

Cognitive Behaviour Therapy for Insomnia and Depression Among Older Adults:
A Mixed Methods Randomised Controlled Clinical Trial

By

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STATEMENT OF AUTHORSHIP

Except where explicit reference is made in the text of the thesis, this thesis contains no other material published elsewhere or extracted in whole or in part from a thesis by which I have qualified for or been awarded another degree or diploma. No other person's work has been relied upon or used without due acknowledgement in the main text and the list of references of this thesis. No editorial assistance has been received in the production of the thesis without due acknowledgement. Except where duly referred to, the thesis does not include material with copyright provisions or requiring copyright approvals.

Student: _____

Date: 8/8/18 _____

Supervisor: _____

Date: 8/8/18 _____

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LIST OF ABBREVIATIONS

CBT-I	Cognitive Behaviour Therapy for Insomnia
CBT-I+	Cognitive Behaviour Therapy for Insomnia Plus Positive Mood Enhancing Strategies
PCG	Psychoeducation Control Group
RCT	Randomised Controlled Clinical Trial
ISI	Insomnia Severity Scale
GDS	Geriatric Depression Scale
DSM-V	Diagnostic and Statistical Manual of Mental Disorders (Fifth Edition)
MINI	Mini International Neuropsychiatric Interview
CSD	Consensus Sleep Diary
DBAS	Dysfunctional Beliefs and Attitudes about Sleep
GAI	Geriatric Anxiety Inventory
BHS	Beck Hopelessness Scale
EQ	The Euroqual Health Group
MMSE	Mini Mental State Examination

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THESIS SUMMARY

Background

A strong relationship exists between insomnia and depression, particularly among older adults (aged 65 years and older). Recently experts in the field of behavioural sleep medicine established cognitive behaviour therapy (CBT) was an effective treatment for comorbid insomnia, however, it was unknown whether cognitive behaviour therapy for insomnia (CBT-I) benefitted older adults with co-occurring depression (literature review published in *Cognitive Behaviour Therapy*). A mixed-methods randomised controlled clinical trial (RCT) was warranted within a community mental health setting to investigate the efficacy of CBT-I for older adults with comorbid insomnia and depression. Furthermore, no study had tested whether an advanced form of CBT-I that included additional positive mood-enhancing strategies produced better outcomes compared to a standard form of CBT-I that only targeted insomnia. It was anticipated that the results from such a trial could influence the evolution of treatment for older adults with these highly prevalent comorbid conditions.

Methodology

An RCT was conducted between 2014 and 2016 across Victoria, Australia, through Latrobe Regional Hospital's and Peninsula Health's Community Mental Health Services (protocol published in *Trials*). Seventy-two older adults with diagnosed comorbid insomnia and depression were randomly assigned to one of three group therapy conditions: cognitive behaviour therapy for insomnia (CBT-I, standard), cognitive behaviour therapy for insomnia plus positive mood strategies (CBT-I+, advanced), psychoeducation control group (PCG, control). The primary outcomes were insomnia severity (Insomnia Severity Index) and depression severity (Geriatric Depression Scale). Primary and secondary measures were collected at pre (week 0), post (week 8), and follow-up (week 20). Participants who completed the experiential conditions were invited to provide feedback in the form of semi-

structured focus groups following the final session of treatment. Thirty-one participants from six groups reflected on their experiences of participating in CBT-I and CBT-I+.

Results

Quantitative analyses demonstrated the experiential CBT conditions both generated significantly greater reductions in insomnia and depression severity compared to PCG from pre to post, which were maintained at follow-up. The standard and advanced conditions showed similar reductions on insomnia and depression severity at post and follow up. These results were also consistent for the secondary measures across conditions. Both active treatments demonstrated large effect sizes, high retention, and strong remission rates for older adults with insomnia and depression (published in journal *SLEEP*).

A qualitative analysis was also conducted to explore the participants' experiences of treatment. Interview data from the reflective focus groups was transcribed into 424 sentences and 60 codes were extracted. Thirty-four initial themes emerged, which were finally transformed into 3 themes and 10 subthemes. The three themes were (1) positive experiences, (2) negative experiences, and (3) suggested modifications. The positive subthemes were (1a) therapists, (1b) togetherness, (1c) use of strategies reduced symptoms, and (1d) acceptance. The negative subthemes were (2a) persistent symptoms, (2b) program too condensed, and (2c) attendance obstacles. The suggested modifications were (3a) lengthen program, (3b) multi-dimensional learning, and (3c) multi-modal delivery options (manuscript under review in *Aging and Mental Health*).

Conclusion

This is the first RCT to demonstrate that specifically treating comorbid insomnia with CBT has an additional positive effect of improving depression for older adults with multiple comorbidities. Both CBT programs were effective at reducing insomnia and depression severity for older adults with comorbidity. Replication of this study is necessary with a larger

sample size to conclusively establish whether the two interventions have different or equivalent effects. It was suggested mental health services that deliver treatment for comorbid insomnia with CBT may improve recovery outcomes for older adults with depression. Future CBT-I programs for older adults may be improved by increasing the length of therapy (e.g., 8 sessions to 12 sessions), adding multi-dimensional learning opportunities (e.g., visual/audio/mentorship), and offering various modes of treatment delivery (e.g., group, individual, internet, telephone).

INTRODUCTION

1.1 Literature Review

1.1.1 Publication Details

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Advancing cognitive behaviour therapy for older adults with comorbid insomnia and depression

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1.1.2 Abstract

Insomnia and depression are two of the most common mental health problems that negatively impact older adults. The burden associated with these highly comorbid conditions requires an innovative approach to treatment. There have been significant advancements in the field of cognitive behaviour therapy for insomnia (CBT-I) over recent years. CBT-I has evolved from targeting homogenous insomnia samples to now showing promising results for comorbid insomnia. CBT-I is not only effective at treating comorbid insomnia, but can also have a positive impact on depression severity. Despite these important clinical developments, limited research has explored whether modifying CBT-I programs to specifically target comorbid depression could improve outcomes for older populations. This paper reviews recent literature and provides therapeutic recommendations to advance CBT-I for older adults with comorbid insomnia and depression.

1.1.3 Introduction

Insomnia and depression share a strong bidirectional relationship that is highly prevalent among older adults (Pigeon et al., 2008; Sadler, McLaren, & Jenkins, 2013). Throughout this article, the term ‘older adults’ refers to a mean age of 65 years and older, whereas ‘adults’ refers to a mean age between 18 and 64 years. Approximately twice as many older adults experience insomnia compared to adults (Crowley, 2011; Ohayon, Zulley, Guilleminault, Smirne, & Priest, 2001), and insomnia is typically more complex among older adults due to increased multiple comorbidities (Foley, Ancoli-Israel, Britz, & Walsh, 2004; Weissman, Greenwald, Nino-Murcia, & Dement, 1997). Studies have reported that the majority of older adults with depression experience significant comorbid insomnia symptoms (Foley et al., 2004; Pigeon et al., 2008). Furthermore, evidence indicates that insomnia often precipitates the onset of depression and can increase the chance of depressive relapse if inadequately treated (Baglioni et al., 2011; Breslau, Roth, Rosenthal, & Andreski, 1996; Franzen & Buysse, 2008; Perlis, Smith, Lyness, Matteson, Pigeon, Jungquist, & Tu, 2006). A meaningful understanding of insomnia and depression also highlights the increased risk of suicide, as researchers have identified insomnia remains an independent predictor of suicidal thinking, even after taking into account depression severity (McCall et al., 2010; Pigeon & Caine, 2010; Turvey et al., 2002). Consequently, insomnia plays an important role when it comes to conceptualizing depression (Breslau et al., 1996; Bootzin & Epstein, 2011; Glovinsky & Spielman, 2007; Siversten et al., 2012), particularly among older adults (Sadler et al., 2013; Turvey et al., 2002). These findings collectively illustrate that both insomnia and depression require significant consideration when it comes to conducting effective assessment, case formulation, and treatment planning.

Cognitive theoretical models with a biopsychosocial application can help understand the possible mechanisms that underpin the insomnia-depression relation (Beck, 2011; Harvey,

2002, 2008, 2009; Sadler et al., 2013). Sadler et al. identified that older adults with increased insomnia severity are at risk of developing depression by endorsing unhelpful beliefs about sleep (e.g., ‘When I have trouble getting to sleep, I should stay in bed and try harder’) and by generating a greater sense of hopelessness (e.g., ‘I might as well give up because there’s nothing I can do to make things better for myself’). Woodley and Smith (2006) also reported that dysfunctional beliefs about sleep predict increased sleep-related safety behaviours (e.g., daytime napping; using bed for purposes other than sleep), which serve to unintentionally maintain the insomnia cycle. These mechanisms are particularly relevant for older adults because they tend to experience more night time awakenings and are generally lighter sleepers compared to adults (Crowley, 2011; Foley et al., 2004). These age-related factors can result in an increased vulnerability to develop comorbid insomnia (Crowley, 2011; Oyayon et al., 2001). Furthermore, dysfunctional sleep beliefs and sleep-related safety behaviours are related to heightened states of psychophysiological arousal (e.g., tension; hyper-alert; ruminations), which interferes with the ability to gain quality sleep (Harvey, 2002; Jansson, & Linton, 2007; Perlis, Giles, Mendelson, Bootzin, & Wyatt, 1997).

These maladaptive insomnia mechanisms can manifest and potentially exacerbate depressive maintenance patterns (Harvey, 2008, 2009; Pigeon et al., 2008; Woodley & Smith, 2006). For instance, people with higher levels of depression tend to use more sleep-related safety behaviours and endorse stronger dysfunctional beliefs about their sleep (Woodley & Smith, 2006). This means that individuals with depression may begin to use their bed or bedroom as a place of refuge to escape the depressive symptoms temporarily (Bartlett, 2014; Bootzin & Epstein, 2011; Glovinsky & Spielman, 2007; Smith et al., 2005). This increased desire to withdraw from daily activities is likely to increase the depressed individual’s attempts to sleep, which in turn, can exacerbate psychophysiological arousal and interfere with overnight sleep quality (Barlett, 2014; Jansson, & Linton, 2007; Perlis et al., 1997).

Cycles of behavioural withdrawal can increase levels of amotivation and tiredness/fatigue, and compromise an individual's ability to motivate change independently (Bartlett, 2014; Smith et al., 2005; Wagley et al., 2013). These dysfunctional mechanisms can strengthen over time, potentially becoming chronic, recurrent, or trans-diagnostic in nature (Harvey, 2008, 2009; Pigeon et al., 2008). Despite this theoretical explanation of the insomnia-depression relationship, cognitive approaches to treatment are often not offered or available to older adults (Belanger, LeBlanc, & Morin, 2012; Crabb & Hunsley, 2006; McCurry, Logsdon, Teri, & Vitiello, 2007).

The medical approach using pharmacotherapy remains the most common form of treatment offered to older adults with comorbid insomnia and depression (Morin, 2006; Staner, 2010). Many studies, however, suggest that medication alone is insufficient to treat both conditions effectively (e.g., Manber, Edinger, Gress, San Pedro-Salcedo, Kuo, & Kalista, 2008; Morin, 2006). For instance, insomnia is the most common persistent residual symptom following antidepressant treatment, present in approximately 50% of treatment completers (Manber et al., 2008). Hypnotic and antidepressant medicines can also pose significant side effects that have the potential to exacerbate sleep and mood problems (Mendelson et al., 2004). Since pharmacotherapy presents several limitations when it comes to treating both insomnia and depression, researchers have been exploring a form of psychological treatment that can complement the medical approach. This article aims to review recent research that has investigated how cognitive behaviour therapy (CBT) impacts comorbid insomnia and depression, and provide suggestions that could improve the delivery of treatment for older adults with both conditions.

1.1.4 Cognitive Behaviour Therapy for Insomnia

Cognitive behaviour therapy for insomnia (CBT-I) is considered a well-established first line intervention (Belanger et al., 2012; Bootzin & Epstein, 2011; Carney & Manber, 2009; Vitiello et al., 2013). This form of therapy is a structured, time-limited, multi-component sleep program that includes a combination of educational, cognitive, and behavioural interventions (e.g., Belanger et al., 2012; McCurry et al., 2007; Morin, 1993, 2004). The main objective of CBT-I is to change factors that perpetuate insomnia, including behavioural factors (poor sleep habits, irregular sleep schedules), cognitive factors (unrealistic expectations about sleep, unhelpful sleep beliefs), and physiological factors (somatic tension, cognitive hyper-arousal). The most commonly applied strategies in CBT-I studies include stimulus control, sleep restriction, relaxation, sleep hygiene and cognitive restructuring (Dzierzewski, O'Brien, Kay, & McCrae, 2010; Siebern & Manber, 2011). Results from meta-analyses suggest CBT-I produces sleep improvements that compare favourably to those achieved with various forms of pharmacotherapy in the long term (Morgenthaler et al., 2006; Morin, Bootzin, Buysse, Edinger, Espie, & Lichstein, 2006). In addition, sleep improvements following CBT-I can endure 12 to 36 months after treatment is completed (Blom, Jernelov, Lindefors, & Kaldo, 2016; Dzierzewski et al., 2010; Morin et al., 2006; Smith, Huang, & Manber, 2005). Evidence has also shown that many participants often prefer CBT-I compared to medication (Morin, 2006). Given such observations, CBT-I has become a preferable treatment option for insomnia.

