protocols, but when used alone as a control for two trials (Chen et al., 2008; Dirksen & Epstein, 2008), was coded as an active control as it has been demonstrated to have minimal efficacy when used alone (Morin, Culbert, & Schwartz, 1994).

Coding intervention length

Intervention length was coded in hours, rather than number of sessions to prevent multiple shorter contacts (e.g. check-in phone calls) skewing data. For self-help interventions, intervention length was not recorded as it was not possible to accurately estimate the time spent by individuals reviewing material.

Coding study quality

Study quality was assessed with the Downs and Black quality tool (1998). This is a 27-item checklist used to assess studies across various domains (internal and external validity, quality, potential bias and confounds). As described by other authors (e.g. Hooper, Jutai, Strong,

& Russell-Minda, 2008; O'Connor et al., 2015) the checklist was adapted by simplifying the originally five point scale for question 27 ("Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%?") to a simplified dichotomous variable (scoring 1 if sample size calculation of sufficient power is reported; Appendix B). The maximum score achievable was therefore 28.

Quality was co-rated by an independent peer researcher, who reviewed a randomly selected 20% of the studies (n = 4). Discrepancies between ratings were resolved by discussion until agreement on final score was reached.

Coding study year

Study year was coded with reference to initial publication date.

Meta-analytic strategy

Effect sizes were calculated for each included paper from unadjusted means and standard deviations supplied within the paper, or later by the authors. Selection of appropriate effect size followed recommendations from Morris (2008), i.e. a between-groups pre-test, post-test design Cohen's *d* calculated by comparing means and standard deviations at both pre- and post-intervention time-points. This effect size (Cohen's d_{ppc2}) was chosen as it allows for correction of errors produced by differing sample sizes and unequal baseline values between control and experimental groups (Morris, 2008). This is relevant to the present review as some studies (i.e. Rybarczyk, Lopez, Benson, Alsten, & Stepanski, 2002) reported significantly different baseline outcome scores for control and experimental groups, which later masked improvement when comparing only post-test scores (the more commonly used method of calculating Cohen's *d*). In two papers, two interventions (variants of CBT-I, or modalities) were compared to each other and also to a single control (Pigeon et al., 2012; Savard, Ivers, Savard, & Morin, 2014). For these

papers, both interventions were extracted separately, and effect sizes were calculated by reducing the number of control group participants by 50% to ensure control participants were not counted twice.

An Internet-based calculator was used to compute individual Cohen's d_{ppc2} effect sizes for all variables of interest reported per paper (Lenhard & Lenhard, 2016). Sample-weighted summary effect sizes, and moderator analyses were then calculated in R using the online MAVIS (Meta-Analysis Via Shiny) frontend interface (version 1.1.3; Hamilton, Aydin & Mizumoto, 2016). Due to the expectation of heterogeneity amongst studies in this review, all summary effect (and later categorical moderator) analysis was calculated through a restricted maximum-likelihood random effects model (Hunter & Schmidt, 2004). Summary effect (from MAVIS) is reported as Hedge's *g*, a directly comparable correction of Cohen's *d* that is robust for smaller groups within studies (Grissom & Kim, 2005). This was appropriate for this review due to the inclusion of studies with smaller groups (e.g. Kapella et al., 2011; Jungquist, Brien, et al., 2010; Pigeon et al., 2012). Following meta-analytic convention, effect sizes were interpreted as small (g = .20), medium (g = .50) and large (g = .80 or above) and statistical significance was assumed at an alpha value of 0.05 or less (Cohen, 1992). Continuous variables (study quality, study year and intervention length) were analysed by restricted-information maximum likelihood model random effects meta-regression in IBM SPSS (version 25) using Wilson's macros (Lipsey & Wilson, 2001).

Heterogeneity

Statistical heterogeneity was analysed by consulting the Q statistic (significant results indicate heterogeneity), and as recommended by Higgins, Thompson, Deeks and Altman (2003), further consulting the I^2 statistic to determine degree of heterogeneity where present. These

authors suggest gradings of low (25%), moderate (50%) and high (75%) heterogeneity when consulting I^2.

Publication bias

Publication bias was assessed by visual inspection of calculated funnel plots for each outcome with imputed trim and fill graphics (as generated by MAVIS). Bias is suggested when distribution around the mean summary effect size on the graph seems asymmetrical. However, visual inspection alone may be insufficient to assess bias, and so Rosenthal's fail-safe *N* calculation (1979) was also used to determine the number of nonsignificant studies that would be necessary to counter the result (i.e. their addition would make the overall result nonsignificant; Oswald & Plonsky, 2010). When this test results in a low number, this is usually a good indication of publication bias. Additionally, to aid interpretation of funnel plots, Egger's regression test is reported (Egger, Davey Smith, Schneider, & Minder, 1997), where significant results indicate likely publication bias.

Results

Included research characteristics

Study characteristics can be seen in Table 3, below.

Table 3.

Study characteristics

Study	Comorbid diagnoses	Intervention type	Control condition	Delivery modality	Treatment hours	Study quality	Outcomes (sleep quality, insomnia, sleep diaries, objective)	Outcomes (fatigue, pain, QoL)	Nc	Ne
Casualt et al. (2015)	Cancer	Adapted CBT-I	WLC	Self-help		21	ISI, SOL, WASO, oTST, oSE, oWASO	MFI QLQ-C30	18	20
Chen et al. (2011)	Conditions requiring haemodialysis	CBT-I	Active	Group	9	21	PSQI	FSS	35	37
Currie et al. (2000)	Chronic pain	CBT-I	WLC	Group	14	18	PSQI, SOL, WASO	MPI	38	32
Dirksen & Epstein (2008)	Breast Cancer	CBT-I	Active	Group	5.5	20	ISI	POMS-F FACT-B	38	34
Espie et al. (2008)	Cancer	CBT-I	TAU	Group	4.5	24	SOL, WASO, oTST, oSE, oWASO	FACT-G	50	100
Jansson-Fröjmark et al. (2012)	Hearing impairment and tinnitus	CBT-I	WLC	Individual	7	21	ISI, TST		15	17
Junquist et al. (2010)	Chronic pain	CBT-I	Active	Individual	7.25	21	ISI, SOL, WASO	MPI	9	19
Kapella et al. (2011)	Chronic Obstructive	CBT-I	Active	Individual	6	21	PSQI, ISI, SOL, WASO, oTST,	POMS-F	9	9

Study	Comorbid diagnoses	Intervention type	Control condition	Delivery modality	Treatment hours	Study quality	Outcomes (sleep quality, insomnia, sleep diaries, objective)	Outcomes (fatigue, pain, QoL)	Nc	Ne
	Pulmonary Disease						oSE, oWASO			
Morgan et al. (2012)	Various chronic illnesses	CBT-I	TAU	Self-help		23	PSQI, ISI	FSS	77	64
Pigeon et al(a). (2012)	Chronic pain	CBT-I	WLC	Individual	NR	20	ISI	MFI, MPI	2	6
Pigeon et al(b), (2012)	Chronic pain	Adapted CBT-I	WLC	Individual	NR	20	ISI	MFI, MPI	2	6
Redeker et al. (2015)	Stable heart failure	CBT-I	Active	Group	6	20	PSQI, ISI, SOL, oTST, oSE	MAF(GFI)	19	29
Ritterband et al. (2012)	Cancer	CBT-I	WLC	Self-help		21	ISI, SOL, WASO	MFI-SF SF-12	14	14
Rybarczyk et al. (2002)	Various chronic illnesses	CBT-I	WLC	Group	12	15	PSQI, SOL, WASO, oTST, oSE, oWASO		13	11
Rybarczyk et al. (2005)	Various chronic illnesses	CBT-I	Active	Group	16	18	PSQI, ISI, SOL, WASO	SF-MPQ	46	46
Savard et al (a). (2014)	Breast Cancer	CBT-I	TAU	Self-help		21	ISI, SOL, WASO	MFI QLQ-C30	40	80
Savard et al (b). (2014)	Breast Cancer	CBT-I	TAU	Individual	6	21	ISI, SOL, WASO	MFI QLQ-C30	41	81

Study	Comorbid diagnoses	Intervention type	Control condition	Delivery modality	Treatment hours	Study quality	Outcomes (sleep quality, insomnia, sleep diaries, objective)	Outcomes (fatigue, pain, QoL)	Nc	Ne
Smith et al. (2015)	Osteoarthritis	CBT-I	Active	Group	6	22	ISI, SOL, WASO, oTST, oSE, oWASO	WOMAC	38	35
Smitherman (2016)	Migraine	CBT-I	Active	Individual	1.5	20	PSQI, oTST, oSE	MIDAS	16	15
Vitiello et al. (2013)	Osteoarthritis	Adapted CBT-I	Active	Group	9	24	ISI, oTST, oSE	CPS	123	108

Note: Nc = Number of participants in control condition; Ne = Number of participants in experimental condition; NR = Not reported, CPS = Chronic Pain Scale (Von Korff, Ormel, Keefe, & Dworkin, 1992), FACT-B = Functional Assessment of Cancer Therapy – Breast (Cella, Eton, Lai, Peterman, & Merkel, 2002), , FACT-G Functional Assessment of Cancer Therapy – General (Cella et al., 1993), FSS = Fatigue Severity Scale (Krupp, LaRocca, Muir-Nash, & Steinberg, 1989), ISI = Insomnia Severity Index (Morin, 1993), MAF(GFI) = Multidimensional Assessment of Fatigue (Global Fatigue Index) (Belza, 1990), MFI = Multidimensional Fatigue Inventory (Smets, Garssen, Bonke, & De Haes, 1995), MFI-SF (Multidimensional Fatigue Inventory – Short Form (Stein, Martin, Hann, & Jacobsen, 1998), MIDAS = Migraine Disability Assessment Test (Stewart, Lipton, Dowson, & Sawyer, 2001), MPI = Multidimensional Pain Inventory (Turk & Rudy, 1988), oTST = Actigraphy-derived objective Total Sleep Time, oSE = Actigraphy-derived objective Sleep Effiency, oWASO = Actigraphy-derived objective Wake After Sleep Onset, POMS-F = Profile of Mood States Fatigue subscale (McNair, Lorr & Droppelman, 1992), PQSI = Pittsburgh Sleep Quality Index (Buysse, Reynolds, Monk & Berman, 1989), QLQ-C30 = European Organisation for Research and Treatment Core Quality of Life Questionnaire (Aaronson et al., 1993), QoL = Quality of Life, SF-12 = 12 Item Short Form Health Survey (Ware, Kosinski, & Keller, 1996), SF-MPQ = Short Form McGill Pain Questionnaire (Melzack, 1987, SOL = Sleep Onset Latency, WASO = Wake After Sleep Onset, WOMAC = Western Ontario and McMaster Universities Arthritis Index (Bellamy, Buchanan, Goldsmith, Campbell, & Stitt, 1988).

Eighteen studies were included with an overall population of 1406 participants. Two studies contributed two separate sets of data as they compared various interventions to a control group (Pigeon et al., 2012; Savard et al., 2014). Publication dates spanned 16 years from 2000 to 2016. Comorbidities with CHCs ranged from single disease samples (predominantly cancer) to groups with mixed CHCs. Most studies utilised CBT-I delivered individually (k = 6) or in a group (k = 8).

Summary effect sizes of CBT-I on all outcomes are presented below and in Table 4. Following this, moderator analysis of selected heterogeneous variables is explored below. Variables for moderator analysis were chosen a-priori with respect to their relevance to the construct of insomnia, to present a parsimonious account of data relationships.

Table 4.

Summary effect sizes, heterogeneity and publication bias statistics per outcome

Outcome	k	Q	I^2	Fail-safe N	*g*	95% CI
ISI	15	39.18***	64%	830	0.92***	0.68 – 1.17
PSQI	7	3.03		135	0.83***	0.62 – 1.05
SOL	12	16.08		180	0.49***	0.31 – 0.68
WASO	11	8.47		181	0.55***	0.40 – 0.70
oTST	7	106.92***	93%	21	-0.29	-1.00 – 0.42
oSE	7	14.03*	54%	4	0.18	-0.10 – 0.46
oWASO	4	0.45		11	0.38***	0.16 – 0.60
Pain	7	7.23		20	0.32**	0.10 – 0.53
Fatigue	11	15.05		140	0.46***	0.30 – 0.62
QoL	7	3.73		19	0.30***	0.13 – 0.47

Note: k = number of studies, Q = Cochrane's Q for statistical heterogeneity, I^2 = degree of heterogeneity (Higgins et al., 2003), Fail-safe N = number of studies required to overturn result, *g* = Hedge's g effect size, * = $p < 0.05$; ** = $p < 0.01$, *** = $p < 0.001$.

Summary effects of CBT-I

Subjective measures of sleep

The ISI questionnaire is utilised in 14 trials to determine insomnia severity. A further six studies report the related construct of sleep quality via the PSQI instead. One study (Morgan, Gregory, Tomeny, David, & Gascoigne, 2012) reports both. Figures 2-5 below show sample weighted effect size distribution for subjective insomnia outcome measures.

Effect sizes for *g* were interpreted through Cohen's (1992) criteria for *d*, to which *g* is analogous. Medium to large summary effect sizes from CBT-I were demonstrated for all subjective sleep questionnaires: ISI ($g = 0.92$), PSQI ($g = 0.83$) and small to medium effects for sleep diary variables: SOL ($g = 0.49$), WASO ($g = 0.55$). All effect sizes were significant ($p < 0.001$). Heterogeneity was significant for only ISI ($Q = 39.18$, $p < 0.001$, $I^2 = 64\%$). Egger's regression test for publication bias was also significant for ISI alone ($t(13) = 2.93$, $p < 0.05$), suggesting there may be publication bias influencing the ISI result. However, visual inspection of funnel plots with imputed trim and fill indicators (represented by unfilled circles; Appendix C) and the relatively large number of studies required to overturn results reported through Fail-safe N analysis ($N = 830$, 135, 180 and 181 respectively) suggested that none of these variables were likely to be significantly affected by publication bias.

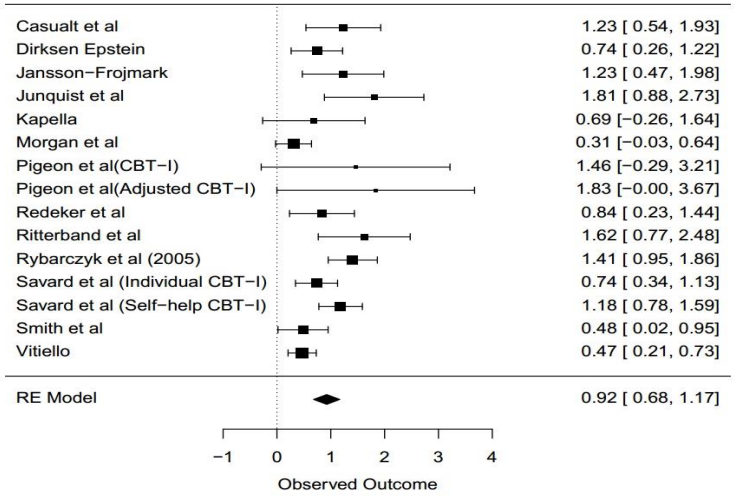

Figure 2: Summary CBT-I effect size on ISI (Hedge's *g*)

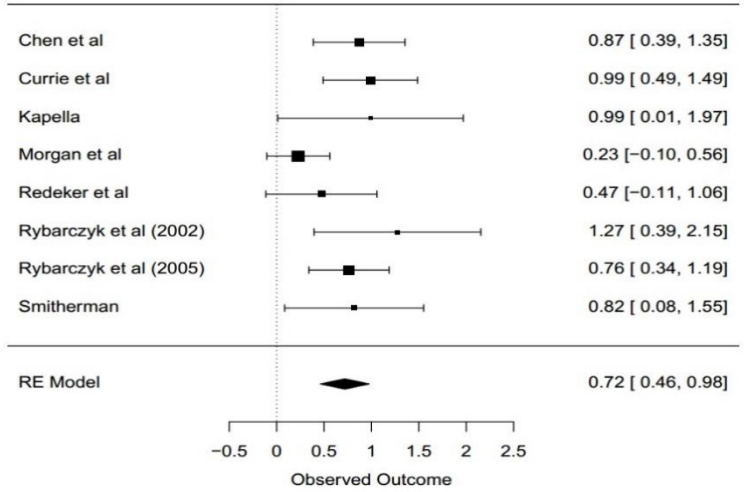

Figure 3: Summary CBT-I effect size on PSQI (Hedge's *g*)

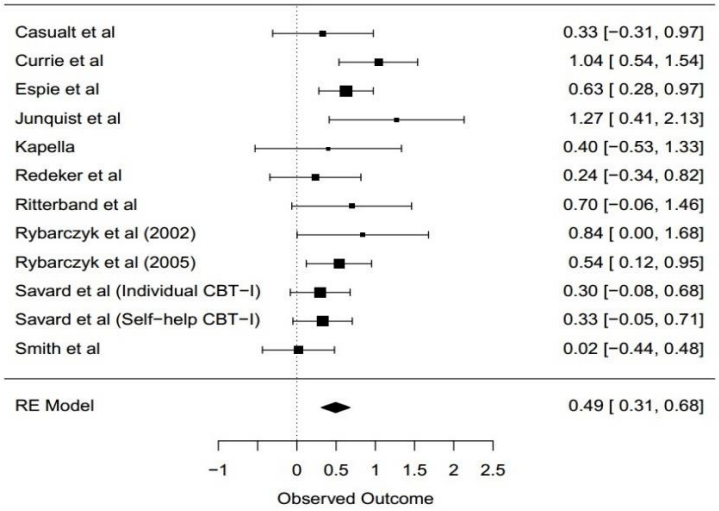

Figure 4: Summary CBT-I effect size on SOL (Hedge's *g*)

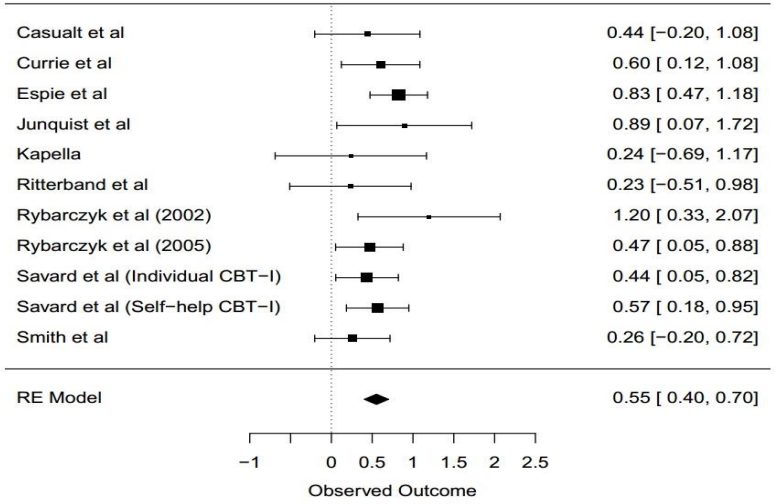

Figure 5: Summary CBT-I effect size on WASO (Hedge's g)

Objective measures of sleep

Seven studies reported sleep-diary variables derived from wrist actigraphy, validated as a satisfactory objective measure (Lichstein et al., 2006). Of those reported, only objective SE (oSE) and objective TST (oTST) were reported consistently across all seven studies, with objective WASO (oWASO) reported in four. Objective SOL was reported in too few studies for analysis ($k = 2$). Figures 6, 7 and 8 (below) show sample weighted effect sizes distribution for objective insomnia outcome measures.

CBT-I did not demonstrate significant summary effects on oTST or oSE, but did show a small summary effect size for oWASO ($g = 0.38$, $p < 0.001$). Heterogeneity was large and significant for oTST ($Q = 106.92$, $p < 0.001$, $I^2 = 93\%$), significant but moderate for oSE ($Q = 14.03$, $p < 0.05$, $I^2 = 54\%$) and nonsignificant for oWASO. Fail-safe N for all objective measures was low (21, 4, 11 respectively) suggesting relatively few studies would be required to overturn these results. Egger's test was nonsignificant for oTST, oSE and oWASO suggesting no publication bias, though funnel plot analysis (Appendix C), may be suggestive of missing high positive effect size studies for oSE and oWASO.

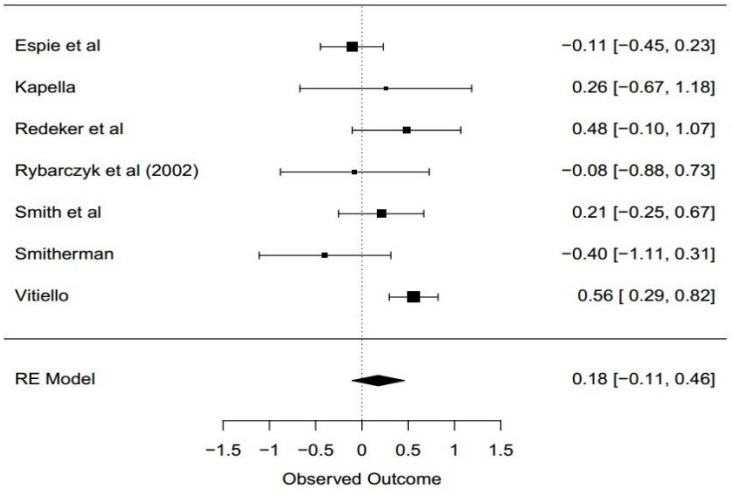

Figure 6: Summary CBT-I effects on objective SE (Hedge's g)

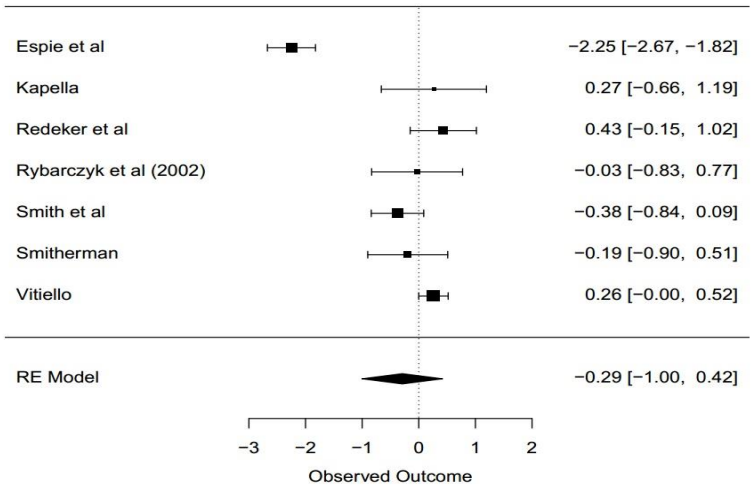

Figure 7: Summary CBT-I effects on objective TST (Hedge's g)

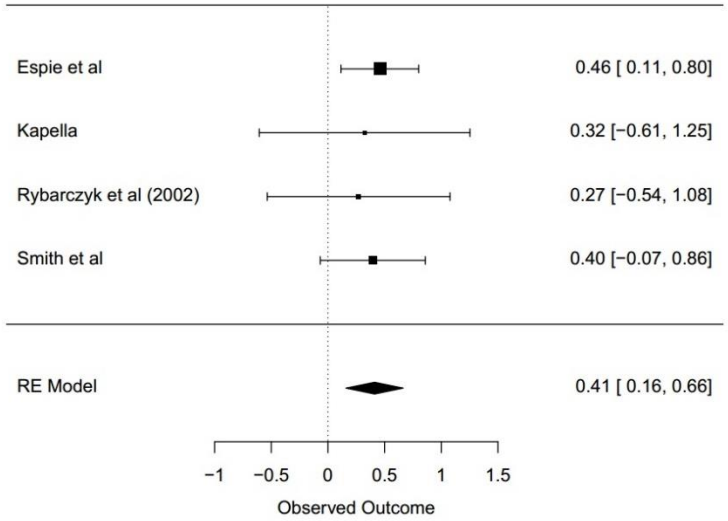

Figure 8: Summary CBT-I effects on objective WASO (Hedge's g)

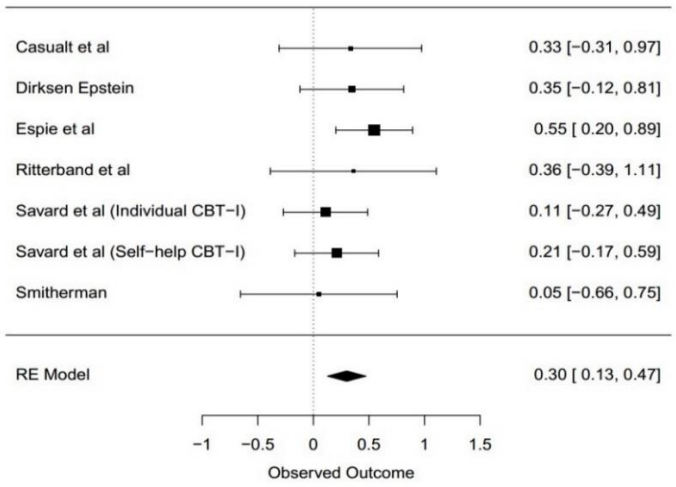

Figure 9: Summary CBT-I effects on quality of life (Hedge's *g*)

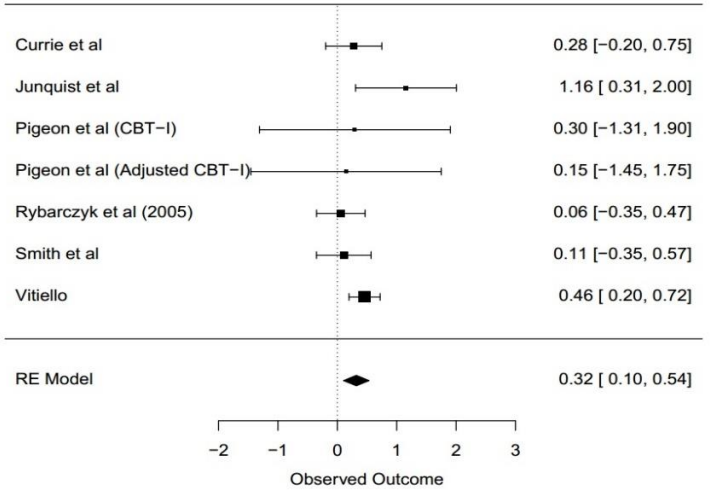

Figure 10: Summary CBT-I effects on pain (Hedge's *g*)

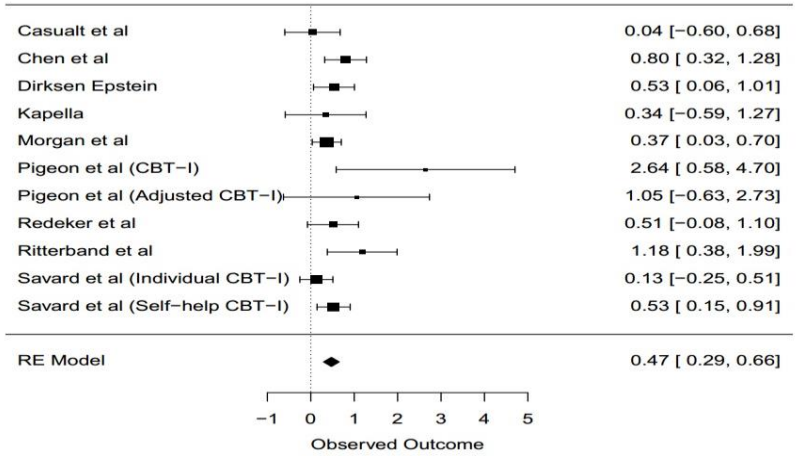

Figure 11: Summary CBT-I effects on fatigue (Hedge's *g*)

Secondary measures

Measures of fatigue, pain and quality of life were included as secondary outcomes to examine possible effects from the implementation of CBT-I. Seven studies contributed pain and QoL results, and eleven contributed fatigue results. Figures 9, 10 and 11 (above) show sample weighted effect size distribution for secondary measures.

CBT-I demonstrated small summary effect sizes for pain (g = 0.32) and QoL (g = 0.30), and a medium summary effect size for fatigue (g = 0.46). All summary effects were significant ($p < 0.01$). Heterogeneity was nonsignificant for all secondary measures. Fail-safe N was relatively low for pain and QoL (N = 20 and 19 respectively), but high for fatigue (N = 140). Egger's test was nonsignificant for all secondary measures, and funnel plot inspection does not indicate significant likelihood of missing studies biasing results (Appendix C).

Moderators of the effects of CBT-I on selected variables

Table 5 details the dichotomous moderators of all selected outcomes and Table 6 details all the continuous moderators analysed through univariate meta-regression analysis. Some analyses could not be performed due to insufficient data (i.e. less than 3 studies per subgroup; Burke, Sussman, Kent, & Hayward, 2015) and for parsimony and clarity, those instances do not appear in the tables.

Table 5.

Dichotomous moderators of the effect of CBT-I on each outcome

Moderator	**k**	**Q**	I^2	***g***	**95% CI**
Effects of CBT-I on Insomnia Severity Index (ISI)					
Control group type	15	39.19***	64%		
TAU	3	10.79**	81%	0.73	0.29 – 1.16
WLC	5	0.87***	0%	1.39	0.85 – 1.92
Active control	7	18.71***	68%	0.85	0.52 – 1.17
Fidelity to CBT-I model	15	39.19***	64%		
Adapted CBT-I	3	5.89**	66%	0.85	0.26 – 1.44
CBT-I	12	30.16***	64%	0.95	0.67 – 1.23
Treatment modality	15	39.19***	64%		
Group	5	13.27***	70%	0.77	0.42 – 1.12
Individual	6	3.29***	0%	1.27	0.82 – 1.72
Self-help	4	11.90***	75%	0.82	0.41 – 1.24
Effects of CBT-I on Sleep Onset Latency (SOL)					
Control group type	12	16.08			
TAU	3	1.98		0.42	0.15 – 0.70
WLC	4	2.95		0.76	0.39 – 1.12
Active control	5	7.27		0.39	0.1 – 0.69
Treatment modality	12	16.08			
Group	6	10.51		0.53	0.34 – 0.72
Individual	3	3.90		0.47	0.15 – 0.79
Self-help	3	0.86		0.37	0.07 – 0.67
Effects of CBT-I on Wake After Sleep Onset (WASO)					
Control group type	11	8.47			
TAU	3	2.26		0.62	0.41 – 0.84
WLC	4	2.95		0.57	0.26 – 0.89
Active control	4	1.93		0.42	0.14 – 0.69
Treatment modality	11	8.47			
Group	5	5.90		0.61	0.41 -0.81
Individual	3	1.08		0.58	0.25 – 0.90
Self-help	3	0.24		0.40	0.10 – 0.70
Effects of CBT-I on fatigue measures					
Control group type	11	15.05			
TAU	3	2.13		0.34	0.13 – 0.55
WLC	4	9.05*	67%	0.63	0.17 – 1.10
Active control	4	1.13		0.60	0.32 – 0.88
Treatment modality	11	15.05			

Moderator	k	Q	I^2	*g*	95% CI
Group	3	0.80		0.63	0.33 – 0.92
Individual	4	4.49		0.58	0.24 – 0.92
Self-help	4	6.23		0.31	0.02 – 0.64
Effects of CBT-I on pain measures					
Control group type (2 vs. 3)	7	7.23			
1. TAU					
2. WLC	3	0.02		0.26	-0.26 – 0.79
3. Active control	4	7.11		0.33	0.06 – 0.61
Treatment modality (1 vs. 2)	7	7.23			
Group	4	3.41		0.29	0.11 – 0.48
Individual	3	1.68		0.82	0.14 – 1.50
Self-help					

Note: k = number of studies, Q = Between-subgroups Cochrane's Q heterogeneity statistic, I^2 = degree of heterogeneity, *g* = effect size in Hedge's g, 95% CI = 95% confidence interval

Table 6.

Continuous moderators of the effect of CBT-I on each outcome

Moderator	k	*β*	Q (1)	95% CI
Effects of CBT-I on Insomnia Severity Index (ISI)				
Study quality	15	-0.180***	17.67***	-0.263 - -0.096
Treatment length (hours)	9	0.412	1.199	-0.007 – 0.890
Publication year	15	-0.47	1.34	-0.1266 – 0.325
Effects of CBT-I on Pittsburgh Sleep Quality Index (PSQI)				
Study quality	7	-0.054	0.627	-0.187 – 0.795
Treatment length (hours)	7	-0.010	0.172	-0.368 – 0.057
Publication year	7	-0.185	0.930	-0.562 – 0.191
Effects of CBT-I on Sleep Onset Latency (SOL)				
Study quality	12	-0.040	1.358	-0.107 – 0.027
Treatment length (hours)	9	0.030	2.396	-0.008 – 0.067
Publication year	12	-0.048**	10.434*	-0.078 - -0.019
Effects of CBT-I on Wake After Sleep Onset (WASO)				
Study quality	11	0.003	0.009	-0.065 – 0.072

Moderator	k	*β*	Q (1)	95% CI
Treatment length (hours)	8	-0.007	2.213	-0.046 – 0.031
Publication year	11	-0.023	0.141	-0.052 – 0.007
Effects of CBT-I on Objective Total Sleep Time (oTST)				
Study quality	7	-0.122	0.856	0.380 – 0.136
Treatment length (hours)	7	0.093	0.575	-0.148 – 0.334
Publication year	7	0.067	0.711	-0.089 – 0.223
Effects of CBT-I on Objective Sleep Efficiency (oSE)				
Study quality	7	0.038	0.138	-0.593 – 0.668
Treatment length (hours)	7	0.096	0.576	-0.028 – 0.163
Publication year	7	0.015	0.079	-0.322 – 0.353
Effects of CBT-I on Objective Wake After Sleep Onset (oWASO)				
Study quality	4	0.030	0.441	-0.59 – 0.12
Treatment length (hours)	4	0.014	0.398	-0.06 – 0.3
Publication year	4	0.006	0.047	-0.05 – 0.06
Effects of CBT-I on Fatigue				
Study quality	11	0.925	1.221	-2.565-0.715
Treatment length (hours)	5	0.949	0.100	-1.768 – 1.958
Publication year	11	-0.320	0.942	-0.965 – 0.326
Effects of CBT-I on Pain				
Study quality	7	0.457	1.786	-0.021 – 0.113
Treatment length (hours)	5	-0.031	1.401	-0.082 - -0.020
Publication year	7	0.013	0.530	-0.021 – 0.047
Effects of CBT-I on QoL				
Study quality	7	0.091	2.261	-0.027 – 0.209
Treatment length (hours)	4	0.009	0.010	-0.161 – 0.178
Publication year	7	-0.047	2.679	-0.103 – 0.009

Note: k – number of studies, β = regression beta-coefficient, Q = Cochrane's Q heterogeneity statistic, 95% CI = 95% confidence interval. * = $p < 0.05$, ** = $p < 0.01$, *** = $p < 0.001$

Study design variables

Control group type

The effects of CBT-I on ISI outcomes were moderated by the type of control group used in the research design, with comparisons to WLC controls reporting significantly higher effect sizes (g = 1.39, $p < 0.001$) than comparisons to TAU (g = 0.73, $p < 0.01$) or Active controls (g = 0.85, $p < 0.001$), Q = 39.19, $p < 0.001$. Control group type did not significantly moderate the effects of CBT-I on any other outcome.

Study quality

Overall study quality for the included papers (M = 20.71, SD = 2.05) was 'good' with reference to the suggested categorisations for similarly modified Downs and Black scales (O'Connor et al., 2015). Most studies did not report adverse events (or lack thereof) and participants and researchers were rarely blinded, though some studies made reasonable attempts. Details of quality scoring can be found in Appendix D. Meta-regression analysis indicated that study quality did moderate the effectiveness of CBT-I on reducing ISI scores, $Q(1) = 17.67$, $p < 0.001$, reporting a significant but weak negative association (β = 0.18, $p < 0.001$), suggesting that better quality studies tend to report lower effect sizes. Study quality did not significantly moderate the effects of CBT-I on any other outcome.

Year of publication

Publication year did significantly moderate the effect of CBT-I on SOL outcomes, $Q(1) = 10.43$, $p < 0.05$, reporting a very weak significant negative correlation (β = -0.048, $p < 0.01$), suggesting that later studies tended to report slightly lower effect sizes. Publication year did not significantly moderate the effects of CBT-I on any other outcome.

Intervention specific variables

Intervention length

Intervention length did not significantly moderate the effects of CBT-I on any outcomes.

Fidelity to CBT-I

Fidelity to the CBT-I model (i.e. whether pure or adjusted CBT-I was employed) significantly moderated the effects of CBT-I on ISI ($Q = 39.19$, $p < 0.001$, $I^2 = 64\%$), demonstrating significantly larger effect sizes for non-adapted CBT-I ($g = 0.95$, $p < 0.001$) compared to adapted CBT-I ($g = 0.85$, $p < 0.01$). Fidelity to CBT-I did not significantly moderate the effects of CBT-I on any other outcomes.

Intervention modality

The delivery modality of the intervention significantly moderated the effectiveness of CBT-I on reducing ISI scores ($Q = 39.19$, $p < 0.001$) with individual one-to-one interventions indicating larger effect sizes ($g = 1.27$, $p < 0.001$) than group interventions ($g = 0.77$, $p < 0.001$) and self-help ($g = 0.82$, $p < 0.001$). Intervention modality did not significantly moderate the effect of CBT-I on any other outcomes.

Discussion

This meta-analysis sought to explore the effectiveness of CBT-I in reducing symptoms of insomnia for people with CHCs (but not MHPs) and to examine the effects on pain, fatigue and quality of life. Results suggest medium to large effect sizes for insomnia severity (ISI) and sleep quality (PSQI), and small to medium effect sizes for the subjective sleep diary variables indicating specific insomnia symptoms: sleep latency (SOL) and early waking (WASO). This suggests that CBT-I was effective at improving subjectively experienced insomnia for this population. Further, CBT-I significantly contributes to improvement in fatigue, pain and quality of life, with effect sizes ranging from small to medium. However, CBT-I did not appear to improve two of the three objectively measured

sleep variables (oTST and oSE), and conclusions drawn about effectiveness for oWASO, pain and quality of life may be influenced by publication bias (see below).

Comparison to meta-analyses with mixed CHC and MHP populations

Comparing these results to previous meta-analyses (Table 7, below) for insomnia comorbid to CHCs and MHPs (Geiger-brown et al., 2015; Okajima & Inoue, 2018; van Straten et al., 2018; Wu et al., 2015), effect sizes are generally lower for sleep onset and early waking (SOL and WASO) than in the previous analyses, but effect sizes for insomnia severity and sleep quality are broadly similar (with the exception of the Geiger-brown et al., 2015 ISI results). This may suggest that CBT-I is as effective at improving insomnia severity and sleep quality for people with CHCs (without diagnosed MHPs) as it is for populations with both CHCs and MHPs together, but less effective at improving sleep onset and early waking. A pattern of substantially higher effect sizes for ISI and PSQI than for SOL and WASO is preserved in all of these previous meta-analyses, as it is in this analysis.

Table 7.

Results comparison to previous meta-analyses

Outcome	This review[e]	Geiger-brown et al. (2015)	Wu et al. (2015)	Okajima & Inoue (2018)[c]	Van Straten et al. (2018)[de]
ISI	0.92	1.22	[a]	0.93	0.90
PSQI	0.83	0.88	[a]	0.90	-
SOL	0.49	0.75	0.8	0.63	0.63
WASO	0.55	0.74	0.68	0.58	-
Objective SE[b]	0.18*	0.17	0.12*	0.48	-
Objective TST[b]	-0.29*	0.03	-	0.11*	-
Objective WASO[b]	0.38	0.25	0.53*	0.41	-

Note: [a] = not reported separately; [b] = may incorporate polysomnography, actigraphy, or both; [c] = drawn from moderator analysis of "medical comorbidity" rather than overall comorbidity; [d] = drawn from moderator analysis as study analysed primary and comorbid mixed insomnias; [e] = effect sizes given in *g*, an adjustment of Cohen's *d* that corrects for small sample sizes.
* = $p > 0.05$, ISI = Insomnia Severity Index, PSQI = Pittsburgh Sleep Quality Index, SOL = Sleep Onset Latency, WASO = Wake After Sleep Onset.

There are several possibilities that may explain these results. Firstly, this may be an artefact of the relatively conservative effect size used to calculate study effects (d_{ppc2}), which typically produces smaller effect sizes than standardised mean difference Cohen's *d,* more commonly used in the literature (Morris, 2008).

Secondly, the ISI and PSQI are completed retrospectively, asking participants to recall a substantial period (2 and 4 weeks respectively). Recall biases (e.g. difficulty remembering, primacy and recency effects and tendency to remember the most extreme nights/days) may render these results less accurate than (daily completion) sleep diaries (Smith & Wegener, 2003).

Finally, CBT-I may be less effective at improving sleep latency and early waking in this population because other sleep-interfering CHC symptoms (such as pain, inflammation or digestive problems; Anderson et al., 2003; Kinnucan, Rubin, & Ali, 2013; Law, Palermo, Lord, & Ritterband, 2012) may be more prevalent, creating a floor effect for how much sleep can improve.

Disparity between objective and subjective measures of insomnia

Continuing a persistent pattern from previous meta-analyses (Geiger-brown et al., 2015; Okajima & Inoue, 2018; Okajima et al., 2011), CBT-I yielded smaller (or non-significant) effects on objective measures compared to subjective measures, perhaps suggesting it was less effective at improving actual sleep achieved. This may be explained by belief change (i.e. perceptions of sleep change through CBT-I, but actual sleep does not; further discussed below). It may also be that the primarily self-report instruments used in CBT-I research are vulnerable to response biases, which are particularly pernicious where blinding is inadequate (Hróbjartsson, Emanuelsson, Skou Thomsen, Hilden, & Brorson, 2014), or effectively impossible, as in psychological intervention research (Button & Munafò, 2015). Thus, it may be argued that subjective measures of sleep are measuring a different

construct (subjective perceptions of and beliefs about sleep) than objective measures (actual sleep achieved). However, even if this is the case, we must be careful not to assign undue import to objective measures, as insomnia is a subjective problem (Smith & Wegener, 2003), with diagnostic criteria reliant only on subjective experience, and over-focus on objective 'verification' risks trivialising insomnia (Harvey & Tang, 2012).

CBT-I may change beliefs and perceptions about sleep

As discussed above the persistent pattern of results across CBT-I literature suggests that some measures may be reflective of changed perceptions and beliefs about sleep. The cognitive components of CBT-I aim to address dysfunctional beliefs about sleep, including the tendency for people with insomnia to over-estimate the consequences of poor sleep, and underestimate the amount and quality of sleep they get (Harvey, 2005; Harvey & Tang, 2012; Morin & Bélanger, 2011). This is robustly reported to occur prior to CBT-I intervention (i.e. at baseline), and is thought to be addressed during CBT-I intervention, as (distorted) beliefs about sleep are changed. It is argued this leads to less distorted perceptions and reporting of sleep at post-intervention timepoints (Harvey & Tang, 2012; Lund, Rybarczyk, Perrin, Leszczyszyn, & Stepanski, 2013). The ISI and PSQI also measure daytime sequelae of insomnia such as satisfaction with sleep, mood and subjectively perceived functional impairment that may be more responsive to changed perceptions than the (numerical) reporting of SOL and WASO. Thus, it may be that improvement on ISI and PSQI measures partially reflects such perception and belief change between timepoints (in addition to amplifying, presumably, the genuine effects of improved sleep latency and early waking).

Belief and perception change in CHCs

It may be that altered and less anxiety-driven perceptions and thinking habits generalise beyond CBT-I practice, to change perceptions and beliefs about the CHCs and their symptoms. Generalisation of (less anxious) perceptions and beliefs may be suggested by

the improvement of anxiety and depression through CBT-I practice (e.g. Okajima et al., 2011), and the improvement on pain, fatigue and quality of life measures in this review. Perceptions and beliefs about illness and symptoms (particularly if anxiety-laden) are important to multiple outcomes for people with CHCs, including quality of life (Petrie, Jago, & Devcich, 2007) and pain experience (Edwards et al., 2011). Some authors (e.g. Okajima et al., 2011) comment that it is not yet certain that belief and perception change is not in fact the primary mechanism of effect for CBT-I. It may be tempting to interpret the relatively weaker effects of CBT-I on specific insomnia symptoms (such as SOL, WASO or objective measures) as evidence of ineffectiveness, but belief and perception change (for example, satisfaction with level of sleep regardless of how many hours are achieved) may be a more valuable goal than specifically improving individual symptoms, particularly for people with CHCs where (perhaps) a greater proportion of insomnia may be physiologically-maintained and unlikely to change. Other therapeutic approaches (i.e. Acceptance and Commitment Therapy; Hayes, Strosahl & Wilson, 1999) emphasise the importance of accepting experiences and 'symptoms' that will not change in adopting or maintaining behaviours that promote engagement in life, and living a valued and more fulfilling existence beyond the 'problem' (rather than, for example, never 'moving on' from worrying about low SE).

Secondary outcomes

CBT-I demonstrated significant but small effects in improving pain and quality of life, and a medium effect in improving fatigue for participants. This may suggest that practice of CBT-I itself improves experience of fatigue or pain (and thus, increases quality of life). This may occur, as above, through a generalisation of cognitive strategies from CBT-I. Reducing potentially catastrophised perceptions and resultant worry has been shown to be effective in the psychological management of chronic pain (Eccleston et al., 2014). Also, improved sleep may contribute to improved disease-related quality life, less healthcare use

and better health in various chronic health conditions (Chasens, Korytkowski, Sereika, & Burke, 2013; Elder et al., 2007; Krishnan et al., 2008; Peoples et al., 2015; Zee & Turek, 2006). Further, behavioural changes instigated by CBT-I practice contribute to consistency in bed and wake-times, associated with increased physical activity (Duncan, Kline, Rebar, Vandelanotte, & Short, 2016), which is demonstrated to reduce fatigue in conditions such as cancer (Manneville et al., 2018).

Limitations and future directions

Heterogeneity and publication bias

There is a relatively low number of studies in this review, partially due to the conservative exclusion criteria. This limited the moderator analysis that it was possible to perform, and may have increased the impact of heterogeneity and publication bias upon the results.

There was significant heterogeneity in three of the ten outcomes (insomnia severity, objective total sleep time and objective sleep efficiency). Similar heterogeneity in summary insomnia severity effect size is reported in previous meta-analyses, suggesting this is not a particular artefact of this review (Okajima & Inoue, 2018; van Straten et al., 2018). However, it may reflect publication bias (specifically missing studies of low effect), though fail-safe N results suggest this is unlikely. Publication bias is perhaps a more significant concern in pain, quality of life and objective sleep measures due to the low number of studies, and particularly the heterogeneity of instruments in secondary measures. Further, although statistical heterogeneity was rejected for outcomes such as oWASO, pain and QOL, Cochrane's Q may be unreliable with small study numbers, reducing the confidence in these results (Hardy & Thompson, 1998).

Other potential moderators

Several variables that may affect outcomes of CBT-I research were not included in this review either as they were not sufficiently reported, or for parsimony, such as medication use, age, specific diagnosis and participant gender. As CHC diagnoses were many and various, it was not possible to include them as a moderator. Unfortunately, this makes it difficult to recommend CBT-I for specific diseases, particularly as insomnia experience and potential physiological maintenance are likely to vary between CHCs (Morin & Benca, 2012).

Follow-up data

All outcome data in this review was taken from baseline and post-intervention timepoints. Follow up data was available for some of the included studies, but was not analysed here due to its relative paucity and variety in outcomes reported, so claims cannot be made about the stability of effects.

Study selection

Only between groups designs (k = 18) were included in the review, excluding within-groups designs (k = 4), aiming to keep effect sizes meaningfully comparable (Morris, 2008). Other reviews have favoured within-groups research (e.g. Smith et al., 2002), which may have increased the available evidence if combining effect sizes of between and within-group designs through conversion to a common effect size (Morris & DeShon, 2002). However, single group designs would remain uniquely vulnerable to time effects.

Data extraction

Finally, due to practical limitations (i.e. availability of second coders), all extracted data was coded solely by the author of this review. Future research would ideally employ an independent second coder to ensure validity and reliability.

Future research

Future research could investigate insomnia exclusively comorbid to CHCs further, potentially with greater power than this analysis as the pool of data grows. This may allow additional moderator analysis that includes diagnosis-specific effects. Further research could also investigate if the moderator findings (particularly the superiority of individual interventions) are robust, as this may have implications for health care provision (see below). Finally, research could investigate further the use of objective measures of sleep, and consider their appropriateness as measures of insomnia as research continues to demonstrate potentially misleading disparities (Harvey & Tang, 2012).

Implications for clinical psychology and practice

Existing guidance recommending CBT-I for those with insomnia comorbid to a medical condition (Grandner & Perlis, 2015; Morin et al., 2012) appears appropriate for the population studied in this review. These results suggest that those with CHCs benefit from CBT-I, though perhaps slightly less than those with primary insomnia or MHP comorbidities. Although moderator analysis suggested a significantly larger effect for un-adapted CBT-I, the Adapted CBT-I category was likely too small ($k = 3$) and heterogenous to conclude that adapted CBT-I is less effective, so no recommendations are made regarding this.

A potential addendum to existing practice may be to recommend face-to-face CBT-I over self-help, at least through a stepped-care model. Moderator analysis suggested individual interventions produced larger effects (on insomnia severity) than group or self-help approaches, echoing contemporary meta-analyses (Geiger-brown et al., 2015; van Straten et al., 2018) and research (Yamadera et al., 2013). Moderator analysis also suggested larger effects for CBT-I compared to WLC than for either active or TAU controls, perhaps suggesting that clinician contact is important to people with CHCs. However, there is evidence from other forms of CBT that suggests self-help is equivalently effective (e.g. for

depression and anxiety; Cuijpers et al., 2010; Ho, Yeung, Ng, & Chan, 2016), and this may contribute to a narrative that CBT-I is also similarly equivocal, particularly in contemporary cost-conscious healthcare environments like the NHS (Robertson, Wenzel, Thompson, & Charles, 2017). This may be inappropriate for people with CHCs and insomnia, who are arguably less likely to adhere to CBT-I regimes to begin with (Matthews, Arnedt, Mccarthy, Cuddihy, & Aloia, 2013) and who may be even less likely to adhere to (for example) internet-based self-help options in real world practice (adherence rates within trials typically outperform adherence rates in common usage; Christensen, Griffiths, & Farrer, 2009). However, it is also important to recognise that whilst (possibly) not as effective, self-help CBT-I appears to be equally effective at improving (most) insomnia symptoms and related health outcomes, and thus should be offered to people with CHCs, particularly if they cannot access individual CBT-I.

Conclusions

CBT-I appears to be effective at reducing subjectively measured core insomnia symptoms (SOL, WASO, ISI and PSQI) in people with chronic health conditions (who do not also have a diagnosed mental health problem) when compared to control groups, and may improve fatigue, pain and quality of life. However, CBT-I did not improve two of the three objective sleep measures, and the third objective sleep measure only improved to a small effect size, suggesting CBT-I does not reliably improve objective sleep measures in this population. This may reflect that CBT-I may be more effective at changing perceptions than specific insomnia symptoms. It is argued in this review that changes in either are valuable to people with chronic health problems and insomnia.

References

*** = included in this review**

Aaronson, N. K., Ahmedzai, S., Bergman, B., Bullinger, M., Cull, A., Duez, N. J., … Takeda, F. (1993). The European Organization for Research and Treatment of Cancer QLQ-C30: A quality-of-life instrument for use in international clinical trials in oncology. *JNCI Journal of the National Cancer Institute*, *85*, 365–376. https://doi.org/10.1093/jnci/85.5.365

Ali, T., Choe, J., Awab, A., Wagener, T. L., & Orr, W. C. (2013). Sleep, immunity and inflammation in gastrointestinal disorders. *World Journal of Gastroenterology*, *19*, 9231–9. https://doi.org/10.3748/wjg.v19.i48.9231

Anderson, K. O., Getto, C. J., Mendoza, T. R., Palmer, S. N., Wang, X. S., Reyes-Gibby, C. C., & Cleeland, C. S. (2003). Fatigue and sleep disturbance in patients with cancer, patients with clinical depression, and community-dwelling adults. *Journal of Pain and Symptom Management*, *25*, 307–318. https://doi.org/10.1016/S0885-3924(02)00682-6

Baglioni, C., Battagliese, G., Feige, B., Spiegelhalder, K., Nissen, C., Voderholzer, U., … Riemann, D. (2011). Insomnia as a predictor of depression: A meta-analytic evaluation of longitudinal epidemiological studies. *Journal of Affective Disorders*, *135*, 10–19. https://doi.org/10.1016/J.JAD.2011.01.011

Bastien, C. H., Morin, C. M., Ouellet, M.-C., Blais, F. C., & Bouchard, S. (2004). Cognitive-behavioral therapy for insomnia: comparison of individual therapy, group therapy, and telephone consultations. *Journal of Consulting and Clinical Psychology, 72*, 653–659. https://doi.org/10.1037/0022-006X.72.4.653

Beck, A. T., & Dozois, D. J. (2011). Cognitive therapy : current status andfuture directions. *Annual Review of Medicine, 62*, 397-409. https://doi.org/10.1146/annurev-med-052209-100032

Beck, A. T., Rush, A. J., Shaw, B. F., & Emery, G. (1979). *Cognitive Therapy of Depression*. New York: The Guilford Press.

Bellamy, N., Buchanan, W. W., Goldsmith, C. H., Campbell, J., & Stitt, L. W. (1988). Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. *The Journal of Rheumatology*, *15*, 1833–40. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/3068365

Belleville, G., Ivers, H., Bélanger, L., Blais, F. C., & Morin, C. M. (2016). Sequential treatment of comorbid insomnia and generalized anxiety disorder. *Journal of Clinical Psychology*, *72*, 880–896. https://doi.org/10.1002/jclp.22300

Belza, B. L. (1990). *Multidimensional Assessment of Fatigue (MAF) Scale Users Guide*. Seattle: University of Washington.

Bootzin, R. R., Epstein, D., & Wood, J. M. (1991). Stimulus control instructions. In P. J. Hauri (Ed.) *Case Studies in Insomnia* (pp. 19–28). Boston, MA: Springer US. https://doi.org/10.1007/978-1-4757-9586-8_2

Borkovec, T. D., Alcaine, O. M., & Behar, E. (2004). Avoidance theory of worry and generalized anxiety disorder. In R. G. Heimberg, C. L. Turk, & D. S. Mennin (Eds.) *Generalized Anxiety Disorder: Advances in Research and Practice* (pp. 77–108). New York: Guilford Press.

Borkovec, T. D., Wilkinson, L., Folensbee, R., & Lerman, C. (1983). Stimulus control applications to the treatment of worry. *Behaviour Research and Therapy*, *21*, 247–251. https://doi.org/10.1016/0005-7967(83)90206-1

Bower, J. E., Ganz, P. A., Irwin, M. R., Kwan, L., Breen, E. C., & Cole, S. W. (2011). Inflammation and behavioral symptoms after breast cancer treatment: do fatigue, depression, and sleep disturbance share a common underlying mechanism? *Journal of*

Clinical Oncology : Official Journal of the American Society of Clinical Oncology, *29*, 3517–22. https://doi.org/10.1200/JCO.2011.36.1154

Burns, P. B., Rohrich, R. J., & Chung, K. C. (2011). The levels of evidence and their role in evidence-based medicine. *Plastic and Reconstructive Surgery*, *128*, 305–10. https://doi.org/10.1097/PRS.0b013e318219c171

Button, K. S., & Munafò, M. R. (2015). Addressing risk of bias in trials of cognitive behavioral therapy. *Shanghai Archives of Psychiatry*, *27*, 144–8. https://doi.org/10.11919/j.issn.1002-0829.215042

Buysse, D. J., Reynolds, C. F., Monk, T. H., Berman, S. R., & Kupfer, D. J. (1989). The Pittsburgh sleep quality index: a new instrument for psychiatric practice and research. *Psychiatry Research*, *28*, 193–213. https://doi.org/10.1016/0165-1781(89)90047-4

Card, N. A., & Little, T. D. (2016). *Applied Meta-Analysis for Social Science Research*. New York: Guilford Press.

*Casault, L., Savard, J., Ivers, H., & Savard, M. H. (2015). A randomized-controlled trial of an early minimal cognitive-behavioural therapy for insomnia comorbid with cancer. *Behaviour Research and Therapy*, *67*, 45–54. https://doi.org/10.1016/j.brat.2015.02.003

Cella, D., Eton, D. T., Lai, J. S., Peterman, A. H., & Merkel, D. E. (2002). Combining anchor and distribution-based methods to derive minimal clinically important differences on the Functional Assessment of Cancer Therapy (FACT) anemia and fatigue scales. *Journal of Pain and Symptom Management*, *24*, 547–61. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/12551804

Cella, D. F., Tulsky, D. S., Gray, G., Sarafian, B., Linn, E., Bonomi, A., … Brannon, J. (1993). The Functional Assessment of Cancer Therapy scale: development and validation of the general measure. *Journal of Clinical Oncology*, *11*, 570–579. https://doi.org/10.1200/JCO.1993.11.3.570

Chasens, E. R., Korytkowski, M., Sereika, S. M., & Burke, L. E. (2013). Effect of poor sleep quality and excessive daytime sleepiness on factors associated with diabetes self-management. *The Diabetes Educator, 39*, 74–82. https://doi.org/10.1177/0145721712467683

*Chen, H. Y., Chiang, C. K., Wang, H. H., Hung, K. Y., Lee, Y. J., Peng, Y. S., … Tsai, T. J. (2008). Cognitive-behavioral therapy for sleep disturbance in patients undergoing peritoneal dialysis: a pilot randomized controlled trial. *American Journal of Kidney Diseases, 52*, 314–323. https://doi.org/10.1053/J.AJKD.2008.03.012

Cheng, S. K., & Dizon, J. (2012). Computerised cognitive behavioural therapy for insomnia: a systematic review and meta-analysis. *Psychotherapy and Psychosomatics, 81*, 206–216. https://doi.org/10.1159/000335379

Christensen, H., Griffiths, K. M., & Farrer, L. (2009). Adherence in internet interventions for anxiety and depression. *Journal of Medical Internet Research, 11*, 13. https://doi.org/10.2196/jmir.1194

Conn, V. S., & Rantz, M. J. (2003). Focus on research methods: managing primary study quality in meta-analyses. *Research in Nursing & Health, 26*, 322–333. https://doi.org/10.1002/nur.10092

Covin, R., Ouimet, A. J., Seeds, P. M., & Dozois, D. J. A. (2008). A meta-analysis of CBT for pathological worry among clients with GAD. *Journal of Anxiety Disorders, 22*, 108–116. https://doi.org/10.1016/J.JANXDIS.2007.01.002

Cuijpers, P., Donker, T., van Straten, A., Li, J., & Andersson, G. (2010). Is guided self-help as effective as face-to-face psychotherapy for depression and anxiety disorders? A systematic review and meta-analysis of comparative outcome studies. *Psychological Medicine, 40*, 1943–1957. https://doi.org/10.1017/S0033291710000772

*Dirksen, S. R., & Epstein, D. R. (2008). Efficacy of an insomnia intervention on fatigue,

mood and quality of life in breast cancer survivors. *Journal of Advanced Nursing*, *61*, 664–675. https://doi.org/10.1111/j.1365-2648.2007.04560.x

Doufas, A. G., Panagiotou, O. A., & Ioannidis, J. P. A. (2012). Concordance of sleep and pain outcomes of diverse interventions: an umbrella review. *Public Library of Science*, *7*. https://doi.org/10.1371/journal.pone.0040891

Downs, S. H., & Black, N. (1998). The feasibility of creating a checklist for the assessment of the methodological quality both of randomised and non-randomised studies of health care interventions. *Journal of Epidemiology and Community Health, 52*, 377–384. DOI: 10.1136/jech.52.6.377

Dugas, M. J., Buhr, K., Ladouceur, R., Heimberg, R. G., Turk, C. L., & Mennin, D. S. (2004). The role of intolerance of uncertainty in etiology and maintenance. In R. G. Heimberg, C. L. Turk, & D. S. Mennin (Eds.), *Generalized Anxiety Disorder: Advances in Research and Practice* (pp. 143–163). New York: Guilford Press.

Duncan, M. J., Kline, C. E., Rebar, A. L., Vandelanotte, C., & Short, C. E. (2016). Greater bed- and wake-time variability is associated with less healthy lifestyle behaviors: a cross-sectional study. *Zeitschrift Fur Gesundheitswissenschaften*, *24*, 31–40. https://doi.org/10.1007/s10389-015-0693-4

Eccleston, C., Palermo, T. M., Williams, A. C., Lewandowski Holley, A., Morley, S., Fisher, E., & Law, E. (2014). Psychological therapies for the management of chronic and recurrent pain in children and adolescents. *The Cochrane Database of Systematic Reviews*, *5*. https://doi.org/10.1002/14651858.CD003968.pub4

Edinger, J. D., Wohlgemuth, W. K., Radtke, R. A., Coffman, C. J., & Carney, C. E. (2007). Dose-response effects of cognitive-behavioral insomnia therapy : a randomized clinical trial. *Sleep, 30,* 203-212. DOI: 10.1093/sleep/30.2.203

Edwards, R. R., Cahalan, C., Mensing, G., Smith, M., Haythornthwaite, J. A., &

Haythornthwaite, J. A. (2011). Pain, catastrophizing, and depression in the rheumatic diseases. *Nature Reviews Rheumatology, 7,* 216–224. https://doi.org/10.1038/nrrheum.2011.2

Egger, M., Davey Smith, G., Schneider, M., & Minder, C. (1997). Bias in meta-analysis detected by a simple, graphical test. *British Medical Journal, 315,* 629–34. https://doi.org/10.1136/BMJ.315.7109.629

Elder, S. J., Pisoni, R. L., Akizawa, T., Fissell, R., Andreucci, V. E., Fukuhara, S., … Saran, R. (2007). Sleep quality predicts quality of life and mortality risk in haemodialysis patients: Results from the Dialysis Outcomes and Practice Patterns Study (DOPPS). *Nephrology Dialysis Transplantation, 23,* 998–1004. https://doi.org/10.1093/ndt/gfm630

Epstein, D. R., Sidani, S., Bootzin, R. R., & Belyea, M. J. (2012). Dismantling multicomponent behavioral treatment for insomnia in older adults: a randomized controlled trial. *Sleep, 35,* 797–805. https://doi.org/10.5665/sleep.1878

Espie, C. A. (2002). Insomnia: conceptual issues in the development, persistence, and treatment of sleep disorder in adults. *Annual Review of Psychology, 53,* 215–243. https://doi.org/10.1146/annurev.psych.53.100901.135243

*Espie, C. A., Fleming, L., Cassidy, J., Samuel, L., Taylor, L. M., White, C. A., … Paul, J. (2008). Randomized controlled clinical effectiveness trial of cognitive behavior therapy compared with treatment as usual for persistent insomnia in patients with cancer. *Journal of Clinical Oncology, 26,* 4651–4658. https://doi.org/10.1200/JCO.2007.13.9006

Espie, C. A., Emsley, R., Kyle, S. D., Gordon, C., Drake, C. L., Siriwardena, A. N., … Luik, A. I. (2019). Effect of digital cognitive behavioral therapy for insomnia on health, psychological well-being, and sleep-related quality of life: a randomized clinical trial. *Journal of the American Medical Association Psychiatry, 76,* 21-30.

https://doi.org/10.1001/jamapsychiatry.2018.2745

Finan, P. H., Goodin, B. R., & Smith, M. T. (2013). The association of sleep and pain: an update and a path forward. *The Journal of Pain : Official Journal of the American Pain Society*, *14*, 1539–52. https://doi.org/10.1016/j.jpain.2013.08.007

Furukawa, T. A., Noma, H., Caldwell, D. M., Honyashiki, M., Shinohara, K., Imai, H., … Churchill, R. (2014). Waiting list may be a nocebo condition in psychotherapy trials: a contribution from network meta-analysis. *Acta Psychiatrica Scandinavica*, *130*, 181–192. https://doi.org/10.1111/acps.12275

Geiger-Brown, J. M., Rogers, V. E., Liu, W., Ludeman, E. M., & Downton, K. D. (2015). Cognitive behavioral therapy in persons with comorbid insomnia : A meta-analysis, *23*, 54-67. DOI: 10.1016/j.smrv.2014.11.007

Glovinsky, P. B., & Spielman, A. J. (1991). Sleep restriction therapy. In P. J. Hauri (Ed.) *Case Studies in Insomnia* (pp. 49–63). Boston, MA: Springer US. https://doi.org/10.1007/978-1-4757-9586-8_4

Grandner, M. A., & Perlis, M. L. (2015). Treating insomnia disorder in the context of medical and psychiatric comorbidities. *Journal of the American Medical Association Internal Medicine*, *175*, 1472–3. https://doi.org/10.1001/jamainternmed.2015.3015

Hardy, R. J., & Thompson, S. G. (1998). Detecting and describing heterogeneity in meta-analysis. *Statistics in Medicine*, *17*, 841–856. https://doi.org/10.1002/(SICI)1097-0258(19980430)17:8<841::AID-SIM781>3.0.CO;2-D

Harvey, A. G. (2002). A cognitive model of insomnia. *Behaviour Research and Therapy*, *40*, 869–893. https://doi.org/10.1016/S0005-7967(01)00061-4

Harvey, A. G. (2005). A cognitive theory and therapy for chronic insomnia. *Journal of Cognitive Psychotherapy*, *19*, 41–59. https://doi.org/10.1891/jcop.19.1.41.66332

Harvey, A. G., & Tang, N. K. Y. (2012). (Mis)perception of sleep in insomnia: a puzzle and a

resolution. *Psychological Bulletin, 138*, 77–101. https://doi.org/10.1037/a0025730

Hayes, S. C., Strosahl, K., & Wilson, K. G. (1999). *Acceptance and Commitment Therapy: An experiential approach to behavior change*. New York: Guilford Press.

Hertenstein, E., Feige, B., Gmeiner, T., Kienzler, C., Spiegelhalder, K., Johann, A., … Baglioni, C. (2019). Insomnia as a predictor of mental disorders: A systematic review and meta-analysis. *Sleep Medicine Reviews*, *43*, 96–105. https://doi.org/10.1016/j.smrv.2018.10.006

Ho, F. Y. Y., Yeung, W. F., Ng, T. H. Y., & Chan, C. S. (2016). The efficacy and cost-effectiveness of stepped care prevention and treatment for depressive and/or anxiety disorders: a systematic review and meta-analysis. *Scientific Reports*, *6*. https://doi.org/10.1038/srep29281

Hooper, P., Jutai, J. W., Strong, G., & Russell-Minda, E. (2008). Age-related macular degeneration and low-vision rehabilitation: a systematic review. *Canadian Journal of Ophthalmology*, *43*, 180–187. https://doi.org/10.3129/I08-001

Hróbjartsson, A., Emanuelsson, F., Skou Thomsen, A. S., Hilden, J., & Brorson, S. (2014). Bias due to lack of patient blinding in clinical trials. A systematic review of trials randomizing patients to blind and nonblind sub-studies. *International Journal of Epidemiology*, *43*, 1272–1283. https://doi.org/10.1093/ije/dyu115

Hubble, M. A., Duncan, B. L., & Miller, S. D. (1999). *The heart and soul of change: What works in therapy*. Washington: American Psychological Association. https://doi.org/10.1037/11132-000

*Jansson-Fröjmark, M., Flink, I. K., Granberg, S., & Danermark, B. (2012). Cognitive-behavioral therapy for insomnia co-morbid with hearing impairment: A randomized controlled trial. *Journal of Clinical Psychology in Medical Settings, 19,* 224–234. https://doi.org/10.1007/s10880-011-9275-y

Johnsen, T. J., & Friborg, O. (2015). The effects of cognitive behavioral therapy as an anti-depressive treatment is falling: A meta-analysis. *Psychological Bulletin*, *141*, 747–768. https://doi.org/10.1037/bul0000015

*Jungquist, C. R., Brien, C. O., Matteson-Rusby, S., Smith, M. T., Pigeon, W. R., Xia, Y., … Perlis, M. L. (2010). The efficacy of cognitive-behavioral therapy for insomnia in patients with chronic pain. *Sleep Medicine*, *11*, 302–309. https://doi.org/10.1016/j.sleep.2009.05.018

*Kapella, M. C., Herdegen, J. J., Perlis, M. L., Shaver, J. L., Larson, J. L., Law, J. A., & Carley, D. W. (2011). Cognitive behavioral therapy for insomnia comorbid with COPD is feasible with preliminary evidence of positive sleep and fatigue effects. *International Journal of COPD*, *6*, 625–635. https://doi.org/10.2147/COPD.S24858

Kennerley, H., Kirk, J., & Westbrook, D. (2016). *An Introduction to Cognitive Behaviour Therapy : Skills and Applications*. London: SAGE Publications Ltd.

Khurshid, K. A. (2018). Comorbid insomnia and psychiatric disorders: an update. *Innovations in Clinical Neuroscience*, *15*, 28–32. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/29707424

Kinnucan, J. A., Rubin, D. T., & Ali, T. (2013). Sleep and inflammatory bowel disease: exploring the relationship between sleep disturbances and inflammation. *Gastroenterology & Hepatology*, *9*, 718–27. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/24764789

Koffel, E. A., Koffel, J. B., & Gehrman, P. R. (2015). A meta-analysis of group cognitive behavioral therapy for insomnia. *Sleep Medicine Reviews*, *19*, 6–16. https://doi.org/10.1016/j.smrv.2014.05.001

Krishnan, V., McCormack, M. C., Mathai, S. C., Agarwal, S., Richardson, B., Horton, M. R., … Danoff, S. K. (2008). Sleep quality and health-related quality of life in idiopathic

pulmonary fibrosis. *Chest*, *134*, 693–698. https://doi.org/10.1378/CHEST.08-0173

Krueger, J. M. (2008). The role of cytokines in sleep regulation. *Current Pharmaceutical Design*, *14*, 3408–16. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/19075717

Krupp, L. B., LaRocca, N. G., Muir-Nash, J., & Steinberg, A. D. (1989). The fatigue severity scale. Application to patients with multiple sclerosis and systemic lupus erythematosus. *Archives of Neurology*, *46*, 1121–3. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/2803071

Krystal, A. D. (2007). Treating the health, quality of life, and functional impairments in insomnia. *Journal of Clinical Sleep Medicine : Official Publication of the American Academy of Sleep Medicine*, *3*, 63–72. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/17557457

Lambert, M. J. (2012). *Bergin and Garfield's handbook of psychotherapy and behavior change*. New York: John Wiley & Sons.

Law, E., Palermo, T., Lord, H., & Ritterband, L. (2012). Co-morbid pain and sleep disturbance: sleep outcomes in a randomized controlled trial of internet-based cognitive-behavioral therapy for insomnia. *The Journal of Pain*, *13*, 97. https://doi.org/10.1016/j.jpain.2012.01.402

Li, L., Wu, C., Gan, Y., Qu, X., & Lu, Z. (2016). Insomnia and the risk of depression: a meta-analysis of prospective cohort studies. *British Medical Counsel Psychiatry*, *16*, 375. https://doi.org/10.1186/s12888-016-1075-3

Lichstein, K. L. (2006). Secondary insomnia: a myth dismissed. *Sleep Medicine Reviews*, *10*, 3–5. https://doi.org/10.1016/j.smrv.2005.10.001

Lichstein, K. L., Stone, K. C., Donaldson, J., Nau, S. D., Soeffing, J. P., Murray, D., … Aguillard, R. N. (2006). Actigraphy validation with insomnia. *Sleep*, *29*, 232–9. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/16494091

Lipsey, M. W., & Wilson, D. B. (2001). *Applied Social Research Methods Series; Vol. 49. Practical Meta-analysis*. California: Sage Publications.