Since the incidence of insomnia increases substantially with older age and is often more chronic and comorbid compared to adults (Foley et al., 2004; Irwin, Cole, & Nicassio, 2006; McRae, & Lichstein, 2001; Roth, 2007), CBT-I needs to consider age-related factors that can influence the delivery of treatment. Researchers who specialize in gero-psychology report that although the core principals of CBT remain unchanged between age groups,

several factors should be taken into account to maximise the potential therapeutic effects (e.g., Cox & D'Oyley, 2011; Evans, 2007; Satre et al., 2006). When assessing and treating older adults, therapists should be mindful of several added complexities, such as physical health status, somatic complaints, medication effects, symptom severity/chronicity, sensory deficits or disabilities, religious orientation, education level, and grief/loss issues (Cox & D'Oyley, 2011; Evans, 2007; Wu, Appleman, Salazar, & Ong, 2015). Practical modifications can be implemented in the delivery of CBT to address these age-related factors. For instance, increasing the type size and simplicity of therapy worksheets can assist visual impairments and lowered literacy levels, and choosing an appropriate treatment venue that has disability access will assist older adults with limited mobility (Cox & D'Oyley, 2011; Evans, 2007). It has also been suggested that encouraging older people to involve trusted supports (e.g., family/friends/professionals) during the therapy process can assist with motivation, homework completion, and commitment to change (Coon, Thompson, Rabinowitz, & Gallagher-Thompson, 2005; Cox & D'Oyley, 2011; Kazantkis, Pachana, & Secker, 2003).

Since many older adults also experience loneliness and social isolation, group CBT-I is often a worthwhile treatment format to consider among this population (Constantino, Manber, Ong, Kuo, Huang, & Arnow, 2007; Koffel, Koffel, & Gehrman, 2015). Group therapy can have the added benefit of increasing one's sense of belonging and assist in providing collaborative support and understanding during the therapy process (Cox & D'Oyley, 2011; Evans, 2007). Group therapy, as opposed to individual therapy, is also much more cost effective to both clients and services, and is less labour intensive (Evans, 2007; Koffel et al., 2015). Studies have highlighted that when considering group CBT among older adults, participants' cognitive abilities should be taken into consideration, as participants with cognitive deficits may require more one-on-one attention and alter the overall group's progress (Coon et al., 2005; Cox & D'Oyley, 2011). Furthermore, programs that are treating

older adults with complex or severe psychiatric problems may benefit from smaller group sizes, co-facilitation by two therapists, and more sessions to promote further clarification and consolidation opportunities (Cox & D'Oyley, 2011; Koffel et al., 2015). Overall, future group-based CBT-I studies that make the appropriate adjustments to account for age-related factors are likely to maximize the therapeutic benefits for the older adult population (Constantino et al., 2007; Cox & D'Oyley, 2011; Koffel et al., 2015; Satre et al., 2006).

CBT-I research has traditionally excluded older adults with comorbid medical, sleep, or psychiatric conditions. More recently, however, growing evidence has emerged that suggests CBT is effective for treating comorbid insomnia (Geiger-Brown et al., 2015; Norell-Clarke et al., 2015; Rybarczyk & Stepanski, 2006; Wu et al., 2015). Several recent studies have shown CBT-I produced similar benefits for adults and older adults with primary insomnia and insomnia that was associated with a mixture of psychiatric disorders (Edinger et al., 2009; Irwin et al., 2006; Wu et al., 2015). Furthermore, research that had not employed the typical exclusionary criteria used in the majority of insomnia treatment studies still found that older adults with comorbid insomnia significantly benefitted from CBT-I (Buysse et al., 2011; Irwin et al., 2006; Rybarczyk, Stepanski, Fogg, Lopez, Barry, & Davis, 2005). For instance, Irwin et al.'s (2006) meta-analysis revealed both adults (<55 years) and older adults (>55 years) showed similar robust improvements in overall sleep quality (Cohen's $d = 0.76$). A more recent meta-analysis reviewed 23 studies (1379 participants) to evaluate the effectiveness of CBT-I for comorbid insomnia across age groups (Geiger-Brown et al., 2015). Inclusion criteria were randomized controlled trials (RCT) that applied standardized insomnia assessments for people with a comorbid medical or psychiatric condition. Results indicated significant improvements on several sleep parameters, for example, changes on insomnia severity from pre to post treatment represented a large aggregated effect (Cohen's $d = >0.80$). Geiger-Brown et al. concluded that CBT-I was an effective and durable treatment for

comorbid insomnia. In light of these results, researchers have started to investigate whether CBT-I has the potential to influence comorbid conditions.

1.1.5 Effects of CBT-I on Depression

One population that has recently received growing CBT-I research involves individuals with comorbid insomnia and depression (Carney & Manber, 2009; Edinger, 2015; Harvey, 2009; Haynes, 2015; Taylor & Pruiksma, 2014). Currently there are no known RCTs that have investigated whether CBT-I is an effective treatment for comorbid insomnia and depression among older adults. Over the past two years, however, more convincing evidence has indicated CBT-I could have a positive effect on comorbid depressive severity among adults (Ashworth et al., 2015; Blom et al., 2015a; Blom et al., 2015b; Blom et al., 2016; Christensen et al., 2016; Norell-Clarke, Jansson-Frojmark, Tillfors, Hollandare, & Engstrom, 2015). Hence, this critical review has focussed on the adult population, as research has not yet expanded to older adults.

Edinger (2015) reported that there has been growing attention on testing digital forms of CBT-I among adults with depression. Online or internet-based CBT-I has been developing momentum due to its low cost and wide dissemination self-help possibilities (Edinger, 2015). Kerstin Blom and colleagues from Sweden have recently made significant contributions in this area (Blom et al., 2015a; Blom et al., 2015b; Blom et al., 2016). Blom et al.'s (2015a) study compared two internet-based CBT programs for 43 younger adults (*M* age 47 years) with comorbid insomnia and depression. Participants were randomised to receive either 9 weeks of internet-delivered CBT for insomnia (ICBT-i; *n* = 22) or internet-delivered CBT for depression (ICBT-d; *n* = 21). The ICBT-i treatment consisted of several therapeutic modules including insomnia psycho-education; sleep hygiene; psychoeducation about sleep medicine and reduction; sleep restriction; stimulus control; stress management; managing fatigue;

cognitive reframing; and planning ahead. The ICBT-d program consisted of traditional CBT for depression (CBT-D) strategies, including depression psychoeducation; behavioural activation; cognitive reframing; managing anxiety and worry; and relapse prevention. Both treatments were delivered via the internet with weekly online feedback from a qualified therapist. The therapist had access to the participant's homework responses and weekly outcomes measures to provide individualised guidance during each module. Blom et al. (2015a) made some important discoveries. The study found ICBT-i and ICBT-d were equally effective at reducing depressive symptoms (ICBT-i Cohen's $d = 0.74$; ICBT-d Cohen's $d = 0.66$), but that ICBT-i was more effective in reducing insomnia severity (ICBT-i Cohen's $d = 1.06$; ICBT-d Cohen's $d = 0.54$). Blom et al. also reported a significant proportion of participants from both conditions did not reach remission of insomnia and depression post-intervention, and subsequently could have benefitted from further treatment. Despite this, Blom et al. (2015a) concluded that ICBT-i was overall more effective than ICBT-d for adults with comorbid insomnia and depression.

Although Blom et al.'s (2015a) study has made a significant contribution to our understanding of treatment for insomnia and depression, their study had several limitations that reduced the strength of their findings. First, Blom et al. (2015a) tested two experiential conditions without implementing a control condition. Second, participants' sleep medication use was unrestricted during the trial. Third, the study was not blinded. Fourth, components of the ICBT-i treatment were delivered in book form, whereas the ICBT-d treatment content was delivered solely via the internet. Finally, the findings were limited to a population of adults who were able to self-refer and engage independently in an internet-based self-help treatment.

Blom and colleagues (2016) conducted a follow up qualitative analysis to investigate factors that may have facilitated or hindered the participants' treatment response. Blom et al.

(2016) interviewed 35 participants (M age = 48 years) via telephone at the 6 month follow up stage of the Blom et al. (2015a) trial. The interviews were audio recorded and later transcribed. The first author conducted 28 interviews and the second author completed 7 interviews. Both interviewers were licenced psychologists with several years of clinical experience treating insomnia and depression. The interviews were based on two central questions: (1) “How did you think the treatment went?” and (2) “Why do you think it went [well/badly]?” Following these introductory questions, the interviewers allowed each participant to reflect more widely on their treatment experience. The interviews were analysed with a grounded theory approach and later coded, condensed and integrated into 11 key themes. Blom et al. (2016) found that participants who received the ICBT-i condition were more positive about their treatment experience and reported fewer hindering factors compared to participants who received the ICBT-d condition. Not surprisingly, increased use of ICBT treatment content for both conditions was positively associated with better outcomes. Symptoms of insomnia, depression, and other comorbidities were perceived as more hindering for ICBT-d than for ICBT-i. This indicates that participants may have been more ready to correct their sleep patterns than their depression, and therefore found more benefit from ICBT-i as opposed to ICBT-d. Blom et al.’s (2016) findings provide further evidence that focussing on addressing insomnia first may be an important step in providing more effective treatment for depression.

Blom et al.’s (2015a, 2015b, 2016) recent collection of studies were limited by small to moderate sample sizes. A larger Australian-based RCT by Christensen et al. (2016) tested whether self-guided online CBT-I had a positive effect on depressive severity. They randomly assigned 1149 participants (M age = 42 years) with current insomnia and mild depression to receive 6 weeks of self-guided online CBT-I ($n = 574$) or to an attention-matched internet control group ($n = 575$). It was found that self-guided online CBT-I

significantly improved depression severity compared to the attention control condition at post and 6 month follow up (Cohen's $d = 0.69$ post, 0.48 f/u). Christensen et al. suggested that online CBT-I could be a practical and effective way to improve and/or prevent depression, and has the potential to become an automated system with worldwide accessibility.

Christensen et al.'s study had a large sample size, with a completion rate of 43% for the CBT-I condition. Specifically, of the 574 participants who commenced the active online CBT-I treatment, 248 completed the 6-week program, and 114 completed the post outcome measures. This trend was similar but slightly better for the control condition. The high percentage of missing data could indicate a potential bias in results. In addition, the study's baseline sample characteristics contained a higher representation of females (74%); those who had completed tertiary education (88%); and those who had a pre-mean depression score of 5.8 on the PHQ (indicating minimal severity). This suggests Christensen's conclusions were likely more relevant to higher functioning younger females with insomnia and minimal levels of depression. Consequently, it remains unclear whether these results can be generalized to older adult comorbid clinical populations.

As older adults gradually become more technologically engaged, digital forms of CBT-I may be a useful option for this generation. Although online forms of CBT-I have shown promising results (e.g., Blom et al., 2015a; Blom et al., 2015b; Christensen et al., 2016), it is anticipated that both adults and older adults with moderate to severe comorbid psychopathology and low computer literacy skills will find it difficult to engage in this form of treatment. Therefore, the traditional face-to-face modes of CBT-I will remain an important treatment option.

Innovative research has recently emerged from Sweden that has investigated whether CBT-I is effective for depression in a sample with comorbidity. Norell-Clarke and colleagues (2015) conducted a well-designed RCT of 64 participants (M age = 51) with comorbid

insomnia and depression who received either group-based CBT-I ($n = 32$) or group-based relaxation training ($n = 32$). Participants received 4 two-hour long bi-weekly sessions. Outcomes were assessed pre-treatment, post-treatment, and at 6 month follow up. Diagnoses and functional impairment were also assessed before and after treatment. Norell-Clarke et al. found CBT-I was more effective than relaxation in reducing insomnia severity (CBT-I $d = 2.02$, relaxation $d = 1.28$), whereas both conditions had similar but less effects on reducing depression severity (CBT-I $d = 0.76$, relaxation $d = 0.26$). CBT-I was associated with a higher proportion of remission for both diagnoses and resulted in less functional impairment than the relaxation condition. Norell-Clarke et al. concluded that group-based CBT-I benefitted adults with comorbid insomnia and depression.

Norell-Clarke et al.'s (2015) study demonstrated a unique methodological strength that previous studies had not yet achieved in the CBT for insomnia and depression literature. They employed an active control condition that controlled for non-specific treatment effects (e.g., therapeutic alliance, expectancy, context). Implementing a comparison group that was similar to the experiential group helped strengthen the internal validity. Despite Norell-Clarke et al.'s study having several design strengths, limitations were also evident. Norell-Clarke noted that conducting telephone diagnostic interviews might have influenced the diagnostic accuracy compared to conducting face-to-face interviews. Furthermore, non-blinded clinicians conducted the treatment integrity ratings, and the sample size was modest. The mixed results regarding depression outcomes also warrants replication in future studies.