Liu, F. F., Shi, W. W., McCusker, M., Li, M., Su, J., Williams, J., … Yip, K. (2017). Association of fatigue and insomnia with inflammatory cytokine and hematopoetic stem cell levels in breast cancer patients undergoing adjuvant radiation therapy. *Journal of Clinical Oncology, 35*. https://doi.org/10.1200/JCO.2017.35.15_suppl.e12048

Lund, H. G., Rybarczyk, B. D., Perrin, P. B., Leszczyszyn, D., & Stepanski, E. (2013). The discrepancy between subjective and objective measures of sleep in older adults receiving CBT for comorbid insomnia. *Journal of Clinical Psychology, 69*, 1108–1120. https://doi.org/10.1002/jclp.21938

Manneville, F., Rotonda, C., Conroy, T., Bonnetain, F., Guillemin, F., & Omorou, A. Y. (2018). The impact of physical activity on fatigue and quality of life during and after adjuvant treatment for breast cancer. *Cancer, 124*, 797–806. https://doi.org/10.1002/cncr.31108

Matthews, E. E., Arnedt, J. T., Mccarthy, M. S., Cuddihy, L. J., & Aloia, M. S. (2013). Adherence to cognitive behavioral therapy for insomnia: a systematic review. *Sleep Medicine Review, 17*, 453-464. https://doi.org/10.1016/j.smrv.2013.01.001

McHugh, R. K., Murray, H. W., & Barlow, D. H. (2009). Balancing fidelity and adaptation in the dissemination of empirically-supported treatments: the promise of transdiagnostic interventions. *Behaviour Research and Therapy, 47*, 946–953. https://doi.org/10.1016/J.BRAT.2009.07.005

McNair D., Lorr, M. & Droppleman, L. (1992). *Manual for the Profile of Mood States.* San Diego, CA: Educational and Industrial Testing Service

Melzack, R. (1987). The short-form McGill Pain Questionnaire. *Pain, 30*, 191–7. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/3670870

Moher, D., Liberati, A., Tetzlaff, J., Altman, D. G., & Group, T. P. (2009). Preferred reporting items for systematic reviews and meta-analyses: the PRISMA Statement. *Public Library of Science Medicine*, *6*. https://doi.org/10.1371/journal.pmed.1000097

Moldofsky, H. (2010). Rheumatic manifestations of sleep disorders. *Current Opinion in Rheumatology*, *22*, 59–63. https://doi.org/10.1097/BOR.0b013e328333b9cc

Moloney, M. E., Konrad, T. R., & Zimmer, C. R. (2011). The medicalization of sleeplessness: a public health concern. *American Journal of Public Health*, *101*, 1429–33. https://doi.org/10.2105/AJPH.2010.300014

*Morgan, K., Gregory, P., Tomeny, M., David, B. M., & Gascoigne, C. (2012). Self-help treatment for insomnia symptoms associated with chronic conditions in older adults: a randomized controlled trial. *Journal of the American Geriatrics Society*, *60*, 1803–1810. https://doi.org/10.1111/j.1532-5415.2012.04175.x

Morin, C. M., & Bélanger, L. (2011). Cognitive therapy for dysfunctional beliefs about sleep and insomnia. In M. Perlis, M. Aloia, & B. Kuhn (Eds.), *Behavioral Treatments for Sleep Disorders* (pp. 107–117). Cambridge: Academic Press. https://doi.org/10.1016/B978-0-12-381522-4.00011-0

Morin, C. M., Bélanger, L., LeBlanc, M., Ivers, H., Savard, J., Espie, C. A., … Grégoire, J.-P. (2009). The natural history of insomnia. *Archives of Internal Medicine*, *169*, 447. https://doi.org/10.1001/archinternmed.2008.610

Morin, C. M., & Benca, R. (2012). Chronic insomnia. *The Lancet*, *379*, 1129–1141. https://doi.org/10.1016/S0140-6736(11)60750-2

Morin, C, M., Culbert, J. P., & Schwartz, S. M. (1994). Nonpharmacological interventions for insomnia: a meta-analysis of treatment efficacy. *American Journal of Psychiatry*, *151*, 1172–1180. https://doi.org/10.1176/ajp.151.8.1172

Morin, C. M., Drake, C. L., Harvey, A. G., Krystal, A. D., Manber, R., Riemann, D., &

Spiegelhalder, K. (2015). Insomnia disorder. *Nature Reviews Disease Primers*, *1*. https://doi.org/10.1038/nrdp.2015.26

Morin, C. M., Hauri, P. J., Espie, C. A., Spielman, A. J., Buysse, D. J., & Bootzin, R. R. (1999). Nonpharmacologic treatment of chronic insomnia. An American Academy of Sleep Medicine review. *Sleep*, *22*, 1134–56. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/10617176

Morin, C. M., Savard, J., & Ouellet, M. C. (2012). Nature and treatment of insomnia. In I. B. Weiner (Ed.) *Handbook of Psychology, Second Edition* (pp. 318-339). Hoboken, NJ, USA: John Wiley & Sons, Inc. https://doi.org/10.1002/9781118133880.hop209014

Morin, C. M., Stone, J., Trinkle, D., Mercer, J., & Remsberg, S. (1993). Dysfunctional beliefs and attitudes about sleep among older adults with and without insomnia complaints. *Psychology and Aging*, *8*, 463–467. https://doi.org/10.1037/0882-7974.8.3.463

Morris, S. B. (2008a). Estimating effect sizes from pretest-posttest-control group designs. *Organizational Research Methods*, *11*, 364–386. https://doi.org/10.1177/1094428106291059

Morris, S. B. (2008b). Estimating effect sizes from pretest-posttest-control group designs. *Organizational Research Methods*, *11*, 364-386. https://doi.org/10.1177/1094428106291059

Morris, S. B., & DeShon, R. P. (2002). Combining effect size estimates in meta-analysis with repeated measures and independent-groups designs. *Psychological Methods*, *7*, 105–125. https://doi.org/10.1037/1082-989X.7.1.105

Neurath, M. F. (2014). Cyctokines in inflammatory bowel disease. *Nature Reviews Immunology*,*14*, 329-342. https://doi.org/10.1038/nri3661

Nolen-Hoeksema, S. (2000). The role of rumination in depressive disorders and mixed anxiety/depressive symptoms. *Journal of Abnormal Psychology*, *109*, 504–511.

https://doi.org/10.1037/0021-843X.109.3.504

O'Connor, S. R., Tully, M. A., Ryan, B., Bradley, J. M., Baxter, G. D., & McDonough, S. M. (2015). Failure of a numerical quality assessment scale to identify potential risk of bias in a systematic review: a comparison study. *British Medical Counsel Research Notes*, *8*, 224. https://doi.org/10.1186/s13104-015-1181-1

Okajima, I., & Inoue, Y. (2018). Efficacy of cognitive behavioral therapy for comorbid insomnia : a meta-analysis. *Sleep and Biological Rhythms*, *16*, 21–35. https://doi.org/10.1007/s41105-017-0124-8

Okajima, I., Komada, Y., & Inoue, Y. (2011). A meta-analysis on the treatment effectiveness of cognitive behavioral therapy for primary insomnia. *Sleep and Biological Rhythms*, *9*, 24–34. https://doi.org/10.1111/j.1479-8425.2010.00481.x

Olatunji, B. O., Naragon-Gainey, K., & Wolitzky-Taylor, K. B. (2013). Specificity of rumination in anxiety and depression: a multimodal meta-analysis. *Clinical Psychology: Science and Practice*, *20*, 225–257. https://doi.org/10.1111/cpsp.12037

Oswald, F. L., & Plonsky, L. (2010). Meta-analysis in second language research: choices and challenges. *Annual Review of Applied Linguistics*, *30*, 85–110. https://doi.org/10.1017/S0267190510000115

Parekh, P. J., Oldfield, E. C., Challapallisri, V., Ware, J. C., & Johnson, D. A. (2015). Sleep disorders and inflammatory disease activity: chicken or the egg? *The American Journal of Gastroenterology*, *110*, 484–488. https://doi.org/10.1038/ajg.2014.247

Pearson, N. J., Johnson, L. L., & Nahin, R. L. (2006). Insomnia, trouble sleeping, and complementary and alternative medicine. *Archives of Internal Medicine*, *166*, 1775. https://doi.org/10.1001/archinte.166.16.1775

Peoples, A. R., Heckler, C. E., Kamen, C. S., Janelsins, M. C., Peppone, L. J., Mustian, K. M., … Roscoe, J. A. (2015). Influence of cognitive behavioral therapy for insomnia

(CBT-I) on quality of life (QOL) in cancer survivors. *Journal of Clinical Oncology*, *33*, 20743. https://doi.org/10.1200/jco.2015.33.15_suppl.e20743

Petrie, K. J., Jago, L. A., & Devcich, D. A. (2007). The role of illness perceptions in patients with medical conditions. *Current Opinion in Psychiatry*, *20*, 163–167. https://doi.org/10.1097/YCO.0b013e328014a871

*Pigeon, W. R., Moynihan, J., Matteson-Rusby, S., Jungquist, C. R., Xia, Y., Tu, X., & Perlis, M. L. (2012). Comparative effectiveness of CBT interventions for co-morbid chronic pain & insomnia: a pilot study. *Behaviour Research and Therapy*, *50*, 685–689. https://doi.org/10.1016/j.brat.2012.07.005

*Redeker, N. S., Jeon, S., Andrews, L., Cline, J., Jacoby, D., & Mohensin, V. (2015). Feasibility and efficacy of a self-management Intervention for insomnia in stable heart falure. *Journal of Clinical Sleep Medicine*, *11*, 1109-1119. http://dx.doi.org/10.5664/jcsm.5082

Reed, D. L., & Sacco, W. P. (2016). Measuring sleep efficiency: what should the denominator be? *Journal of Clinical Sleep Medicine : Official Publication of the American Academy of Sleep Medicine*, *12*, 263–6. https://doi.org/10.5664/jcsm.5498

Robotham, D. (2011). Sleep as a public health concern: insomnia and mental health. *Journal of Public Mental Health*, *10*, 234–237. https://doi.org/10.1108/17465721111188250

Rosenthal, R. (1979). The file drawer problem and tolerance for null results. *Psychological Bulletin*, *86*, 638-641. Retrieved from http://datacolada.org/wp-content/uploads/2016/12/3386-Rosenthal-1979-The-file-drawer-problem-and-tolerance-for-null-results.pdf

*Rybarczyk, B., Lopez, M., Benson, R., Alsten, C., & Stepanski, E. (2002). Efficacy of two behavioral treatment programs for comorbid geriatric insomnia. *Psychology and Aging*, *17*, 288–298. https://doi.org/10.1037/0882-7974.17.2.288

*Rybarczyk, B., Stepanski, E., Fogg, L., Barry, P., Lopez, M., & Davis, A. (2005). A placebo-controlled test of cognitive-behavioral therapy for comorbid insomnia in older adults. *Journal of Consulting and Clinical Psychology*, *73*, 1164–1174. https://doi.org/10.1037/0022-006X.73.6.1164

Samoocha, D., Bruinvels, D. J., Elbers, N. A., Anema, J. R., & van der Beek, A. J. (2010). Effectiveness of web-based interventions on patient empowerment: a systematic review and meta-analysis. *Journal of Medical Internet Research*, *12*, 23. https://doi.org/10.2196/jmir.1286

*Savard, J., Ivers, H., Savard, M. H., & Morin, C. M. (2014). Is a video-based cognitive behavioral therapy for insomnia as efficacious as a professionally administered treatment in breast cancer? Results of a randomized controlled trial. *Sleep*, *37*, 1305–1314. https://doi.org/10.5665/sleep.3918

Schutte-Rodin, S., Broch, L., Buysse, D., Dorsey, C., & Sateia, M. (2008). Clinical guideline for the evaluation and management of chronic insomnia in adults. *Journal of Clinical Sleep Medicine : Official Publication of the American Academy of Sleep Medicine*, *4*, 487–504. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/18853708

Sivertsen, B., Omvik, S., Pallesen, S., Bjorvatn, B., Havik, O. E., Kvale, G., … Nordhus, I. H. (2006). Cognitive behavioral therapy vs zopiclone for treatment of chronic primary insomnia in older adults. *Journal of the American Medical Association*, *295*, 2851-8. https://doi.org/10.1001/jama.295.24.2851

Slater, G., & Steier, J. (2012). Excessive daytime sleepiness in sleep disorders. *Journal of Thoracic Disease, 4*, 608-616. https://doi.org/10.3978/J.ISSN.2072-1439.2012.10.07

Smets, E. M., Garssen, B., Bonke, B., & De Haes, J. C. (1995). The Multidimensional Fatigue Inventory (MFI) psychometric qualities of an instrument to assess fatigue. *Journal of Psychosomatic Research*, *39*, 315–25. Retrieved from

http://www.ncbi.nlm.nih.gov/pubmed/7636775

Smith, M. T., Perlis, M. L., Park, A., Smith, M. S., Pennington, J., Giles, D. E., & Buysse, D. J. (2002). Comparative meta-analysis of pharmacotherapy and behavior therapy for persistent insomnia. *American Journal of Psychiatry*, *159*, 5–11. https://doi.org/10.1176/appi.ajp.159.1.5

Smith, M. T., & Wegener, S. T. (2003). Measures of sleep: the Insomnia Severity Index, Medical Outcomes Study (MOS) Sleep Scale, Pittsburgh Sleep Diary (PSD), and Pittsburgh Sleep Quality Index (PSQI). *Arthritis & Rheumatism*, *49*, 184–196. https://doi.org/10.1002/art.11409

*Smith, M. T., Finan, P. H., Buenaver, L. F., Robinson, M. Haque, U., Quain, A.,…Haythornwaite, J. A. (2015). Cognitive-behavioral therapy for insomnia in knee osteoarthritis. *Arthritis & Rheumatology*, *67*, 1221-1233. doi: 10.1002/art.39048.

*Smitherman, T. A., Walters, A. B., Davis, R. E., Ambrose, C. E., Roland, M., Houle, T. T., & Rains, J. C. (2016). Randomized controlled pilot trial of behavioral insomnia treatment for chronic migraine with comorbid insomnia. *Headache, 56*, 276–291. https://doi.org/10.1111/head.12760

Soehner, A. M., Kaplan, K. A., & Harvey, A. G. (2013). Insomnia comorbid to severe psychiatric illness. *Sleep Medicine Clinics*, *8*, 361–371. https://doi.org/10.1016/j.jsmc.2013.04.007

Spiegelhalder, K., Regen, W., Nanovska, S., Baglioni, C., & Riemann, D. (2013). Comorbid sleep disorders in neuropsychiatric disorders across the life cycle. *Current Psychiatry Reports*, *15*, 364. https://doi.org/10.1007/s11920-013-0364-5

Staner, L. (2010). Comorbidity of insomnia and depression. *Sleep Medicine Reviews*, *14*, 35–46. https://doi.org/10.1016/j.smrv.2009.09.003

Stein, K. D., Martin, S. C., Hann, D. M., & Jacobsen, P. B. (1998). A multidimensional measure of fatigue for use with cancer patients. *Cancer Practice*, *6*, 143–52. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/9652245

Stepanski, E. J., & Rybarczyk, B. (2006). Emerging research on the treatment and etiology of secondary or comorbid insomnia. *Sleep Medicine Reviews*, *10*, 7–18. https://doi.org/10.1016/j.smrv.2005.08.002

Stewart, W. F., Lipton, R. B., Dowson, A. J., & Sawyer, J. (2001). Development and testing of the Migraine Disability Assessment (MIDAS) Questionnaire to assess headache-related disability. *Neurology*, *56*, 20-28. https://doi.org/10.1212/wnl.56.suppl_1.s20

Taylor, D. J., Mallory, L. J., Lichstein, K. L., Durrence, H. H., Riedel, B. W., & Bush, A. J. (2007). Comorbidity of chronic insomnia with medical problems. *Sleep*, *30*, 213–8. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/17326547

Trikalinos, T. A., Churchill, R., Ferri, M., Leucht, S., Tuunainen, A., Wahlbeck, K., & Ioannidis, J. P. (2004). Effect sizes in cumulative meta-analyses of mental health randomized trials evolved over time. *Journal of Clinical Epidemiology*, *57*, 1124–30. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/15612138

Turk, D. C., & Rudy, T. E. (1988). Toward an empirically derived taxonomy of chronic pain patients: integration of psychological assessment data. *Journal of Consulting and Clinical Psychology*, *56*, 233–8. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/3372831

Robertson, R., Wenzel, L., Thompson, J., & Charles, A. (2017). *Understanding NHS financial pressures. How are they affecting patient care?* London: The King's Fund. Retrieved from https://www.kingsfund.org.uk/sites/default/files/field/field_publication_summary/Understanding NHS financial pressures - report summary.pdf

Van De Water, A. T. M., Holmes, A., & Hurley, D. A. (2011). Objective measurements of sleep for non-laboratory settings as alternatives to polysomnography - a systematic review. *Journal of Sleep Research*, *20*, 183–200. https://doi.org/10.1111/j.1365-2869.2009.00814.x

Van Straten, A., van der Zweerde, T., Kleiboer, A., Cuijpers, P., Morin, C. M., & Lancee, J. (2018). Cognitive and behavioral therapies in the treatment of insomnia: A meta-analysis. *Sleep Medicine Reviews*, *38*, 3–16. https://doi.org/10.1016/J.SMRV.2017.02.001

Vgontzas, A. N., Liao, D., Bixler, E. O., Chrousos, G. P., & Vela-Bueno, A. (2009). Insomnia with objective short sleep duration is associated with a high risk for hypertension. *Sleep*, *32*, 491–497. https://doi.org/10.1093/sleep/32.4.491

Vgontzas, A. N., Liao, D., Pejovic, S., Calhoun, S., Karataraki, M., & Bixler, E. O. (2009). Insomnia with objective short sleep duration is associated with type 2 diabetes: a population-based study. *Diabetes Care*, *32*, 1980–5. https://doi.org/10.2337/dc09-0284

Vincent, N., & Lionberg, C. (2001). Treatment Preference and Patient Satisfaction in Chronic Insomnia. *Sleep*, *24*, 411–417. https://doi.org/10.1093/sleep/24.4.411

*Vitiello, M. V., McCurry, S. M., Shortreed, S. M., Balderson, B. H., Baker, L. D., Keefe, F. J., … Von Korff, M. (2013). Cognitive-behavioral treatment for comorbid insomnia and isteoarthritis pain in primary care: the lifestyles randomized controlled trial. *Journal of the American Geriatrics Society*, *61*, 947–956. https://doi.org/10.1111/jgs.12275

Von Korff, M., Ormel, J., Keefe, F. J., & Dworkin, S. F. (1992). Grading the severity of chronic pain. *Pain*, *50*, 133–49. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/1408309

Wampold, B. E., Minami, T., Tierney, S. C., Baskin, T. W., & Bhati, K. S. (2005). The placebo is powerful: estimating placebo effects in medicine and psychotherapy from

randomized clinical trials. *Journal of Clinical Psychology*, *61*, 835–854. https://doi.org/10.1002/jclp.20129

Ware, J., Kosinski, M., & Keller, S. D. (1996). A 12-item short-form health survey: construction of scales and preliminary tests of reliability and validity. *Medical Care*, *34*, 220–33. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/8628042

Wolfe, F. (2015). Editorial: the status of fibromyalgia criteria. *Arthritis & Rheumatology*, *67*, 330–333. https://doi.org/10.1002/art.38908

Wu, J. Q., Appleman, E. R., Salazar, R. D., & Ong, J. C. (2015). Cognitive behavioral therapy for insomnia comorbid with psychiatric and medical conditions: a meta-analysis. *Journal of the American Medical Association Internal Medicine*, *175*, 1461-72. https://doi.org/10.1001/jamainternmed.2015.3006

Yamadera, W., Sato, M., Harada, D., Iwashita, M., Aoki, R., Obuchi, K., … Nakayama, K. (2013). Comparisons of short-term efficacy between individual and group cognitive behavioral therapy for primary insomnia. *Sleep and Biological Rhythms*, *11*, 176–184. https://doi.org/10.1111/sbr.12019

Zee, P. C., & Turek, F. W. (2006). Sleep and health: everywhere and in both directions. *Archives of Internal Medicine*, *166*, 1686-8. https://doi.org/10.1001/archinte.166.16.1686

Appendix A: Data extraction table examples

Table 7.

Data extraction table examples – study characteristics

Study	Year	Baseline Control group (n)	Baseline Experimental group (n)	Comorbid diagnosis	Intervention	Control	Delivery	Treatment hours	Outcomes (sleep)	Outcomes (other)	Notes
Casualt et al.	2015	18	20	Cancer	Adapted CBT-I	WLC	Self-help	n/a	ISI, SOL, WASO, oTST, oSE, oWASO	MFI, EORTOC - QOL	Standard error provided, SD obtained via transformation.
Chen et al.	2011	35	37	Conditions requiring haemodialysis	CBT-I	Active	Group	9	PSQI	FSS	SE from PSQI CBT-I during haemodialsysis 3 x 30 min x 6 weeks. Active control = sleep hygiene and attention condition
Currie et al.	2000	38	32	Chronic pain	CBT-I	WLC	Group	14	PSQI, SOL, WASO	MPI	MPI pain severity subscale used

Note: FSS = Fatigue Severity Scale (Krupp, LaRocca, Muir-Nash, & Steinberg, 1989), ISI = Insomnia Severity Index (Morin, 1993), MFI = Multidimensional Fatigue Inventory (Smets, Garssen, Bonke, & De Haes, 1995), MPI = Multidimensional Pain Inventory (Turk & Rudy, 1988), oTST = Actigraphy-derived objective Total Sleep Time, oSE = Actigraphy-derived objective Sleep Effiency, oWASO = Actigraphy-derived objective Wake After Sleep Onset, PQSI = Pittsburgh Sleep Quality Index (Buysse, Reynolds, Monk & Berman, 1989), SOL = Sleep Onset Latency, WASO = Wake After Sleep Onset

Table 8

Data extraction extract for ISI

Study	ISI at baseline (control group = CNT, experimental group = EXP)						ISI at post-intervention (control group = CNT, experimental group = EXP)					
	CNT (n)	**EXP (n)**	**CNT mean**	**CNT SD**	**EXP mean**	**EXP SD**	**CNT (n)**	**EXP (n)**	**CNT mean**	**CNT SD**	**EXP mean**	**EXP SD**
Casault et al. (2015)	18	20	12.10	5.40	12.10	4.00	17	18	11.31	5.32	5.32	3.17
Morgan et al. (2012)	95	98	15.6	5.00	17.7	4.6	76	62	5.11	4.09	5.11	4.57

Note: ISI = Insomnia Severity Index, CNT = Control group, EXP = experimental group, SD = standard deviation

Appendix B: Sample modified Downs and Blacks (1988) quality assessment tool

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Removed in line with copyright restrictions

Removed in line with copyright restrictions

Removed in line with copyright restrictions

Appendix C: Funnel plots

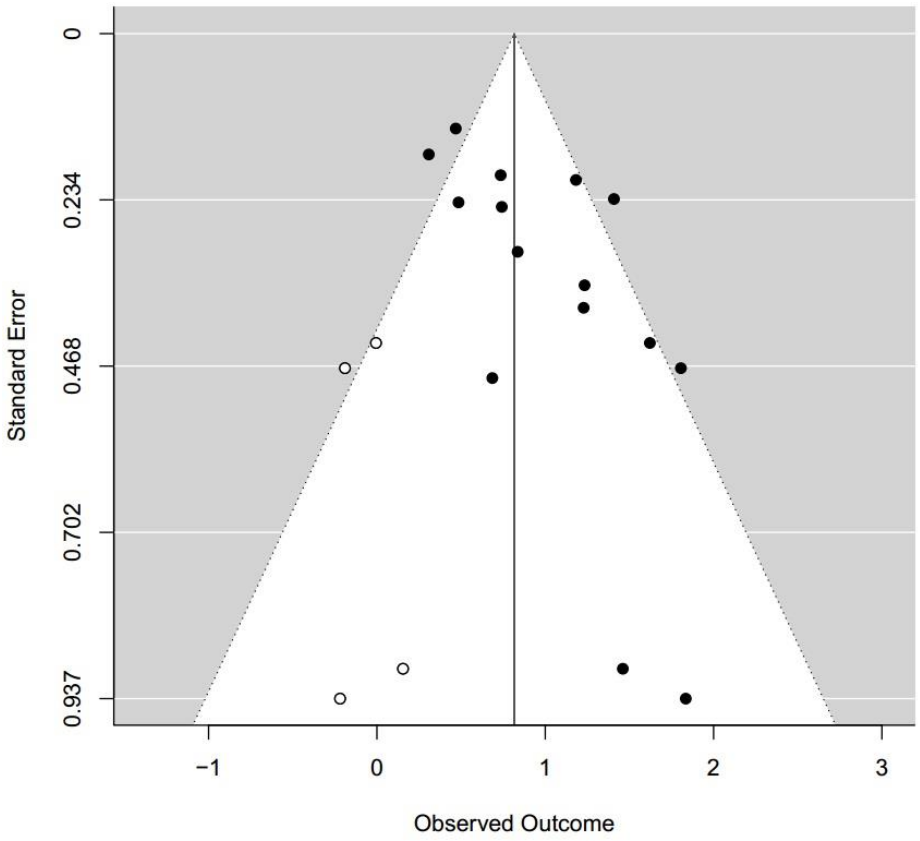

Figure 12: Summary effect of CBT-I on ISI funnel plot

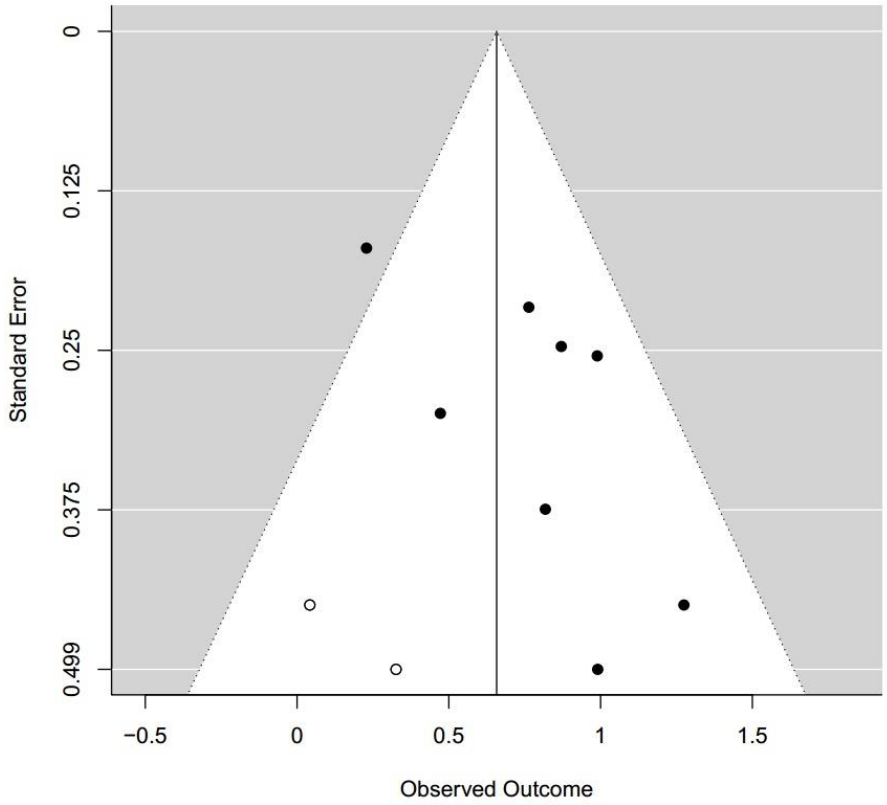

Figure 13: Summary effect of CBT-I on PSQI funnel plot

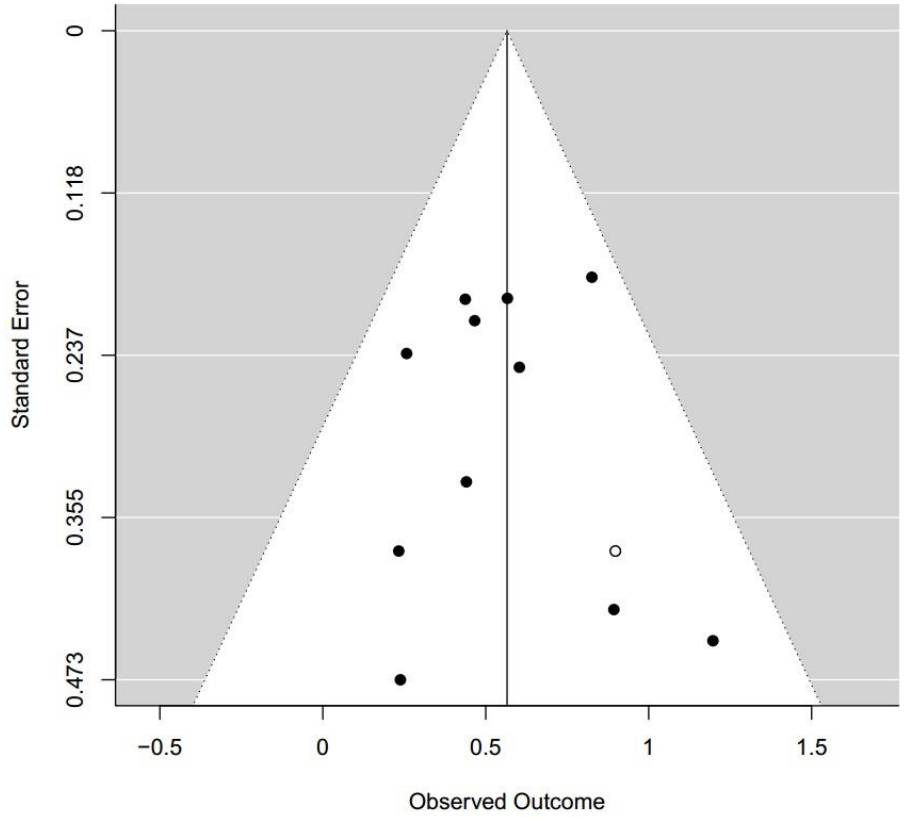

Figure 14: Summary effect of CBT-I on WASO funnel plot

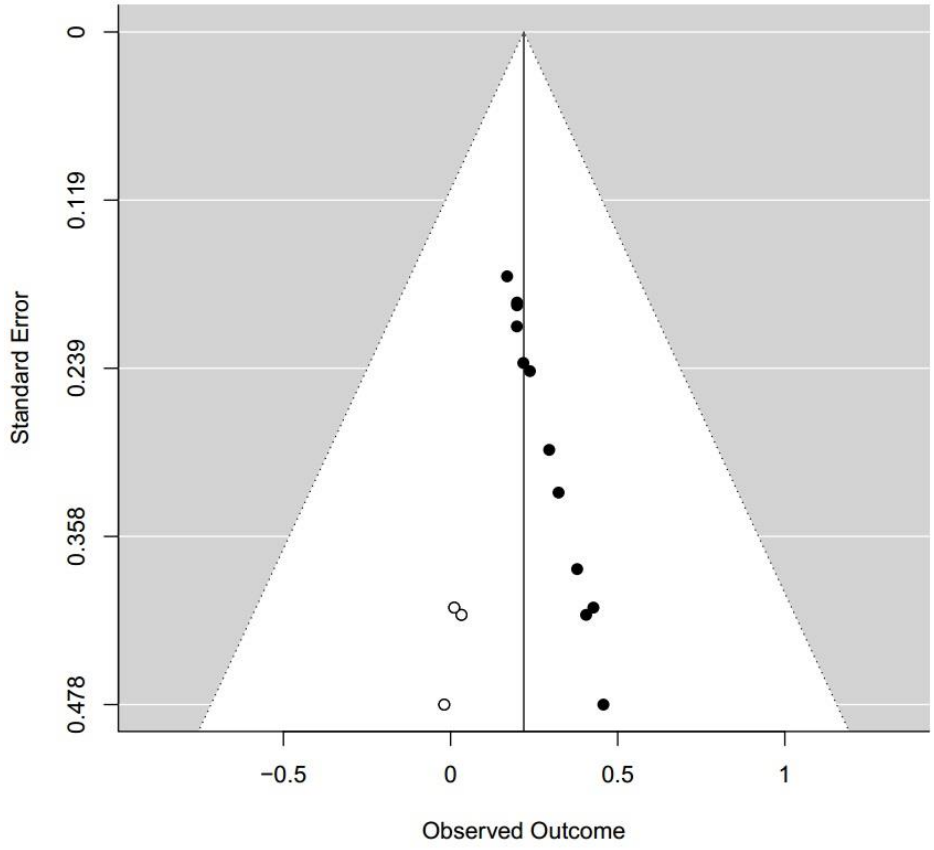

Figure 15: Summary effect of CBT-I on SOL funnel plot

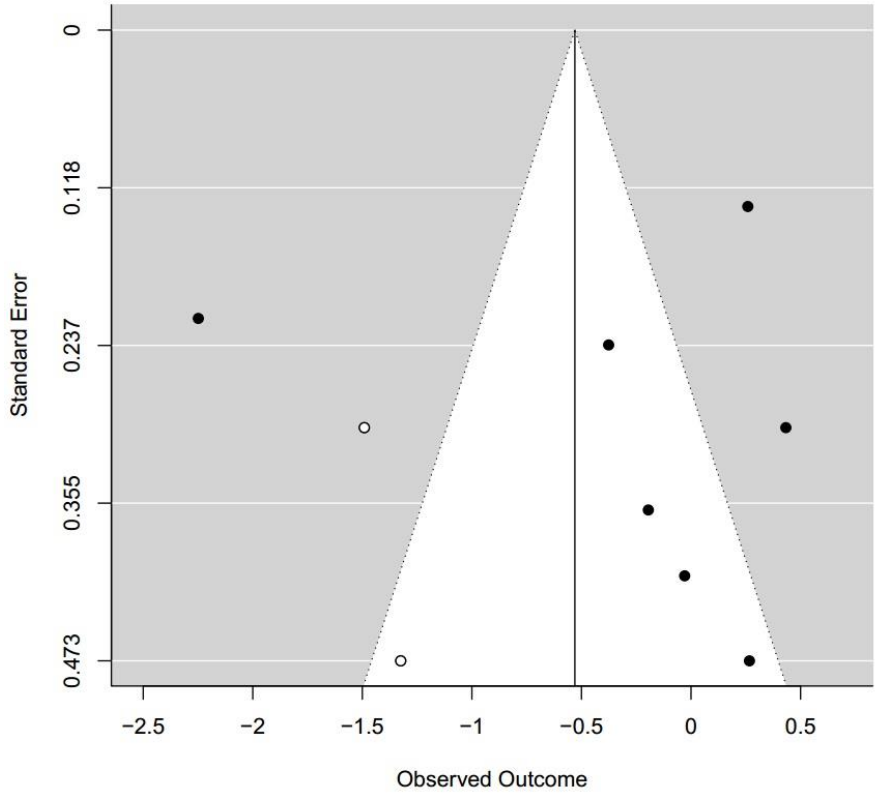

Figure 16: Summary effect of CBT-I on oTST funnel plot

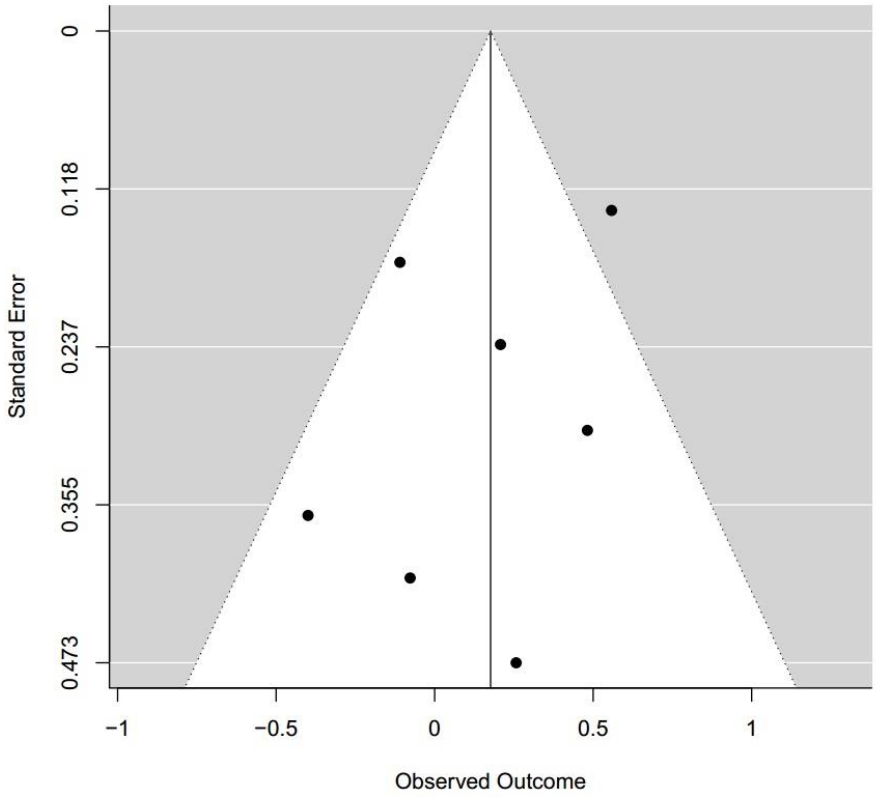

Figure 17: Summary effect of CBT-I on oSE funnel plot

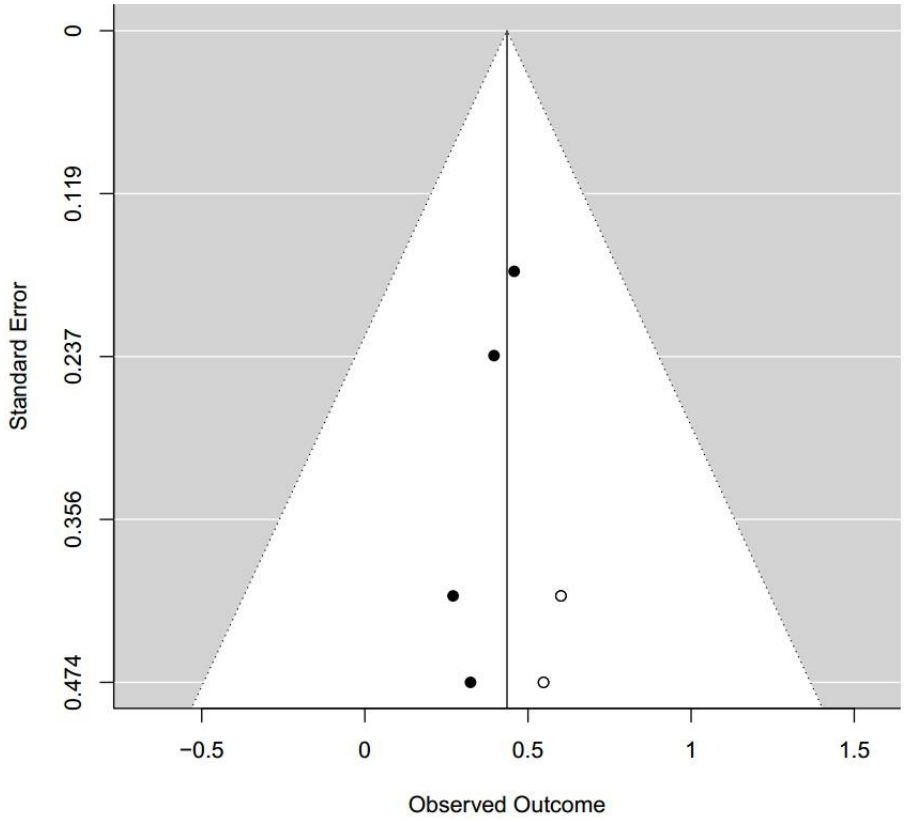

Figure 18: Summary effect of CBT-I on oWASO funnel plot

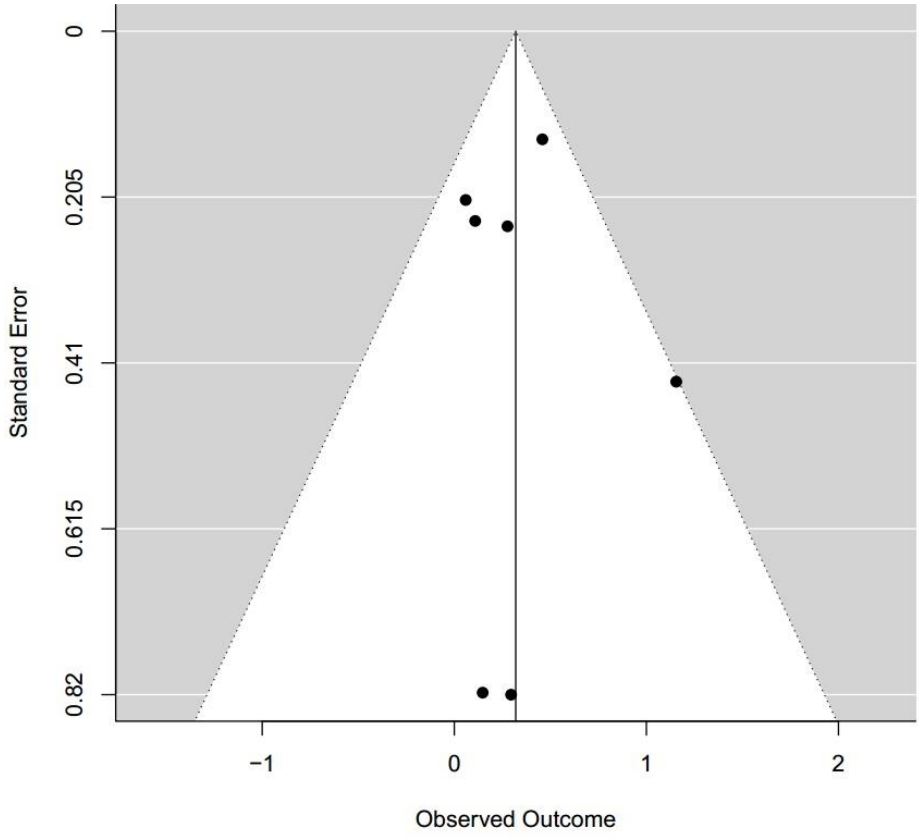

Figure 19: Summary effect of CBT-I on pain funnel plot

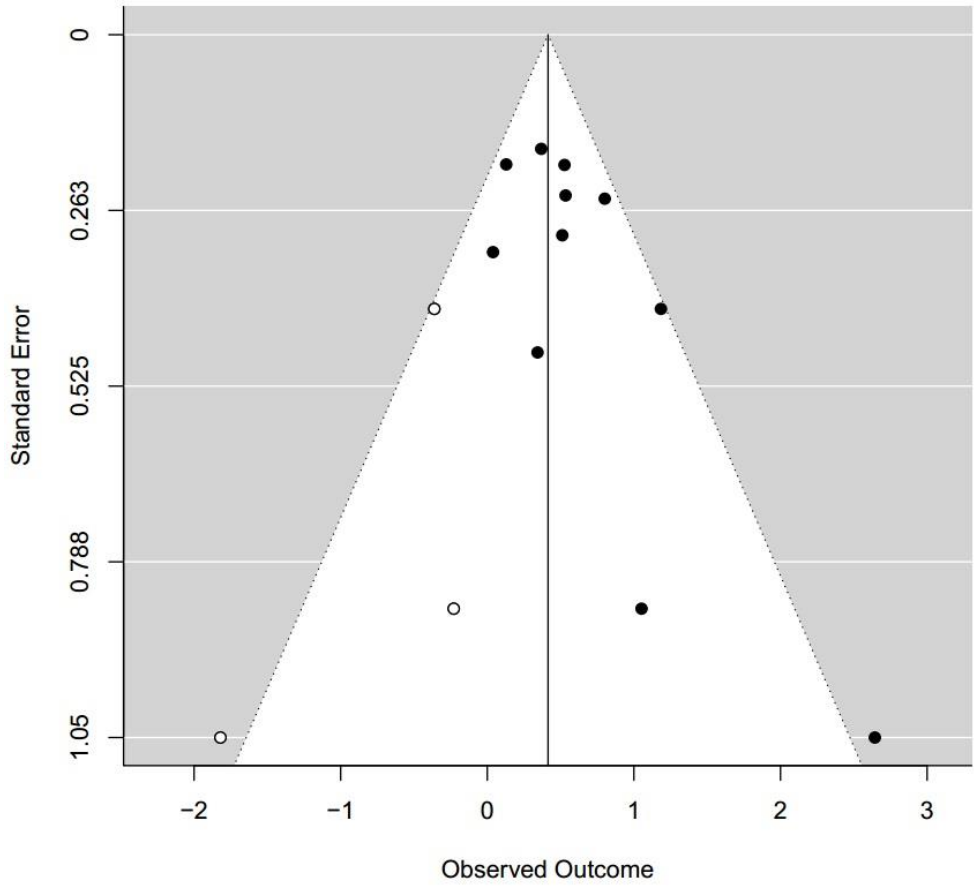

Figure 20: Summary effect of CBT-I on fatigue funnel plot

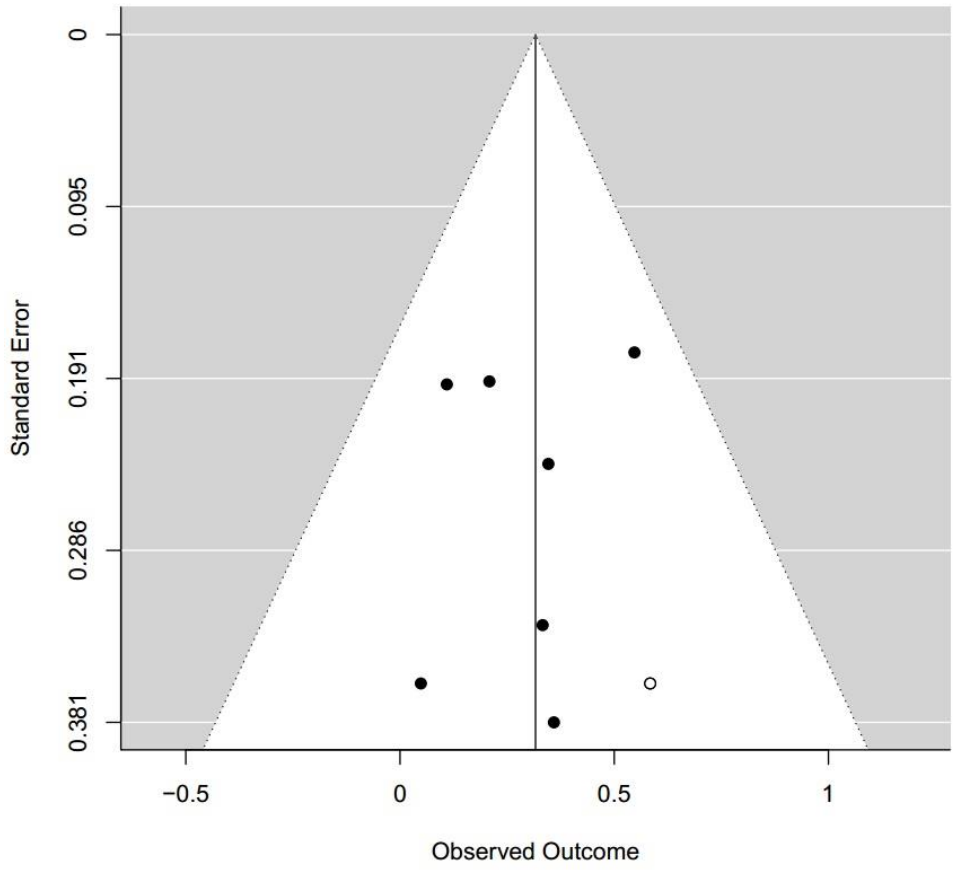

Figure 21: Summary effect of CBT-I on quality of life funnel plot

Appendix D: Downs and Black's Quality Assessment Results in Detail Per Study

Study	Score for Each Question on Down and Black's Quality Assessment Tool																											
	1. Hypothesis clearly described	2. Clear outcomes	3. Participants described	4. Clear interventions	5. Confounds described	6. Findings described	7. Variability estimates	8. Adverse events reported	9. Describes loss to follow-up	10. P-values reported	11. Sampling representative	12. Participants representative	13. Delivery representative	14. Participants blinded	15. Researchers blinded	16. Didn't dredge data	17. Follow up length reported	18. Statistical tests appropriate	19. Compliance monitored	20. Measures reliable and valid	21. Single sample participants	22. Recruited over same period	23. Randomisation to condition	24. Randomisation concealed	25. Adjusted for confounds	26. Lost to follow up analysed	27. Power reported	Total quality score	Categorical quality assessment (O' Connor et al., 2015)
Casualt et al. (2015)	1	1	1	1	1	1	1	1	0	1	1	0	0	1	0	0	1	1	1	1	1	1	1	0	1	1	1	21	Good
Chen et al. (2011)	1	1	1	1	1	1	1	0	1	1	1	1	1	0	0	1	1	1	1	1	1	1	1	0	0	0	1	21	Good
Currie et al. (2000)	1	1	1	1	1	1	1	0	1	0	0	0	0	0	0	1	1	1	1	1	1	1	1	0	1	1	0	18	Fair
Dirksen & Epstein (2008)	1	1	1	1	1	1	1	0	1	1	0	0	1	0	0	1	1	1	1	1	1	1	1	0	0	1	1	20	Good
Espie et al. (2008)	1	1	1	1	1	1	1	1	1	1	1	1	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1	24	Excellent

Study	Score for Each Question on Down and Black's Quality Assessment Tool																											
	1. Hypothesis clearly described	2. Clear outcomes	3. Participants described	4. Clear interventions	5. Confounds described	6. Findings described	7. Variability estimates	8. Adverse events reported	9. Describes loss to follow-up	10. P-values reported	11. Sampling representative	12. Participants representative	13. Delivery representative	14. Participants blinded	15. Researchers blinded	16. Didn' t dredge data	17. Follow up length reported	18. Statistical tests appropriate	19. Compliance monitored	20. Measures reliable and valid	21. Single sample participants	22. Recruited over same period	23. Randomisation to condition	24. Randomisation concealed	25. Adjusted for confounds	26. Lost to follow up analysed	27. Power reported	Total quality score	Categorical quality assessment (O' Connor et al., 2015)
Jannson-Frojmark et al. (2012)	1	1	1	1	1	1	1	0	1	1	0	1	0	0	0	1	1	1	1	1	1	1	1	1	1	1	0	21	Good
Jungquist et al. (2010)	1	1	1	1	1	1	1	1	0	1	0	1	0	1	0	1	1	1	1	1	1	1	1	0	1	1	0	21	Good
Kapella at al. (2011)	1	1	1	1	1	1	1	1	0	1	1	1	0	0	1	0	1	1	1	1	1	1	1	0	1	1	0	21	Good
Morgan et al. (2012)	1	1	1	1	1	1	1	1	0	1	1	1	1	0	1	1	1	1	1	1	1	1	1	0	1	1	1	23	Excellent
Pigeon et al. (2012)	1	1	1	1	1	1	1	1	0	1	1	0	0	0	0	1	1	1	1	0	1	1	1	1	1	1	0	20	Good
Redeker et al. (2015)	1	1	1	1	1	1	1	0	1	1	0	0	0	0	0	1	1	1	1	1	1	1	1	0	1	1	1	20	Good

Study	Score for Each Question on Down and Black's Quality Assessment Tool																											
	1. Hypothesis clearly described	2. Clear outcomes	3. Participants described	4. Clear interventions	5. Confounds described	6. Findings described	7. Variability estimates	8. Adverse events reported	9. Describes loss to follow-up	10. P-values reported	11. Sampling representative	12. Participants representative	13. Delivery representative	14. Participants blinded	15. Researchers blinded	16. Didn' t dredge data	17. Follow up length reported	18. Statistical tests appropriate	19. Compliance monitored	20. Measures reliable and valid	21. Single sample participants	22. Recruited over same period	23. Randomisation to condition	24. Randomisation concealed	25. Adjusted for confounds	26. Lost to follow up analysed	27. Power reported	Total quality score	Categorical quality assessment (O' Connor et al., 2015)
Ritterband et al. (2012)	1	1	1	1	1	1	1	0	1	1	1	0	1	0	0	1	1	1	1	1	1	1	1	0	0	1	1	20	Good
Rybarczyk et al. (2002)	1	1	1	1	1	1	1	0	1	0	0	0	0	0	0	0	1	1	0	1	1	1	1	0	0	1	0	21	Good
Rybarczyk et al. (2005)	1	1	1	1	1	1	1	0	0	0	0	0	0	1	1	1	1	1	1	1	1	0	1	0	1	1	0	15	Fair
Savard et al. (2014)	1	1	1	1	1	1	1	0	0	1	1	1	1	0	0	0	1	1	1	1	1	1	1	0	1	1	1	18	Fair
Smith et al. (2015)	1	1	1	1	1	1	1	0	1	1	0	0	1	1	1	1	1	1	1	1	1	1	1	0	1	1	0	21	Good
Smitherman et al. (2016)	1	1	1	1	1	1	1	0	0	1	0	0	0	1	0	1	1	1	1	1	1	1	1	1	1	1	0	21	Good

Study	Score for Each Question on Down and Black's Quality Assessment Tool																											
	1. Hypothesis clearly described	2. Clear outcomes	3. Participants described	4. Clear interventions	5. Confounds described	6. Findings described	7. Variability estimates	8. Adverse events reported	9. Describes loss to follow-up	10. P-values reported	11. Sampling representative	12. Participants representative	13. Delivery representative	14. Participants blinded	15. Researchers blinded	16. Didn' t dredge data	17. Follow up length reported	18. Statistical tests appropriate	19. Compliance monitored	20. Measures reliable and valid	21. Single sample participants	22. Recruited over same period	23. Randomisation to condition	24. Randomisation concealed	25. Adjusted for confounds	26. Lost to follow up analysed	27. Power reported	Total quality score	Categorical quality assessment (O' Connor et al., 2015)
Vitiello et al. (2013)	1	1	1	1	1	1	1	0	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	21	Good

Section 2

Research Report

Exploring the Experience of Sleep in People with Inflammatory Bowel Disease: An Interpretative Phenomenological Analysis

Abstract

Objectives

Inflammatory Bowel Disease (IBD) is a relapsing and remitting condition that includes diagnoses of Crohn's Disease and Ulcerative Colitis, affecting around 6 people per 100,000. Symptoms are varied and wide-reaching resulting from inflammation, ulceration and damage to the intestinal tract, and can include significant pain, toileting urgency, fatigue, and many experience disturbed sleep. Poor sleep may be both psychologically and physiologically maintained, and the relationship between sleep and IBD may be bi-directional, but little is understood about the experience of sleep for people with IBD. This study aims to explore and understand further the experience of sleep in people with IBD.

Methods

Eight people with IBD were recruited to the study, and interviewed in line with a semi-structured interview schedule. Procedure and analysis followed the methodology of Interpretative Phenomenological Analysis. Recommended steps were taken to ensure reflexivity, reliability and validity of the analysis.

Results

Four superordinate themes emerged: *Frustration, worry and flare – night-time struggles; My self changed – variations in feeling ok about the way things are; Reinforcing cycles: IBD, stress and sleep; Seeking control of sleep and IBD.*

Conclusions

Participants experienced sleep disturbed by pain and toileting during disease flare, but more commonly by worry, arousal and fatigue complications during remission. They reported self-directed anger at failure to sleep, and found sleep changes difficult to accept or talk

about. Interviewees suggested theories of reciprocal worsening between IBD, fatigue, sleep and anxiety, and engaged in efforts to manage this.

Practitioner points

- People with IBD linked poor sleep reciprocally to flare and fatigue. Addressing sleep difficulties may be important to disease management.
- Participants experienced psychological sleep disruption. CBT-I may be appropriate for these difficulties.
- Participants reported feeling dismissed or invalidated and may struggle to seek help. Care should be taken to acknowledge and validate the effects of IBD upon sleep.

Limitations

- This small sample was predominantly white British, working and educated and thus results may not be transferable to everyone with IBD.
- As IPA is double hermeneutic, results are subjective (co-)constructions and may not represent 'truth'.

Keywords. Inflammatory Bowel Disease, IBD, sleep, insomnia, experience, Interpretative Phenomenological Analysis, qualitative

Introduction

Inflammatory Bowel Disease (IBD) refers primarily to Crohn's Disease (CD) and Ulcerative Colitis (UC), relapsing and remitting diseases whereby the body's immune system attacks the digestive system causing inflammation and ulceration. Symptoms during a "flare" include abdominal pain, fatigue, rectal bleeding, diarrhoea, toilet urgency and weight loss (NHS, 2017). IBD affects around 6 people per 100,000, IBD, is predominantly diagnosed in adolescence or early adulthood, and more commonly affects those in industrialised countries (Kaplan, 2015; Kappelman, Moore, Allen, & Cook, 2013). Treatment commonly involves medication (Carter, Lobo, & Travis, 2004) and eventually surgery, (47% require surgery within 10 years of diagnosis; Frolkis et al., 2013).

Chronic sleep disturbance (such as insomnia and other sleep disorders) appears relatively common in diseases of immune function inflammation (Kinnucan, Rubin, & Ali, 2013). Research suggests sleep deprivation can activate molecules and cytokines[8] that contribute to IBD (Ali & Orr, 2014), potentially implicated in the disease's pathogenesis (Ananthakrishnan, 2015). Active phase symptoms can disturb sleep (Ali, Madhoun, Orr, & Rubin, 2013) and disturbances may continue in remission, through sub-clinical inflammation and the release of wakefulness-promoting cytokines (Vgontzas et al., 1997; Ananthakrishnan, Long, Martin, Sandler, & Kappelman, 2013). Disturbed sleep can increase flare risk and pain sensitivity in UC (Ananthakrishnan et al., 2013; Haack, Sanchez, & Mullington, 2007). Further, steroidal IBD medications are linked to sleep disturbance (Vgontzas & Chrousos, 2002). Thus, there appears to be a reciprocally maintaining biological relationship between IBD and poor sleep.

Research into IBD sleep disturbance predominantly focuses on biological mechanisms, but there is growing evidence of contributions from psychological factors such

[8] Cytokines are messenger proteins similar to hormones that regulate immune system response (Neurath, 2014).

as stress, fatigue, and emotional health (Ali & Orr, 2014). Stress is linked to poor sleep in the general population (Akerstedt, 2006) and symptom worsening in IBD (Hirsch & Sirois, 2016). Poor emotional health is also associated with both poor sleep and IBD (Pirinen, Kolho, Ashorn, & Aronen, 2014). Psychological factors may exert influence both through biological factors (e.g. depression is associated with inflammation; Berk et al., 2013) and independently of them. Anxiety and disease perceptions predict qualitative sleep outcomes, whereas inflammation blood markers only predict quantitative measures of sleep duration and efficiency (Benhayon et al., 2013), suggesting that during disease remission, anxiety and symptom perceptions may uniquely contribute to sleep difficulties.

Fatigue is a research priority in IBD (James Lind Alliance, 2015), but is considered difficult to assess and treat and is poorly understood by health care professionals (Czuber-Dochan et al., 2014). People with IBD have cited poor sleep as a proposed cause of their fatigue (Czuber-Dochan, Dibley, Terry, Ream, & Norton, 2013), and reciprocally fatigue has been linked to increased stress and auto-immune function (Graff et al., 2011; Hirsch & Sirois, 2016). Further, stress promotes poor sleep (Akerstedt, 2006), suggesting a reciprocal relationship between stress, fatigue and sleep.

Research suggests psychological factors are important to the maintenance of insomnia (Morin et al., 2006). Beliefs that poor sleep has negative long-term consequences may be instrumental in insomnia development in IBD (Jansson-Fröjmark & Linton, 2008), by promoting anxiety and unhelpful behaviours which maintain insomnia after initial triggers (i.e. disease flare) subside. Psychological insomnia interventions such as Cognitive Behavioural Therapy for Insomnia (CBT-I; Morin et al., 1999) attempt to correct these 'dysfunctional' beliefs, such as exaggeration of potential consequences, or unrealistic expectations of a perfect night's sleep (e.g. Morin et al., 2009). CBT-I has demonstrated good effectiveness with the general population (Morin et al., 2006; Trauer, Qian, Doyle,

Rajaratnam, & Cunnington, 2015) and populations with However, people with IBD may have sleep-related beliefs or concerns beyond the norm for the healthy population (Czuber-Dochan et al., 2013), and their assumptions about the effects of poor sleep (i.e. flare ups and worsening mental health) may be accurate (e.g. Brooks et al., 2016).

Meta-analytic research suggests effectiveness for CBT-I in addressing insomnia comorbid to various illnesses (Geiger-brown, Rogers, Liu, Ludeman, & Downton, 2015; Okajima & Inoue, 2018; Wu, Appleman, Salazar, & Ong, 2015). CBT-I used for people with IBD has not been assessed, and there has been little research to explore sleep for people with IBD. Green and colleagues (2017) interviewed 15 people with IBD about their sleep, identifying themes of stress, hypervigilance and poor sleep hygiene. However, their methodology and reflexivity are not reported, and their interviews appear focussed toward determining the acceptability of CBT-I.

Thus, this research aims to better understand the experience of sleep for people with IBD. Richer understanding may help us explore potential psychological components of insomnia maintenance in IBD, and better tailor existing interventions (or indeed, create others). As psychological research into the relationship between sleep and IBD is at an early stage, an inductive method is used to gather data and identify potential directions for further study.

Aims

To use semi-structured interviews to understand the experience of sleep in people with IBD.

Method

Design

This research used a qualitative phenomenological design (Interpretative Phenomenological Analysis; IPA; Smith, Flowers, & Larkin, 2009), conducting semi-

structured interviews about experience of sleep with people who have an IBD diagnosis. This approach aimed to explore and interpret individual experiences and identify themes among the data. An IPA method was used to analyse the resultant data, aiming to allow participants to 'give voice' to their experiences (Larkin & Thompson, 2012). IPA is well established in health psychology, used to understand the emic perspective of the individual (Pietkiewicz & Smith, 2014). Constructivist Grounded Theory (GT; Charmaz, 2014) was also considered. However, the analysis process of GT involves breaking participant narratives into granular sections of data before reassembly as theory and it seemed possible to the author that individual nuances of experience may be lost in this process. Further, IPA promotes attention to the process of consciousness (van Manen, 2017), and thus it was felt particularly appropriate for psychological research.

Ethics and data protection

Ethical approval was granted by the University of Sheffield Department of Psychology Ethics Committee (Appendix A). Informed consent was obtained from all participants included in the analysis (Appendix B). Confidentiality and anonymity were preserved by following the University of Sheffield's data storage guidelines (Appendix C), participant names are pseudonyms and identifying details were removed. Ethical approval was later also granted (Appendix D) to conduct interviews via Skype.

Participants may find the retelling of IBD related difficulties upsetting, or experience IBD-related discomfort during the interview. Toilet access and pausing/abandoning interview procedures were sensitively discussed prior to interview. Participants were offered helpline numbers or advised to consult their GP should they feel particularly affected. No participants reported adverse reactions.

Recruitment

A purposive sampling method was employed. To attempt to keep the sample as representative as possible (accepting that generalisability is not feasible in small samples), the only inclusion criteria specified were that participants must be above 16 years of age and have a diagnosis of IBD. Participants were not screened based upon existing sleep difficulties or mental health in order to capture a range of experiences.

Potential participants were identified by reviewing a database (held by the University of Sheffield) of previous research volunteers with IBD diagnoses who had agreed to be contacted for future research. They were contacted by e-mail, by a researcher known to them, and sent information about the study (Appendix E). Further recruitment took place via Twitter (Appendix F), asking interested parties to contact the author by email, whereupon information was provided. Between four and ten participants are recommended for IPA studies, as IPA analysis prioritises deeper understanding of smaller data sets over a broader but shallower analysis (Smith et al., 2009; Thompson, Larkin & Smith, 2011; Turpin et al., 1997), thus recruitment ceased once nine interviews were completed.

Participants

Participants were eight adults with a diagnosis of IBD (Table 1), drawn from 13 responders who expressed interest. Of those responders, one withdrew (time commitments), three stopped responding to emails prior to arranging interviews and one participant completed a Skype interview but did not return their consent form via post, so their consent was assumed to be withdrawn.

Table 9.

Participant demographics (n = 8)

Alias	Diagnosis	Age	Gender	Ethnicity	Employment status
Sarah	Crohn's disease	37	Female	White British	Student (graduate)
Jess	Ulcerative Colitis	34	Female	White British	Student (post-graduate)
David	Crohn's disease	45	Male	White British	Employed (full time)
Lisa	Crohn's disease	36	Female	White British	Employed (full time)
Helen	Crohn's disease	27	Female	White British	Employed (full time)
Amir	Crohn's disease	38	Male	British Asian	Employed (full time)[1]
Robert	Crohn's disease	65	Male	White British	Retired
Carl	Ulcerative Colitis	44	Male	White British	Unemployed[2]

Note: [1] Amir was currently on sick leave from work following two significant flares
[2] Carl referred to himself as a "house husband", with significant child-care duties

Data collection

Participants engaged in semi-structured interviews with the author, (40-70 minutes), consisting of 5-6 topics. Questions progressed from open-ended and to occasional prompts where participants appeared to find questions too abstract. Questioning aimed to direct the participant to report their experience through thoughts, feelings and representations. The interview schedule (Table 2) was created through initially reviewing previous IPA and IBD literature to identify questions suitable for IPA research (Smith et al., 2009; Pietkiewicz & Smith, 2012). Questions were refined through discussion in research supervision and consultation with an established IPA researcher during the University's research approval

process. Opinions were also sought from peer researchers and the first participant interviewed.

Table 2.

Interview schedule

Core question	**Prompts**
1. Could you tell me a little about your IBD?	What comes to mind first? Could you describe a typical day? What do you do? How do you feel about IBD? (if flares/worsening mentioned) What do you feel typically happens before flares? What do you feel typically happens after flares?
2. Could you describe a typical night's sleep?	What sort of night is it overall? How does it start? What do you do? What happens as the night continues? What do you think about during a typical night? How do you feel during a typical night? What do you make of this now?
3. Could you tell me about your sleep in regards to your day to day life?	What comes to mind first? Describe anything you notice about your day to day life related to sleep. (if relationship implied) What sort of relationship do you think sleep has to your day to day life? How does this feel to you? What do you think about this now?
4. Could you tell me about your sleep in regards to your IBD?	What comes to mind first? (if relationship implied) Are IBD and sleep related for you? Describe how? How would you describe a typical night for you regarding your IBD? What about during a flare of your symptoms? What about during a remission of your symptoms? How do you feel about your sleep in regards to IBD? How do you feel about your IBD in regards to your sleep?
5. Can you remember a time before you were diagnosed with IBD, or perhaps a long time period without symptoms?	What is the first thing that comes to mind? How would you describe a typical night's sleep in this period? What would you do in a typical night in this period? How would you describe you typically felt about sleep in this period? How would you describe how you typically thought about sleep in this period? What do you think about this now?

Interviews were preceded by neutral conversation to help the interviewee acclimatise (Pietkiewicz & Smith, 2012). Interviews were conducted upon premises of the University of Sheffield (n = 3), by Skype (n = 4) or at the participant's home (n = 1), following University lone-working procedures (Appendix G). Interviews were recorded on an encrypted device, and confidentially transcribed by University approved staff (Appendix H; I).

Each participant was asked to complete psychometric measures of sleep quality, IBD severity and fatigue (after interview to prevent influence on interview responses). These results were used to provide context for the analysis but were not statistically analysed.

Measures

Sleep quality was measured via the Pittsburgh Sleep Quality Index (PSQI; Buysse, Reynolds, Monk, Berman, & Kupfer, 1989; Appendix J), a 19-item retrospective self-report sleep questionnaire comprising seven subcomponent scores (sleep quality, latency, duration, efficiency, disturbance, daytime dysfunction and medication use) combined for a global sleep quality index. Higher scores indicate worse sleep quality. The PSQI demonstrates good test-retest reliability and high correlations with patient-report sleep diaries (Backhaus et al., 2002), including with medical patients (Cronbach's $\alpha = 0.80$; Carpenter & Andrykowski, 1998).

Fatigue was measured through use of the Multidimensional Assessment of Fatigue (MAF), a 16 item self-report questionnaire incorporating four dimensions of fatigue: Distress, severity, timing and effect on activities of daily living. It has demonstrated high reliability and validity (Belza, Miyawaki, Liu, Zhang & Fessel, 2015; Appendix K), validity in assessing fatigue in IBD (Dittner, Wessely, & Brown, 2004), and high internal consistency as an assessment of fatigue in chronically ill patients (Cronbach's $\alpha > 0.9$; Behrangrad & Kordi Yoosefinejad, 2018).

IBD symptom severity and related quality of life was assessed by use of the Inflammatory Bowel Disease Questionnaire (IBDQ; Guyatt et al., 1989; Appendix L). This self-report, 32-item questionnaire assesses the effect of IBD symptoms on quality of life across four domains (bowel symptoms, systemic symptoms, emotional health and social function), and can also be used as a reliable proxy of symptom severity (Peyrin-Biroulet et al., 2016). The IBDQ demonstrates good reliability and validity across several countries (Pallis, Mouzas, & Vlachonikolis, 2004), including good internal consistency in English samples (Cronbach's $\alpha = 0.72 – 0.89$; Cheung, Garratt, Russell, & Williams, 2000; Han, McColl & Steen, 1998).

Finally, interviewees were verbally asked to rate, on a scale of 1 to 10, their sleep from the previous night (10 = a perfect night's sleep), and their current fatigue (10 = not fatigued at all) after the interview, to provide proximal context to the analysis.

Analysis

Analysis by the author followed IPA stages suggested as "flexible guidelines" (Pietkiewicz & Smith, 2012, p.366). Firstly, each transcript was read several times and the audio recordings listened to, to help immerse the researcher in the atmosphere of the interview. The author made notes throughout on observations and reflections on the content, process (e.g. language, cadence, volume) and early interpretative comments (Smith et al., 2009). Analysis then moved to coding: examination of each transcript line by line (by hand and in Microsoft Word; Appendix M) examining participants' word choices, repetitions, pauses, emphasis and silences, considering how experiences are described, use of metaphor, simile, symbolism and their inferences and assumptions. The codes generated were then compared and contrasted, with similar codes grouped under broader themes NVivo software (QSR International, 2018), becoming more abstract but aiming to remain grounded in individual nuanced experience by frequently consulting with the original transcripts

(Appendix N). These broader themes were then interpreted in relation to the whole interview to consider emerging narratives, themes and inferred mindsets, agendas or moods (Eatough & Smith, 2017). Novice IPA researchers (like the author) tend to under-interpret findings (Smith et al., 2009), thus analysis aimed to provide interpretation beyond simple description, lending a somewhat poetic quality to some analysis. The 'ideal' degree of interpretation remains contested within phenomenological research (Finlay, 2009). Connections between themes (i.e. similarities, differences, relationships) were explored within each transcript (i.e. per participant) and finally between participants to consider sample-wide themes, relationships, tensions and spectrums (Appendix O). Finally, superordinate and subordinate themes and relationships were identified, using conceptual maps to explore relationships (Appendix P; Q).

Quality Control

To improve research quality, Yardley (2000), and Elliott, Fischer, and Rennie (1999) suggest that the researcher attempts to: Demonstrate sensitivity to data context; employ commitment and rigour to data gathering and analysis; remain coherent and transparent in analysis; and ensure the research is likely to have value or importance.

Regarding value, this research may contribute to our understanding of sleep and fatigue, with fatigue being identified as a top ten research priority by the James Lind Alliance (2015) committee, which includes people with IBD. In pursuit of rigour, transparency, and keeping analysis 'grounded' to participant's experiences (e.g. Bradley, Curry, & Devers, 2007), participants were consulted for their views on analysis. One participant agreed to review a section of their coded transcribed interview and broader coding (Appendix R), which contributed to analysis refinement in conjunction with research supervision (Appendix S), and peer auditing of analysis (Appendix T).

Reflexivity

The influence of the author's assumptions on emergent coding and interpretation should be acknowledged (Brocki & Wearden, 2006). Reflective diary-keeping (Appendix U) facilitated the researcher in considering personal contributions to the co-construction of data (Spencer & Ritchie, 2012), such as avoiding accidentally pursuing specific answers or directions during interviews. The researcher was concurrently performing a CBT-I meta-analysis that suggests CBT-I is useful for people with chronic health conditions and had previously used CBT-I clinically. This perhaps contributed to assumptions that insomnia can be a psychological problem (rather than purely physiological), and knowledge of theorised maintenance and change mechanisms (i.e. beliefs about sleep, poor sleep hygiene). Where these elements arose in the data, extra care was taken to consider these influences, attempting to 'bracket off' or at least maintain awareness of these 'fore-structures' (Husserl, 1931; Smith et al., 2009).

Results

Through analysis of interview data, four superordinate themes emerged, comprising ten subordinate themes (Table 3; Appendix V). All participants but Carl experienced disturbed sleep, usually struggling to fall or stay asleep, and used night-time or daytime efforts to address sleep, and the difficulties poor sleep causes for IBD and lifestyle. Participants were aged between 27 and 65 years, mostly diagnosed with CD (75%), 50% identified as female. Education level was not formally assessed, though anecdotally all participants referred to experiences of undergraduate or beyond education. All but Robert (retired) and Carl ("house husband") were currently employed or studying (Table 1). Participants descriptions of their IBD symptoms, fatigue and sleep quality were usually consistent with quantitative measure scores (Table 4), but is discussed where divergent or informing analysis.

Themes are discussed below, with illustrative quotes (Appendix W for further examples).

Table 3.

Theme contributions per participant

Superordinate theme	Subordinate theme	Sarah	Jess	David	Lisa	Helen	Amir	Robert	Carl
1. Frustration, worry and flare – night-time struggles	1a. A different conversation – sleep in flare and remission	✓	✓	✓	✓	✓	✓	✓	✓
	1b. Lying awake, thinking and worrying about sleep and symptoms – the limbo state	✓	✓	✓		✓	✓	✓	
	1c. Frustration and anger at the body and the self	✓	✓	✓	✓	✓	✓	✓	
2. My self changed – variations in feeling ok about the way things are	2a. The type of sleeper I am – before and after IBD	✓	✓	✓	✓	✓	✓	✓	✓
	2b. The problem talking about my problem	✓	✓	✓	✓	✓	✓	✓	✓
3. Reinforcing cycles: IBD, stress and sleep	3a. How my body keeps me awake – immediate and painful symptoms and sleep	✓	✓	✓		✓	✓	✓	✓
	3b. Tiring myself out – the interaction between fatigue and sleep		✓	✓	✓	✓	✓	✓	
	3c. Anxiety, stress and IBD	✓	✓	✓	✓	✓	✓	✓	✓
4. Seeking control of sleep and IBD	4a. Managing the night - worry and night-time arousal	✓	✓	✓	✓	✓	✓	✓	✓
	4b. Managing the day– fatigue and other IBD symptoms	✓	✓	✓	✓	✓	✓	✓	✓

Table 4.

Contextual outcome measure scores per participant

	PSQI (/21, higher scores = more severe sleep problems)	**IBDQ (/224, higher scores = better quality of life)**	**MAF (/50, higher scores = worse fatigue and QoL)**	**Previous night's sleep (0 – 10, 10 = best)**	**Fatigue that day (0 – 10, 10 = not fatigued)**
Sarah	7	161	20.6	6	6
Jess	13	149	34.3	7	8
David	5	187	16.8	6	8
Lisa	7	143	39.4	9	3
Helen	4	144	33.86	7	8
Amir[a]	*	*	*	7	5
Robert	9	111	36.2	9	6
Carl	4	220	2	10	10

Note: PSQI = Pittsburgh Sleep Quality Index (Buysse, Reynolds, Monk, Berman, 1989); IBDQ = Inflammatory Bowel Disease Questionnaire (Han, McColl, & Steen, 1998); MAF = Multidimensional Assessment of Fatigue (Belza, 1990). QoL = Quality of life.

[a] = Amir returned consent forms but not questionnaires after interview and did not respond to request emails

1. **Frustration, worry and flare – night-time struggles**

Participant's descriptions of their night-time experiences were nuanced, describing different outcomes dependent partially on whether they were currently in an active disease flare or not. Experiences included sleep disruption from disease symptoms, night-time arousal, over-thinking and worry, and a sense of frustration and anger at the body and the self.

1a. "A different conversation" – sleep in flare and remission

Carl reported relatively undisturbed sleep, whilst most others spoke of difficulty sleeping. Only Amir and Jess suggested toileting urgency or pain were currently disturbing their sleep, other participants recounted the impact of a flare through anecdotes of worse

days, implying a hushed dread of flares returning. Participants were clear that sleep experience (and perhaps whether sleep occurred or not) differed significantly between during a disease flare and remission:

> *"See, at the minute, because I'm in remission, [my IBD's] not affecting me at night time, other than it's quite noisy... um... whereas if I'd been talking to you when I'd been flaring up, I think we'd be having a different conversation." (Sarah)*

Sarah's referral to a "different conversation" ominously suggests greater sleep upset during flare. Having referred to her sleep as "very disturbed", Jess illustrates total sleep disruption during disease flare:

> *"... if I'm in an active flare, ... it's difficult to sleep at night for say eight hours in a stretch because I will be so sick that I will be needing to go to the toilet at like every 10 minutes or something, so it's impossible to sleep in those circumstances. And the pain will be too severe." (Jess)*

Jess quickly moves to sleep rendered "impossible" by toileting and severe pain. This suggests a forceful, physical intrusion by IBD into sleep, rendering the first clause ("eight hours in a stretch") almost unimaginable. When present, a flare was sometimes regarded as all-encompassing, but participants noted that other factors continued to disturb sleep in disease remission (see below).

1b. Lying awake, thinking and worrying about sleep and symptoms – the limbo state

In disease remission, participants suggest sleep was still disturbed, but by behavioural and psychological factors. Night-time over-thinking or worrying appeared near-universal in this sample, with only Carl reporting it in the past rather than the present. Interviewees reported a "limbo" state (Sarah, Jess, David, Robert, Amir), lying half-awake with

"churning" minds, a dissatisfying sleep in comparison to many participants' cited ideal: Eight unconscious hours.