Another recently published face-to-face trial (Ashworth et al., 2015) investigated the effect of CBT-I on depression among adults in Australia. Ashworth and colleagues (2015) examined whether therapist-led CBT-I was more effective than self-help CBT-I for 41 adults (M age = 37 years) with comorbid insomnia and depression. All participants had been on a form of antidepressant medication for at least 6 weeks prior to commencing CBT-I. Eligible

participants were randomized to receive 4 sessions of either therapist CBT-I or self-help CBT-I over a course of 8 weeks. Insomnia and depression severity was measured utilizing both self-report questionnaires and actigraphy, and were assessed at baseline, post, and 3-month follow up. The study found large effect sizes, with the therapist-led CBT-I condition producing strong reductions in both insomnia (Cohen's $d = 0.92$) and depression severity (Cohen's $d = 1.24$). At the 3-month follow-up, effect sizes for the therapist-led CBT-I condition were even larger for insomnia severity (Cohen's $d = 1.87$) and depression severity (Cohen's $d = 1.65$). The authors suggested therapist-led CBT-I was effective for treating comorbid insomnia and depression and needs to be considered as an important adjunct treatment option to pharmacotherapy.

Ashworth et al. (2015) acknowledged several limitations in their study. The choice of utilizing a sole therapist for both conditions and having a self-help comparison group were notable design weaknesses. The comparison self-help condition was problematic because the overall outcomes could have been largely due to the face-to-face therapeutic alliance effects rather than the CBT-I intervention itself. Furthermore, the participants and single therapist could not be blinded, which possibly contributed to larger effects. Ashworth et al. suggested future studies should consider utilizing a psycho-education or supportive therapy comparison group to control for nonspecific therapeutic effects (e.g., therapeutic alliance). Consistent with previous research, adults were the predominant focus of their study. Currently there is a paucity of research that explores whether CBT-I specifically benefits older adults with comorbid insomnia and depression.

Some valuable earlier research contributions in this field are also worth highlighting (Lancee, van den Bout, van Straten, & Spoormaker, 2013; Manber, Bernert, Suh, Nowakowski, Siebern, & Ong, 2011; Taylor, Taylor, Lichstein, Weinstock, Sanford, & Temple, 2007; Wagley, Rybarczyk, Nay, Danish, & Lund, 2013). The authors of these

studies noted the results should be interpreted with caution due to substantial methodological weaknesses. For instance, Taylor et al. (2007) conducted one of the first preliminary studies that tested whether CBT-I impacted depression severity in a sample of adults with mild depression. Taylor et al.'s pilot project found CBT-I had a positive effect on depression severity, but their study had a very small sample size ($N = 10$), of which two participants discontinued CBT-I treatment. Taylor et al.'s study was also conducted in an academic setting, which included four therapists plus two supervisors to only eight participants. This labour intensive approach would not be realistic in most clinical settings. Another study by Lancee et al. (2013) contained similar methodological flaws that jeopardized the strength of its findings. Lancee et al.'s research was not an RCT design and did not have a control or comparison condition, which meant causal implications of CBT-I on depression were restricted. In addition, Wagley et al.'s (2013) study indicated positive trends towards reduced depressive severity in the CBT-I group compared to a treatment as usual control group, although the results were not statistically significant. This meant that the treatment as usual group demonstrated similar changes in insomnia and depression compared to the active CBT-I treatment group. Wagley et al. acknowledged their study could not assess whether CBT-I or careful monitoring of participants resulted in changes in insomnia and depression severity. The limitations inherent within this fast developing literature base highlight more RCTs are needed to test the efficacy of CBT-I on depression and the mechanisms involved in this effect.

In summary, insomnia and depression are common co-occurring problems. Research has established that insomnia is more than a correlate or symptom of depression, it also affects the course of depression, response to treatment, and when unresolved, is a risk factor for relapse. Most adults and older adults with depression report difficulties initiating or maintaining sleep, however, insomnia is often overlooked as a specific target for treatment. This is evident in the pharmacotherapy literature, where symptoms of insomnia often persist

after antidepressant treatment. This highlights to therapists that insomnia is often inadequately addressed in the treatment of comorbid insomnia and depression and warrants a more innovative approach. Although there is insufficient current evidence to make widespread conclusions about the efficacy of CBT-I for depression, this growing collection of studies have set a foundation for CBT-I research to advance.

1.1.6 Cognitive Behaviour Therapy for Insomnia and Depression

CBT-I originated from the well-established principals of cognitive behaviour therapy for depression (CBT-D). CBT-D is an effective treatment for older adults with large effect sizes reported for reductions in depression severity (Cohen's $d = 0.93$, Piquart, Duberstein, & Lyness, 2007). Despite this, CBT-D has not typically included CBT-I interventions that adequately address comorbid insomnia (e.g., Blom et al., 2015a). A logical step in advancing treatment could be combining insomnia and depression strategies within the one therapeutic program. Not surprisingly, CBT-I can be easily integrated with CBT-D interventions. Tables 1 and 2 highlight therapeutic content and process modifications that could be added to CBT-I programs to potentially improve comorbid depressive symptoms.

Table 1

Therapeutic content modifications to target depression among older adults with comorbid insomnia

Therapeutic Content	Rationale
Behavioural Activation	Behavioural activation involves scheduling purposeful and age-appropriate daily activities that are designed to reduce depression severity. This intervention could strengthen sleep and mood outcomes by changing sedentary safety behaviours with more constructive daily activities.
Behavioural Experiments	Behavioural experiments are designed to provide helpful evidence following a planned activity to disconfirm an unhelpful cognition. Implementing behavioural experiments that are targeted to improve both sleep and mood will likely compliment standard CBT-I strategies.
Cognitive Reframing for Depression	Cognitive reframing involves developing insight into the relationship between thoughts and feelings, and learning to reframe negative thoughts into more adaptive thoughts. CBT-I currently targets insomnia-related cognitions rather than depression-related cognitions. CBT-I-D would also involve correcting influential negative cognitions that perpetuate depressed mood.
Hope Affirmations	Implementing affirmation tasks that are specifically designed to increase hope (e.g., positive cue cards; hope diaries) could further consolidate the effects from cognitive reframing.
Therapeutic Materials	New therapeutic materials (worksheets, videos, CDs, DVDs) could be developed to highlight the relationship between sleep and mood. Age-related contextual factors should be acknowledged to increase applicability.
Length of Therapy	More sessions will likely be required in CBT-I-D programs to allow for additional therapeutic content. In addition, since older adults often present with comorbid and chronic sleep and mood disturbances, longer programs may be warranted to maximise therapeutic effects.

Table 2

Therapeutic process modifications to target depression among older adults with comorbid insomnia

Therapeutic Process	Rationale
Engagement	Recruitment and therapeutic engagement can pose a particular challenge for practitioners treating older adults with insomnia and depression. Researchers and therapists need to consider providing sustained encouragement and increased support to strengthen motivation to change.
Session Breaks	High levels of tiredness/fatigue are common among older adults with insomnia and depression. Scheduling brief session breaks could improve concentration and offer opportunities to model in-situ behavioural experiments.
Group Therapy	Older adults can experience increased loneliness and isolation from insomnia and depression, hence offering a group therapy format could promote socialisation and connectedness in a cost effective manner.
Group Co-facilitation	Multiple challenges can present during group therapy that may benefit from having two therapists. Co-facilitation is preferred to manage clinical risks (e.g., suicide ideation) more effectively and cross-validate treatment protocol.
Support Person	Encouraging older adults to have a nominated support person during CBT-I could improve motivation, homework compliance, and relapse prevention.
Senior Mentors	Inviting older adults who have successfully completed CBT-I to participate in future programs as mentors may increase hope and engagement for depressed clients.
Multidisciplinary	Few psychogeriatric professionals are trained to deliver CBT-I. Training clinicians from various disciplines and settings could increase dissemination and access. This is particularly important in rural and remote areas where treatment options are even more limited.
Modes of Therapy	Informing clients about the emerging multiple modes of therapy (e.g., individual, group, internet, phone, self-help) could strengthen engagement and better inform individualised treatment planning.

Behavioural activation, or activity scheduling, is a common first intervention included in CBT-D programs (e.g., Beck, 2011; Greenberger & Padesky, 2016; Yon & Scogin, 2009). Behavioural activation aims to increase an individual's level of activity, socialization, and sense of achievement/pleasure (Beck, 2011; Greenberger & Padesky, 2016). This involves setting specific goals and scheduling daily activities to explore how changing behaviour impacts mood before and after an activity. Since people with insomnia and depression report persistent tiredness, amotivation, and displeasure, introducing behavioural activation early in the course of CBT-I may compliment behavioural sleep strategies (Bartlett, 2014; Smith et al., 2005). Behavioral activation could be synchronized with CBT-I strategies such as stimulus control, sleep restriction, and sleep hygiene to enhance therapeutic effects. For example, an individual who reports strong patterns of sedentary behaviour each day may aim to gradually increase their level of morning exercise, and also aim to implement a stimulating activity each afternoon to better manage periods of drowsiness. These combined behavioural interventions could be documented on the client's daily activity schedule to review, adjust, and monitor the therapeutic effects.

Additional age-related challenges could arise for therapists who introduce behavioural activation with older adults (Cox & D'Oyley, 2011; Satre, Knight, & David, 2006; Yon & Scogin, 2009). Since older adults often experience comorbid physical disabilities or medical limitations, setting age-appropriate behavioural strategies (e.g., low impact-based exercises) will be more effective for this cohort (Cox & D'Oyley, 2011; Yon & Scogin, 2009). Furthermore, behavioural activation could be particularly important for older adults who exhibit increased levels of loneliness or isolation at night (Ellis, Hampson, & Cropley, 2007; Woodley & Smith, 2006). In this instance, setting regular social contact in the evening (e.g., phoning friends/family; going to a seniors group; utilizing social media) could be a valuable intervention to change safety behaviours that maintain maladaptive cycles of insomnia and

depression (Ellis et al., 2007; Woodley & Smith, 2006). These additional behavioural options highlight how activity scheduling could compliment standard CBT-I interventions for older adults.

Another significant treatment modification could be integrated into CBT-I to address the association between automatic negative thoughts and depression. Cognitive reframing or restructuring is a core intervention in both CBT-I (Belanger et al., 2012; Morin, 1993) and CBT-D programs (Beck, 2011; Fennell, Bennett-Levy, & Westbrook, 2004; Greenberger & Padesky, 2016). This cognitive processing strategy often involves use of thought diaries or behavioural experiments to capture a problematic situation; check the accuracy of the automatic thoughts; and correct influential unhelpful thoughts to a more balanced appraisal of the situation (Beck, 2011; Fennell et al., 2004; Greenberger & Padesky, 2016). When cognitive restructuring is applied effectively, it assists in regulating the intensity of emotions and developing a more helpful cognitive interpretation.

Currently standard CBT-I programs specially target dysfunctional beliefs about sleep, rather than addressing idiosyncratic cognitions that also perpetuate depressed mood. In a hybrid CBT for insomnia and depression (CBT-I-D) program, cognitive restructuring could be expanded to address both dysfunctional beliefs about sleep and negative automatic thoughts that trigger comorbid depression. Spending additional time learning to reframe both insomnia and depressive cognitions could strengthen patterns of balanced thinking and have a transferable effect onto comorbid conditions. In addition, practicing positive affirmations towards the end of treatment could further consolidate cognitive restructuring and increase hope for the future (Sadler et al., 2015). It is anticipated that these additional cognitive therapy techniques for depression could enhance pre-existing CBT-I cognitive skills.

Limited research has explored how to implement cognitive therapy for comorbid insomnia and depression among older adults within the one treatment program. This is a

significant consideration for therapists when formulating treatment because older adults can present with age-specific contextual beliefs that are strongly associated with insomnia and depression (Ellis et al., 2007; Sadler et al., 2013). Ellis and colleagues found that older adults with insomnia often endorse specific unhelpful sleep beliefs such as, “I am concerned that chronic insomnia may have serious consequences on my physical health”. Sadler et al. (2013) also demonstrated that older adults with insomnia and depression report strong hopelessness cognitions, such as “I might as well give up because there is nothing I can do about making things better for myself”. Identifying influential dysfunctional beliefs that are negatively influencing an older adult’s sleep and mood will likely strengthen the therapeutic rationale for setting up successful cognitive restructuring activities.

Advanced CBT-I-D programs will likely require extended treatment time due to the added therapeutic content involved to adequately address each condition. The length of multi-component CBT-I programs are typically between 4 to 6 weekly 60 minute sessions (Morin et al., 2006). It is anticipated that CBT-I-D programs would double the treatment length and offer 8 to 12 weekly 90 minute sessions (Sadler et al., 2015). Adding more sessions over time will assist in (1) developing realistic expectations for improvement, (2) provide more opportunities for relapse prevention, and (3) recognise the complexity, chronicity, and recurrent nature of these conditions (Sadler et al., 2015). Since older adults with insomnia and depression experience high levels of tiredness and poor concentration (Sadler et al., 2013), scheduling regular 5-minute session breaks would likely help manage increased periods of fatigue and encourage participation. This strategy could generate moments of therapeutic consolidation and present opportunities to model in-situ behavioural experiments.

CBT-I programs that are specifically designed for older adults to simultaneously address both conditions will likely create a therapeutic synergy and enhance sleep and mood outcomes. Sadler et al.’s (2015) protocol reports a team of researchers are currently

conducting an RCT in Australia, testing whether CBT-I-D produces better results compared to CBT-I alone within aged persons' community mental health services. Research that explores how standard CBT-I compares to an integrated form of CBT-I-D will inform professionals which treatment program is more effective for older adults presenting with comorbid insomnia and depression (Sadler et al., 2015). The implications from this research could assist in developing more targeted CBT programs because a wider range of evidence-based treatment options could be available to therapists and clients.

1.1.7 Conclusion

Currently there is no research to guide therapists on the best treatment program to simultaneously address comorbid insomnia and depression among older adults. This is an important direction for future research because insomnia and depression frequently co-occur and are highly prevalent among this age group. Promising recent evidence indicates that CBT-I has a positive impact on insomnia and depression severity. Despite this important clinical development, these studies possess significant weaknesses and are primarily focussed on adult populations. Further research is needed to investigate whether the effects of CBT-I for depressive symptoms generalize to older adults, and explore the mechanisms that may underpin this process. Future trials also need to test whether CBT-I requires modification for depressed individuals. Redesigning CBT-I to include depressive treatment modules may produce stronger transdiagnostic effects.

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1.2 Bridge between Introduction and Methodology

The introductory chapter (published in *Cognitive Behaviour Therapy*) involved a critical review of research in the field of CBT for insomnia and depression. This review identified significant gaps in the literature; namely, that the efficacy of CBT-I had not been tested among older adults with comorbid insomnia receiving community mental health services, and that a new CBT-I program that added positive mood-enhancing strategies for depression had not been compared to a standard form of CBT-I. This provided the rationale to develop a mixed-methods RCT. The protocol article (published in *Trials*) outlined two central aims that needed testing through an RCT methodology. The primary aim involved investigating whether CBT-I was an effective treatment for older adults with comorbid insomnia and depression within a community mental health setting. A second aim was to examine whether an advanced form of CBT-I+ produced better outcomes compared to a standard CBT-I program. A supplementary aim was to explore the older adults' experiences of treatment.

METHODOLOGY

2.1 Protocol

2.1.1 Publication Details

Title:

Cognitive behaviour therapy for older adults experiencing insomnia and depression in a community mental health setting: Study protocol for a randomised controlled trial

Journal:

Trials (Biomed Central)

Impact Factor 1.969

Status: Published

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Sadler, P., McLaren, S., Klein, B., Jenkins, M., & Harvey, J. (2015). Cognitive behaviour therapy for older adults experiencing insomnia and depression in a community mental health setting: Study protocol for a randomised controlled trial. *Trials*, *16*, 538-547.

2.1.2 Abstract

Background

Cognitive behaviour therapy for insomnia (CBT-I) is a well-established treatment, however, the evidence is largely limited to homogenous samples. Although emerging research has indicated that CBT-I is also effective for comorbid insomnia, CBT-I has not been tested among a complex sample of older adults with comorbid insomnia and depression.

Furthermore, no study has explored whether modifying CBT-I to target associated depressive symptoms could potentially enhance sleep and mood outcomes. Therefore, this study aims to report a protocol designed to test whether an advanced form of CBT for insomnia and depression (CBT-I-D) is more effective at reducing insomnia and depressive symptoms compared to a standard CBT-I and psychoeducation control group (PCG) for older adults in a community mental health setting.

Method

We aim to recruit 150 older adults with comorbid insomnia who have presented to community mental health services for depression. Eligible participants will be randomly allocated via block/cluster randomisation to one of three group therapy conditions: CBT-I, CBT-I-D, or PCG. Participants who receive CBT-I will only practice strategies designed to improve their sleep, whereas participants who receive CBT-I-D will practice additional strategies designed to also improve their mood. This trial will implement a mixed-methods design involving quantitative outcome measures and qualitative focus groups. The primary outcome measures are insomnia and depression severity, and secondary outcomes are anxiety, hopelessness, beliefs about sleep, comorbid sleep conditions, and health. Outcomes will be assessed at pre-intervention (week 0), post-intervention (week 8), and 3 month follow up (week 20).

Discussion

This CBT study protocol has been designed to address comorbid insomnia and depression for older adults receiving community mental health services. The proposed trial will determine whether CBT-I is more effective for older adults with comorbid insomnia and depression compared to a PCG. It will also establish whether an advanced form of CBT-I-D generates greater reductions in insomnia and depression severity compared to standard CBT-I. It is anticipated that the results from the proposed trial will have important clinical implications for older adults, researchers, therapists, and community mental health services.

Trial Registration

Australian and New Zealand Clinical Trials Registry (ANZCTR)

URL: <https://www.anzctr.org.au>

Trial ID: ACTRN12615000067572

Date Registered: 12th December 2014

2.1.3 Introduction

Leaders in the field of cognitive behaviour therapy for insomnia (CBT-I) have suggested that this form of psychological treatment needs to be tested in more diverse samples and settings (Bootzin & Epstein, 2011; Morin et al., 2006; Vitiello, McCurry, & Rybarczyk, 2013). Promising research has indicated that CBT-I is effective at treating comorbid or secondary insomnia (Geiger-Brown et al., 2015; McCurry et al., 2011), however, the effectiveness of CBT-I has not been examined among a complex sample of older adults receiving community mental health services for depression.

Insomnia and depression are common co-occurring conditions experienced by older adults (Sadler, McLaren, & Jenkins, 2013). Studies have reported that up to 90% of individuals with depression report problems with comorbid insomnia (Tsuno, Besset, & Ritchie, 2005). Historically, insomnia was believed to have been primarily a symptom or natural consequence of depression (Manber & Chambers, 2009). More recent evidence has demonstrated that insomnia often precedes the onset of depression among older adults (Perlis et al., 2006; Sadler et al., 2013) and can serve as an influential risk factor for depressive relapse (Pigeon & Perlis, 2007). Furthermore, studies have suggested that many of the symptoms required for the diagnosis of depression (e.g., tiredness, amotivation, depressed mood, hopelessness, poor concentration) can be attributed to increased levels of insomnia (Manber & Chambers, 2009; Spielman & Anderson, 1999). Collectively these findings have lead researchers to hypothesise that, in some cases, the relationship between insomnia and depression is reciprocal, as the two disorders can aggravate and maintain each other (Bootzin & Epstein, 2011; Manber et al., 2008). Therefore, insomnia becomes not only a symptom of depression, but can become an independent dysfunctional process and a comorbid disorder that can subsequently jeopardise depression treatment.

There is preliminary data that suggests CBT-I could have a positive effect on comorbid depression (e.g., Lancee et al., 2013; Manber et al., 2008; Wagley et al., 2013). This body of research, however, is still in its infancy and contains several significant limitations that restrict the strength and generalisability of the findings (e.g., younger participants, small sample sizes, homogenous groups, no randomisation design or comparison/control group). Therefore, constructing a study protocol that investigates whether CBT-I is effective for older adults who are engaged with a mental health service for depression would significantly contribute to this body of literature.

No CBT-I trial has specifically investigated whether additional therapeutic modifications need to be considered when treating depression among older adults. Researchers have suggested this is an important area of future research because older adults with depression may require a more advanced treatment program than standard CBT-I alone (McCurry et al., 2011; Siebern & Manber, 2011; Smith et al., 2005). The original CBT for depression manual (Beck, Rush, Shaw, & Emery, 1979) briefly discussed strategies to address symptoms of insomnia, most notably cognitively reframing negative predictions about poor sleep and increasing meaningful activities during the day. Integrating CBT for insomnia and depression (CBT-I-D) could be particularly helpful when staying in bed becomes an escape from the distress associated with the depression itself (Siebern & Manber, 2011; Smith et al., 2005). This increased desire to sleep and withdraw from daily activities is likely to increase the attempts to sleep, which in turn, can exacerbate cognitive and somatic arousal and interfere with overall sleep quality (Smith et al., 2005). Thus working simultaneously on both issues could create an increased therapeutic effect and further enhance sleep and mood outcomes. To date, no study has examined whether an advanced form of CBT-I-D produces greater reductions in insomnia and depression severity compared to CBT-I alone.

2.1.4 Aims and Hypotheses

The purpose of this study is to present a protocol that has been designed to evaluate whether CBT-I is effective for older adults with comorbid insomnia and depression in community mental health settings. This study aims to investigate whether there are significant differences between the three conditions (CBT-I, CBT-I-D, PCG), with a particular focus on whether CBT-I-D produces greater reductions in insomnia and depression severity compared to CBT-I. The final aim of the study is to qualitatively explore the participants' experience of taking part in the trial. This feedback will play an important role in improving future studies that explore the delivery of CBT-I for older adults with complex conditions.

There are two central hypotheses in this study. First, it is expected that participants who are randomised to the CBT-I condition will report a significant reduction in insomnia severity compared to participants who are randomised to the PCG condition at post (week 8) and follow-up (week 20) assessments. Second, it is hypothesised that participants who are randomised to the CBT-I-D condition will report greater reductions in insomnia and depression severity compared to participants who are randomised to the CBT-I and PCG conditions at post and follow-up assessments.

2.1.5 Methodology

2.1.5.1 Trial Design

This trial will follow the International CONSORT (Consolidated Standards of Reporting Trials) guidelines and evaluate conditions using a randomised control trial (RCT) design (Schulz, Altman, & Moher, 2010). Recruitment began in August 2014 and will continue until June 2016. Participants who are eligible for the trial will be randomly allocated to one of three conditions: CBT-I, CBT-I-D, or PCG. Outcomes will be assessed at pre-

intervention (week 0), post-intervention (week 8), and 3 month follow up (week 20). Figure 1 illustrates the study's design and expected participant flow chart.

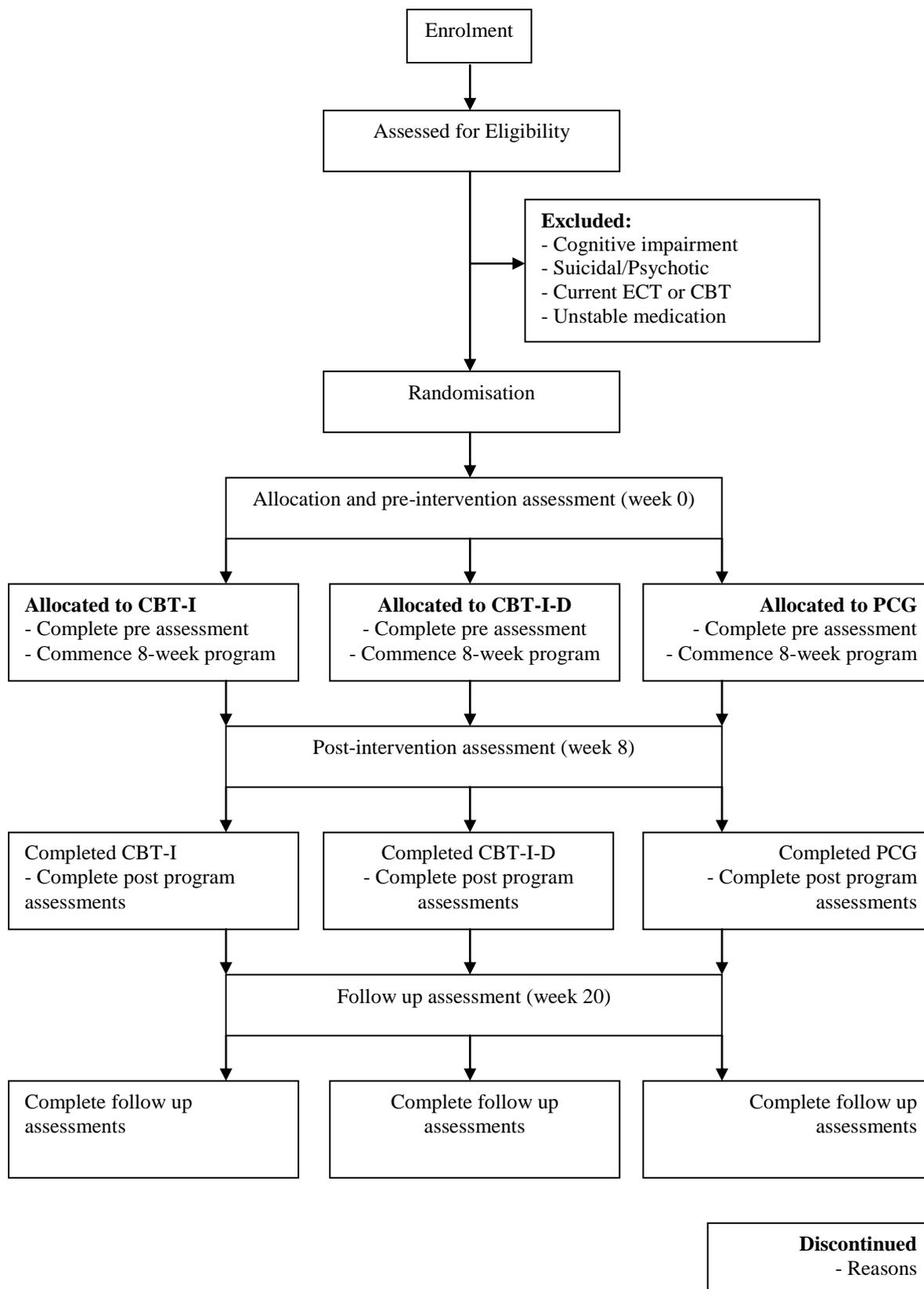


Figure 1. Study design and participant flow chart

2.1.5.2 Participants

Recruitment of participants occurred through aged persons' community mental health services in regional catchments of Victoria, Australia. A highly inclusive approach will be used to maximise participation and increase generalisability. Participants will be eligible for the trial if they meet the following criteria: aged 65 years or above; been referred to an aged persons' mental health service; current Comorbid Insomnia Disorder (American Psychiatric Association, APA, 2013); and past and/or current Major Depressive Disorder (APA, 2013).