Most participants reported worrying about IBD-related concerns about work, social occasions and holidays:

"[Not finding a toilet on holiday's] not my worry, my worry is that I'll just feel crap and I won't be able to do something." (Helen)

"So, it's not as if going to the toilet is unpredictable in that sense, it hasn't necessarily been that, it's the worry that um, that I'll just feel crap, that I'll be ill …" (Lisa)

Helen and Lisa quickly distance themselves from worries about toileting, perhaps inferring the author's focus and feeling embarrassed, though others (David) explicitly report such worries. Worries about feeling ill seemed tied to worries about not getting the 'right' amount of sleep:

"I can't function unless I get a good 7, 8 hours' sleep…" (Helen)

"I think my target's about 8 hours sleep but um, 7 hours, you know, minimum" (Lisa)

Perhaps exacerbating these concerns, some participants suggested potentially unrealistic expectations of sleep (considering their experiences thus far). Jess, reporting the worst sleep quality in the sample (PSQI = 13), recounts her attempts at keeping a diary of sleeping hours:

"I need to change the scales … the lowest point on my thing [record sheet in diary] is like 5 hours sleep, which – and it goes up to 12, which is incredibly optimistic of me." (Jess)

Jess explains that the scales she chose for recording sleep in her diary were unrealistic in comparison to her actual experience as both the minimum and maximum were optimistically high.

1c. Frustration and anger at the body and the self

Participants appeared to direct anger at their bodies when contributing factors to their sleeplessness were perceived as automatic and physiological, or towards themselves where behavioural control was inferred. Physiological factors (such as IBD symptoms) were located outside their control, by placing them within an almost-separate 'problem' body:

"...I feel like my body is being deliberately rebellious in that it will not let me sleep even though it wants to be asleep" (Jess)

Jess separates herself from her problem body, lending it agency and suggesting a disappointed anger directed at its embodied disloyalty. Discussing how poor sleep affects her fatigue, Lisa gives agency to an externalised body, enlisting its coercion as if to address guilt for (perceived) productivity shortcomings:

"You see other people and you think 'oh, you can do so much in a day', like people get into the office and for like 7 or 8 in the morning, I wish I could but my body will just not really let me. I just can't ... I'll get in when my body is ok with me getting in." (Lisa).

Where participants appeared to feel a measure of control over their sleep, they began directing this frustration at themselves instead. Robert, experiencing the worst IBD symptom impact amongst the participants that returned the IBDQ (with a score of 111), implicitly takes responsibility for his sleeplessness through night-time over-thinking, his humour perhaps belying his final anger towards himself for 'being' this way:

"I'm lying there thinking 'I'm wide awake here', (LAUGH), I'm staring at the curtains thinking (LAUGH), you know 'I'm just wide awake, this is ridiculous' (LAUGH), 'why am I, why am I so like this?'" (Robert)

2. My self changed – variations in feeling ok about the way things are

Participant reflections on their experiences of changes to health and sleep implied varying degrees of acceptance or resistance to such changes. Interviewees also appeared to demonstrate guilt or shame when discussing the extent of their difficulties with both IBD and sleep, and their experiences of diagnosis may have informed this, perhaps making them feel their problems are mild or illegitimate.

2a. The type of sleeper I am – before and after IBD

Most interviewees offered unprompted stories of personal change following IBD diagnosis, describing slow transition from 'being' well (i.e. attempting to continue to pursue unaltered pre-IBD lifestyles) to acceptance of 'being' unwell, including a need to change in order to manage their illness.

Participants appeared to vary in willingness (or ability) to 'be' unwell, and similarly in their willingness to 'be' a poor sleeper. Jess appears to accept an unwell identity, redrawing the boundaries for "symptom free", and allowing herself to 'be' "sick":

"… the stomach pains that I have are pretty much constant… [on most days] it's not enough to disrupt me, so those days would probably count more or less as symptom free." (Jess)

"[I might struggle]…if I'm feeling particularly exhausted, in a way that I've had a very busy day and am very exhausted, in a way that I wouldn't have been before I got this sick…" (Jess)

However, Jess appears less willing to 'be' a poor sleeper, describing a bitter tug-of-war with her IBD, equating control over sleep to control over her life:

"… I just spent a year not working because of the IBD and so to continue having problems because of it through not sleeping, I feel like it's something else that the

IBD is sort of taking from me, it's sort of taking away my... the control that I have over my own life." (Jess)

David's interview similarly encapsulates this dilemma, caught between (perhaps more peaceful) acceptance of a new 'normal' for sleep and hopeful resistance in a potentially reignited search for answers. His first response to being asked about his average night's sleep is to juxtapose his pre-diagnosis self in dramatic fashion:

"...long before I was diagnosed with IBD, I used to be quite a keen sleeper and I used to sleep for a good 9 hours a night and I used to really like my sleep. And I remember one time when I was a kid and um, I slept through a fire in the house, ha…fire engines and the chimney was on fire …" (David)

David polarises his before and after IBD-self, alluding to a strongly held 'natural' identity as a keen sleeper, disrupted by the intrusion of IBD. He contrasts this to his current acceptance of his sleep problems:

"... eventually I got to a place of, of feeling a bit more um, at ease with the fact that I wasn't having proper night's sleep … almost feels unremarkable as it were. Um, and then other times I sort of think actually, that's not necessarily a normal, normal person's sleeping pattern" (David)

David's final sentence and repetition of "normal" suggests a disgruntled equipoise between seeking answers and accepting 'abnormal' sleep.

2b. The problem talking about my problem

In several interviews, a complex and sometimes contradictory picture of sleep and IBD-related difficulties was presented, that offered the impact upon the self as simultaneously significant and negligible. Participants appeared to struggle with feelings of guilt or shame when describing the impact of their IBD and poor sleep. Most participants offered fulsome, medically knowledgeable and convincing accounts of IBD and its impact on

sleep and lifestyle, as if trying to convince the interviewer of the legitimacy of their distress. However, many participants began equivocating as if embarrassed or ashamed at their complaints. Social comparison to others considered 'worse-off' was a common vehicle for this, appearing to almost apologise for previous statements outlining their difficulties:

"…one of the things I notice when I'm chatting to other people who have it much worse is I feel um, you know, I feel glad that I'm not in the same boat as them…" (David)

David's PQSI and IBDQ scores do suggest relatively less pronounced difficulties than others in the sample (Table 3), but he spontaneously returns to his relative 'fortune' frequently, as did Carl, Sarah, Robert and Lisa.

All participants (excepting Carl, married to a medical professional) recounted very negative experiences of seeking initial IBD diagnosis, unprompted by interview questioning. Interviewees reported feeling dismissed or ignored by medics (historically and currently), citing medical apathy and invalidation by doctors. Sarah aptly demonstrates what may be a key concern for those who have needed to 'make a fuss' to receive treatment:

"…I'm very conscious that other people might think 'bloody hell, wish she'd shut up!' It's like, ha, it could be worse." (Sarah)

It appeared that participants felt caught between explicit and compelling description of their difficulties (perhaps often necessary to receive treatment) and an expectation of those concerns being dismissed or minimised. Perhaps accordingly, none of the people interviewed reported seeking help for sleep difficulties from their medical specialists (though this was not explicitly asked).

3. Reinforcing cycles: IBD, stress and sleep.

Participants suggested their own theories of how poor sleep appears to promote increased flare activity and symptom sensitivity, increase fatigue and stress (particularly

concerning work). Fatigue was often discussed separately to other IBD symptoms such as pain or toileting, its affects upon sleep seen as less immediate. Reciprocal relationships between sleep and each of the areas below was common (i.e. anxiety about fatigue affecting sleep) but is presented separately for ease of comprehension.

3a. My body keeps me awake – immediate and painful symptoms and sleep

Most participants suggested pain and toileting had the most immediate and disruptive effects on sleep, particularly during a flare (see 1a. above). However, as well as flares disrupting sleep, interviewees suggested disturbed sleep then further increased the likelihood of a flare or worsened symptoms. Lisa links a poor night's sleep to increased "little" symptoms the following day, her repeated emphasis ("really tired"; "really struggle") and IBDQ score (143, the second most severe in the sample) revealing significant impact:

> *"…I'm going to be really tired the next day, I'm going to really struggle the next day, and you know, I could have a sore throat or something, it just seems to add like little symptoms, like I said before, like achy joints and things if I'm overtired" (Lisa)*

Jess suggests a circular and reciprocal relationship between sleep and IBD symptoms:

> *"…my experience is so far I feel that the more stress that my body is under, the worse the symptoms can become, so I – yeah, the symptoms get worse if I'm not well rested." (Jess)*

Some participants (Amir, David, Robert and Helen) reported other indirect bodily contributions to poor sleep from IBD such as from medication side-effects. Helen describes how a drug prescribed to reduce flare symptoms keeping her awake instead led to further sleep disruption from frequent urination, her emphasis of "infection" suggestive of the corruption of something meant to help:

"…one of the complications a while ago, from medication…it completely wipes out your immune system …I just got infection after infection and I just got continuous water infections." (Helen)

3b. Tiring myself out – the interaction between fatigue and sleep

Fatigue was suggested to have a more indirect effect on sleep than painful symptoms, toileting or worry, though similarly reciprocal. Interviewees suggested both poor sleep and other IBD symptoms (separately and together) contributed to increased fatigue:

"Because in a flare, I could sleep 8 hours and go to work, right, but then 2 hours into work I'd be like 'whoa', fatigue kicks in, I can't do this. Can't do this, and I think, well, I've slept 8 hours, because my body needs more TLC, more growth and repair time." (Amir)

Amir describes the impact of flare-disturbed sleep, suggesting fatigue as a physiological consequence of interrupted night-time healing, his repetition of "can't do this" and the abruptness of fatigue's impact ("whoa") illustrating a powerful wave slamming against Amir's will to be productive. Multiple disruptive effects on daytime activities (particularly work) were concerns with fatigue, citing difficulties with concentration, intellectual capacity and mood, and participants reported these concerns contributed to anxiety and further difficulty sleeping (see below).

Some participants also suggested that fatigue perpetuates sleeping problems, by increasing the amount of sleep required to feel refreshed and prompting potentially unhelpful daytime napping or going to bed too early. Lisa, experiencing the worst fatigue in the sample (MAF = 39.4) describes the essential tension between recovering from fatigue and preserving a healthy sleep pattern:

"…it is something that I find really hard to balance; sleeping enough but also not having too much…." (Lisa)

3c. Anxiety, stress and IBD

Anxiety (or stress) was positioned as a mediator between the effects of IBD and disturbed sleep on everyday life, and their reciprocation in further disturbed sleep. Worries about the impact on work or social commitments from IBD symptoms, fatigue and tiredness, were commonly cited. Helen describes how her night-time worry about not getting enough sleep cascades into worry about coping when busy at work, and then cyclically, that it will prompt a flare that would make coping even harder:

> *"So I was worrying on Wednesday night, um, not worrying, it was just a bit like, 'oh, I don't' – it was that – dread is too strong a word, but it was that 'oh, I've got a lot of stuff to do' and you know, I want it to go well and stuff. I don't really want to worry about it, and it did cross my mind, I thought 'well, this worry is going to make me ill.'" (Helen)*

Helen approaches and then avoids her "dread", suggesting the power of the lurking worry that anxiety will provoke flare, a common concern for the interviewees:

> *"I toss and turn, I think about… the events from previous day – I listen to my – my stomach's quite noisy at night as well… um, I worry… yeah, I worry. Um… think about what I've got coming up... I never seem to be able to switch off…" (Sarah)*

Sarah's experience encapsulates a typical disturbed night: Reviewing past events, worrying about the future and vigilant to potential signs of a flare, even in remission. Amir (currently on sick leave from work) aptly summarises the connective role of anxiety in a feared spiral of deterioration from sleepless nights in flare:

> *"…it's a process, isn't it? You're flaring, as soon as you're flaring, anxiety levels increase, anxiety levels increase, it's harder to get to sleep. Now, you then push, pull, fight, whatever, take your medication, and the side effects of the medication can then affect your sleep…" (Amir)*

He appears to describe a desperate, scrappy wrestling match, pushing and pulling for control, but inevitably ceding ground and becoming hopeless as even the strongest techniques (medication) fail by disrupting sleep and beginning the cycle anew.

4. Seeking control of sleep and IBD

Participants reported attempting to gain control over the reciprocally casual effects of fatigue, anxiety and IBD symptoms during the day and night, Many attempts at management were logistically separate (i.e. monitoring food intake is unlikely to occur in the middle of the night) but were connected by their consequent effects (reduced stomach pain, better sleep). Managing IBD and fatigue symptoms during the day (to prevent a flare or exhaustion) contributed to expectations of better sleep and less anxiety or stress. Likewise, managing night-time anxiety was expected to reduce sleeplessness, reducing impact on the next day (and potentially lowering risk of a flare).

4a. Managing the night - worry and night-time arousal

As night-time arousal and worry were common, a substantial part of most participant's night-time experiences were efforts to reduce anxiety. Robert describes an attempt to reduce perceived increased physiological arousal resulting from computer use:

> *"Yeah so avoid [screen use] in the evening because I know for a fact that I've only got to go on the laptop for half an hour … during the evening hours and I think that definitely does have an effect on the brain when it comes to getting to sleep" (Robert)*

Robert's assertive language ("fact", "definitely") suggests a comfortable certainty in identifying this embodied (othered) source of arousal. Participants reported controlling their pre-bed routines, hoping to cue sleep, such as changing into pyjamas early (Helen), or systematically relaxing at home and 'whisking' the self to bed when about to fall asleep (David).

Participants also reported actively diverting their attention from worry once in bed:

"I think I would potentially be having trouble turning off my thoughts and falling asleep so that's when I would stay and listen to an audiobook or something." (Jess)

"…I've started not watching TV in bed, to improve my sleep hygiene. I go to bed about half 10, I listen to a podcast to get me to sleep." (Sarah)

Both interviewees appear to imply automaticity, and a felt lack of control over night-time thinking: Jess suggests it needs to be 'turned off', and Sarah gives the podcast responsibility for 'getting' her to sleep.

Currently experiencing the best reported sleep (qualitatively and by outcome measures), Carl reports using a technique he developed following previous experience of poor sleep:

"…I've tried a lot of stuff in the past and it hasn't [worked] but I, I visualise numbers…and do that in rhythm with breathing …So if you concentrate on visualising a number, it can be a different shape… sometimes you wander off and you can either start back at one or where you left off…" (Carl)

Carl's temporary revisiting of past failures to combat sleeplessness may indicate a latent fear that this method of control too will fail, but he suggests an interesting paradox in his attempts: By accepting that concentration will wander, he implicitly accepts that full control of automatic processes is impossible, which perhaps offers him better sleep than attempting to control his mind.

4b. Managing the day– fatigue and other IBD symptoms

As the effects of both IBD and (disrupted) sleep extend into daytime hours, so did participants' attempts to mitigate those effects and take control over their day. Some interviewees reported daytime routines, aimed at managing tiredness or IBD symptoms, reducing their potential to affect sleep. Jess describes routines meant to mitigate abdominal and joint pains (common contributors to her sleep difficulties), the immediacy and ordered

fashion of her recall (responding to an open prompt to describe a "typical day") suggests their centrality for Jess:

> *"So, typical day – so I get up in the morning, maybe about 8 o'clock, I'll have breakfast and I tend to eat something quite simple at breakfast because otherwise I can like exacerbate symptoms that I'm having. I do some simple Pilates stretches because I get joint pains…" (Jess)*

Jess also employs careful budgeting of effort, protecting her concentration and preventing disruption to an ordered sleep routine:

> *"…I get very fatigued and so I can't concentrate on the work I'm doing or I'm too tired, like I'll fall asleep while I'm doing something …So if I over-push one day I can just spend the next day not doing anything productive, just sleeping or resting." (Jess)*

Other participants (Sarah, David, Lisa, Helen and Amir) describe diligent attention to food intake and attempts to manage fatigue to help their sleep. Robert describes efforts at sleep protection, illustrating the need to "break" the circular links between IBD-induced sleeplessness and behavioural contributions (napping) that continue the effects:

> *"…if you're going through a period of [flare] like the last couple of weeks for me, you may well find if you've had a lot of pain ...you may find that you've got to go and have a rest in the afternoon…you might get away with it the first night but the second night you'll go to bed …and you can't get to sleep and then you wake up at 7/8 o'clock and you've had around four hours and you think that means that come the afternoon I'll be tired, you know you've got to try and break that somehow." (Robert)*

Robert's dilemma illustrates the trap of tiredness within IBD. Fatigue necessitates rest to attempt to manage life, but daytime rest disrupts regular sleep which further aggravates IBD.

Discussion

This research aimed to better understand the experience of sleep for people with IBD. Analysis yielded four superordinate and ten subordinate themes. Participants appeared to struggle to accept changed sleep and seemed to experience guilt or shame discussing their difficulties, perhaps resulting from reported experiences of feeling non-emergency symptoms were dismissed or minimised. Most participants experienced disrupted sleep, affected by worry, arousal and (most commonly during a flare) IBD symptoms directly. Interviewees appeared to feel anger towards themselves or their bodies about this. Participants suggested circular systems through which IBD, fatigue, anxiety and poor sleep reciprocally worsened each other, with time spent both day and night towards attempting to control this. How these findings relate to previous research and psychological theory is discussed below.

Some participants seemed to struggle to accept poor sleep in the way they had accepted IBD. Adjustment to illness may involve gradual movement from an adopted 'sick role' (i.e. Parsons, 1951), through approximate stages of achieving emotional regulation, preserving adaptivity and functionality and achieving satisfaction in life domains (De Ridder, Geenen, Kuijer, & Van Middendorp, 2008). Others argue the 'sick role' is a dynamically adopted perspective, shifting back and forth between the foregrounding of illness or wellness in response to pressures, symptoms, pragmatism and necessity and may be a means of negotiating access to medical attention (Paterson, 2001). Thus, participants may be unlikely to shift to sleep 'illness' perspectives in the absence of offered help.

Participants may struggle to seek such help. They appeared to feel guilty or self-conscious 'complaining' about their difficulties, perhaps owing to experiences of feeling neglected, ignored or suspected of hypochondria when pursuing diagnosis. Interviewed patients with IBD commonly suggest feeling 'non-serious' symptoms are ignored by doctors (Sawczenko et al., 2001; Card, Siffledeen, & Fleming, 2014), and that specialists

underestimate the impact of IBD (Ghosh & Mitchell, 2007). Indeed, research demonstrates that gastroenterologists appear to underestimate how difficult patients find it to live a 'normal' life with IBD in comparison to patient self-reports (Rubin et al., 2009).

In trying to avoid or mitigate flares and fatigue, participants cited various ways they tried to take control through, for example, routines around food or self-care. Routines built around illness may represent stress-lowering compassionate self-management (Sirois & Rowse, 2016), and help individuals to monitor and care for their health (Schulman-Green et al., 2012). They may also act as 'illness work': care-focussed behaviours and rituals operating as a way of managing illness trajectory (Corbin & Strauss, 1985), and may also be behaviours that continuously reconstruct the unwell self (Charmaz, 2002).

Dysfunctional and inaccurate beliefs about sleep, arousal-promoting bed-time habits (e.g. staying in bed whilst awake for too long) and night-time worrying are key components of the CBT-I model of insomnia maintenance (Morin, Savard, Ouellet, & Daley, 2003). The exemplars offered by the participants of such beliefs, habits and worrying suggest CBT-I may be useful for this sample. Common dysfunctional beliefs may be inaccurate causal attributions (i.e. insomnia is purely biochemical), unrealistic expectations of sleep (i.e. 'I need 8 hours minimum') and exaggerated health consequences of poor sleep (Morin, Savard, & Ouellet, 2012). The reciprocity theories forwarded by the participants may suggest such beliefs, though they may not be unrealistic in IBD (e.g. poor sleep has been found to increase flare risk in CD; Ananthakrishnan, Long, Martin, Sandler, & Kappelman, 2013), and research suggests a complex reciprocal relationship between sleep and IBD disease activity (Kinnucan et al., 2013). Predictions of the impact of sleeplessness on working days (via fatigue, symptom sensitivity or increase, or tiredness) was a source of stress for participants, angry with themselves for being unable to sleep. Stress is reported to reciprocally worsen symptoms, disrupt sleep and undermine self-compassion in chronic illness (Akerstedt, 2006;

Ali & Orr, 2014; Sirois & Rowse, 2016), suggesting poor sleep, IBD symptoms and stress may share a reciprocally reinforcing relationship.

Participants appeared vigilant and anxious about future flares, with poor sleep suggested to worsen flare risk. Symptom hypervigilance has been suggested in other IBD sleep research (Green et al., 2017). Participants reported lying in bed worrying or ruminating, without getting up, in restless 'limbo'. Commonly, those with sleep difficulties stay in bed to increase chances to 'drop off', but consequently may condition arousal to bed, contributing to fragmented sleep (Spielman, Saskin, & Thorpy, 1987).

Participants employed strategies to prevent night-time overthinking, with most listening to audio materials to occupy attention. The ability to distract oneself from unpleasant content is associated with better sleep (Gellis & Park, 2013). The media of distraction (spoken word) may occupy the phonological loop interfering with production of worrying verbal cognitions (Rapee, 1993).

Strengths, limitations and future directions

The results of this study should be considered in the context of its strengths and limitations. Although a robust IPA sample size was achieved (Smith et al., 2009), selection bias may have influenced who volunteered to participate (Heckman, 2010), perhaps towards those expecting a psychological answer (or therapy) for sleep difficulties, considering the interviewer's profession. Participants were predominantly white British, educated and employed, and experiences may vary across cultures, employment status (and profession) and income brackets, However, quantitative data (Table 4) are similar to previously reported norms for people with IBD, suggesting the sample may be somewhat representative (Belza, Miyawaki, Liu, & Fessel, 2015; Graff et al., 2011; Habibi et al., 2017; Huamán et al., 2010).

One participant's psychological occupation may have contributed to co-construction of 'insider' stories[9] (Merton, 1972), which is considered during reflexivity (Appendix U).

Whilst qualitative inductive methodology allows room for fuller responses (unlike for example questionnaires in hypothetico-deductive research), analysis tends to converge on points of commonality, and rarer experiences may be less represented (Willig, 2008). Carl's relatively positive experiences of diagnosis and sleep may therefore be submerged within the more dominant narrative of disturbed sleep and difficulty with medical professionals.

IPA is a double hermeneutic method: Each experience interpreted subjectively by interviewee then interviewer through a co-construction between parties, so we cannot presume to know the 'truth' of experience (Smith et al., 2009). However, some strengths of this research may have improved the research quality: the author engaged in reflexivity, utilised contextual quantitative data during analysis and reviewed analysis with peers, supervisors and a participant (Finlay & Gough, 2003).

Future research could explore some topics in depth that were present in the current study to lesser degrees, such as more explicit review of fatigue experiences and experiences seeking help for sleep problems. Ideally, future research would consider the impact of ethnicity, occupation and culture upon the results. Finally, as CBT-I appeared suitable for this population, a trial of its effectiveness seems appropriate.

Implications for clinical practice

These results suggest some considerations in improving clinical practice for working with sleep problems in IBD.

Perceptions of dismissal or invalidation whilst seeking diagnosis were near-universal in this sample and may represent a help-seeking barrier for sleep problems. People with IBD

[9] Insider stories refer to the reconstruction of experience when retold to other (usually similar) professionals, reinforcing professional norms and boundaries through the reconstruction of narrative (Merton, 1972)

may benefit from care teams explicitly acknowledging the role of sleep in IBD to promote help seeking (Ali, 2014). This may suggest benefits for an emphasis on increased collaboration and promoting client validation (e.g. Leahy, 2008) and perhaps explicitly acknowledging that insomnia in IBD remission seems at least partially physiologically maintained (Ananthakrishnan et al., 2013).

Some participant self-management behaviours could be targets of change during CBT-I intervention. It may be difficult for participants to abandon coping behaviours and instruction to change may feel de-legitimising or shameful, affecting willingness to engage. Negative treatment experiences (pre-CBT-I) and difficulty incorporating behavioural change is associated with higher attrition rates in CBT-I practice (Matthews, Arnedt, Mccarthy, Cuddihy, & Aloia, 2013), so care should be taken to remain collaborative and respectful of existing coping. Participants suggested external agency for some difficulties, perhaps finding this more palatable (Wallston, Wallston, & DeVellis, 1978). Clinicians could utilise such externalisation to reduce shaming consequences of recognising personal behavioural contributions to sleep problems, for example referring to 'the napping' getting in the way of sleep restriction working. Similar techniques are used to facilitate change discussions in narrative therapy (Morgan, 2000).

Conclusions

Most people with IBD interviewed in this research commonly experienced sleep disrupted by arousal, worry and fatigue during disease remission, and more severely by toileting and pain during a flare. Participants suggested theories linking IBD, sleep, fatigue and anxiety in circular maintenance of each other, and tried to control this directly at night and indirectly during the day. Participants' prior experiences of feeling invalidated may impact any future help seeking for sleep problems, and care should be taken that possibly

helpful psychological sleep interventions (i.e. CBT-I) are administered sensitively and collaboratively, and that sleep is routinely discussed in IBD care.

References

Akerstedt, T. (2006). Psychosocial stress and impaired sleep. *Scandinavian Journal of Work, Environment & Health*, *32*, 493–501. doi: 10.5271/sjweh.1054

Ali, T. (2014). Sleep and inflammatory bowel disease. *Gastroenterology & Hepatology*, *10*, 748–751. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/28435412

Ali, T., Madhoun, M. F., Orr, W. C., & Rubin, D. T. (2013). Assessment of the relationship between quality of sleep and disease activity in inflammatory bowel disease patients. *Inflammatory Bowel Diseases*, *19*, 2440–2443. https://doi.org/10.1097/MIB.0b013e3182a0ea54

Ali, T., & Orr, W. C. (2014). Sleep disturbances and inflammatory bowel disease. *Inflammatory Bowel Diseases*, *20*, 1986–1995. https://doi.org/10.1097/MIB.0000000000000108

Ananthakrishnan, A. N. (2015). Environmental risk factors for inflammatory bowel diseases: a review. *Digestive Diseases and Sciences*, *60*, 290–8. https://doi.org/10.1007/s10620-014-3350-9

Ananthakrishnan, A. N., Long, M. D., Martin, C. F., Sandler, R. S., & Kappelman, M. D. (2013). Sleep disturbance and risk of active disease in patients with Crohn's disease and ulcerative colitis. *Clinical Gastroenterology and Hepatology*, *11*, 965–971. https://doi.org/10.1016/j.cgh.2013.01.021

Backhaus, J., Junghanns, K., Broocks, A., Riemann, D., Hohagen, F., Spiegel, R., … Rafecas, J. (2002). Test-retest reliability and validity of the Pittsburgh Sleep Quality Index in primary insomnia. *Journal of Psychosomatic Research*, *53*, 737–40. https://doi.org/10.1016/S0022-3999(02)00330-6

Baddeley, A. (2011). Working memory: theories, models, and controversies. *Annual Review*

of Psychology, 63, 1–29. https://doi.org/10.1146/annurev-psych-120710-100422

Behrangrad, S., & Kordi Yoosefinejad, A. (2018). Validity and reliability of the multidimensional assessment of fatigue scale in Iranian patients with relapsing-remitting subtype of multiple sclerosis. *Disability and Rehabilitation, 40*, 673–677. https://doi.org/10.1080/09638288.2016.1271024

Belza, B. L. (1990). *Multidimensional Assessment of Fatigue (MAF) Scale Users Guide*. Seattle: University of Washington.

Belza, B., Miyawaki, C., Liu, M., & Fessel, M. (2015, September). *The multidimensional assessment of fatigue scale: a 25-year Review and evaluation.* Poster session presented at American College of Rheumatology Annual Meeting, San Francisco, CA. Retrieved from https://acrabstracts.org/abstract/the-multidimensional-assessment-of-fatigue-scale-a-25-year-review-and-evaluation/

Benhayon, D., Youk, A., McCarthy, F. N., Davis, S., Keljo, D. J., Bousvaros, A., … Szigethy, E. M. (2013). Characterization of relationships between sleep, inflammation, and psychiatric Dysfunction in depressed youth with Crohn's disease. *Journal of Pediatric Gastroenterology and Nutrition, 57*, 335–342. https://doi.org/10.1097/MPG.0b013e31829641df

Berk, M., Williams, L. J., Jacka, F. N., O'Neil, A., Pasco, J. A., Moylan, S., … Maes, M. (2013). So depression is an inflammatory disease, but where does the inflammation come from? *BMC Medicine*, *11*, 200. https://doi.org/10.1186/1741-7015-11-200

Bradley, E. H., Curry, L. A., & Devers, K. J. (2007). Qualitative data analysis for health services research: developing taxonomy, themes, and theory. *Health Services Research*, *42*, 1758–1772. https://doi.org/10.1111/j.1475-6773.2006.00684.x

Brooks, A. J., Rowse, G., Ryder, A., Peach, E. J., Corfe, B. M., & Lobo, A. J. (2016). Systematic review: psychological morbidity in young people with inflammatory bowel

disease - risk factors and impacts. *Alimentary Pharmacology & Therapeutics*, *44*, 3–15. https://doi.org/10.1111/apt.13645

Brown, F. C., Buboltz, W. C., & Soper, B. (2002). Relationship of sleep hygiene awareness, sleep hygiene practices, and sleep quality in university students. *Behavioral Medicine*, *28*, 33–38. https://doi.org/10.1080/08964280209596396

Buysse, D. J., Reynolds, C. F., Monk, T. H., Berman, S. R., & Kupfer, D. J. (1989). The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. *Psychiatry Research*, *28*, 193–213. http://dx.doi.org/10.1016/0165-1781(89)90047-4

Card, T. R., Siffledeen, J., & Fleming, K. M. (2014). Are IBD patients more likely to have a prior diagnosis of irritable bowel syndrome? Report of a case-control study in the General Practice Research Database. *United European Gastroenterology Journal*, *2*, 505–512. https://doi.org/10.1177/2050640614554217

Carpenter, J. S., & Andrykowski, M. A. (1998). Psychometric evaluation of the Pittsburgh Sleep Quality Index. *Journal of Psychosomatic Research*, *45*, 5–13. https://doi.org/10.1016/S0022-3999(97)00298-5

Carter, M. J., Lobo, A. J., & Travis, S. P. L. (2004). Guidelines for the management of inflammatory bowel disease in adults. *Gut*, *53*, 1–16. https://doi.org/10.1136/GUT.2004.043372

Charmaz, K. (2002). The self as habit: the reconstruction of self in chronic illness. *Occupational Therapy Journal of Research: Occupation, Participation and Health*, *22*, 31–41. https://doi.org/10.1177/15394492020220S105

Charmaz, K. (2014). *Constructing Grounded Theory (2nd edition).* London: Sage Publications

Cheung, W., Garratt, A. M., Russell, I. T., & Williams, J. G. (2000). The UK IBDQ—A British version of the inflammatory bowel disease questionnaire. *Journal of Clinical Epidemiology*, *53*, 297–306. https://doi.org/10.1016/S0895-4356(99)00152-3

Corbin, J., & Strauss, A. (1985). Managing chronic illness at home: three lines of work. *Qualitative Sociology, 8,* 224–247. https://doi.org/10.1007/BF00989485

Czuber-Dochan, W., Dibley, L. B., Terry, H., Ream, E., & Norton, C. (2013). The experience of fatigue in people with inflammatory bowel disease: an exploratory study. *Journal of Advanced Nursing, 69,* 1987–1999. https://doi.org/10.1111/jan.12060

Czuber-Dochan, W., Norton, C., Bredin, F., Darvell, M., Nathan, I., & Terry, H. (2014). Healthcare professionals' perceptions of fatigue experienced by people with IBD. *Journal of Crohn's and Colitis*, *8*, 835–844. https://doi.org/10.1016/j.crohns.2014.01.004

De Ridder, D., Geenen, R., Kuijer, R., & Van Middendorp, H. (2008). Psychological adjustment to chronic disease. *The Lancet, 19,* 246-255. doi: 10.1016/S0140-6736(08)61078-8.

Dittner, A. J., Wessely, S. C., & Brown, R. G. (2004). The assessment of fatigue: a practical guide for clinicians and researchers. *Journal of Psychosomatic Research, 56,* 157-170. https://doi.org/10.1016/S0022-3999(03)00371-4

Eatough, V., & Smith, J. A. (2017). Interpretative Phenomenological Analysis. In C. Willig & W. S. Rogers (Eds.) *The SAGE Handbook of Qualitative Research in Psychology* (pp. 179–194). London : SAGE. https://doi.org/10.4135/9781848607927.n11

Elliott, R., Fischer, C. T., & Rennie, D. L. (1999). Evolving guidelines for publication of qualitative research studies in psychology and related fields. *The British Journal of Clinical Psychology*, *38*, 215–29. DOI: 10.1348/014466599162782

Espie, C. A., MacMahon, K. M. A., Kelly, H. L., Broomfield, N. M., Douglas, N. J., Engleman, H. M., … Wilson, P. (2007). Randomized clinical effectiveness trial of nurse-administered small-group cognitive behavior therapy for persistent insomnia in general practice. *Sleep*, *30,* 574–584. https://doi.org/10.1093/sleep/30.5.574

Finlay, L., & Gough, B. (2003). *Reflexivity : a practical guide for researchers in health and social sciences*. Oxford: Blackwell Science.

Frolkis, A. D., Dykeman, J., Negrón, M. E., deBruyn, J., Jette, N., Fiest, K. M., … Kaplan, G. G. (2013). Risk of surgery for inflammatory bowel diseases has decreased over time: a systematic review and meta-analysis of population-based studies. *Gastroenterology*, *145*, 996–1006. https://doi.org/10.1053/J.GASTRO.2013.07.041

Geiger-Brown, J. M., Rogers, V. E., Liu, W., Ludeman, E. M., & Downton, K. D. (2015). Cognitive behavioral therapy in persons with comorbid insomnia : a meta-analysis, *Sleep Medicine Review, 23,* 57-65. doi: 10.1016/j.smrv.2014.11.007

Gellis, L. A., & Park, A. (2013). Nighttime thought control strategies and insomnia severity. *Cognitive Therapy and Research*, *37*, 383–389. https://doi.org/10.1007/s10608-012-9479-y

Ghosh, S., & Mitchell, R. (2007). Impact of inflammatory bowel disease on quality of life: sesults of the European federation of Crohn's and ulcerative colitis associations (EFCCA) patient survey. *Journal of Crohn's and Colitis*, *1*, 10–20. https://doi.org/10.1016/j.crohns.2007.06.005

Graff, L. A., Vincent, N., Walker, J. R., Clara, I., Carr, R., Ediger, J., … Bernstein, C. N. (2011). A population-based study of fatigue and sleep difficulties in inflammatory bowel disease. *Inflammatory Bowel Diseases*, *17*, 1882–1889. https://doi.org/10.1002/ibd.21580

Guyatt, G., Mitchell, A., Irvine, E. J., Singer, J., Williams, N., Goodacre, R., & Tompkins, C. (1989). A new measure of health status for clinical trials in inflammatory bowel disease. *Gastroenterology*, *96*, 804–810. https://doi.org/10.1016/0016-5085(89)90905-0

Haack, M., Sanchez, E., & Mullington, J. M. (2007). Elevated inflammatory markers in response to prolonged sleep restriction are associated with increased pain experience in

healthy volunteers. *Sleep*, *30*, 1145–52. doi: 10.1093/sleep/30.9.1145.

Habibi, F., Habibi, M. E., Gharavinia, A., Mahdavi, S. B., Akbarpour, M. J., Baghaei, A., & Emami, M. H. (2017). Quality of life in inflammatory bowel disease patients: a cross-sectional study. *Journal of Research in Medical Sciences : The Official Journal of Isfahan University of Medical Sciences*, *22*. https://doi.org/10.4103/jrms.JRMS_975_16

Heckman, J. J. (2010). Selection bias and self-selection. In S. N. Darlauf & L. E. Blume (Eds.) *Microeconometrics* (pp. 242–266). London: Palgrave Macmillan. https://doi.org/10.1057/9780230280816_29

Hirsch, J. K., & Sirois, F. M. (2016). Hope and fatigue in chronic illness: the role of perceived stress. *Journal of Health Psychology*, *21*, 451–456. https://doi.org/10.1177/1359105314527142

Huamán, J., Casellas, F., Borruel, N., Peláez, A., Torrejón, A., Castells, I., … Guarner, F. (2010). Cutoff values of the Inflammatory Bowel Disease Questionnaire to predict a normal health related quality of life. *Journal of Crohn's and Colitis*, *4*, 637–641. https://doi.org/10.1016/j.crohns.2010.07.006

Jansson-Fröjmark, M., & Linton, S. J. (2008). The role of psychological mechanisms to insomnia in its early phase: a focus on arousal, distress, and sleep-related beliefs. *Psychology & Health*, *23*, 691–705. https://doi.org/10.1080/14768320701302791

Kaplan, G. G. (2015). The global burden of IBD: from 2015 to 2025. *Nature Reviews Gastroenterology & Hepatology*, *12*, 720–727. https://doi.org/10.1038/nrgastro.2015.150

Kappelman, M. D., Moore, K. R., Allen, J. K., & Cook, S. F. (2013). Recent trends in the prevalence of Crohn's disease and ulcerative colitis in a commercially insured US population. *Digestive Diseases and Sciences*, *58*, 519–25. https://doi.org/10.1007/s10620-012-2371-5

Kinnucan, J. A., Rubin, D. T., & Ali, T. (2013). Sleep and inflammatory bowel disease: exploring the relationship between sleep disturbances and inflammation. *Gastroenterology & Hepatology*, *9*, 718–27. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/24764789

Leahy, R. L. (2008). The therapeutic relationship in cognitive behavioral therapy. *Behavioural and Cognitive Psychotherapy*, *36*, 769–777. https://doi.org/10.1017/S1352465808004852

Matthews, E. E., Arnedt, J. T., Mccarthy, M. S., Cuddihy, L. J., & Aloia, M. S. (2013). Adherence to cognitive behavioral therapy for insomnia: a systematic review. *Sleep Medicine Reviews, 13,* 453-464. https://doi.org/10.1016/j.smrv.2013.01.001

Merton, R. K. (1972). Insiders and outsiders: a chapter in the sociology of knowledge. *American Journal of Sociology*, *78,* 9-47. https://doi.org/10.2307/2776569.