Participants who meet criteria for Comorbid Insomnia Disorder will report (a) dissatisfaction with their sleep associated with either difficulty initiating sleep, difficulty maintaining sleep, or early morning awakening with inability to return to sleep; (b) causing significant impairment of functioning; (c) at least 3 nights per week; and (d) is present for at least 3 months. Participants who meet criteria for past and/or current Major Depressive Disorder will report (a) depressed mood or lack of interest/pleasure consistently over a two week period; (b) five or more of the following symptoms, including change of appetite/weight, sleep disturbance, psychomotor agitation/retardation, loss of energy, worthlessness/guilt, indecisiveness, or suicide ideation; and (c) the symptoms cause significant functional impairment.

Participants will be excluded if they are: cognitively impaired (Mini Mental State Exam score below 24; Folstein, Folstein, & McHugh, 1975); in crisis stage of mental illness (e.g., exhibiting psychotic features, demonstrating active suicidal intent/plan); on unstable doses of medication (this means eligible participants will need to be on the same doses of their prescribed medications for at least one month prior to commencing the intervention); currently participating in Electro-Convulsive Therapy (ECT); or currently participating in CBT with another psychotherapist.

2.1.5.3 Assessment

Potential participants will be provided with a trial invitation via the aged persons' mental health service staff. Interested participants will be asked to sign an informed consent document prior to commencing the eligibility assessment. Once consent is obtained, participants will be invited to participate in a preliminary insomnia screen. This screen will correspond with the *Diagnostic and Statistical Manual for Mental Disorders 5th edition (DSM-V)* criteria for Comorbid Insomnia Disorder (APA, 2013) and follow Morin and Benca's (2012) insomnia assessment guidelines. Participants meeting comorbid insomnia criteria will then be invited to participate in a clinical interview eligibility assessment.

Demographic information will be collected, including age, gender, relationship status, education level, income source, accommodation type, religious beliefs, past occupation, medical history, and medications. Participants will be asked if they have been diagnosed with a sleep disorder, and if so, their treatment (e.g., CPAP) and perceived treatment effectiveness. Participants will also be screened for sleep apnea and other comorbid sleep conditions (e.g., restless legs) by administering the SLEEP-50 (Spoormaker, Verbeek, Van den Bout, & Klip, 2005). It is important to note that participants with comorbid medical, sleep, and psychiatric conditions will be included in this trial.

The Mini International Neuropsychiatric Interview (MINI 6.0; Sheehan et al., 1998) will be administered to assess Major Depressive Disorder (past/current episode) and other high prevalence mental disorders. The MINI is a clinical psychiatric diagnostic tool with structured 'yes' or 'no' responses, (e.g., 'Were you ever depressed or down, most of the day, nearly every day, for two weeks?'). The MINI is more efficient to administer compared to other structured diagnostic instruments (e.g., SCID), taking approximately 15-30 minutes to complete. The MINI corresponds with the *DSM-IV* diagnostic criteria, which is commonly applied in research settings. The MINI has demonstrated inter-rater and test-retest reliability

and validity across diverse populations (e.g., Sheehan et al., 1997; Sheehan et al., 1998) including older adults (Ritchie et al., 2004). Since the MINI was standardised on the *DSM-IV*, the principal investigator updated the items for each disorder to be consistent with the *DSM-V* criteria.

The Mini-Mental State Examination (MMSE; Folstein et al., 1975) will be used to screen for possible cognitive impairment. The MMSE contains 30 items that assesses a range of cognitive functions, such as orientation, short term memory, language, comprehension, attention and calculation (Folstein et al., 1975). Total scores on the MMSE range from 0 to 30. Participant scores of 23 or below are considered to likely have a cognitive impairment (Folstein et al., 1975). The MMSE has shown high levels of reliability and validity, for instance, studies have reported internal consistencies of up to Cronbach's $\alpha = .90$, and test-retest reliabilities over a 24 hour period above $r = .85$ (Mitchell, 2009). In addition, Mitchell (2009) found the MMSE demonstrated adequate sensitivity (71.1% to 85.1%) and specificity (81.3% to 95.6%) across a range of settings.

2.1.5.4 Measures

Once the eligible clinical assessment has been completed, eligible participants will be asked to complete a self-report questionnaire package at pre-treatment (week 0) to collect baseline outcome measures. Participants will also be asked to complete the outcome measures at post-intervention (week 8) and 3 month follow-up (week 20). Participants will be financially reimbursed (\$20) each time they complete the questionnaire pack (\$60 total) to acknowledge this additional time dedicated towards the study. Table 3 shows the schedule and frequency of assessments during the trial.

Table 3. Assessments and administration frequency

Concept	Measure	Instrument	Conditions		
			Week 0	Week 8	Week 20
Primary Outcomes	Insomnia Severity	ISI	x	x	x
	Depression Severity	GDS	x	x	x
Secondary Outcomes	Sleep Quality	CSD	x	x	x
	Diagnosis	MINI 6.0	x	x	x
	Anxiety	GAI-SF	x	x	x
	Hopelessness	BHS	x	x	x
	Beliefs About Sleep	DBAS-10	x	x	x
	Sleep Conditions	SLEEP-50	x	x	x
	Health	EQ-5D-3L	x	x	x
Eligibility	Insomnia Diagnosis	DSM-V Insomnia Screen	x	x	x
	Cognitive Screen	MMSE	x	-	-
Moderators	Demographics	Demographic Information	x	-	-
Treatment	Expectations	TCI	x	-	-
	Feedback	Reflective Focus Group	-	x	-

Note: ISI: Insomnia Severity Index, CSD: Consensus Sleep Diary, GDS: Geriatric Depression Scale, MINI: Mini International Neuropsychiatric Interview, GAI-SF: Geriatric Anxiety Inventory Short Form, BHS: Beck Hopelessness Scale, DBAS-10: Dysfunctional Beliefs and Attitudes About Sleep 10-Item Scale, EQ-5D-3L: EuroQol Health Scale, MMSE: Mini Mental State Examination, TCI: Treatment Credibility Index.

The Insomnia Severity Index (ISI; Morin, 1993) is a self-report instrument measuring the participant's perception of his or her level of insomnia. The ISI assesses the subjective symptoms and consequences of insomnia, as well as the degree of concerns or distress caused by those difficulties during the previous two weeks. The ISI comprises seven items assessing: the severity of sleep-onset and sleep maintenance difficulties (both nocturnal and early morning awakenings); satisfaction with current sleep pattern; interference with daily

functioning; ability to notice the level of sleep impairment; and degree of distress or concern caused by the sleep problem. Each item is rated on a five-point scale (0 = none, to 4 = very). Total scores range from 0 to 28, with higher scores representing more severe levels of insomnia. Total scores of 0 to 7 indicate no clinically significant insomnia; scores of 8 to 14 indicate sub-threshold insomnia; and scores of 15 to 28 indicate moderate to severe levels of insomnia. Bastien et al. (2001) conducted a psychometric study of the ISI among older adults. It was found that the mean item-total correlations were $r = .56$ at pre-treatment, $r = .69$ at post-treatment, and $r = .72$ at follow-up. The internal reliability coefficients remained stable from $.76$ at baseline to $.78$ at follow-up. Bastien et al. concluded that the ISI was a useful clinical tool for screening insomnia severity among older adults or as an outcome measure in insomnia treatment research.

The Consensus Sleep Diary (CSD; Carney et al., 2012) allows individuals to record information about their nightly sleep pattern. A recent panel of international sleep experts (Carney et al., 2012) developed the CSD as the current standardised sleep diary measure for insomnia research. The CSD contains 9 items that were considered by the expert panel to represent the most critical sleep parameters (e.g., “What time did you get into bed?”). The CSD was formatted so that one week of nightly sleep data could be recorded on a single diary page. The CSD instructions included general information, such as what to do if the respondent misses recording on a particular day, and an item-by-item instruction guide to enhance likelihood of correct item interpretation. Additional instructions indicate that all items should be completed in the morning within one hour of getting out of bed. Previous research (e.g., Rogers, Caruso, & Aldrich, 1993) has reported that sleep diaries were accurate when compared to polysomnographic data ($\kappa = .87$; sensitivity = 92.3%; specificity, 95.6%). Researchers agree that having individuals prospectively self-monitor their sleep with

a sleep diary is a useful psychometric tool for insomnia assessment and for examining treatment effects (e.g., Buysse et al., 2006).

The SLEEP-50 (Spoormaker et al., 2005) is designed to measure the intensity of an individual's subjective sleep complaints on a range of sleep conditions, including sleep apnea, insomnia, narcolepsy, restless legs, circadian rhythms, sleepwalking, nightmares, other factors influencing sleep, and functioning impairment. The SLEEP-50 is scored on a 4-point Likert scale from 1 'not at all' to 4 'very much'. An example sleep apnea item includes "I am told that I hold my breath when sleeping". The SLEEP-50 is considered a reliable and valid screening tool for comorbid sleep conditions, Spoormaker et al. reporting a 3-week test-retest reliability of $r = .78$ and Cronbach's α of $.85$.

The Dysfunctional Beliefs and Attitudes About Sleep 10-Item Scale (DBAS-10; Espie et al., 2000) measures the intensity of maladaptive beliefs about sleep (e.g. "When I have trouble getting to sleep, I should stay in bed and try harder"). Espie et al. redeveloped this measure into a shorter version of 10 items from the original 30-item DBAS scale of Morin (1993). Participants complete each question using a 10-cm visual analogue scale, anchored with strongly disagree and strongly agree. Added together, the 10 item responses provide the final DBAS score. Total scores range from 0 to 100, with higher scores representing more rigid or stronger levels of dysfunctional beliefs and attitudes about sleep. The DBAS-10 has been found to be a reliable measure of dysfunctional beliefs about sleep among older adults (Cronbach's $\alpha = 0.88$; Sadler et al., 2013).

The Geriatric Depression Scale (GDS; Yesavage et al., 1982) is a 30-item clinician-rated questionnaire used to assess depression severity specifically for older adults. Participants are asked to respond 'yes/no' to each item, for example, "Over the past week have you felt that your life has been empty?" Possible scores range from 0 to 30, with higher scores indicating the presence of more depressive symptomatology. Total scores of 0 to 9

indicate normal levels of depression, 10 to 19 indicate mild to moderate levels of depression, and 20 to 30 indicates severe depression (Yesavage et al., 1982). Yesavage et al. reported that the GDS had a high degree of internal consistency (Cronbach's $\alpha = .94$) and weekly test-retest reliability ($r = .85$), and displayed strong correlations with other well-validated depression measures (e.g., Hamilton Rating Scale for Depression, $r = .83$).

The Geriatric Anxiety Inventory Short Form (GAI-SF; Byrne & Pachana, 2011) is a 5-item version of the original 20-item Geriatric Anxiety Inventory (Pachana, et al., 2007), which assesses anxiety severity among older adults. Respondents answer yes/no to the 5 items, for example, 'I worry a lot of the time'. A score of 3 or more indicates probable anxiety disorder. At this cut off, sensitivity was 75% and specificity was 87%. Internal consistency was also found to be high, Cronbach's α at .81 (Byrne & Pachana, 2011).

The Beck Hopelessness Scale (BHS; Beck et al., 1974) is a self-report instrument which entails 20 true/false statements designed to assess the degree to which an individual holds negative beliefs about the future over the previous week. For example, a participant that answers 'True' to the follow question, "My future seems dark to me", would score 1 point and represent a pessimistic response. Each of the 20 statements is scored 0 or 1, with the total being calculated by summing the pessimistic responses for the 20 items. The total BHS score ranges from 0 to 20, with higher scores reflecting higher levels of hopelessness. Total scores ranging from 0 to 3 identify minimal hopelessness, 4 to 8 identify mild hopelessness, scores from 9 to 14 identify moderate hopelessness, and scores greater than 14 identify severe hopelessness. The BHS has been used widely among older adult community samples (e.g., Tanaka, Sakamoto, Ono, Fujihara, & Kitamura, 1996). Test-retest reliability of the BHS over a six week period ranged from $r = .66$ to $r = .69$, and internal consistency was high, Cronbach's $\alpha = .93$ (Beck & Steer, 1988).

The EQ-5D-3L scale (The EuroQol Group, 1990) measures perceived health status. It comprises of 5 items measuring mobility, self-care, usual activities, pain, and mood. Each item is rated on 3 point Likert scale (1= no problems, 2 = some problems, 3 = extreme problems). The EQ-5D-3L also contains an additional item, which asks respondents to rate their overall current health level using a visual analogue scale from ‘0 = worst imaginable health’ to ‘100 = best imaginable health’. The EQ-5D-3L has been validated across several populations and countries (e.g., Greiner et al., 2003) and is considered an appropriate outcome measure of health status (Brooks, 1996).

The Treatment Credibility Index (TCI; Devilly & Borkovec, 2000) measures treatment credibility and expectancy for use in clinical trials. It involves 6 items which covers two factors, thinking-based credibility (e.g., ‘How logical does the therapy offered to you seem?’) and feeling-based expectancy (e.g., ‘How much improvement in your symptoms do you really feel will occur?’). The TCI demonstrated high internal consistency (Cronbach’s $\alpha = .85$) and good test-retest reliability ($r = .82$ for expectancy and $r = .75$ for credibility).