Morgan, A. (2000). *What is narrative therapy?* Adelaide, Australia: Dulwich Centre Publications.

Morin, C. M., Bootzin, R. R., Buysse, D. J., Edinger, J. D., Espie, C. A., & Lichstein, K. L. (2006). Psychological and behavioral treatment of insomnia: update of the recent evidence (1998-2004). *Sleep*, *29*, 1398–414. DOI: 10.1093/sleep/29.11.1398.

Morin, C. M., Hauri, P. J., Espie, C. A., Spielman, A. J., Buysse, D. J., & Bootzin, R. R. (1999). Nonpharmacologic treatment of chronic insomnia. An American Academy of Sleep Medicine review. *Sleep*, *22*, 1134–56. DOI: 10.1093/sleep/22.8.1134

Morin, C. M., Savard, J., & Ouellet, M. C. (2012). Nature and treatment of insomnia. In I. B. Weiner (Ed.) *Handbook of Psychology, Second Edition* (pp. 318-339). Hoboken, NJ, USA: John Wiley & Sons Inc. https://doi.org/10.1002/9781118133880.hop209014

Morin, C. M., Savard, J., Ouellet, M.-C., & Daley, M. (2003). Insomnia. In I. B. Weiner (Ed.) *Handbook of Psychology* (pp. 317-338). Hoboken, NJ, USA: John Wiley & Sons, Inc.

https://doi.org/10.1002/0471264385.wei0914

Morin, C. M., Vallieres, A., Guay, B., Ivers, H., Savard, J., Merette, C., … Baillargeon, L. (2009). Cognitive behavioral therapy, singly and combined with medication, for persistent insomnia. *Journal of the American Medical Association*, *301*, 2005-2015. https://doi.org/10.1001/jama.2009.682

Naliboff, B. D., Kim, S. E., Bolus, R., Bernstein, C. N., Mayer, E. A., & Chang, L. (2012). Gastrointestinal and psychological mediators of health-related quality of life in IBS and IBD: a structural equation modeling analysis. *The American Journal of Gastroenterology*, *107*, 451–9. https://doi.org/10.1038/ajg.2011.377

Neurath, M. F. (2014). Cyctokines in inflammatory bowel disease. *Nature Reviews Immunology,14,* 329-342. https://doi.org/10.1038/nri3661

Okajima, I., & Inoue, Y. (2018). Efficacy of cognitive behavioral therapy for comorbid insomnia : a meta-analysis. *Sleep and Biological Rhythms*, *16*, 21–35. https://doi.org/10.1007/s41105-017-0124-8

Pallis, A. G., Mouzas, I. A., & Vlachonikolis, I. G. (2004). The inflammatory bowel disease questionnaire: a review of its national validation studies. *Inflammatory Bowel Diseases*, *10*, 261–9. DOI: 10.1097/00054725-200405000-00014

Parsons, T. (1951). *The Social System.* London: Routedge.

Paterson, B. L. (2001). The shifting perspectives model of chronic illness. *Journal of Nursing Scholarship*, *33*, 21–26. https://doi.org/10.1111/j.1547-5069.2001.00021.

Peyrin-Biroulet, L., Panés, J., Sandborn, W. J., Vermeire, S., Danese, S., Feagan, B. G., … Rycroft, B. (2016). Defining disease severity in inflammatory bowel diseases: current and future directions. *Clinical Gastroenterology and Hepatology*, *14*, 348–354. https://doi.org/10.1016/j.cgh.2015.06.001

Pietkiewicz, I., & Smith, J. A. (2014).A practical guide to using interpretative

phenomenological analysis in qualitative research psychology. *Czasopismo Psychologiczne Psychological Journal*, *20*, 7-14. https://doi.org/10.14691/CPPJ.20.1.7.

Pirinen, T., Kolho, K.-L., Ashorn, M., & Aronen, E. T. (2014). Sleep and emotional and behavioral symptoms in adolescents with inflammatory bowel disease. *Sleep Disorders*, *2014*, 1-5. https://doi.org/10.1155/2014/379450

Rapee, R. M. (1993). The utilisation of working memory by worry. *Behaviour Research and Therapy*, *31*, 617–620. https://doi.org/10.1016/0005-7967(93)90114-A

Rubin, D. T., Siegel, C. A., Kane, S. V., Binion, D. G., Panaccione, R., Dubinsky, M. C., … Hopper, J. (2009). Impact of ulcerative colitis from patients' and physicians' perspectives. *Inflammatory Bowel Diseases*, *15*, 581–588. https://doi.org/10.1002/ibd.20793

Han, S. W., McColl, E., Steen, N., Barton, J. R., & Welfare, J. R. (1998). The Inflammatory Bowel Disease Questionnaire: a valid and reliable measure in ulcerative colitis patients in the North East of England. *Scandinavian Journal of Gastroenterology*, *33*, 961–966. https://doi.org/10.1080/003655298750026994.

Sawczenko, A., Sandhu, B. K., Logan, R. F., Jenkins, H., Taylor, C. J., Mian, S., & Lynn, R. (2001). Prospective survey of childhood inflammatory bowel disease in the British Isles. *Lancet*, *357*, 1093–4. https://doi.org/10.1016/S0140-6736(00)04309-9

Schulman-Green, D., Jaser, S., Martin, F., Alonzo, A., Grey, M., McCorkle, R., … Whittemore, R. (2012). Processes of self-management in chronic illness. *Journal of Nursing Scholarship*, *44*, 136–144. https://doi.org/10.1111/j.1547-5069.2012.01444.

Smith, J. A., Flowers, P., & Larkin, M. (2009). *Interpretative phenomenological analysis : theory, method, and research*. London:SAGE.

Spielman, A. 1, Saskin, P., & Thorpy, M. J. (1987). Treatment of chronic insomnia by restriction of time in bed. *Sleep, 10,* 45-56. Retrieved from

https://academic.oup.com/sleep/article-abstract/10/1/45/2742552

Trauer, J. M., Qian, M. Y., Doyle, J. S., Rajaratnam, S. M. W., & Cunnington, D. (2015). Cognitive behavioral therapy for chronic insomnia. *Annals of Internal Medicine, 163*, 191-204. https://doi.org/10.7326/M14-2841

van Manen, M. (2017). But is it Phenomenology? *Qualitative Health Research, 27,* 775-779. DOI: 10.1177/1049732317669570

Vgontzas, A. N., & Chrousos, G. P. (2002). Sleep, the hypothalamic-pituitary-adrenal axis, and cytokines: multiple interactions and disturbances in sleep disorders. *Endocrinology and Metabolism Clinics of North America, 31,* 15–36. https://doi.org/10.1016/S0889-8529(01)00005-6

Vgontzas, A. N., Papanicolaou, D. A., Bixler, E. O., Kales, A., Tyson, K., & Chrousos, G. P. (1997). Elevation of plasma cytokines in disorders of excessive eaytime sleepiness: role of sleep disturbance and obesity. *The Journal of Clinical Endocrinology & Metabolism, 82,* 1313–1316. https://doi.org/10.1210/jcem.82.5.3950

Vitiello, M. V., Mccurry, S. M., Shortreed, S. M., Balderson, B. H., Baker, L. D., Keefe, F. J., … Korff, M. Von. (2013). Cognitive behavioral treatment for comorbid insomnia and osteoarthritis pain in primary care: the lifestyles randomized controlled trial, *Journal of the American Geriatrics Society, 61,* 947–956. https://doi.org/10.1111/jgs.12275

Wallston, K. A., Wallston, B. S., & DeVellis, R. (1978). Development of the Multidimensional Health Locus of Control (MHLC) scales. *Health Education Monographs, 6,* 160–70. https://doi.org/10.1177/109019817800600107

Willig, C. (2008). *Introducing qualitative research in psychology : adventures in theory and method*. Buckingham: Open University Press.

Wu, J. Q., Appleman, E. R., Salazar, R. D., & Ong, J. C. (2015). Cognitive behavioral therapy for insomnia comorbid with psychiatric and medical conditions: a meta-analysis,

Journal of the American Medical Association Internal Medicine, 175, 1461-1472. https://doi.org/10.1001/jamainternmed.2015.3006

Yardley, L. (2000). Dilemmas in qualitative health research. *Psychology & Health, 15,* 215–228. https://doi.org/10.1080/08870440008400302.

Appendix A: Ethics Approval and Research Governance Approval

Downloaded: 25/11/2018
Approved: 16/05/2018

Daniel Ulrich
Registration number: 160124400
Psychology
Programme: Doctorate of Clinical Psychology

Dear Daniel

PROJECT TITLE: Exploring the Experience of Sleep in People with Inflammatory Bowel Disease
APPLICATION: Reference Number 017733

On behalf of the University ethics reviewers who reviewed your project, I am pleased to inform you that on 16/05/2018 the above-named project was **approved** on ethics grounds, on the basis that you will adhere to the following documentation that you submitted for ethics review:

- University research ethics application form 017733 (dated 08/05/2018).
- Participant information sheet 1039427 version 1 (04/02/2018).
- Participant consent form 1039428 version 1 (04/02/2018).

If during the course of the project you need to deviate significantly from the above-approved documentation please inform me since written approval will be required.

Yours sincerely

Thomas Webb
Ethics Administrator
Psychology

The University Of Sheffield.

Department Of Psychology.
Clinical Psychology Unit.

Doctor of Clinical Psychology (DClin Psy) Programme
Clinical supervision training and NHS research training & consultancy.

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UK

Address: Daniel Ulrich
Clinical Psychologist
Department of Psychology
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Cathedral Court
Sheffield

Telephone: 0114 22 26650
Email: a.sinha@sheffield.ac.uk

Date: 26.11.2018

Project title: Exploring the Experience of Sleep in People with Inflammatory Bowel Disease

URMS number: **156076**

Dear Daniel,

The University has reviewed the following documents:

1. A University approved URMS costing record;
2. Confirmation of independent scientific approval;
3. Confirmation of independent ethics approval.

All the above documents are in place. Therefore, the University now **confirms** that it is the project's research governance sponsor and, as research governance sponsor, **authorises** the project to commence any non-NHS research activities. Please note that NHS R&D/HRA approval will be required before the commencement of any activities which do involve the NHS.

You are expected to deliver the research project in accordance with the University's policies and procedures, which includes the University's Good Research & Innovation Practices Policy: www.shef.ac.uk/ris/other/gov-ethics/grippolicy, Ethics Policy: www.sheffield.ac.uk/ris/other/gov-ethics/ethicspolicy and Data Protection Policies: www.shef.ac.uk/cics/records

Your Supervisor, with your support and input, is responsible for providing up-to-date study documentation to all relevant sites, and for monitoring the project on an ongoing basis. Your Head of Department is responsible for independently monitoring the project as appropriate. The project may be audited during or after its lifetime by the University. The monitoring responsibilities are listed in **Annex 1**.

Yours sincerely

Andrew Thompson

cc. Georgina Rowse
Head of Department/School: Glenn Waller

Annex 1

To access the University's research governance website go to:
www.sheffield.ac.uk/ris/other/gov-ethics/governance

Monitoring responsibilities of the Supervisor:

The primary responsibility for project monitoring lies with the Supervisor. You agree to:

1. Establish a **site file** before the start of the project and ensure it remains up to date over the project's entire lifetime:
   www.sheffield.ac.uk/ris/other/gov-ethics/governance/rg-forms

2. Provide **progress reports/written updates** to the Head of Department at reasonable points over the project's lifetime, for example at:

   a. three months after the project has started; and
   b. on an annual basis (only if the project lasts for over 18 months); and
   c. at the end of the project.
   See: www.sheffield.ac.uk/ris/other/gov-ethics/governance/rg-forms

3. Report **adverse events**, should they occur, to the Head of Department:
   www.sheffield.ac.uk/ris/other/gov-ethics/governance/rg-forms

4. Provide progress reports to the research funder (if externally-funded).

5. Establish appropriate arrangements for recording, reporting and reviewing significant developments as the research proceeds – i.e. developments that have a significant impact in relation to one or more of the following:

   - the safety or physical or mental integrity of the participants in the project;
   - the project's scientific direction;
   - the conduct or management of the project.

   The Head of Department should be alerted to significant developments in advance wherever possible.

6. Establish appropriate arrangements to record, handle and, as appropriate, store all information collected for or as part of the research project in such a way that it can be accurately reported, interpreted and verified without compromising the confidentiality of individual care users.

****

Monitoring responsibilities of the Head of Department

You agree to:

1. Review the **standard monitoring progress reports**, submitted by the Supervisor, and follow up any issues or concerns that the reports raise with the Supervisor.

2. Verify that **adverse events**, should they occur, have been reported properly and that actions have been taken to address the impact of the adverse event(s) and/or to limit the risk of similar adverse event(s) reoccurring.

3. Verify that a project is complying with any **ethics conditions** (e.g. that the information sheet and consent form approved by ethics reviewers is being used; e.g. that informed consent has been obtained from participants).

4. Introduce a form of **correspondence** (e.g. regular email, annual meeting) with a project's Supervisor, that is **proportionate to the project's potential level of risk**, in order to verify that a project is complying with the approved protocol and/or with any research funder conditions. Whatever correspondence is chosen the Head of Department should, as a minimum, ensure that s/he is informed sufficiently in advance about significant developments wherever possible.

Appendix B: Sample consent form (second version, including Skype details)

The University Of Sheffield.

Participant Consent Form

Consent form for "Exploring the Experience of Sleep in People with Inflammatory Bowel Disease"

Please tick the appropriate boxes	Yes	No
Taking Part in the Project		
I have read and understood the project information sheet dated October 2nd 2018, or the project has been fully explained to me. (If you will answer No to this question please do not proceed with this consent form until you are fully aware of what your participation in the project will mean.)	☐	☐
I have been given the opportunity to ask questions about the project.	☐	☐
I agree to take part in the project. I understand that taking part in the project will include an interview with the researcher (either in person or by Skype software) about my sleep and IBD, and that this interview will be recorded and analysed. I also understand I will be asked to fill in questionnaires after the interview.	☐	☐
I understand that my taking part is voluntary and that I can pause or withdraw from the interview at any time, and that I can ask for my data to be removed from the project within the next 14 days. I understand that I do not have to give any reasons for why I no longer want to take part and there will be no adverse consequences if I choose to withdraw.	☐	☐
How my information will be used during and after the project		
I understand my personal details such as name, phone number, address and email address etc. **will not** be revealed to people outside the project.	☐	☐
I understand and agree that my words may be quoted in publications, reports, web pages, and other research outputs. I understand that I **will not** be named in these outputs unless I specifically request this.	☐	☐
I understand and agree that other authorised researchers will have access to this data **only** if they agree to preserve the confidentiality of the information as requested in this form.	☐	☐
I understand and agree that other authorised researchers may use my data in publications, reports, web pages, and other research outputs, **only** if they agree to preserve the confidentiality of the information as requested in this form.	☐	☐
I give permission for the interview and questionnaire that I provide to be deposited in Clinical Psychology Unit data depository so it can be used for future research and learning	☐	☐
So that the information you provide can be used legally by the researchers		
I agree to assign the copyright I hold in any materials generated as part of this project to The University of Sheffield.	☐	☐

Name of participant [printed] Signature Date

Name of Researcher [printed] Signature Date

Project contact details for further information:
Lead researcher: Daniel Ulrich (dulrich1@sheffield.ac.uk)
Supervisor: Dr Georgina Rowse (g.rowse@sheffield.ac.uk)

If you wish to complain about any aspect of this research, please contact Dr Rowse (above) or, if this is not satisfactory contact the head of the Department of Psychology Professor Glenn Waller (g.waller@sheffield.ac.uk)

The template of this consent form has been approved by the University of Sheffield Research Ethics Committee and is available to view here: https://www.sheffield.ac.uk/rs/ethicsandintegrity/ethicspolicy/further-guidance/homepage

Appendix C: Data Collection, Storage and Transcribing Guidelines

UREC May 2018

Specialist Research Ethics Guidance Paper

PRINCIPLES OF ANONYMITY, CONFIDENTIALITY AND DATA PROTECTION

Note: This guidance document aims to develop further the information relating to anonymity, confidentiality and data protection that is covered in the University's 'Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue', in line with changes to data protection legislation during 2018 (the implementation of the General Data Protection Regulation (GDPR) and the UK Data Protection Bill 2018), and provides signposting to guidance from useful external sources, in particular the Information Commissioner's Office, the Health Research Authority (HRA), which has produced useful guidance on implementing the GDPR for health research, the Medical Research Council's Regulatory Support Centre, and the EU's Article 29 Working Party. A useful practical summary by the HRA on the implications of the GDPR for research in the UK can be found here.

This document will be updated as further changes to legislation are put in place, and more guidance becomes available.

In summary:

If you are processing (i.e. collecting, storing, using, disclosing or destroying) *identifiable* personal information about *living* individuals, then you should ensure that you comply with the requirements of the General Data Protection Regulation (GDPR) and the Common Law Duty of Confidentiality. In the UK, once the Data Protection Bill becomes law, its requirements will also need to be met (staff and students working at the International Faculty in Greece will need to ensure that any relevant local data protection regulation is met in addition to the GDPR).

If you are processing (i.e. collecting, storing, using, disclosing or destroying) *identifiable* personal information about *deceased* individuals, then you should ensure that you comply with

the requirements of the Common Law Duty of Confidentiality. You should also be aware of the possibility of living individuals (e.g. relatives of the deceased) being identified in this information, which would then need to be treated in line with the relevant data protection legislation as stated in the previous paragraph.

If you are processing (i.e. collecting, storing, using, disclosing or destroying) *anonymised* personal information, whether relating to the living or the deceased, then your research activity falls outside the scope of these guidelines.

The use of *identifiable* personal information in research should be reduced so far as possible. You should think carefully about how it may be possible to use *less* identifiable data (e.g. rather than collecting full date of birth, would it be sufficient to collect only 'month and year'? Is it necessary to collect, or retain, the full post-code?). All processing of personal information should be defensible as both relevant and accurate.

If it is necessary to use identifiable personal information, you should aim at all times to ensure that the processing is defensible as both 'fair, lawful and transparent'. This requires you to be as transparent as possible about the uses to which data will be put and any risks involved. The data subject (i.e., the individual whose data are being processed) should be fully informed about how and why their data will be processed, including the legal basis for the processing (for most research this will be 'a task in the public interest'; additional conditions apply to Special Categories of personal data). You should usually only use identifiable personal information with the consent of the data subject. It may be possible to use such data without consent, providing consent is not being used as the legal basis for the processing (e.g. in the

case of research involving large datasets obtained from social media, where it may be infeasible to seek informed consent from all individuals concerned); however, consent is to be preferred unless it can be shown to be inappropriate for some reason.

You should ensure that personal information is kept secure at all times. The level of security should be proportionate to the risks but all personal information should be kept securely.

You should not keep personal information for longer than necessary; however, it is recognised that (as long as relevant conditions are satisfied) research may require the retention of data for long periods and this may be justified (e.g. to meet legal or funder requirements).

You should avoid disclosing identifiable information, including information that may be identifiable to others, wherever possible. If it is necessary to disclose personally identifiable information, or information that may be potentially identifiable, then this should usually only be done with the consent of the individual/s involved.

1. Introduction

A researcher who processes (i.e. collects, stores, uses, discloses or destroys) identifiable personal information - as defined in the box below - about living individuals, must comply with the requirements of the relevant data protection legislation, and the Common Law Duty of Confidentiality.

A researcher who processes identifiable personal information about deceased individuals, must still consider the requirements of the Common Law Duty of Confidentiality. Individuals have a reasonable expectation of privacy with respect to confidential information that refers to them. Any use of such confidential information that exceeds that which an ordinary person could reasonably be said to expect constitutes a breach of confidentiality. In addition, researchers should be aware of the possibility of living individuals (e.g. relatives of the deceased) being identified in this information, which would then need to be treated in line with the relevant data protection legislation as stated in the previous paragraph.

From 25 May 2018, the relevant data protection legislation in the EU (including the UK) will be the GDPR, and it is expected that the requirements of the GDPR will continue to apply in the UK after it leaves the EU. In addition, a new UK Data Protection Bill is progressing through Parliament which will make some specific changes/additions to the GRPR requirements, as they apply in the UK. Staff and students working at the International Faculty in Greece will need to ensure that any relevant local data protection regulation is met in addition to the GDPR.

The new legislation strengthens the rights of the individual whose data are being processed

(the 'data subject'), but also incorporates a range of exemptions from these rights for research purposes, providing appropriate safeguards are in place (e.g. there will normally be no right for research participants to access their data, rectify it or have the data erased, if this would prevent or seriously impair the achievement of the research purpose). For more guidance, see the Health Research Authority's guidance on 'Data Subject Rights and Research Exemptions'.

Any processing of personal data must have a defined 'Data Controller' in place (the individual or organisation which determines the purposes and means of processing personal data). For research undertaken by staff or students of the University of Sheffield, the Data Controller will usually be the University of Sheffield (i.e. not a particular individual or research team). Collaboration with other institutions may result in alternative or joint Data Controllers; there

should be agreement of which organisation(s) take on this responsibility at the outset of a research project, and this should be clearly documented via collaboration agreements.

Data protection legislation applies to 'personal data'. This is defined in the General Data Protection Regulation (GDPR) as:

'any information relating to an identified or identifiable natural (living) person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.'

The processing of fully anonymised personal information, whether relating to the living or the deceased, falls outside the scope of these legal requirements. Fully anonymised data are those from which the original data subject cannot be identified by any member of the research team, using either the dataset itself, or any other dataset that may be accessed by members of the research team.

In practice, in the case of discrete research projects, it is highly unlikely that members of the

research team will come into contact with data from other parts of the University that may result in the re-identification of participants whose data have been anonymised. However, researchers should think carefully about this possibility when seeking to anonymise their data; strictly speaking, if there is any possibility that anonymised data could be traced back to the data subject via any other data held by, or likely to come into the possession of, the Data Controller, then the data has in fact only been 'pseudonymised'. This means that it would in fact still be classed as personal data. Two examples of situations in which this problem is more likely to arise include:

● administrative research, in which research staff may have access to central University records that may link data to the participants that provided it;

● types of research in which there are particular identifiers that are widely used outside the research team (e.g. health research involving NHS numbers).

In addition, you should also be aware that, if the research team encompasses individuals from other organisations as part of a research collaboration, those individuals may have access to datasets that may enable the identification of participants.

The use of identifiable personal information in research should be reduced as far as possible, consistent with achieving the research aims. Thus researchers should always think carefully about (a) whether it is necessary to use identifiable personal information, (b) what is the earliest stage at which de-identification might be possible without compromising the integrity of the research and (c) how full, robust anonymisation can be achieved. All uses of personal information should be defensible as accurate, relevant and not excessive.

For more guidance on anonymisation, refer to the ICO's 'Anonymisation Code of Practice' (this is due to be updated soon, in line with GDPR but is still a helpful document).

2. Identifying an appropriate legal basis for the processing of personal data

If it is necessary to use identifiable personal data, then an appropriate legal basis for the processing of this data must be identified, and researchers must be explicit about this and

document it as part of their ethics application, and in the information they provide to participants.

Article 6 of the GDPR sets out six possible legal bases for processing of data that does not include 'Special Categories' (these are discussed later in this document and have additional requirements). At least one of these legal bases must apply whenever personal data is collected and used as part of a research project.

The University's view is that, for the vast majority of research undertaken at the University, the appropriate legal basis will be:

6(e) Public interest: the processing is necessary for you to perform a task in the public interest or for your official functions.

Further details are set out in the University's Privacy Notice, and a link to this can be included in the information that is provided to participants: https://www.sheffield.ac.uk/govern/dataprotection/privacy/general. Other legal bases are available and may apply to other aspects of

University business, but are unlikely to apply for research purposes. If you feel that the research you are undertaking cannot be justified as being 'a task in the public interest', please contact the University Research Ethics Committee for further guidance.

Although the legal basis for processing a person's data is most likely to be 'a task in the public interest' rather than 'consent', from an ethical perspective, obtaining a person's informed consent for their involvement in the research is still likely to be required, unless it can be shown to be inappropriate for some reason (e.g. if the material is already in the public domain, for example). If a researcher intends to process data without informed consent, then further advice should be sought from the University Research Ethics Committee.

Further guidance on legal bases is provided in the HRA's guidance document: 'A Lawful basis for health research under the Data Protection Law' and the MRC's guidance document: 'Guidance note 3: GDPR, Consent in Research and Confidentiality'.

3. Data Protection Safeguards

'Safeguards' are measures to protect the rights and freedoms of individuals whose personal data you are processing. Under the GDPR there is greater emphasis on implementing safeguards for research. In practical terms, this means giving careful consideration to:

- Only collecting personal data where it is necessary for the research purpose (known as 'data minimisation');
- Ensuring that data are pseudonymised or anonymised wherever possible and as early as possible;
- Ensuring appropriate arrangements are in place for security and storage of data, proportionate to the risks inherent in the nature of the data e.g. portable devices must be encrypted.

For processing of 'Special Category' personal data, additional safeguards will be required: Further information about this can be found in section 6 of this document: 'Research involving 'Special Categories' of personal data'.

It should be noted that safeguards will not be sufficient if the processing is likely to cause substantial damage or distress to an individual. In addition, currently, the GDPR states that

safeguards will not be sufficient if the processing is 'carried out for the purpose of measures or decisions with respect to a particular data subject'. An amendment stating that this will be allowed if the processing is for the purpose of 'approved medical research' (i.e. approved via the HRA, NHS research ethics committee, etc.) is being proposed as part of the Data Protection Bill, to prevent a negative impact on interventional health research.

More guidance on safeguards can be found in the Health Research Authority's guidance document: 'Data Protection Safeguards'.

4. The right to be informed

When gathering identifiable personal data researchers should aim at all times to ensure that its processing is defensible as 'fair, lawful and undertaken in a transparent manner'. This requires that the participant be provided with appropriate information about the uses to

which data will be put and any risks that might be involved. This information must be:

● Concise, transparent, intelligible

● Provided in easily accessible form, using clear, plain language

● Prepared in consideration of the needs of the audience e.g. information addressed specifically to a child

● Provided by an appropriate means (e.g. in writing, electronically, orally)

Under the GDPR, this information should specifically cover the legal basis that is being applied in order to process someone's personal data. In many contexts, taking into account the language and literacy of potential participants, a fact-sheet (often referred to as a participant information sheet) is a useful and documented means of providing this information. However, a 'layered' approach to providing this information may be useful (e.g. utilising webpages, posters, leaflets or newsletters as well as information sheets).

Taken together, the information provided should normally include:

• the nature and purpose of the project;

• the legal basis for the collection and use of the participants' data (and the additional condition(s) required for processing of 'Special Categories' of data, if required);

• the research methods to be employed by the project;

• full explanation of any technical terms used;

• the conditions under which the project will be conducted;

• who is undertaking and who is sponsoring the project (i.e. the details of the 'Data Controller', the research team, the funder and/or the research governance sponsor if applicable);

• the potential risks and inconveniences that may arise;

• the potential benefits that may result;

• what participation in the research will require in practice and what data will be collected;

• information about the right to withdraw from the research, and how to go about

this;

• what will happen to the data and who will have access to it (including any further use of the data beyond the immediate research project, any intention to transfer data to any third party, and the appropriate safeguards which will be adopted);

• how participant confidentiality will be safeguarded;

• how the data will be stored, and when it will be destroyed (or the criteria that will be used to determine when it will be destroyed);

• how to raise concerns, or to complain, about the research, and to whom (see note below); and

• the consequences of non-participation (such as alternative treatments in the case of some medical research, or alternative educational activities in the case of some educational research).

In connection with the above, it should be noted that the appropriate channels for the registration of complaints within the University, should a participant be unhappy with their treatment and unable to resolve them directly with the researcher and/or research team, is the Head of the relevant department. Participants should also be informed of their right to contact the Data Protection Officer for the Data Controller organisation, or the Information Commissioner's Office, if they have a complaint about the use of their personal information within the research.

Personal information should not be retained for longer than necessary. However, it is recognised that research may require the retention of data for long periods and that this may be justified, for example due to funder requirements. The participant should be given full information about how their data will be used, how it will be stored and for how long (if the latter is not possible, then the participant should be informed of the criteria that will be used to determine retention periods.)

5. Research involving 'Special Categories' of personal data

Sensitive data is referred to as 'Special Category' data in the GDPR and UK Data Protection Bill, and includes:

- data revealing racial or ethnic origin,
- political opinions, religious or philosophical beliefs, or
- trade union membership;
- the processing of genetic data or biometric data for the purpose of uniquely identifying a natural (living) person;
- data concerning health;
- data concerning a natural person's sex life or sexual orientation; or
- criminal records or allegations of criminal/illegal activities

[It should be noted that from an ethical perspective, the University considers a number of other types of data to be sensitive: the full list can be found in Research Ethics Policy Note no.6 'Research involving vulnerable people': https://www.sheffield.ac.uk/polopoly_fs/1.112756!/file/Research-Ethics-Policy-Note-6.pdf.

In order to process Special Category data lawfully, you must identify both a lawful basis under Article 6 of the GDPR (set out in section 2 of this document) and a separate condition for processing Special Category data under Article 9(2). The condition most likely to apply to research is:

9(2)(j) processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes

In order for this condition to be relied upon, it must be justifiable that this processing is in the public interest, must not cause substantial damage or distress to the data subject, and appropriate safeguards must be in place (e.g. processes to ensure data security - see section 3 of this document for details of safeguards). The University's view is that the information provided in an ethics application (e.g. concerning the aims and objectives of the research), and the assessment of this via the process of ethical review, will meet the researcher's obligations in respect of the need to justify that the research is in the public interest.

Other conditions which may apply in certain circumstances (researchers should contact the University Research Ethics Committee for advice if they wish to rely on these) are:

9(2)(a) the data subject has given explicit consent to the processing of the personal data for one or more specified purposes (ONLY TO BE USED IF NO OTHER CONDITION IS POSSIBLE – MORE STRINGENT CONSENT REQUIREMENTS WILL APPLY);

9(2)(e) processing relates to personal data which are manifestly made public by the data subject (this may apply when using certain social media data, for example);

9(2)(i) processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices.

Researchers who need to process Special Category personal data as part of their projects must explicitly state which legal basis AND which condition they are relying on, as part of their ethics application, and in the information they supply to participants.

Further guidance on the use of Special Categories of personal data for research purposes can be found in the Health Research Authority's document 'A Lawful Basis for Health Research under Data Protection Law'. This is primarily intended for health research but has wider applicability.

6. Re-using personal data for a different purpose & sharing with third parties

If a researcher wishes to re-use personal data that were collected for a particular purpose (e.g. a specific research project) for a new purpose (e.g. a new research project), and the data subject was not informed of this as part of the original informed consent procedures, then the researcher would be required to contact the data subject to inform them of this BEFORE the new processing commenced. If the data from the original project had already been fully anonymised before use in the second project, it would no longer constitute personal data and would therefore no longer be subject to data protection legislation and the data subject would not need to be contacted about the re-use of their data.

Where personal data is to be used by a researcher but they have NOT obtained the data directly from the data subject, the original data controller supplying the data must have informed the data subject of relevant information relating to this new processing. However, the receiving data controller should check that the providing data controller has met their obligations in this regard, and it is also good practice for the receiving data controller to provide relevant study-level information to the data subject.

Guidance on the relevant information that should be provided to the data subject in these circumstances, and the appropriate time frames for providing this information, are provided in the Health Research Authority's guidance document: 'Transparency, Health Research and Data Protection Law'.

In some circumstances, where personal data has NOT been obtained directly from the data subject, then the requirement to provide information to the data subject does not apply. This is where:

- Data has been pseudonymised and the new research activity is conducted without using identifiable data AND
- The provision of information would be impossible or involve a disproportionate effort (taking into consideration the number of participants, the age of the data, etc.) OR
- The provision of information would render impossible or seriously impair the objectives of the research.

Such a decision should be documented as part of the ethics review procedure. Where information is not provided to the data subjects due to the above exemptions, the information should instead be made publicly available (e.g. via a study webpage).

7. Common Law Duty of Confidentiality

The Common Law Duty of Confidentiality applies to research involving confidential personal information. Under the law of confidentiality, it is recognised that individuals have a reasonable expectation of privacy in relation to confidential information: any use of confidential

information that exceeds that which an ordinary person could reasonably be said to expect will constitute a breach of confidence.

Information will be considered confidential if an individual could be understood to have an objective reasonable expectation that the information will, in the circumstances, be kept private.

The easiest way to affect an individual's reasonable expectations is by explaining clearly what will happen with their personal information. Minimally, it should be made clear who will have access to their data, for what purpose(s), and for how long. Special considerations apply, and further specific advice should be sought, if considering seeking consent from children (0-18), from vulnerable persons with capacity to consent, and vulnerable persons without capacity to consent. Further information about these issues can be found in Research Ethics Policy Note no.2 'Principles of Consent':

https://www.sheffield.ac.uk/polopoly_fs/1.112749!/file/Research-Ethics-Policy-Note-2.pdf

If the intention is to use confidential information for a research purpose, then that should be clearly explained to an individual and their consent, either express or implied, sought for such use.

It should also be made clear to an individual that, wherever possible, there is an ongoing entitlement to withdraw consent to the processing of data for specific purposes. It may not always be possible to grant participants the entitlement to withdraw – for example if data have been anonymised, once publication has taken place, if participatory research processes mean that withdrawal will invalidate the contributions of others. The parameters within which withdrawal is possible should be explained to participants.

Researchers must make clear to participants any intention to provide third party access to confidential information, including after the project's conclusion. Without an express indication to the contrary, access must be restricted to the lead researcher and researchers directly involved in the research.

A researcher may not disclose the identity of a person, or disclose any information that could identify that person, without having obtained, in advance, that person's consent to do so, preferably in writing. If the research process is such that it is unavoidable that participants may in some circumstances be explicitly identified to others, then the researchers should explain why this is the case, and described what precautions may be taken (for example, the case of a focus group, this may include discussing confidentiality with all participants at the start of the session and asking individuals not to report details of what has been discussed outside of the group).

Researchers should be aware of the risks to anonymity, confidentiality and privacy posed by technologies of personal information storage and processing which directly identify a person: audio and video recordings, electronic and paper-based files, and e-mail records. Measures to prevent accidental breaches of confidentiality should be taken. Provisions for data security at the end of a project must be made (see the University of Sheffield's Good Research & Innovation Practices policy, Sections 3.1: https://www.sheffield.ac.uk/rs/ethicsandintegrity/index).

The use of confidential information in ways that are consistent with a valid consent will not represent a breach of confidentiality. However, it may be that there is no valid consent to rely upon and re-contact for fresh consent is not practicable. Any researcher considering this is advised to contact the UREC for further advice.

Appendix D: Ethical Approval Update to Use Skype Software

Hi Tom, — 2 Oct 2018, 10:11

As discussed, please find attached a completed request form. I have also attached the adapted information sheet.

Kind regards,

Dan Ulrich

Thomas Webb <t.webb@sheffield.ac.uk> — 1 Oct 2018, 16:15

to Georgina, me

Thanks Dan.

You seem to have thought through the potential ethical implications of interviewing participants via Skype. In terms of obtaining consent, it would probably be best to have this in writing, as you will have for the face-to-face interviews. Therefore, can I suggest that you email participants the information about the study and ask them to complete and return a consent form (by email is fine) before you conduct the interview? If you are happy to do so, then I think we can approve this amendment as a Chair's action.

Please note also that the University does not have a registrar and secretary and so this section of your information sheet needs to be removed and the correct procedure for complaints inserted in it's place - please see https://www.sheffield.ac.uk/polopoly_fs/1.646698!/file/ETHICS_CHECKLIST_for_staff_and_students_2016_17_updated_07_01_2017.pdf . You also need to include information about data protection in line with the GDPR regulations https://www.sheffield.ac.uk/polopoly_fs/1.780458!/file/Guidance_on_GDPR_for_researchers_in_psychology_FINAL.pdf . Therefore, can I ask that you amend your information sheet and send it to me to be checked?

Thanks,

Tom

As Chair, DESC

Appendix E: Research Information Sheet

Information sheet – 2nd October 2018

The University Of Sheffield.

Department of Psychology.
Clinical Psychology Unit.

Doctor of Clinical Psychology (DClin Psy) Programme
Clinical supervision training and NHS research training & consultancy.

Clinical Psychology Unit
Floor F
University of Sheffield
Cathedral Court
1 Vicar Lane
Sheffield S1 2LT

Telephone: 0114 222 6650

What is the purpose of the study?
This study aims to interview people diagnosed with Inflammatory Bowel Disorder to investigate their experiences of sleep.

Why have I been invited?
You have been invited because you have a diagnosis of Inflammatory Bowel Disorder.

Do I have to take part?
You are not obliged to take part if you do not wish to.

What will happen if I take part?
You will meet with the researcher who will interview you for about an hour (in person, or via Skype), asking questions about Inflammatory Bowel Disease and your experiences of sleep. After the interview, you will be asked to complete some questionnaires. You may meet in a neutral location (such as a room at the university), at your home, or conduct the interview via Skype. You will receive a copy of this information sheet, and will be asked to sign a form giving your consent to take part in the research.

What are the benefits of taking part?
By taking part in this research, you may be contributing to the understanding of sleep for people with Inflammatory Bowel Disease, which may lead to improvements in psychological help for people with sleep difficulties and IBD in the future.