2.1.5.5 Outcome Assessors

The post and follow up outcome assessments will be conducted by provisional and general registered psychologists who are on clinical placement or employed with the aged persons’ mental health services. The independent assessors will have no therapeutic involvement with the intervention group they are testing. They will also be blinded to the condition they are evaluating. The assessors will receive training and supervision by the principal investigator throughout the trial.

2.1.5.6 Primary Outcomes

The primary outcomes being assessed are insomnia and depression severity. Participants' level of insomnia (ISI; Morin, 1993) and depression (GDS; Yesavage et al., 1982) will be assessed using validated self-report questionnaires.

2.1.5.7 Secondary Outcomes

The secondary outcomes being assessed are sleep quality (CSD; Carney et al., 2012), mental health diagnosis (MINI 6.0; Sheehan et al., 1998), anxiety (GAI-SF; Byrne & Pachana, 2011), hopelessness (BHS; Beck et al., 1979), beliefs/attitudes about sleep (DBAS-10; Morin, 1993), comorbid sleep conditions (SLEEP-50; Spoormaker et al., 2005), and health status (EQ-5D-3L; The EuroQol Group, 1990).

2.1.5.8 Interventions

2.1.5.8.1 Cognitive Behaviour Therapy for Insomnia (CBT-I)

CBT-I is a structured, time limited, multi-component program that includes a combination of educational, cognitive, and behavioural interventions (e.g., Belanger et al., 2012; McCurry et al., 2007; Morin, 1993, 2012). The main objective of CBT-I is to change factors that perpetuate insomnia, including behavioural factors (poor sleep habits, irregular sleep schedules), psychological factors (unrealistic expectations about sleep, unhelpful sleep beliefs), and physiological factors (somatic tension, cognitive hyper-arousal). The CBT-I program will closely follow Morin's CBT-I treatment guidelines (e.g., Belanger et al., 2012; Morin, 1993, 2012; Morin & Espie, 2003), and also acknowledge the works from Lichstein (e.g., Lichstein & Morin, 2000) and Rybarczyk (e.g., Rybarczyk et al., 2005) in treating comorbid insomnia.

Participants assigned to the CBT-I condition will attend eight weekly, 60-90 minute sessions, which will include small groups comprising of 5 to 6 participants. Group therapy was chosen instead of individual therapy because working in groups is more cost effective and time efficient (Koffel, Koffel, & Gehrman, 2015). This is particularly important for regionally-based community mental health settings where resources can be limited (Sadler & McIlvena, 2015). Group therapy also creates an opportunity to increase participants' sense of belonging, provide peer-to-peer support and motivation (Koffel et al., 2015). The format and delivery of treatment will follow a clear CBT session structure (Lichstein & Morin, 2000; Morin, 2012). Information handouts and homework worksheets for each CBT-I intervention will be provided and kept in a daily workbook. The principal investigator of this study carefully designed these worksheets to be easily legible and workable for older adults. Participants will be educated about the strong relationship between homework compliance, group connectedness, attendance, and treatment effect (Espie, 2009; Kazantzis, Pachana, & Secker, 2003). Each participant will also be encouraged to have a supportive person (e.g., family, friend) to assist their homework compliance during the trial (Kazantzis et al., 2003).

The behavioural sleep interventions of CBT-I will be introduced in the first 4 sessions of the program, and include stimulus control/restriction, sleep hygiene, and relaxation skills (Morin, 1993, 2012; Morin & Espie, 2003). The cognitive sleep interventions in CBT-I will be covered in the latter half of the program, which includes cognitive restructuring. During this second half of the program, there will be considerable discussion devoted to relapse prevention and maintaining progress (Morin, 2012; Morin & Espie, 2003).

2.1.5.8.2 Cognitive Behaviour Therapy for Insomnia and Depression (CBT-I-D)

Participants who are assigned to the CBT-I-D group will complete the same program as the participants assigned to the CBT-I group (e.g., eight sessions of CBT-I), however, the

CBT-I-D group will include an additional three CBT strategies to address comorbid depression (behavioural activation, cognitive reframing for depression, and affirmations).

The first additional intervention in this group will include behavioural activation. Behavioural activation, or activity scheduling, is a common intervention included in CBT for depression, which aims to increase an individual's level of activity, socialisation, and sense of achievement/pleasure (Beck, 2011; Westbrook, Kennerley, & Kirk, 2011; Yon & Scogin, 2008). This involves setting behavioural goals and planned activities, and keeping a daily activity schedule to explore how the participants' feel before and after an activity. These behavioural experiments will be regularly discussed and monitored during the program.

The second and third additional elements of CBT-I-D involves including a broader focus on cognitive reframing and positive affirmations. In addition to reframing sleep-related dysfunctional beliefs, participants in this group will also learn to reframe important negative thoughts related to their depression (e.g., Beck, 2011; Beck et al., 1979; Westbrook et al., 2011). This will be achieved through additional thought records and positive affirmation hope cards introduced during the latter 4 sessions of the program.

2.1.5.8.3 Psychoeducation Control Group (PCG)

Participants assigned to the PCG will also attend eight weekly, 60-90 minute sessions, in small groups comprising of 5 to 6 participants. The content of these sessions will include psycho-education about sleep, insomnia, and depression, with no active cognitive or behavioural change strategies (e.g., instructions, guidelines, homework tasks, relapse prevention). This group will take a more supportive approach rather than a structured CBT format. Morin et al. (2006) and Morgenthaler et al. (2006) reported that only providing psycho-education is an appropriate control condition in insomnia treatment research. Table 4 summarises the differences in therapeutic content between the conditions.

Table 4. Summary of session interventions

Session	CBT-I	CBT-I-D	PCG
1	Introduction	Introduction	Introduction
2	Stimulus Control Sleep Restriction	Stimulus Control Sleep Restriction Behavioural Activation	Insomnia
3	Sleep Hygiene	Sleep Hygiene Behavioural Activation	Sleep Health
4	Relaxation	Relaxation Behavioural Activation	Sleep and Mood
5	Relaxation Cognitive Reframing (Insomnia)	Relaxation Cognitive Reframing (Insomnia)	Sleep and Mood
6	Cognitive Reframing (Insomnia)	Cognitive Reframing (Insomnia/Depression)	Beliefs About Sleep
7	Cognitive Reframing (Insomnia)	Cognitive Reframing (Depression) Affirmations	Beliefs About Sleep
8	Relapse Prevention	Affirmations Relapse Prevention	Summary

Note: CBT-I Cognitive Behaviour Therapy for Insomnia; CBT-I-D Cognitive Behaviour Therapy for Insomnia and Depression; PCG Psychoeducation Control Group

2.1.5.9 Therapists

The therapists who co-facilitate the groups will be provisionally registered psychologists who are completing their final clinical psychology placement within the aged persons' mental health services. The groups will be co-facilitated due to the heterogeneous and complex nature of this sample. The therapists will receive daily training and clinical supervision throughout the trial by the principal investigator.

2.1.5.10 Focus Groups

At the end of the final session of each condition (session 8), participants will be invited to participate in a focus group to reflect on their experiences from participating in the trial. They will be asked eight questions (e.g., 'What specific strategy was most helpful during the program?') that have been designed to inform future CBT programs in this field. The focus groups will be conducted by the principal investigator and audio recorded for qualitative statistical analysis. The principal investigator will approach the focus groups in a non-judgemental and curious manner, encouraging open discussion and reflection rather than challenging the participants' responses (Reid, Flowers, & Larkin, 2009).

2.1.5.11 Randomisation

The randomisation allocation process of participants to treatment groups will comply with CONSORT guidelines (e.g., Mohor et al., 2010). A block/cluster randomisation design utilising random permuted blocks with randomised block sizes will be implemented to randomly allocate each participant group to one of three conditions throughout the trial. Block randomisation is commonly used in small to moderate sized RCTs to ensure that approximately equal numbers of participant groups in the clustered context are allocated to each condition (Suresh, 2011). The computer-generated random allocations will be generated

by an independent researcher at Federation University Australia and will be stored on a password protected computer back up to a secure university file server. Random allocation will occur after the pre-treatment assessments have been completed to ensure eligibility has been met. Each successive random allocation will be communicated to the principal investigator only when 5-6 eligible participants are ready to commence a group. Participants will be unaware of the study's hypotheses or which group they have been randomly allocated. The co-therapists will not be blinded to the treatment conditions.

2.1.5.12 Sample Size Calculation

Statistical power analysis was based on an examination of treatment-time interactions in a repeated measures analysis of covariance (RMANCOVA) of the ISI measure (Morin, 1993), with adjustment for confounders. We specified an initial value of 18 points in the adjusted mean of the ISI score at pre intervention (Garland et al., 2014); a mean reduction of 10 points from pre to post intervention for the CBT-I treatment (Garland et al., 2014); and a target value of 2 points difference between the pre-post changes for each of the three treatment conditions (i.e. -8, -10, -12 points respectively) (Morin et al., 1999), with no further change at follow-up (Morin et al. 1999), and assumed a 'within-treatments' *SD* of 3.4 points (Garland et al., 2014). This resulted in an effect size of 0.23. Under the assumptions of constant correlation over time (sphericity), with an estimated magnitude of $r = 0.6$ based on reported test-retest reliabilities of 0.79 (Chung et al., 2011) and 0.86 (Yong et al., 2014), and allowance for a design effect (Donner & Klar 2000) of 1.07 due to clustering of participants within treatment groups (based on an assumed cluster size of 5 and an intraclass-correlation of 0.017, Garland et al., 2014), with a significance level of 5% and 80% power, the required sample size calculated using GPower software (Faul, Erdfelder, Lang, & Buchner, 2007) is $N = 35 (33 \times 1.07)$. Maintaining the same specifications, but focusing solely on the CBT-I and

CBT-I-D conditions, the specific target difference of 2 points between the pre-post changes for these two particular treatments corresponds to an effect size of 0.13. In order to have 80% power to detect this particular difference in a post hoc pairwise comparison, the required sample size is increased to $N = 85$ (78×1.07).

With regard to the GDS measure (Yesavage et al., 1982), Secker and Brown (2005) reported pre and post intervention means of 7.0 and 4.4 in a treatment group, and 5.8 and 4.7 in a control group, a difference of 1.5 units $[(7.0 - 4.4 = 2.6) - (5.8 - 4.7 = 1.1)]$ in the change pre-post, and an average within-treatments *SD* of 3.5. Replacing the values of 2.0 and 3.4 in the ISI analysis with 1.5 and 3.5 results in effect sizes of 0.16 with respect to comparisons across the three conditions and 0.10 with respect to comparisons between the two conditions. This leads to required sample sizes of $N = 68$ with respect to comparison of mean GDS across the three conditions, and $N = 150$ with respect to comparison of mean GDS between two of the conditions. Because this is larger than $N = 85$ from the ISI projection, $N = 150$ becomes our target sample size, which equates to 50 participants or 10 groups per condition.

2.1.5.13 Statistical Analyses

Data will be entered, screened, and analysed using SPSS Version 21 (Howell, 2013). A RMANCOVA will be implemented to explore differences between the conditions over time, and calculate effect sizes to investigate the treatment effect. An intention-to-treat methodology will be applied via multiple imputation. The qualitative data obtained from the focus groups will be analysed according to the Interpretative Phenomenological Analysis (IPA) method (e.g., Reid et al., 2009; Smith & Osborn, 2003). This will be achieved by transcribing the data verbatim from audio recordings into text. The text transcripts will be read several times to extract emerging codes, which will then be transformed into themes (Reid et al., 2009). Themes are likely to identify both something of importance to the

participants, and also convey a meaning of their reflection (Smith & Osborn, 2003). These themes will form the basis for the qualitative results. Direct quotes from the participants will also be reported to highlight the thematic findings (Smith & Osborn, 2003).

2.1.5.14 Ethics Approval and Trial Registration

This trial will be conducted in accordance with the ethical guidelines outlined in the National Statement on Ethical Conduct in Human Research (National Health and Medical Research Council, 2013). Ethics approval for this project has been granted by the Federation University Australia Human Research Ethics Committee (E-14-042), the Latrobe Regional Hospital Human Research Ethics Committee (2014-02-LNR), and the Peninsula Health Human Research Ethics Committee (HREC-15-PH-4). The trial has also been registered with the Australian New Zealand Clinical Trial Registry, ACTRN: 12615000067572.

2.1.6 Discussion

This paper describes the study protocol for the development and evaluation of a CBT program for older adults with comorbid insomnia and depression. The results from this trial will represent a significant step forward in this field and assist in advancing CBT-I for older adults receiving mental health services for depression. It is anticipated that several important clinical implications could result from this project.

One of the primary aims is to evaluate whether CBT-I is effective among a complex sample of older adults with comorbid insomnia and depression in a community mental health setting. We predict that CBT-I will be more effective at reducing insomnia severity compared to the PCG. If this hypothesis is supported, it will demonstrate that CBT-I is helpful at reducing insomnia severity for older adults with depression in a community mental health setting. This evidence will add to a growing research base that suggests CBT-I needs to be

considered as a treatment option for individuals with comorbid insomnia (Martinez et al., 2013; Stepanski & Ryberczyk, 2006; Vitiello et al., 2013).

Since previous research has suggested that comorbid insomnia is often misunderstood and inadequately treated (Espie, 2009; Morin, 2012; Smith et al., 2005), education and training play a vital role to address this disparity between research and clinical practice. This could involve providing workshops to mental health practitioners to raise their awareness of addressing comorbid insomnia during the assessment, case conceptualisation, and treatment planning phases. To ensure older adults with comorbid insomnia have access to this form of psychological treatment, mental health services could also consider training a therapist on their multidisciplinary team in CBT-I, or at least source an external CBT sleep specialist as a referral option. These implications could potentially improve therapeutic outcomes for older adults receiving mental health services by ensuring clinicians are better equipped to address comorbid insomnia.

This project also plans to explore whether improving an older adult's sleep pattern with CBT-I has an associated positive impact on their mood. Recent preliminary evidence suggests CBT-I can have a positive effect of depression levels (Lancee et al., 2013; Manber et al., 2008; Wagley et al., 2013), however, these studies have substantial methodological limitations which restrict the generalisability of the results. Consequently, this study aims to test whether CBT-I generates greater reductions in depressive severity compared to a PCG. If the results indicate that CBT-I is more effective at improving depression compared to the control condition, aged psychiatric services could consider adding CBT-I as a regular treatment option for their clients presenting with comorbid insomnia and depression.

A unique feature of this trial involves testing an advanced form of CBT-I that includes additional strategies to address comorbid depression among older adults. Although recent studies (e.g., Vitiello et al., 2013) have suggested that specifically designed CBT-I programs

may produce better overall outcomes for targeted populations (e.g., older adults with comorbid insomnia and depression), no study has tested whether an advanced CBT-I-D program is more effective than a standard CBT-I program. The results following this specific investigation could highlight CBT-I is sufficient to address both insomnia and depression, or indicate CBT-I-D is clinically indicated to better treat these conditions simultaneously. This result could guide future CBT-I treatment programs in relation to either broadening or lessening the scope of treatment.

Finally, we are interested in studying the participants' experiences from taking part in a CBT trial for insomnia and depression. The information gained from a mixed methods design will provide an opportunity to gather rich, personal data through older adults that can either confirm or disconfirm the questionnaire outcome measures (Cheung et al., 2013; Matthews et al., 2013). This can open new avenues of explanation for particular findings that traditional quantitative measures cannot detect (Patton, 2005). For example, results from the reflective focus groups may indicate participants benefitted from specific CBT strategies that would not be revealed through quantitative data (Matthews et al., 2013). In addition, participants may provide innovative feedback that is particularly relevant to the delivery of CBT-I among this complex aged population. Therefore, it is expected that the qualitative findings from this project will enhance the direction of future research in this field.

Despite the important implications that may result from this study protocol, the project will likely include limitations. First, no physiological measure of sleep (e.g., polysomnography) will be assessed to cross-validate the clinical interview and self-report data. This means that the assessments throughout the trial will be reliant on subjective measures from the participants and researchers, as opposed to objective biological data. Since no standardised clinical diagnostic instrument has been established yet for the *DSM-V*, the authors updated existing *DSM-IV* diagnostic instruments (e.g., MINI 6.0) to be consistent

with the *DSM-V* diagnostic criteria. Finally, participant recruitment and retention rates could be negatively affected due to this population likely experiencing stronger symptoms of tiredness, hopelessness, and amotivation. Hence, recruiting participants and keeping them engaged throughout the program will likely create significant challenges. Notwithstanding these limitations, the results following this study protocol will likely contribute important knowledge that improves case formulation and treatment planning for older adults with comorbid insomnia and depression.

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2.2 Bridge between Methodology and Quantitative Results

The initial literature review provided the rationale to develop a mixed-methods RCT research design (published in *Trials*). Three conditions were tested using a group therapy format: CBT-I (standard), CBT-I+ (advanced), and PCG (control). Primary and secondary measures were collected at pre (week 0), post (week 8), and follow-up (week 20). Two results chapters were generated to test three research questions, which were: (1) Does CBT-I benefit older adults with comorbid insomnia and depression within a community mental health setting better than a psychoeducation control group? (2) Does an advanced form of CBT-I+ produce better outcomes compared to a standard form of CBT-I? (3) What were the participants' experiences of CBT-I and CBT-I+ and how these may inform future research? The first results chapter addressed the two primary research questions through quantitative data analyses (published in *SLEEP*).

QUANTITATIVE RESULTS

3.1 Randomised Controlled Clinical Trial

3.1.1 Publication Details

Title:

Cognitive behaviour therapy for insomnia and depression among older adults: A randomized controlled trial in community mental health services

Journal:

SLEEP (Oxford University Press)

Impact Factor 4.923

Status: Published online 25th May 2018

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3.1.2 Abstract

Study Objectives

To investigate whether cognitive behaviour therapy was effective for older adults with comorbid insomnia and depression in a community mental health setting, and explore whether an advanced form of cognitive behaviour therapy for insomnia produced better outcomes compared to a standard form of cognitive behaviour therapy for insomnia.

Methods

An 8 week randomized controlled clinical trial was conducted within community mental health services, Victoria, Australia. Seventy-two older adults (56% female, *M* age 75 years \pm 7) with diagnosed comorbid insomnia and depression participated. Three conditions were tested using a group therapy format: cognitive behaviour therapy for insomnia (CBT-I, standard), cognitive behaviour therapy for insomnia plus positive mood strategies (CBT-I+, advanced), psychoeducation control group (PCG, control). The primary outcomes were insomnia severity (Insomnia Severity Index) and depression severity (Geriatric Depression Scale). Primary and secondary measures were collected at pre (week 0), post (week 8), and follow-up (week 20).

Results

CBT-I and CBT-I+ both generated significantly greater reductions in insomnia and depression severity compared to PCG from pre to post ($p < .001$), which were maintained at follow-up. Although the differences between outcomes of the two treatment conditions were not statistically significant, the study was not sufficiently powered to detect either superiority of one treatment or equivalence of the two treatment conditions.

Conclusion

CBT-I and CBT-I+ were both effective at reducing insomnia and depression severity for older adults. Mental health services that deliver treatment for comorbid insomnia with cognitive behaviour therapy may improve recovery outcomes for older adults with depression.

Statement of Significance

This is the first randomized controlled clinical trial to demonstrate that specifically treating insomnia with cognitive behaviour therapy has a positive effect onto improving depression for older adults with multiple comorbidities. Standard and advanced cognitive behaviour therapy programs revealed similar reductions in insomnia and depression severity, however, this trial had inadequate power to detect non-equivalence. Both active treatments demonstrated large effect sizes, high retention, and strong remission rates among older adults with insomnia and depression. Replication of this study is necessary with a larger sample size to conclusively establish whether or not the two interventions have different or equivalent effects. Replication with other age groups and settings is also required to establish generalizability of results.

Trial Registration

Australian and New Zealand Clinical Trials Registry (ANZCTR)

URL: <https://www.anzctr.org.au>

Trial ID: ACTRN12615000067572

Date Registered: 12th December 2014

3.1.3 Introduction

Insomnia is a common sleep-wake problem among older adults with severe mental illness. Insomnia and depression share a strong bidirectional relationship.¹ Studies have reported that up to 70 percent of older adults with depression can experience comorbid insomnia symptoms.^{2,3} Researchers have established that insomnia often plays a significant role in precipitating and perpetuating depressive symptoms.⁴⁻⁶ Although most older adults with depression experience difficulties initiating or maintaining sleep, insomnia is often discounted as a specific target for treatment.⁷ When comorbid insomnia is not adequately assessed or treated, a greater risk of depressive relapse and suicide is possible.^{8,9} The association between insomnia and depression not only has the potential to cause life-threatening consequences, but also presents significant direct and indirect costs to the wider healthcare system.¹⁰ Since mental health services have limited budgets and stretched resources, an efficient approach is to target highly prevalent comorbid conditions with innovative evidence-based treatments.

A compelling literature base has emerged over the past 30 years highlighting the positive effects of cognitive behaviour therapy for insomnia (CBT-I). This treatment program offers several practical skills to help change unhelpful cognitive and behavioural patterns that exacerbate insomnia.¹¹⁻¹³ Meta-analyses have shown CBT-I to be an effective and first line treatment option for insomnia disorder.¹⁴⁻¹⁶ CBT-I compares favourably against pharmacotherapy treatments and produces longer lasting positive effects.¹⁷⁻²⁰ Historically CBT-I research focussed on primary insomnia and excluded people with comorbidities, however, a growing body of research has now established that CBT-I is also efficacious for comorbid insomnia.²¹⁻²³ Despite these important research developments, CBT-I trials have been primarily based on younger or middle-aged adults (mean age below 65 years). As a

result, older adults (mean age above 65 years) with comorbid severe mental illnesses have been under-represented in the CBT-I literature.

Currently it is unknown whether CBT-I is effective for older adults who are receiving outpatient aged persons mental health services. This is an essential group to include in clinical research because the older adult population is growing rapidly,²⁴ which will inevitably place greater demands mental health practitioners.²⁵ From a CBT-I ‘stepped care’ framework,²⁶ the needs of this aged cohort likely meet the middle to top tiers of CBT-I service delivery. Older adults who require community mental health services typically present with heterogeneous biopsychosocial formulations and tend to have severe, recurrent/persistent, and multiple interrelated comorbidities.^{25,27} A randomized controlled trial (RCT) is needed within this setting because promising evidence indicates CBT-I not only improves insomnia, but has the potential to also reduce depression.

Recent RCTs suggest CBT-I reduces both insomnia and depression severity (for review see²⁸). Two recent innovative studies have come from Blom et al.²⁹ and Norell-Clarke et al.³⁰ Both of these trials were based in Sweden and included middle-aged adults with comorbid insomnia and depression. Blom et al. tested two internet-based CBT programs over a course of 9 weeks ($N = 43$, M age = 47 years). One condition focused on treating insomnia (iCBT-I) and the other focused on treating depression (iCBT-D). Blom et al. found iCBT-I was more effective at reducing insomnia severity (Cohen’s $d = 1.06$) compared to iCBT-D (Cohen’s $d = 0.54$), and reported both conditions were equally as effective at reducing depressive symptoms (iCBT-I Cohen’s $d = 0.74$; iCBT-D Cohen’s $d = 0.66$). Notable weaknesses in Blom et al.’s trial were the absence of a control condition, modest sample size, and the study was not blinded. Another important consideration was Blom et al.’s participants were able to self-refer and engage independently in an internet-based self-help program. This means that people with low computer literacy and complex comorbidities will unlikely

engage in this form of treatment.^{26,28} Therefore, traditional face-to-face modes of therapy remain a central CBT-I option. Norell-Clarke et al.³⁰ compared a group-based CBT-I program with a relaxation control group over four biweekly sessions ($N = 64$, M age = 51 years). Norell-Clarke et al. found CBT-I was more effective than relaxation in reducing insomnia severity (CBT-I Cohen's $d = 2.02$, relaxation Cohen's $d = 1.28$), whereas both conditions had similar but less effects on reducing depression severity (CBT-I $d = 0.76$, relaxation $d = 0.26$). Despite the small yet emerging base of research that has found CBT-I to have a positive impact on comorbid insomnia and depression, recent studies have reported some discrepancies in results. For instance, the recent Carney et al.⁵⁹ trial did not find differential improvement in insomnia severity among conditions, and it is not clear that it found differential improvement on depression levels as each condition showed similar improvements. Manber et al.⁶⁵ also found no differential improvement of CBT-I plus antidepressants on depression severity or remission relative to a control group in a large heterogeneous sample, thus failing to replicate their earlier pilot results. These inconsistent findings create an opportunity to advance treatment by considering whether a modified form of CBT-I that includes additional mood-enhancing strategies could strengthen outcomes.

Researchers have recently proposed a hybrid form of CBT that simultaneously treats comorbid insomnia and depression may produce better outcomes.³¹⁻³⁴ 'Advanced' cognitive behaviour therapy for insomnia includes additional therapeutic content designed to reduce both insomnia and depression within the one multicomponent program.^{27,28} 'Standard' CBT-I, on the other hand, limits its focus to treating insomnia.^{27,28} Since insomnia and depression are strongly intertwined and can aggravate each other, researchers have suggested a logical step is to test whether proactively addressing both problems produce stronger results.^{27,28} Cognitive behaviour therapy for insomnia plus positive mood strategies (CBT-I+) combines well-proven CBT strategies for depression (e.g., behavioural activation, cognitive reframing

for depression, and hopeful affirmations) with established CBT-I interventions (e.g., stimulus control, sleep restriction, sleep hygiene, relaxation, cognitive reframing for insomnia).

Although it is currently unknown whether advanced CBT-I+ produces better outcomes than standard CBT-I, Lichstein and colleagues³⁴ recently published pilot data that suggested a telehealth mode of CBT that combined interventions for insomnia and depression may be effective for older adults with co-occurring insomnia and depression. Five participants (*M* age 65 years) from remote parts of Alabama, USA, completed 10 weekly sessions of CBT for insomnia and depression via Skype in their primary care setting. Lichstein et al. reported the participants experienced significant reductions on both insomnia and depression severity from pre to post, which were maintained at a 2-month follow up. Large post effect sizes were also found for insomnia (Cohen's $d = 1.64$) and depression (Cohen's $d = 1.14$). Lichstein et al.'s small pilot study provides a platform to test whether advanced CBT-I+ improves insomnia and depression more than standard CBT-I. The implications from a well-designed RCT could influence the future direction of CBT-I program development and delivery.