What if there is a problem?
If you have any difficulties, you can request to pause or stop the interview at any time. You will not be asked to provide a reason for doing so, but you will be asked if there is anything the researcher can do to help. We can arrange to have breaks during the interview also.

If the interview is conducted via Skype, it is possible for the connection to unexpectedly break. In this case, the researcher will wait for you to contact them (via Skype or email) before attempting to re-establish the connection, in case you have decided to end the interview. If you do not contact the researcher within 1 week of the interview ending unexpectedly in this way, he will assume you have withdrawn your consent, and will not contact you again unless you request it.

Will all the information be kept confidential?
Yes. All interviews will be recorded on digital voice recorders that store encrypted files. All the information that we collect about you during the course of the research will be kept strictly confidential and will only be accessible to members of the research team, who are bound by ethical guidelines to keep the information private and confidential. No real names will be used, any identifying details will be obscured or changed and your information will be kept in encrypted files with 128-bit AES security. Interviews via Skype will be recorded at the researcher's location, with his questions and the output of his computer (i.e. your answers relayed through computer speakers) recorded. You will not be able to be identified in any reports or publications unless you have given your explicit consent for this. If you agree to us sharing the information you provide with other researchers (e.g. by making it available in a data archive) then your personal details will not be included unless you explicitly request this.

According to data protection legislation, we are required to inform you that the legal basis we are applying in order to process your personal data is that 'processing is necessary for the performance of a task carried out in the public interest' (Article 6(1)(e)). Further information can be found in the University's Privacy Notice https://www.sheffield.ac.uk/govern/data-protection/privacy/general.

The University of Sheffield will act as the Data Controller for this study. This means that the University is responsible for looking after your information and using it properly.

Will I receive any reimbursement of expenses for taking part in this research?
Yes, you will be provided with a day travel pass for public transport in Sheffield if you need to travel.

What will happen to the results of the study?
The results will appear as part of a doctoral thesis for the University of Sheffield Doctor of Clinical Psychology programme. In some cases, the author may then seek to publish these results in research journals to further understanding. Data from this study will be kept by the university for a maximum of 5 years post-qualification of the author (thus until approximately 2024) before it is destroyed. Should you wish to access the finished thesis, it will be available in the university's library.

Due to the nature of this research it is very likely that other researchers may find the data collected to be useful in answering future research questions. We will ask for your explicit consent for your data to be shared in this way. In all cases, your anonymity and confidentiality will be preserved.

What if I wish to complain about the way the study has been carried out?
If you wish to complain you can contact the researcher's supervisor or the director of research training at the Clinical Psychology Unit of the University of Sheffield:

Research supervisor: Dr Georgina Rowse (g.rowse@sheffield.ac.uk)
Director of Research Training: Dr Andrew Thompson (a.r.thompson@sheffield.ac.uk)

If you feel that your complaint has not been handled to your satisfaction following this, you can contact the head of the Department of Psychology: Professor Glenn Waller (g.waller@sheffield.ac.uk)

Can I withdraw at any time?
Due to the large amount of time it takes to transcribe interviews and then analyse them, it would be unfeasible to allow participants to withdraw their data at any time. However, for 14 days following the interview, if you wish to withdraw your data, you may do so by contacting the researcher (dulrich1@sheffield.ac.uk).

You are also free to pause or stop an interview at any time.

This project has been ethically approved via the University of Sheffield's Ethics Review Procedure, as administered by the Clinical Psychology Unit.

Contact Information
This research is being conducted by Daniel Ulrich, Trainee Clinical Psychologist. This research will be used to write a thesis which fulfils part of their doctoral training. If you have any questions about the research, you can leave a telephone message with the Research Support Officer on: 0114 222 6650 and he will ask Daniel to contact you.

Thank you for your interest in this project.

Appendix F: Recruitment tweet

Appendix G: University of Sheffield Lone Working Procedures

The University Of Sheffield.

Health & Safety.

Lone Working Guidelines

Employers have a duty to assess the risks faced by lone workers to determine: -

- Whether the work can be done safely by an unaccompanied person, and;
- What arrangements will be required to ensure that the person is not exposed to greater risks than employees who work together.

There is no clear definition of "Lone workers" but there are a large number of occupations that tend to work on their own. Examples are: -

- Doctors, district nurses, milkmen, salesmen, postmen, meter readers, maintenance men, lorry drivers.
- Less obvious examples include Home workers, mobile staff, teachers and lecturers, maintenance men on large industrial sites, security staff, cleaners, home visitors, etc.

However, most people at some time during their normal work activity will be engaged in a solo activity out of sight or sound of others. Similarly, someone has to be first to arrive at work and someone will be the last to leave. So concentrating on "aloneness" is unnecessarily limiting and the assessment of who is a lone worker must be based on those where the risks are higher, or those who work alone for considerable periods.

Legislation does not prohibit lone working in a general sense, although there are some types of work which require supervision, e.g. where young people are undergoing training, where work on live electrical equipment is being performed, or work under the Construction (Health, Safety & Welfare) Regulations.

The following "Lone worker checklist" should help you assess the risk to employees.

The University Of Sheffield.

Health & Safety.

Lone Worker Checklist

IN THE WORKPLACE

1. Does the workplace present a special hazard?
2. Is the access to, or exit from, the workplace safe?
3. Is the lighting and ventilation sufficient?
4. Will other adjacent processes and activities present a risk?
5. Is equipment safe and regularly maintained?
6. What risks will the worker be exposed to in the event of equipment failure?
7. Can substances and goods be handled safely?
8. Does the worker have the appropriate PPE and is he/she trained in its use?
9. Has the worker been trained to do the task properly?
10. Has the worker demonstrated his ability to do the task satisfactorily?
11. Is the worker medically fit to undertake the task?
12. Has the worker sufficient information about the job, equipment or substances?
13. Is cash is being handled, will he/she be at risk of violence?
14. Is the worker known to be reliable and seek help when they reach the limit of their knowledge or experience?
15. What is the appropriate level of supervision for the task?
16. What first aid provision is required?
17. How will you communicate with the worker to ensure his/her well being?
18. What are the arrangements for the worker in the event of an emergency?

Some useful pointers for managers

- Carry out informal inspections of the workplace and access on a regular basis to make sure the workplace is safe, and that people are working safely.
- Ask yourself how you would feel working there - would you feel safe?
- Check to make sure equipment is being maintained properly and records are kept.
- Make sure Materials Safety Data Sheets are available for all materials used and stored on the premises.
- Make sure risk assessments of all processes and activities are available for workers to refer to and that Safe Working Procedures are available.
- Make sure you know workers are fully aware of local rules, especially those related to "working out of hours".
- Check the "working out-of-hours" signing in book to make sure people are signing in, and that they have the Head of Departments permission.

- Periodically speak to those who work alone informally to find out if they have any concerns that can be dealt with easily.
- Make sure they know you do not want them to put themselves at risk. Ask them how the job could be made safer.
- Make sure you have a reliable system for contacting the lone worker and for establishing he is unharmed – this could be by a call-in system, a tracking device, a mobile phone, etc.
- Consider what emergency situations could arise and make sure you have procedures in place to cover them.

Useful pointers for staff

- Make sure someone knows where you are, and establish a contact system so that you can tell someone you're at work and when you're leaving.
- Don't do anything which you feel might put you in danger – report any dangerous incident or situation to your supervisor and ask for advice.
- Don't "cut corners" or rush the work, set yourself a reasonable target and work towards it – do your best.
- If you start to feel tired either stop for a short break, take a walk outside in the fresh air, or go home after contacting your supervisor and/or signing out.
- Make sure you know, and follow, relevant safe working procedures and guidelines for operating equipment and handling and using substances.
- If you don't know how to do something – don't do it – leave it until someone is around to help you.
- If you get injured stay calm, use your training, and if you need assistance contact Campus Control on 24085 or, if off campus, ring 999 giving clear instructions to them of where you are.

FOR HOME VISITS & MEETING THE PUBLIC

Have your loneworking staff: -

1. Been fully trained in strategies for the prevention of violence?
2. Been briefed about the areas where they work, or will work?
3. Been made aware of attitudes, traits or mannerisms that can annoy clients?
4. Been given all available information about the client from all relevant agencies?
5. Understood the importance of previewing cases?
6. Left an itinerary?
7. Made plans to keep in contact with colleagues?
8. The means to contact you – even when the switchboard may not be in use?
9. Got your home telephone number (and you theirs)?
10. A sound grasp of your organisation's preventative strategy?
11. Authority to arrange an accompanied visit, security escort, or use of a taxi?

Do your loneworking staff: -

1. Carry forms for reporting incidents, including violence or threats of violence?

2. Appreciate the need for this procedure and use it?
3. Know your attitude to premature termination of interviews?
4. Know how to control and defuse potentially violent situations?
5. Appreciate their responsibility for their own safety?
6. Understand the provisions for support by your organisation?

Some useful pointers: -

- Greet customers politely and with eye contact.
- Be aware of body language, signs of anger, tension, stress, or nervousness, adopting a hostile or aggressive stance. Bear in mind that you may be sending out body language messages.
- Avoid invading other people's personal space or touching them.
- If attacked your voice is the best defence – shout a positive command or yell loudly to "Stop".
- Have a mobile phone for emergencies but keep it secure and out of sight with a number pre-programmed for emergency use.
- Procedures for call-in of staff should be in place together with those for non-arrival.
- If using car parks in busy areas, use ones which are well-lit at night.
- Don't leave a brief case or lap top visible in the car. Lock all doors.
- Trust your intuition – if the situation feels unsafe or makes you uneasy, use a plausible excuse and get out. Consider taking a colleague with you.
- Consider meeting clients in public places e.g. hotels.

Appendix H: Transcriber confidentiality agreement

Type of project: Research thesis

Project title _ Exploring the Experience of Sleep in People with Inflammatory Bowel Disease

Researcher's name __Daniel Ulrich

The recording you are transcribing has been collected as part of a research project. Recordings may contain information of a very personal nature, which should be kept confidential and not disclosed to others. Maintaining this confidentiality is of utmost importance to the University.

We would like you to agree:

1. Not to disclose any information you may hear on the recording to others,

2. If transcribing digital recordings – only to accept files provided on an encrypted memory stick or via secure means such as UniDrive,

3. To keep the tapes and/or encrypted memory stick in a secure locked place when not in use,

4. When transcribing a recording ensure it cannot be heard by other people,

5. To adhere to the Guidelines for Transcribers (appended to this document) in relation to the use of computers and encrypted digital recorders, and

6. To show your transcription only to the relevant individual who is involved in the research project.

7. If you find that anyone speaking on a recording is known to you, we would like you to stop transcription work on that recording immediately and inform the person who has commissioned the work.

Declaration

I have read the above information, as well as the Guidelines for Transcribers, and I understand that:

1. I will discuss the content of the recording only with the individual involved in the research project

2. If transcribing digital recordings – I will only accept files provided on an encrypted memory stick or via secure means such as UniDrive

3. I will keep the tapes and/or encrypted memory stick in a secure place when not in use

4. When transcribing a recording I will ensure it cannot be heard by others

5. I will treat the transcription of the recording as confidential information

6. I will adhere to the requirements detailed in the Guidelines for transcribers in relation to transcribing recordings onto a computer and transcribing digital audio files

7. If the person being interviewed on the recordings is known to me I will undertake no further transcription work on the recording

I agree to act according to the above constraints

Your name ___Sharon Keighley_____

Signature _____Sharon Keighley_____

Date _____11/11/18_____

<u>Occasionally, the conversations on recordings can be distressing to hear. If you should find it upsetting, please stop the transcription and raise this with the researcher as soon as possible.</u>

Declaration

I have read the above information, as well as the Guidelines for Transcribers, and I understand that:

1. I will discuss the content of the recording only with the individual involved in the research project
2. If transcribing digital recordings – I will only accept files provided in an encrypted format
3. I will keep the encrypted files in a secure place when not in use
4. When transcribing a recording I will ensure it cannot be heard by others
5. I will treat the transcription of the recording as confidential information
6. I will adhere to the requirements detailed in the Guidelines for transcribers in relation to transcribing recordings onto a computer and transcribing digital audio files
7. If the person being interviewed on the recordings is known to me I will undertake no further transcription work on the recording

I agree to act according to the above constraints

Your name SARAH FOX

Signature SFOX

Date 25 JAN 19.

Occasionally, the conversations on recordings can be distressing to hear. If you should find it upsetting, please stop the transcription and raise this with the researcher as soon as possible.

Appendix I: Guidelines for transcribers

Guidelines for transcribers

Introduction

The course has created the guidelines below for anyone who is involved in transcribing data for staff or trainees in the Clinical Psychology Unit, University of Sheffield.

In addition to adhering to the following guidelines, **transcribers must sign a confidentiality form** prior to beginning any work. If you are unsure about any of the information given below, or for a copy of the confidentiality form, please contact the relevant trainee/member of staff.

When undertaking transcribing, whether from tapes or digital recording, you must:

- Password protect the computer files you are typing **before you type any text –** this can be done easily in Microsoft Word (instructions below)
- Anonymise any personal information contained in the data you are transcribing as you type e.g. names. Please contact trainee or member of staff who transcribing you are doing if you have any queries about this.
- Delete any files from your computer (including from your 'Trash' folder) once you have submitted your completed transcription.
- Keep the tapes/encrypted memory stick in a secure locked place when not in use.
- If transcribing from a digital recording, you must also adhere to the specific guidance on this (appendix 2 of this document).

Instructions for a password protecting files on a PC

For Word 2007:

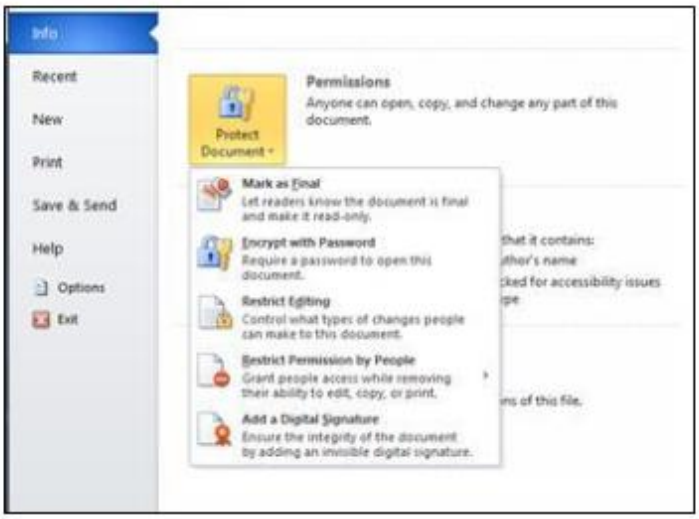
1) Open a blank Word document
2) Go to Save As and choose the compatible mode
3) Click Tools, then select General Options
4) Enter a password to open the document. You will asked to re-type this, then please ensure you click ok before closing the dialogue box.

For Word 2010 onwards:

APPLIES TO: Excel 2016, Word 2016, PowerPoint 2016, Excel 2013, Word 2013, PowerPoint 2013, Excel 2010, Word 2010, PowerPoint 2010, Excel Starter, Office 2010, Word Starter, Word Starter 2010

- In an open document, click **File** > **Info** > **Protect Document**.

  You see the following options.



- **Mark as Final:** Make the document read-only.

  When a document is marked as final, typing, editing commands, and proofing marks are disabled or turned off and the document becomes read-only. The **Mark as Final** command helps you communicate that you are sharing a completed version of a document. It also helps prevent reviewers or readers from making inadvertent changes to the document.

  When you mark a document as final, Word asks you to save the file. The next time you open it, you will see a yellow **MARKED AS FINAL** message at the top of the document. If you click **Edit Anyway**, the document will no longer be marked as final.

- **Encrypt with Password:** Set a password for the document.

  Caution: Keep your password in a safe place. If you lose or forget the password, it cannot be recovered

  When you select **Encrypt with Password**, the **Encrypt Document** dialog box appears. In the **Password** box, type a password, and then type it again when prompted. **Important:** Microsoft cannot retrieve lost or forgotten passwords, so keep a list of your passwords and corresponding file names in a safe place.

- **Restrict Editing:** Control what types of changes can be made to the document.

When you select **Restrict Editing**, you see three options:

- **Formatting restrictions** This reduces formatting options, preserving a look and feel. Click **Settings** to select which style are allowed.
- **Editing restrictions** You control how the file can be edited or you can disable editing. Click **Exceptions** or **More users** to control those who can edit.
- **Start enforcement** Click **Yes, Start Enforcing Protection** to select password protection or user authentication. You can also click **Restrict permission** to add or remove editors who'll have restricted permissions.
- **Restrict Permission by People:** Use a Windows Live ID to restrict permissions.

Use a Windows Live ID or a Microsoft Windows account to restrict permissions. You can apply permissions via a template that is used by your organization, or you can add permissions by clicking **Restrict Access.** To learn more about Information Rights Management see Information Rights Management in Office.

- **Add a Digital Signature:** Add a visible or invisible digital signature.

Digital signatures authenticate digital information such as documents, email messages, and macros by using computer cryptography. Digital signatures are created by typing a signature or by using an image of a signature to establish authenticity, integrity, and non-repudiation. See the link at the end of this topic to learn more about digital signatures.

To learn about digital signatures, see Digital signatures and certificates.

Instructions for password protecting files on a Mac:

1) Open a blank Word document
2) Go to Word on the menu bar and select Preferences
3) Click on Security and insert a password to open the document. You will be asked to re-type this, then click ok.

Appendix J: Pittsburgh Sleep Quality Index Sample

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Removed in line with copyright restrictions

Removed in line with copyright restrictions

Appendix K: Multidimensional Assessment of Fatigue Sample

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Appendix L: Inflammatory Bowel Disease Questionnaire Sample

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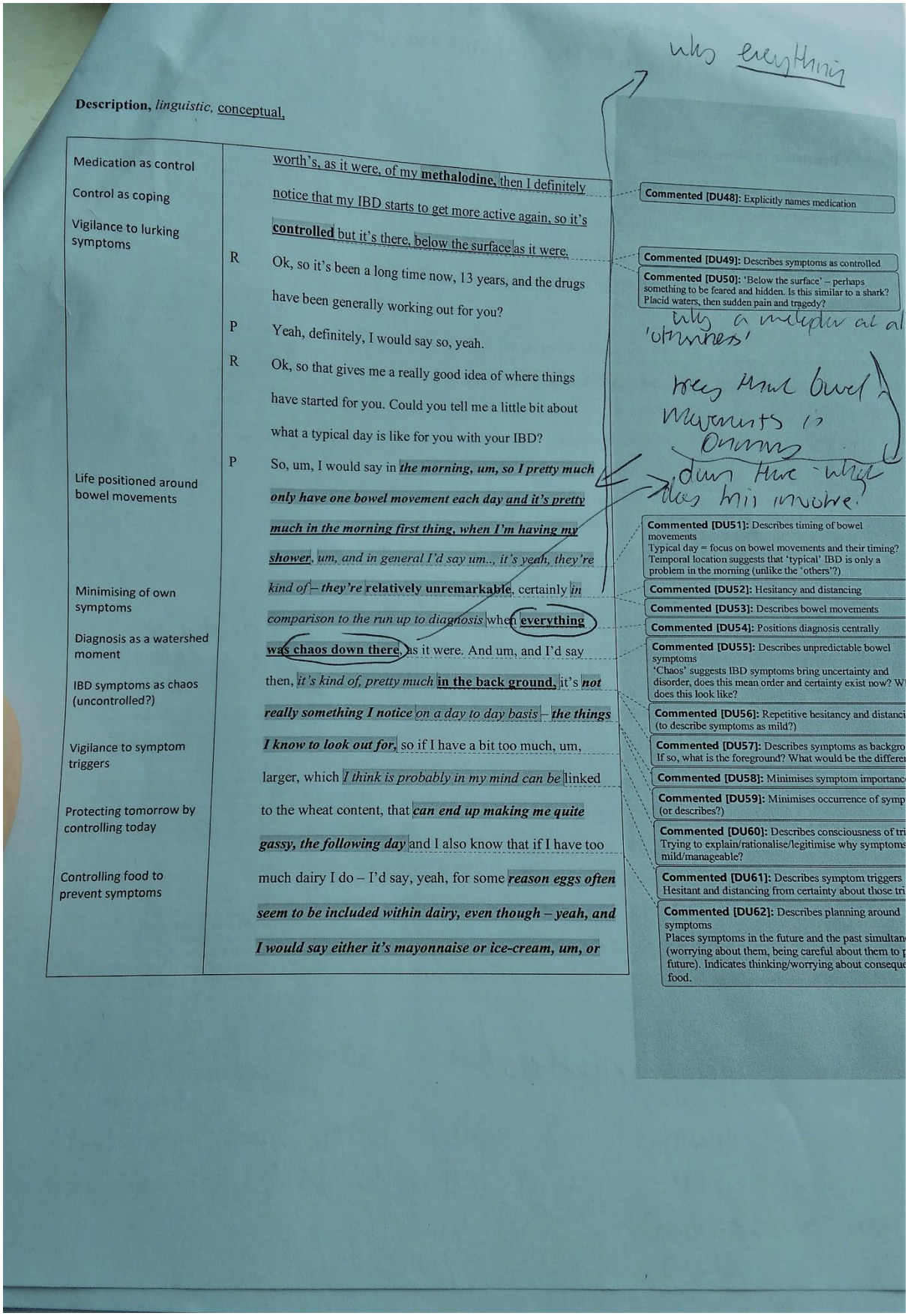
Appendix M: Line by Line Coding Examples



Description, *linguistic,* conceptual,

Medication as control		worth's, as it were, of my **methalodine,** then I definitely
Control as coping		notice that my IBD starts to get more active again, so it's
Vigilance to lurking symptoms		**controlled** but it's there, below the surface as it were.
	R	Ok, so it's been a long time now, 13 years, and the drugs
		have been generally working out for you?
	P	Yeah, definitely, I would say so, yeah.
	R	Ok, so that gives me a really good idea of where things
		have started for you. Could you tell me a little bit about
		what a typical day is like for you with your IBD?
	P	So, um, I would say in ***the morning, um, so I pretty much***
Life positioned around bowel movements		***only have one bowel movement each day and it's pretty***
		much in the morning first thing, when I'm having my
		shower*, um, and in general I'd say um.., it's yeah, they're*
Minimising of own symptoms		*kind of* – ***they're*** **relatively unremarkable**, certainly *in*
		comparison to the run up to diagnosis when **everything**
Diagnosis as a watershed moment		**was chaos down there**, as it were. And um, and I'd say
IBD symptoms as chaos (uncontrolled?)		then, *it's kind of, pretty much* **in the back ground,** it's ***not***
		really something I notice *on a day to day basis* – ***the things***
Vigilance to symptom triggers		***I know to look out for,*** so if I have a bit too much, um,
		larger, which *I think is probably in my mind can be* linked
Protecting tomorrow by controlling today		to the wheat content, that ***can end up making me quite***
		gassy, the following day and I also know that if I have too
Controlling food to prevent symptoms		much dairy I do – I'd say, yeah, for some ***reason eggs often***
		seem to be included within dairy, even though – yeah, and
		I would say either it's mayonnaise or ice-cream, um, or

Commented [DU48]: Explicitly names medication

Commented [DU49]: Describes symptoms as controlled

Commented [DU50]: 'Below the surface' – perhaps something to be feared and hidden. Is this similar to a shark? Placid waters, then sudden pain and tragedy?

Commented [DU51]: Describes timing of bowel movements
Typical day = focus on bowel movements and their timing? Temporal location suggests that 'typical' IBD is only a problem in the morning (unlike the 'others'?)

Commented [DU52]: Hesitancy and distancing

Commented [DU53]: Describes bowel movements

Commented [DU54]: Positions diagnosis centrally

Commented [DU55]: Describes unpredictable bowel symptoms
'Chaos' suggests IBD symptoms bring uncertainty and disorder, does this mean order and certainty exist now? W does this look like?

Commented [DU56]: Repetitive hesitancy and distanci (to describe symptoms as mild?)

Commented [DU57]: Describes symptoms as backgro If so, what is the foreground? What would be the differe

Commented [DU58]: Minimises symptom importanc

Commented [DU59]: Minimises occurrence of symp (or describes?)

Commented [DU60]: Describes consciousness of tri Trying to explain/rationalise/legitimise why symptoms mild/manageable?

Commented [DU61]: Describes symptom triggers Hesitant and distancing from certainty about those tri

Commented [DU62]: Describes planning around symptoms
Places symptoms in the future and the past simultan (worrying about them, being careful about them to p future). Indicates thinking/worrying about conseque food.

well, can I do it through diet and is there things I can and can't eat, so like the differences between the fats, I could um, I don't know enough about it and nobody does really. So I said can I be referred to a dietitian? And he said you can, but it's a 6 month waiting list to get an appointment. So I thought, oh, so then I did give in and go private to see a dietitian who supposedly specialised in IBD, however, that was questionable because she just gave me the print out that I'd printed out online. Ha, um, but it was kind of nice to hear that we were kind of doing the right thing, I guess, or as much as I could. But she *actually* pointed out that I don't have enough calcium in my diet, purely because I've never been a dairy lover. Um, and she sort of suggested to take a	Describes continuing to struggle with symptoms – attempting to control IBD through diet Concept that symptoms/disease are mysterious/unknowable - positions knowledge at level of consultants? (I don't know enough, nobody does) Seeks referral to dietitician Frustration at waitlist for dietitian (6 months) Sought private dietitian as alternative Concept – NHS dismissive/doesn't have resources/doesn't' try – forced to private medicine. Positions private medicine as equally uninformed – dietitian used internet printout. 'supposedly' specialised in IBD – positions private 'specialist' as equally uninformed. Concept – no one knows what to do with me or my illness – trying to take control yourself. Concept – what if there's nothing wrong with me? Is this dismissal of other's expertise defensive? "See, there is something wrong with me, just because you can't find it doesn't make me wrong"?

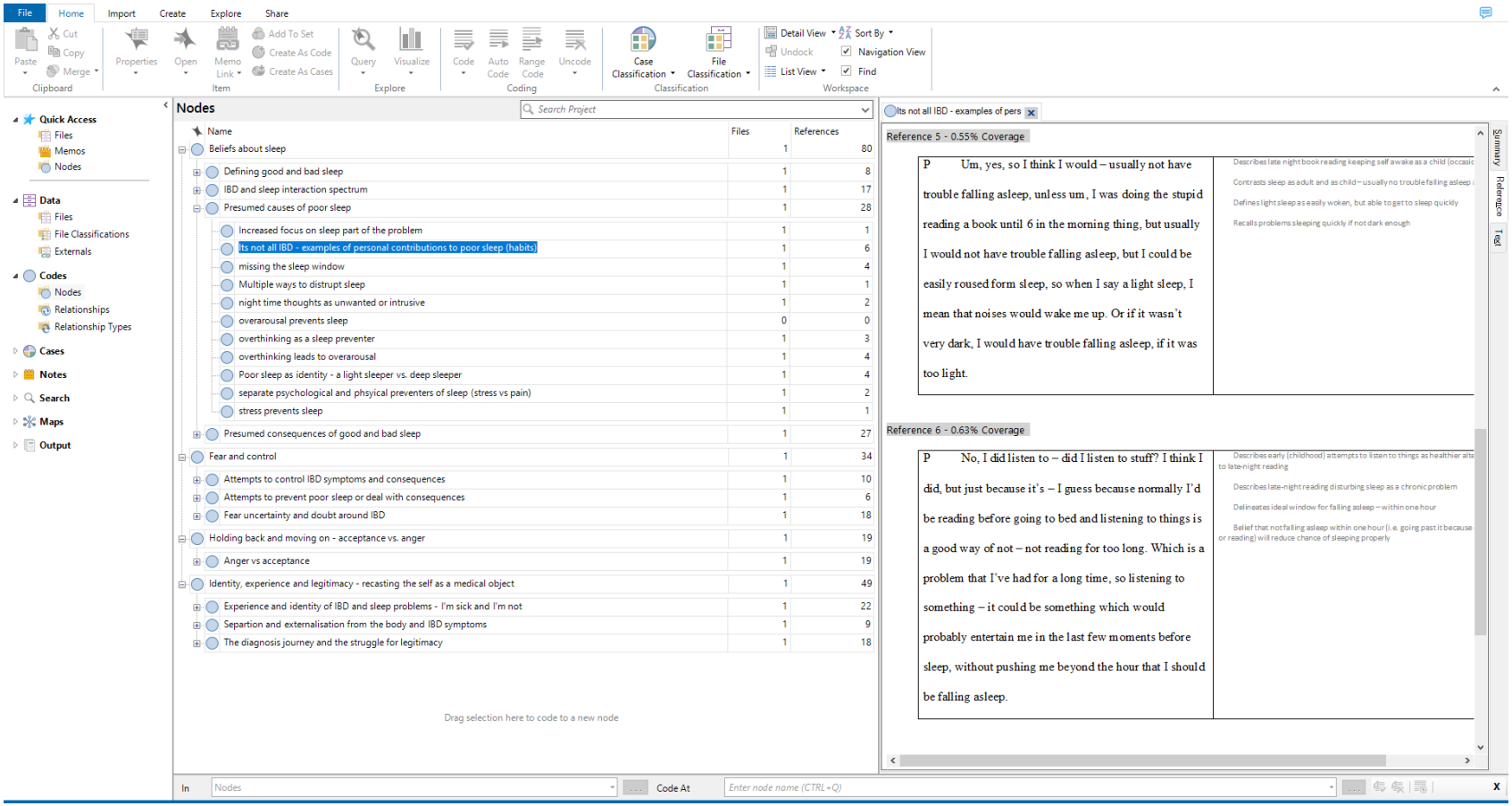
were very much like 'there's nothing wrong with you, you're a drunk student'. *Prescribed me Gaviscon*, and just sent me on my way. And it wasn't *actually* until a few months *after I'd kind of collapsed and got blue-lighted into hospital* um, even then they didn't believe me that it was anything to do with that, they actually thought I was having an ectopic pregnancy of all things – up here, which is very strange. Um, and again, they sort of said 'there's nothing wrong with you, you're fine.' Um, sent me on my way – that happened to just be in Y hospital, because that's where my parents are; I was in Uni in S. And then a few months later collapsed again, got taken to S hospital, so then managed to go under the gastroenterologist at H and he – he wasn't overly	'drunk student' – highlighting the dismissive / paternalistic attitude Brand name of over the counter drug emphasised – to demonstrate little effort made / problem felt to be 'common'? Actually – contrasts with before, highlights the lack of action/acceptance/investigation until major incident 'blue lighted' – metaphor evokes ambulance scenes, emergency – explicit about hospital 'even then they didn't believe me' – continuing story of dismissal – positions medical staff as unreasonable, intransigent 'of all things' – suggests medics were grasping at straws. Repeats dismissal by medics 'there's nothing wrong with you, you're fine' 'Sent me on my way' imagery of being physically dismissed and abandoned? 'collapsed' used twice – unclear if unconscious or overcome with illness/pain – word choice highlights feelings/beliefs about severity of IBD symptoms?

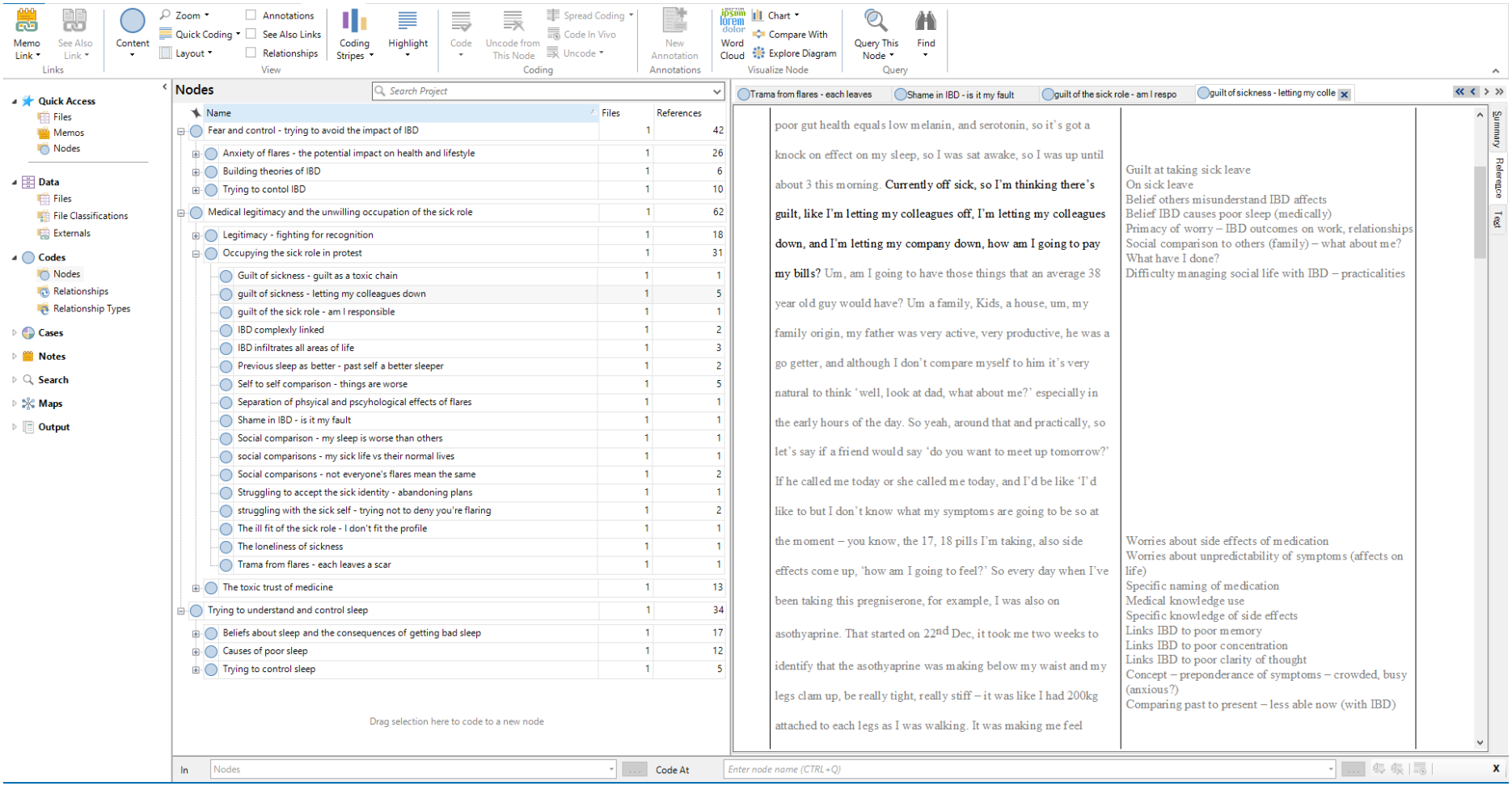
Appendix N: Theme Generation Examples Within Individual Transcripts

Communicating medical knowledge – setting the scene for the audience Learning from the past – moving on The pull of bad flares – omnipresent lurking threat Life separated by IBD – good and bad Centrality of medication – relief sought and sometimes gained Life interrupted – IBD splitting life Feeling left behind – peers continuing as 'normal' Helpless vs. control	evidence to suggest that it's entirely stress and they say like it's an interplay of environment and genes and stuff but I do think it were that period of stress that induced it because I were really hard on myself. Um, so yeah, so that's the first think I think of, I just jump straight back there and years in-between are a bit of a blur. Into chunks of good times, bad times.. yeah, it's gone very fast. But when – when I'm in the bad times, it's really bad, like I had a period of 7 years where I were relying on steroids and no other treatments really	Medical knowledge of Crohn's (research? Survival vs. power?) Belief Crohn's = environment/gene interaction. - Plus stress. Review of previous actions – pressure on self – separating from the old self – change? Diagnosis remains important - Strong memories - Traumatic? Life blurs after diagnosis Life into chunks – bad and good (life as dictated by Crohns? Bad times – 7 years of minimal treatments. Bad, really bad repetition – emphasis – emotional recollection? Making the point to novice audiences?

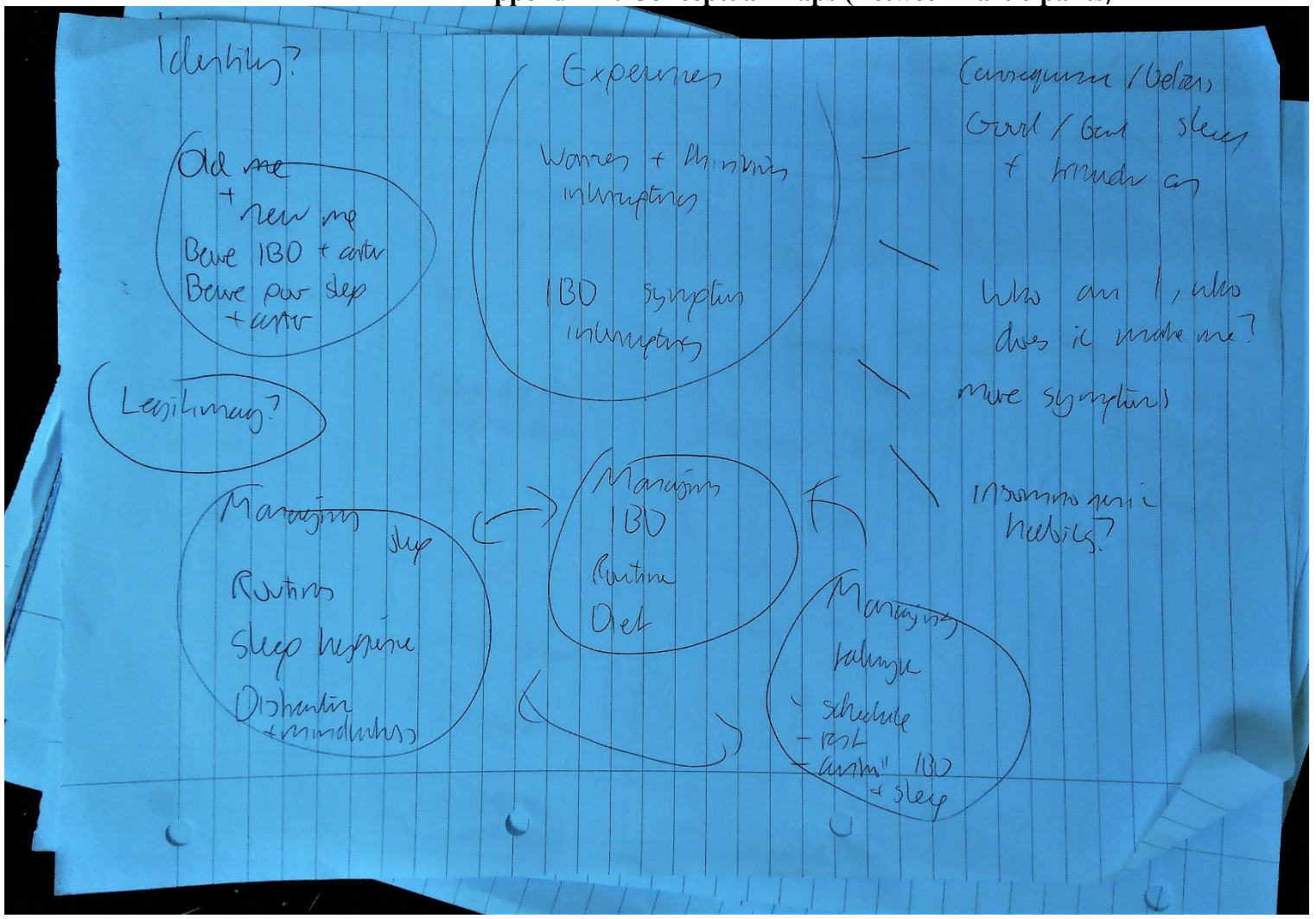
	you tell me a little bit about your IBD?	
Diagnosis story retelling Diagnosis as setting story – centrality and primacy Experience of dismissal and misdiagnosis Feeling passive vs. medical power IBD and identity IBD overtaking the self – had it more than not IBD identity as the unwanted sick role From resistance to acceptance of IBD	¶7: P Yeah, so, um, I was diagnosed with Crohn's disease at the age of 16 in 1998, 37 now. Um, and yeah, it came after like 3 years of having symptoms, them not really knowing what to do with me, thinking it were IBS, anorexia, um, it took quite a while for me to have the diagnostic test, you know, barium meal and then a colonoscopy which confirmed it, so yeah, so I've had it like 20 – 20 years now, yeah. I've had Crohn's more than I've not had it, which is a bit weird. Yeah. But, I don't	Primacy of diagnosis Specific age and date of diagnosis Highlights long time to get diagnosed Experience of medical confusion Receiving multiple (wrong) diagnoses (feeling passed about? Ignored?) Waiting and waiting for investigations – "quite a while" Highlights invasive investigations Long period diagnosed (20 years) Had IBD more than not – (Crohn's accommodated / resisted as part of identity?)

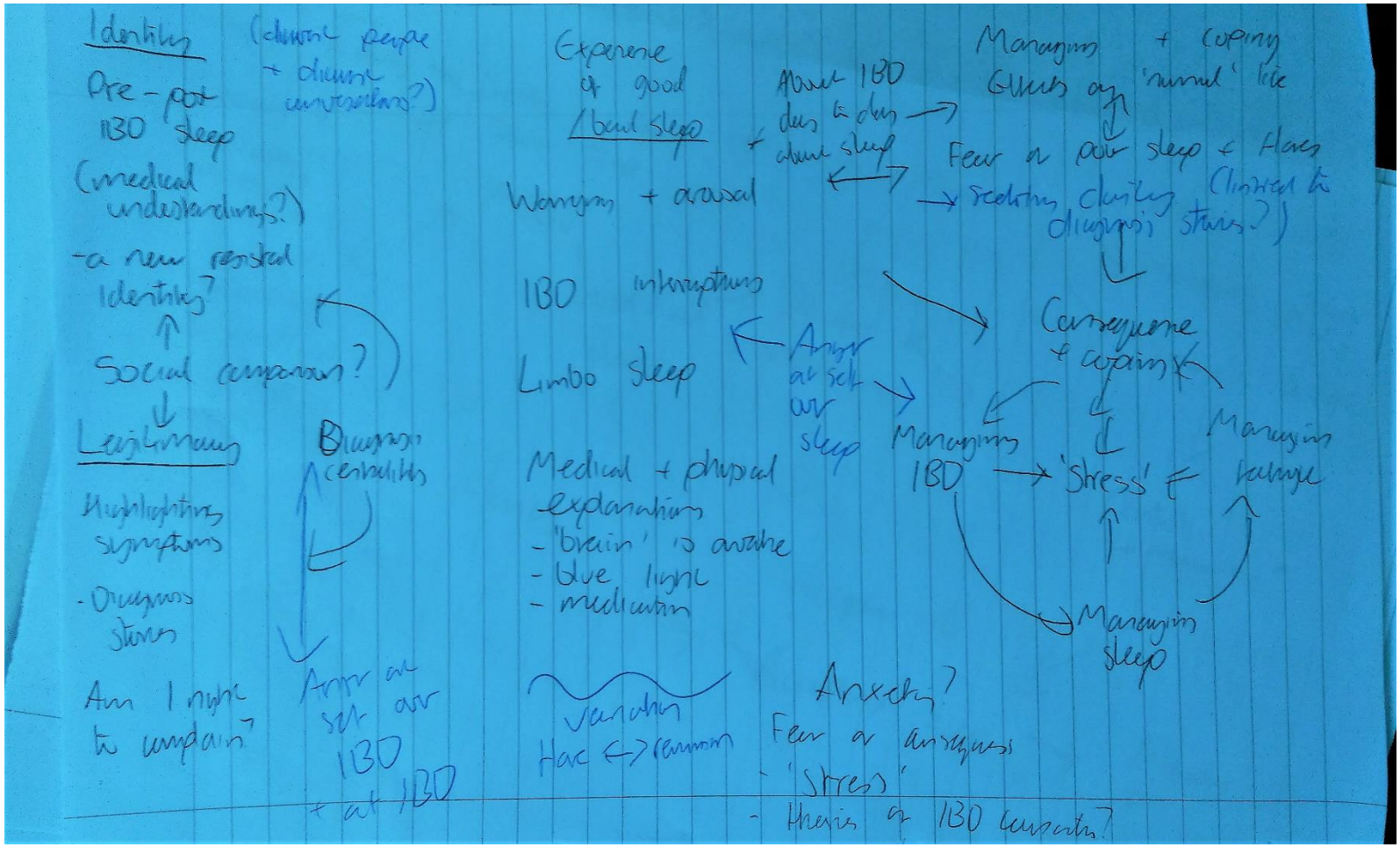
Appendix O: NVivo Screenshot During Within-participant Theme Generation



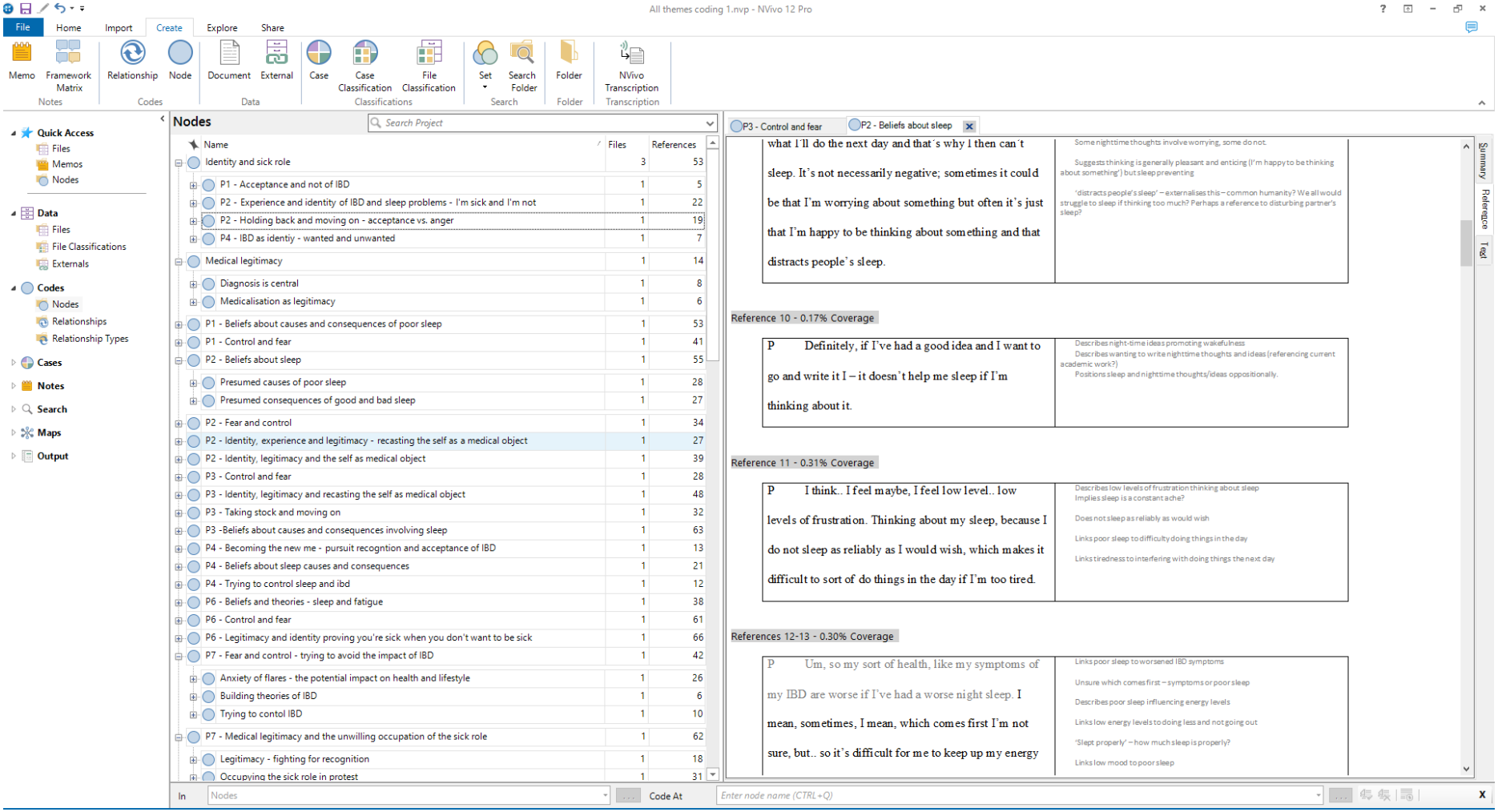

Memo Link
See Also Link
Content
Zoom
Quick Coding
Layout
Annotations
See Also Links
Relationships
Coding Stripes
Highlight
Code
Uncode from This Node
Spread Coding
Code In Vivo
Uncode
New Annotation
Word Cloud
Chart
Compare With
Explore Diagram
Query This Node
Find
Links
View
Coding
Annotations
Visualize Node
Query
Quick Access
Files
Memos
Nodes
Data
Files
File Classifications
Externals
Codes
Nodes
Relationships
Relationship Types
Cases
Notes
Search
Maps
Output
Nodes
Search Project
Name
Files
References
Fear and control - trying to avoid the impact of IBD 1 42
Anxiety of flares - the potential impact on health and lifestyle 1 26
Building theories of IBD 1 6
Trying to contol IBD 1 10
Medical legitimacy and the unwilling occupation of the sick role 1 62
Legitimacy - fighting for recognition 1 18
Occupying the sick role in protest 1 31
Guilt of sickness - guilt as a toxic chain 1 1
guilt of sickness - letting my colleagues down 1 5
guilt of the sick role - am I responsible 1 1
IBD complexly linked 1 2
IBD infiltrates all areas of life 1 3
Previous sleep as better - past self a better sleeper 1 2
Self to self comparison - things are worse 1 5
Separation of phsyical and pscyhological effects of flares 1 1
Shame in IBD - is it my fault 1 1
Social comparison - my sleep is worse than others 1 1
social comparisons - my sick life vs their normal lives 1 1
Social comparisons - not everyone's flares mean the same 1 2
Struggling to accept the sick identity - abandoning plans 1 1
struggling with the sick self - trying not to deny you're flaring 1 2
The ill fit of the sick role - I don't fit the profile 1 1
The loneliness of sickness 1 1
Trama from flares - each leaves a scar 1 1
The toxic trust of medicine 1 13
Trying to understand and control sleep 1 34
Beliefs about sleep and the consequences of getting bad sleep 1 17
Causes of poor sleep 1 12
Trying to control sleep 1 5
Drag selection here to code to a new node
Trama from flares - each leaves
Shame in IBD - is it my fault
guilt of the sick role - am I respo
guilt of sickness - letting my colle
poor gut health equals low melanin, and serotonin, so it's got a knock on effect on my sleep, so I was sat awake, so I was up until about 3 this morning. Currently off sick, so I'm thinking there's guilt, like I'm letting my colleagues off, I'm letting my colleagues down, and I'm letting my company down, how am I going to pay my bills? Um, am I going to have those things that an average 38 year old guy would have? Um a family, Kids, a house, um, my family origin, my father was very active, very productive, he was a go getter, and although I don't compare myself to him it's very natural to think 'well, look at dad, what about me?' especially in the early hours of the day. So yeah, around that and practically, so let's say if a friend would say 'do you want to meet up tomorrow?' If he called me today or she called me today, and I'd be like 'I'd like to but I don't know what my symptoms are going to be so at the moment – you know, the 17, 18 pills I'm taking, also side effects come up, 'how am I going to feel?' So every day when I've been taking this pregniserone, for example, I was also on asothyaprine. That started on 22nd Dec, it took me two weeks to identify that the asothyaprine was making below my waist and my legs clam up, be really tight, really stiff – it was like I had 200kg attached to each legs as I was walking. It was making me feel
Guilt at taking sick leave
On sick leave
Belief others misunderstand IBD affects
Belief IBD causes poor sleep (medically)
Primacy of worry – IBD outcomes on work, relationships
Social comparison to others (family) – what about me?
What have I done?
Difficulty managing social life with IBD – practicalities
Worries about side effects of medication
Worries about unpredictability of symptoms (affects on life)
Specific naming of medication
Medical knowledge use
Specific knowledge of side effects
Links IBD to poor memory
Links IBD to poor concentration
Links IBD to poor clarity of thought
Concept – preponderance of symptoms – crowded, busy (anxious?)
Comparing past to present – less able now (with IBD)
Summary
Reference
Text
In
Nodes
Code At
Enter node name (CTRL+Q)

Appendix P: Conceptual Maps (Between Participants)




Identity
(chronic people + chronic conversations?)
Pre-post IBD sleep
(medical understandings?)
-a new rooted identity?
Social comparison?
Legitimacy
Highlighting symptoms
- Diagnosis stories
Am I right to complain?
Blaming (sensibility)
Anger at self over IBD + at IBD
Experience of good / bad sleep
Worrying + arousal
IBD interruptions
Limbo sleep
Medical + physical explanations
- 'brain' is awake
- blue light
- medication
Variation
Have ↔ remember
Anger at self over sleep
Managing + coping
Efforts on 'normal' life
Fear of poor sleep + flares
→ resisting, clarity (linked to diagnosis stories?)
Consequence + cost
Managing IBD
'Stress'
Managing sleep
Anxiety?
Fear of consequences
- 'stress'
- theories of IBD (experts?)

Appendix Q: NVivo Screenshot During Inter-participant Theme Generation



Appendix R: Declaration of Participant Consultation During Analysis

Exploring the Experience of Sleep in People with Inflammatory Bowel Disease

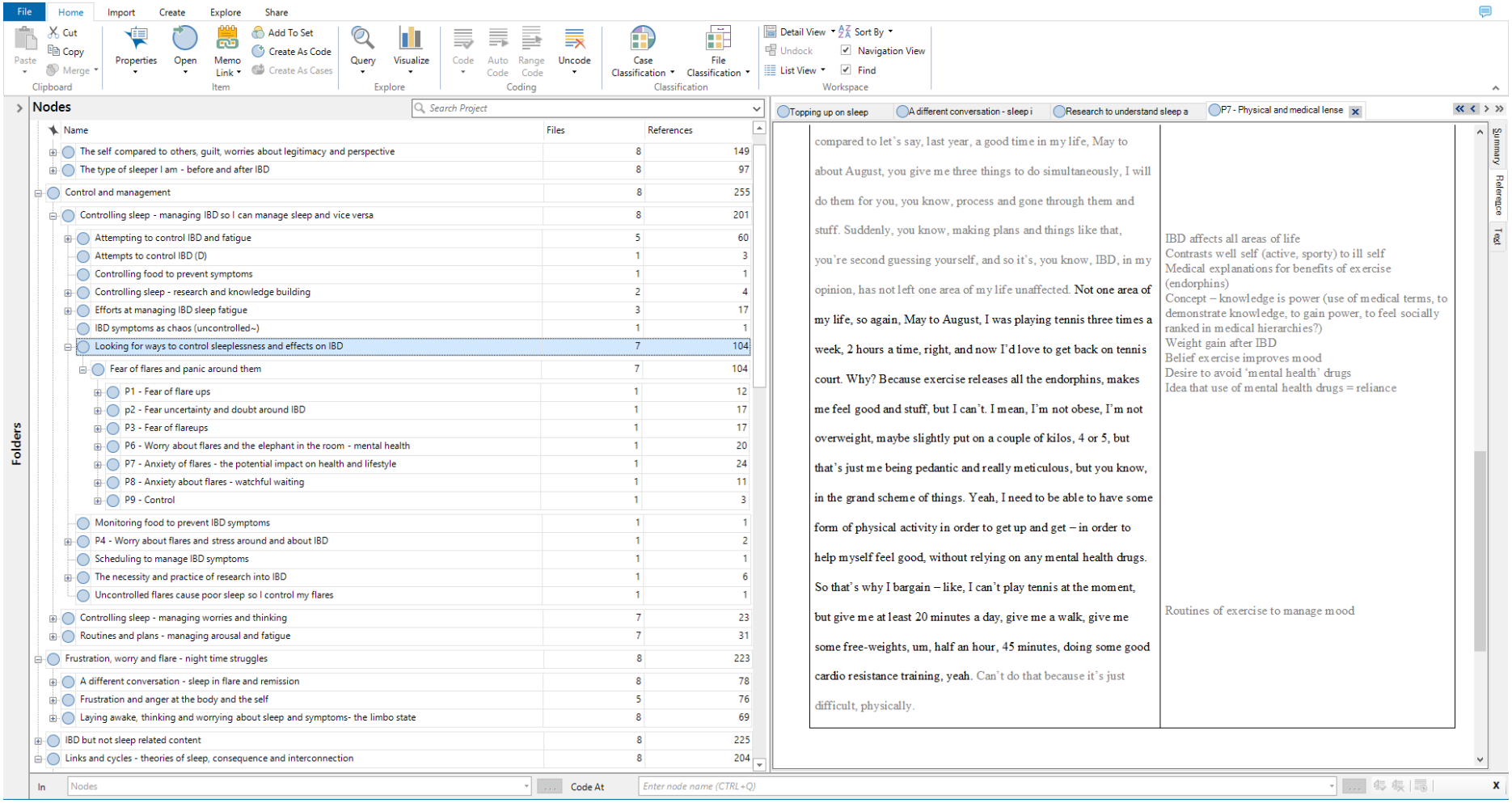
I can confirm that my opinion was sought on the coding and interpretation of excerpts of my interview with the researcher, Daniel Ulrich. I have personally reviewed excerpts of my interview and discussed the resulting data with the researcher.

Name: [redacted]

Date: 23/04/19.

Signature: [redacted]

Appendix S: Refining Codes Following Participant Discussion and Research Supervision



Appendix T: Coding Process Audit by Peer Researcher

Peer Audit - The Experience of Sleep in People with Inflammatory Bowel Disease: An Interpretative Phenomenological Analysis

(adapted from Elliot, Fischer & Rennie, 1999; Yardley, 2000).

Please underline or highlight the appropriate response.

Situating the sample

1. Did the researcher provide descriptive data about the participants, including data directly relevant to the phenomenon of interest (such as demographics, IBD diagnosis and severity, sleep quality)? **Yes / Partially / No**

Analysis credibility

2. Did the researcher provide examples of the analysis process (for example, sections of coding, specifics of how analysis was performed)? **Yes / Partially / No**

3. Did the researcher attempt to check the credibility of results by discussion with peers, supervisors or participants? **Yes / Partially / No**

4. Does coding appear to be systematic (i.e. line by line)? **Yes / Partially / No**

5. Do codes appear to reflect a reasonable interpretation of the data? **Yes / Partially / No**

6. Did the researcher appear to define themes and suggest structure or grouping to these themes (i.e. super-ordinate and sub-ordinate themes)? **Yes / Partially / No**

General vs. specific

7. Are the questions asked during interviews on-topic to achieve the stated aim of the research? **Yes / Partially / No**

8. Is the analysis process informing these aims? **Yes / Partially / No**

9. Did the researcher describe limitations of this sample and focus (i.e. generalisability concerns)? **Yes / Partially / No**

Reflexivity and perspective

10. Did the researcher make efforts to consider the impact of their theoretical orientations, assumptions, interests and values upon the interviewing and analysis processes? **Yes / Partially / No**

11. Did the researcher demonstrate use of reflexive methods such as diary keeping or reflective comments in coding notes? **Yes / Partially / No**

12. Did the researcher provide an excerpt of reflexive materials for the auditor? **Yes / Partially / No**

Audit date: 18/05/2019

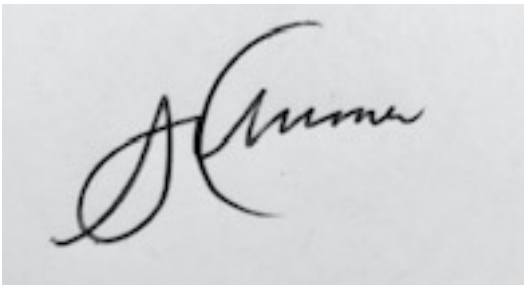
Researcher: Mr Daniel Ulrich (Trainee Clinical Psychologist)

Researcher's signature (digital):

Auditor:

Miss Aisling McFadden (Trainee Clinical Psychologist; Peer qualitative researcher)

Auditor's signature (digital):



Appendix U: Reflexive Diary Excerpts

Prior to Interview 1

Morning prior to interview of P1

Somewhat anxious about upcoming interview.

Have re-read the relevant area of Smith et al IPA book. Note to self to tolerate silence, particularly as anxious that interviewee may not provide enough.

Know that booked room is rather cold, and concerned about this impacting interview. May ask participant if she is ok with the temperature. If not, I can book a room at the Diamond and interview her in a better environment later on.

Re-read protocol this morning, feel quite 'open' at the moment, as don't really know enough about IBD to draw many conclusions. Wonder if this participant will want to appear more well and adjusted (as currently at university and apparently functioning well).

Note to self: Watch for leading questions towards CBT areas (i.e. beliefs about sleep), re-check transcript after and consider if co-constructing. Check this again when coding, as reading lots about CBT-I for meta.

Following Interview 2

Noticed this interview felt much more driven by the participant. She offered some conceptions of IBD and sleep as projections (humanoid characters) that felt important at the time, a real window into her experience. I wonder if this was more interesting to me than her? Felt like she had been struggling for a long time, yet she seemed relatively ambivalent about this.

Conversation began somewhat formal and became more personal as time went on, noticed her answers got longer and more verbose. Context of interview may be a little lost in the transcript, as she's just back to university completing a master's degree and (I think) was deep in her reading, so some answers reflect academic struggle.

Noticed that she used humour several times, perhaps defensively when feeling embarrassed. Wondered if I had been too cold / professional for the interview and prompted defensiveness initially? I felt she was very likeable in the preamble conversation, and tried not to let the interview become too informal.

Noticed myself feeling sympathy for her struggle with sleep, able to empathise as also struggling with sleep and writing academic work. Noticed her worries echoed my own, tried not to let this influence me into prompting exploration (i.e. my anxiety, not hers).

A couple of times noticed explanations linked specifically how IBD can interrupt sleep (though she noted it doesn't actually happen much to her at the moment). Really seemed to lean on severity at times, felt that there was an element of ensuring her problems weren't dismissed here. Will have to see if this seems apparent on re-listening.

Following P6 interview

Good interview, good flow and lots to say. Seems to be managing well, but very very busy trying to keep on top of it all like P4?

Works allied to psychology (discussed after interview). Interested in getting on DClin course, wonder if this added to psychological explanations of sleep?

Consider for analysis: Do questions prompt psychological answers? Does participant acknowledge bias in knowledge?

Coding Interview 7

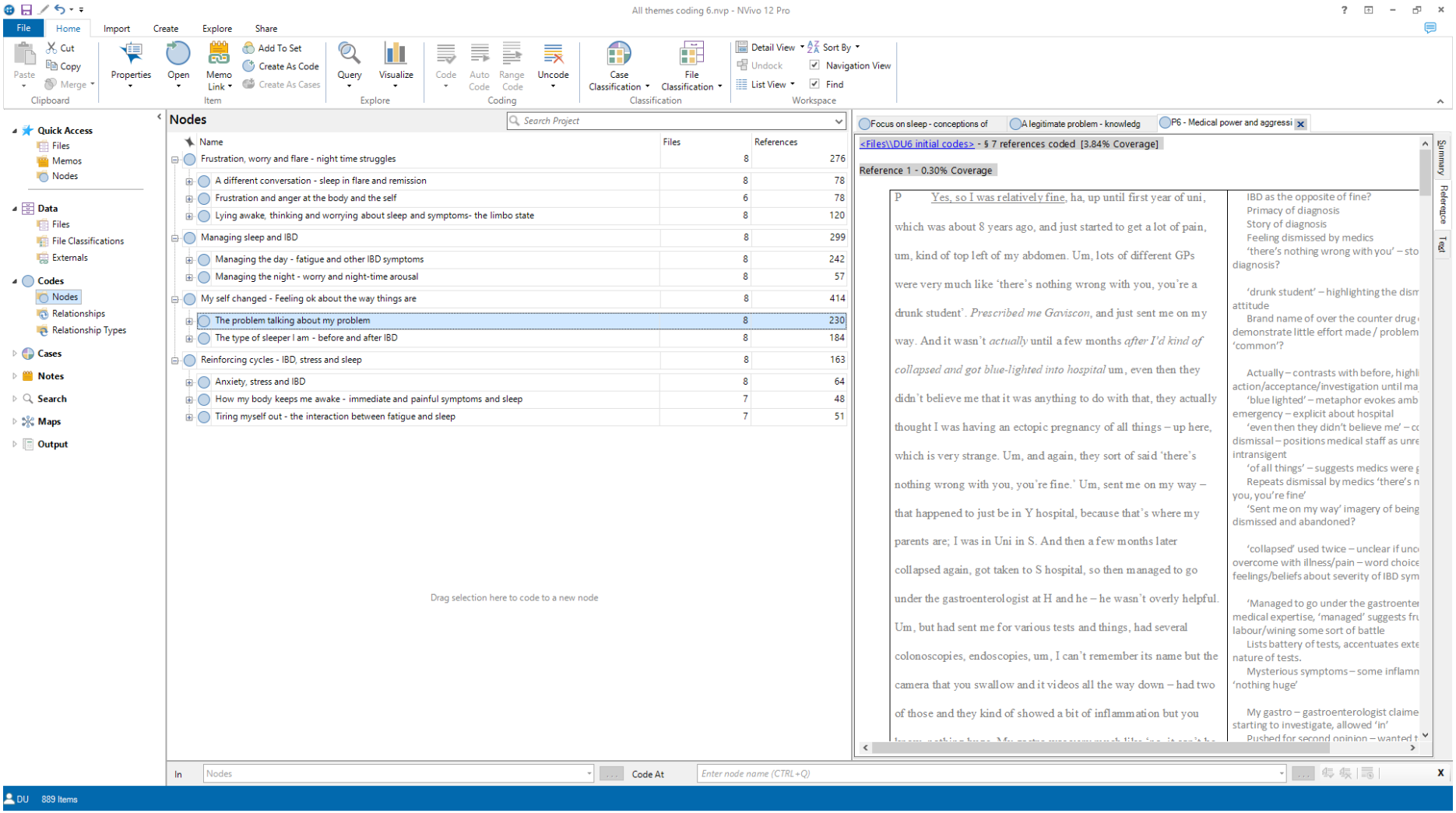
Difficult to keep up with this interview on re-listening again. Participant talks extremely quickly and jumps from topic to topic. Remember feeling exhausted after this interview, did again on listening back.

I remember he had seemed slightly irritated before the interview that there was no remuneration. I wonder if this affected the interview? He seemed to try hard to give full answers and I felt guilty about the effort he was putting in for free. Element of telling his story I felt, some socially aimed actions, felt like he was trying hard to convince me at times.

I think he started cooking mid-way through which obscures some of the conversation, used a few food metaphors – presumably was hungry and interacting with food. May be interesting to consider if food is a central part of life, however, lots of talk about nutrition.

Struck upon re-reading some of the abstract language he used, some very useful concepts in that and I believe demonstrates he has given this area plenty of thought.
Noticed I nudged a couple of times to try to keep him on topic, which seemed to work well, but will have shaped the answers somewhat – consider during analysis.

Appendix V: Final Codes – NVivo Screenshot



Appendix W: Further Illustrative Quotes

Table 5.

Superordinate and Subordinate Themes with Example Quotes

Superordinate theme	Subordinate themes	Example quotes
1. Frustration, worry and flare – night-time struggles	1a. A different conversation – sleep in flare and remission	*"I kept a record of sleep during that time and I may have had a few unbroken nights erm but again that would have actually have been while I was off work but during kind of a period of time when I would class myself as being unwell in terms of a pretty ongoing flare-up, so yeah, so broken sleep during a flare-up maybe but not outside of that."(Carl)* (Discussing how sleep is different during flare) *"At night, waking up in the night, having really bad griping pains at night... just feeling like 'should I go to hospital, what should I do?' um, just getting really upset as well. Because when you're in – when you're having a flare up it just feels like things aren't going to go back to how they were." (Sarah)*
	1b. Lying awake, thinking and worrying about sleep and symptoms – the limbo state	*"...since November, I just wait until I'm absolutely exhausted until I get to bed, otherwise I run the risk of lying in bed, catastrophizing and that's not going to do me any good" (Amir)* *"Because you know when you can kind of feel yourself – you're like half asleep and half awake, because you're aware of various things but not really awake to kind of think about it too much. I kind of have more of those thoughts now, so I feel like I'm maybe sleeping less deep more often or have been across the summer. Um, but that's because I've had a lot on so I've been worrying about it." (Helen)*

	1c. Frustration and anger at the body and the self	*"So like today, today's walk, I was calling myself out, like 'why didn't you sleep until 3o'clock? Why? ... Ok, I can sleep, why not? Don't feel tired, why didn't you feel tired? Didn't do nothing all day, I didn't have enough energy" (Amir)* (discussing difficult night's sleep) *"and then maybe kind of finally dropping into a slightly deeper sleep, um. But what I also find then is that at the other end of the night, I'm pretty much without success so I haven't needed to set an alarm for waking up to for pretty much of the last 13 years or whatever, so my um, body / brains ability to wake up before when I need to, it's 100% annoyingly so sometimes" (David)*
2. My self changed – variations in feeling ok about the way things are	2a. The type of sleeper I am – before and after IBD	(discussing the impact of his sleep problems) *"Erm well it doesn't really affect me other than the fact that if, if I've had a really bad night, like one of these three or four in the morning jobs I'm conscious of the next day, you know am I gonna do something, you know have I got any driving to do, how tired am I gonna be, you know is it sensible." (David)* (discussing change in ability since IBD affected sleep): *"And I know that sleeping is not going to help me – not sleeping is not going to help me. You know, you're talking to someone who for years used to wake up at 5 or 6 o'clock in the morning, make a tea, um, you know, start each day off, no drink, no drugs, nothing like that, for many years…" (Amir)*
	2b. The problem talking about my problem	(answer to "Would you mind telling me a little about your IBD please?") *"Yes, so I was relatively fine, ha, up until first year of uni, which was about 8 years ago, and just started to get a lot of pain, um, kind of top left of my abdomen. Um, lots of different GPs were very much like 'there's nothing wrong with you, you're a drunk student'. Prescribed me Gaviscon, and just sent me on my way. And it wasn't actually until a few months after I'd kind of collapsed and got blue-lighted into hospital um, even then they didn't believe me that it was anything to do with that, they actually thought I was having an ectopic pregnancy of all things – up here, which is very strange. Um, and again, they sort of said 'there's nothing wrong with you, you're fine.' Um, sent me on my way" (Helen)*

		"When I was in the hospital and they thought it was my appendix, and the doctor – there was one doctor who actually started to look a bit further into things, and she said 'oh, I think it might be your appendix, go to'- whatever the next stage is from A&E, she admitted me to the hospital and I was in there for two days and they were testing and they just didn't know and the doctors just kind of discharged me, and it wasn't until my mum actually said 'do you think it could be Crohn's because it does run in the family', even the doctor then just shrugged it off and said 'oh, I don't think it will be, but we'll test, seeing as you've said'" (Lisa)
3. Reinforcing cycles: IBD, stress and sleep	3a. How my body keeps me awake – immediate and painful symptoms and sleep	*"Ok, after 8 hours of sleep, not rested, right? Um, yeah, so it could be because the 8 hours I've had are not adequate to help me help up my body, it could be that I'm that fatigued, it could be that physically the vitamins and minerals are obviously out of synch because I'm in a flare at that point, so that's affecting – it's affecting me, or it could be dirty sleep; waking up on the hour every couple of hours" (Amir)* *"…recently the reason I've been having trouble sleeping is that my body is in pain due to the IBD and that makes it very difficult for me to get comfortable enough in bed to fall asleep. Um, so I feel that the two there are very sort of interwoven, so then in the day if I haven't slept, I feel worse and the IBD feels worse, so they're sort of bouncing off each other." (Jess)*
	3b. Tiring myself out – the interaction between fatigue and sleep	(discussing how poor sleep leads to workplace tiredness and worrying about doing the work properly): "…*so I think sometimes when I've been at work and I've not been sleeping well I've ended up feeling quite knackered and actually not always able to um, get on with doing the work that I need to do. So I think in some – in sometimes it's been quite um, disabling" (David)* (Discussing the difficulty keeping a 'normal' life and sleep routine) *"probably since I met my husband, probably got diagnosed just about when I met him and um, I can't – by the time it gets to Friday evening, I cannot normally go out on a Friday evening for meals and*

		stuff because I'm that – normally my body is that tired that by like 8 or 9 o'clock I could be asleep on the sofa because I'm just that worn out." (Lisa)
	3c. Anxiety, stress and IBD	*"…so at the minute it's quite a crucial year for me with last year of my undergrad and I were – I were laid in bed last night struggling to get to sleep thinking 'I've got a pain' and then I seem to catastrophize it and I'm like 'you're flaring up, you're going to have to drop out of uni, you're not going to graduate with your peers, you're going to have a bowel resection', and it's like.. the rational part of me knows that it's – I'm jumping to a massive conclusion, but... I can't stop myself." (Sarah)* *"Poor gut health, I would say – the reason why people maybe misunderstood, a lot of it is – you know, poor gut health equals low melanin, and serotonin, so it's got a knock on effect on my sleep, so I was sat awake, so I was up until about 3 this morning. Currently off sick, so I'm thinking there's guilt, like I'm letting my colleagues off, I'm letting my colleagues down, and I'm letting my company down, how am I going to pay my bills?" (Amir)*
4. Seeking control over sleep and IBD	4a. Managing the night – worry and night-time arousal	Sarah: *"I do think a lot, that's why I started listening to pod-casts to kind of zone me out a bit."* Researcher: *"Ok, ok, so the pod casts help you to zone out?"* Sarah: *"Yeah, so I put like a really boring political one on, ha."* Researcher: *Ha. Try and bore yourself to sleep?* Sarah: *"Ha, yeah. And then I find, because I'm like listening intently to that, at some point I just go. It doesn't work every night, for instance, last night I listened to about 3 podcasts in succession because I couldn't fall to sleep."* *"…so sometimes I'm quite conscious that my brain is kind of rotating through thoughts, and when I become conscious of it I'll sort of try and um, stop it or calm it down or find something to try and sooth it, so one of the things I've learned over the years is to do a bit of um, meditation using the breathing in and out, counting whilst breathing in and out, and this is the equivalent of counting sheep as it were and that sort of seems to help" (David)*

	4b. Managing the day – fatigue and other IBD symptoms	(Discussing the intrusion of managing sleep into daytime routines, even at work): *"I'm noticing slightly less that the um, the lack of sleep, but the solution to it so far seems to have only been by kind of really becoming quite regimental about it, so it's almost, in my mind, that I'm kind of thinking I want to avoid – it's not something I – I would describe it as I'm not yet obsessed with it, but I'm conscious that I could become obsessed" (David)* (Discussing trying to manage IBD, fatigue and sleep at the same time) *"… the other stuff you can manage a lot easier, in relation to stress you can kind of balance it out a bit or with food, certain food items you know aggravates stuff then you know not to eat them, only in moderation. It's like alcohol, I know I can't drink too much alcohol because I know it will effect it the next day. So you can kind of stop certain aspects, but with sleep, you can't – you can't seem to cure that side, as such, because you're just always going to be tired." (Lisa)*