The primary aim of this study involved investigating whether CBT-I was an effective treatment for older adults with comorbid insomnia and depression within a community mental health setting. It was hypothesized that CBT-I would generate greater reductions in insomnia and depression severity than a psychoeducation control post-treatment. A second aim was to explore whether an advanced form of CBT-I+ produced better outcomes compared to a standard CBT-I program. It was anticipated that CBT-I+ would have larger reductions in insomnia and depression severity compared to CBT-I post-treatment.

3.1.4 Methodology

3.1.4.1 Participants and Recruitment

This RCT was open to older adults who had been referred to or were case managed by an aged persons' community mental health service in regional parts of Victoria, Australia. Ethics approval was granted by Federation University Australia, Latrobe Regional Hospital, and Peninsula Health Human Research Ethics Committees. Recruitment was conducted between 2014 and 2016 via telephone or face-to-face by mental health clinicians (e.g., psychologists, psychiatric nurses, social workers, occupational therapists, psychiatrists). An inclusive approach was adopted in this trial to capture the heterogeneous nature of older adults who require involvement from community-based mental health services. Interested participants who provided consent underwent a face-to-face assessment process at their home or an outpatient mental health clinic. The multi-dimensional assessment process involved conducting a clinical interview, administering and collecting a questionnaire package and sleep diary. Figure 1 illustrates the participants' pathway throughout the trial.

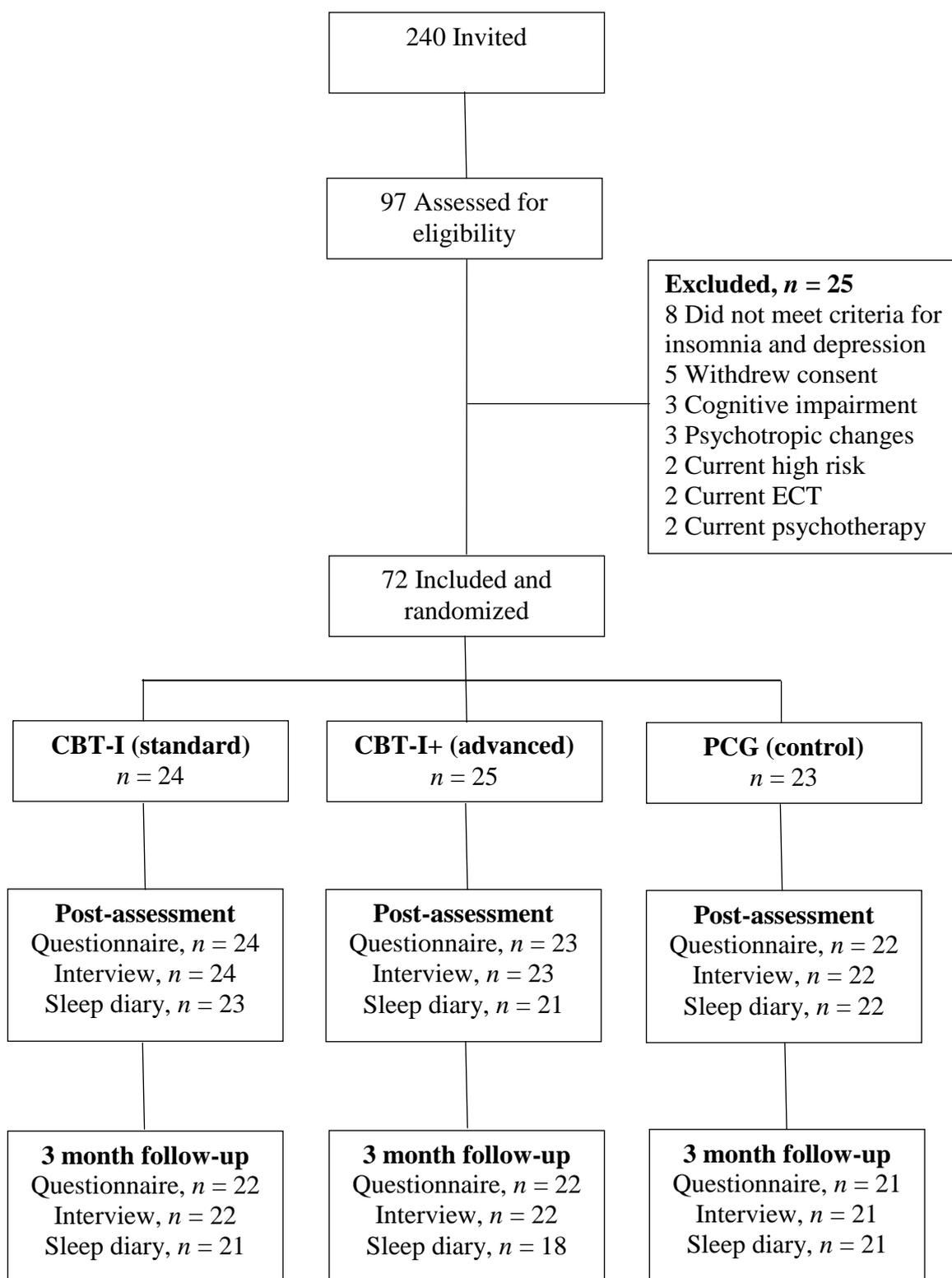


Figure 2 Participant flow chart. CBT-I, Cognitive Behaviour Therapy for Insomnia; CBT-I+, Cognitive Behaviour Therapy for Insomnia plus; PCG, Psychoeducation Control Group.

Participants were eligible if they met the following criteria:

- (1) Aged 65 years old or above,
- (2) Referred to and/or case managed by a community mental health service between 2014 and 2016,
- (3) Met the *Diagnostic and Statistical Manual for Mental Disorders (5th edition, DSM-V)* criteria for Insomnia Disorder (with comorbidity) and Major Depressive Disorder.³⁵

The following exclusion criteria were applied:

- (1) Did not meet criteria for comorbid insomnia and major depression,³⁵
- (2) Cognitive impairment (Mini Mental State Exam, MMSE < 24),³⁶
- (3) Changes to psychotropic medications within 4 weeks of commencing the trial and/or changes made throughout treatment,
- (4) Current high risk (e.g., suicide plan/intent, manic/psychotic symptoms),
- (5) Current course of maintenance electroconvulsive therapy (ECT),
- (6) Current engagement in course of psychotherapy.

3.1.4.2 Diagnosis

A two-step assessment process was implemented to diagnose the presence of Insomnia Disorder with comorbidity and Major Depressive Disorder.³⁵ Step 1 involved co-assessors (provisional and generalist psychologists) conducting a face-to-face clinical interview. A semi-structured insomnia clinical interview based on Buysse et al.'s⁴⁰ and Morin and Benca's⁴¹ assessment guidelines was implemented to formulate insomnia, and the major depression module of the Mini International Neuropsychiatric Interview⁴² was delivered to assess depression. Since no standardized *DSM-V* diagnostic instrument was available when the trial commenced, slight modifications were made to the insomnia and depression clinical interviews⁴⁰⁻⁴² to correspond with the updated *DSM-V* criteria. Secondly, a

collaborative clinical judgement was made by applying the *DSM-V* criteria during multidisciplinary clinical review meetings involving the co-assessors, community mental health clinicians (e.g., consultant psychiatrist, psychiatric nurses) and clinical supervisor to either confirm or disconfirm the comorbid insomnia and depression diagnoses. Of note, although questionnaire-based clinical cut-off criteria weren't applied in this study for inclusion or remission, all participants' pre-treatment scores on the Insomnia Severity Scale³⁸ and Geriatric Depression Scale⁴³ were ≥ 10 , and their baseline sleep diary metrics were consistent with the presence of insomnia (e.g., mean wakefulness after sleep onset > 60 minutes, mean sleep efficiency $< 75\%$, mean sleep onset latency > 30 minutes).

3.1.4.3 Randomization

A block/cluster randomization design was implemented to randomly allocate each eligible participant to one of three conditions (CBT-I; CBT-I+; PCG). The random group allocations were generated by an independent senior statistician at Federation University Australia. Although the participants were informed the trial was testing different forms of CBT, participants were blinded to the study's hypotheses and condition they had been randomly allocated to complete. More details on the randomization process are available in Sadler et al.²⁷

3.1.4.4 Outcome Measures

Outcome measures were completed on three occasions throughout the RCT, at pre-treatment (week 0), post-treatment (week 8), and 3-month follow-up (week 20). Eligible participants were given a voucher (AUS\$20) each time they completed the outcome measures (pre, post, follow-up) to acknowledge their time and commitment during the trial.

3.1.4.5. Primary Measures

Since insomnia and depression were conceptualized as being comorbid conditions in this trial, two primary measures were applied, the Insomnia Severity Index (ISI)³⁸ and the

Geriatric Depression Scale (GDS).⁴³ The ISI is a 7-item self-report measure of insomnia severity commonly used in research with older adults.^{16,19} It possesses acceptable psychometric properties and is sensitive to treatment response.⁴⁵ The GDS is a 30-item reliable and valid measure that assesses and detects changes in depression severity for older adults.⁴³ A full description of the primary and secondary measures for this trial can be found in Sadler et al.²⁷

3.1.4.6 Secondary Measures

The Consensus Sleep Diary (CDS)³⁷ was completed by participants at each assessment point. Sleep onset latency (SOL), wakefulness after sleep onset (WASO), total sleep time (TST), sleep efficiency (SE), and sleep quality (SQ) were calculated from the sleep diary data. The sleep diary was completed over a 1-week period, instead of the recommended 2 weeks, to increase compliance and reduce a possible attention placebo effect for insomnia. The sleep diary was used as a secondary outcome instead of a primary outcome because there was no equivalent measure for assessing depression.²⁹

Additional secondary measures included the Dysfunctional Beliefs and Attitudes About Sleep 10-item Scale (DBAS-10),⁴⁶ Geriatric Anxiety Inventory-Short Form (GAI-SF),⁴⁷ Beck Hopelessness Scale (BHS),⁴⁴ and The EuroQol 5-D 3-L Scale (EQ-5D-3L).⁴⁸

3.1.4.7 Assessors and Therapists

The assessors and therapists ($n = 10$) were registered provisional and generalist psychologists who were undertaking a gero-psychology post-graduate clinical placement within a community mental health service. Each assessor and therapist commenced the placement with at least 12 months of theoretical and practical training in assessing psychopathology and implementing CBT. They each received training and daily supervision throughout their placement in (1) assessing and conceptualising psychogeriatric comorbid insomnia and depression, (2) administering and interpreting the assessments/outcome

measures, and (3) delivering the therapy protocols to older adults. The training considered Manber et al.'s⁴⁹ and Espie's²⁶ guidelines. Clinical supervision sessions were provided by the first author (PS), who is a senior clinical psychologist and is experienced in delivering CBT to older adults with comorbid insomnia and depression. Therapist protocol adherence was closely monitored by the clinical supervisor via group supervision meetings, audio recordings, and written materials (e.g., protocol session checklist, homework tasks). The groups were delivered by co-therapists. The co-therapists delivered between 2 to 3 groups during their placement. The therapists were aware of the study's hypotheses and differences between conditions. Each assessor and therapist had opportunities to perform both roles throughout their placement. The post and follow-up assessors were blinded to the condition the participant had completed. The therapists did not conduct post or follow-up assessments on participants they had treated.

3.1.4.8 Interventions

3.1.4.8.1 Standard

Cognitive behaviour therapy for insomnia (CBT-I) is a well-established time-limited multicomponent treatment program that includes a combination of educational, cognitive, and behavioural interventions.¹¹⁻¹³ CBT-I aims to improve sleep by correcting dysfunctional cognitive and behavioural patterns that perpetuate insomnia.⁵⁰⁻⁵² Participants who received CBT-I attended eight, weekly, 60 to 90 minute sessions, which included small groups of five or six participants. A small group-based mode of therapy was chosen to increase the participants' sense of connectedness and present opportunities for socialization.³⁰ Larger group sizes were not offered due to the severity and complexity of the participants' psychopathology. Two therapists co-facilitated the groups, which assisted in crosschecking treatment protocols, managing clinical risks, and increasing group cohesiveness.

The standard CBT-I program considered guidelines from experts in the field of treating late-life comorbid insomnia.^{11,13,19,52} The session format and treatment delivery followed a focused CBT structure.⁵²⁻⁵⁴ Therapy worksheets and homework activities were reviewed each week and kept in the participant therapeutic workbooks. The behavioural modification interventions were provided in the first four sessions, these included stimulus control (e.g., go to bed only when sleepy), sleep restriction (e.g., initially limit time spent in bed to increase sleep efficiency), sleep hygiene (e.g., remove stimulating sources from the bedroom, such as television/radio/clock), and relaxation (e.g., diaphragmatic breathing, guided imagery). Cognitive restructuring of unhelpful sleep beliefs (e.g., thought diaries, behavioural experiments) and relapse prevention (e.g., summary of effective skills, maintaining progress) were implemented in the latter half of the program. For a more detailed description of the experiential conditions tested in this RCT, see Sadler et al.^{27,28}

3.1.4.8.2 Advanced

The advanced CBT-I+ program was identical to the standard CBT-I program, but included three additional CBT strategies that specifically targeted comorbid depression.^{27,28} The first additional technique involved behavioural activation (e.g., daily positive activity scheduling). This task was practiced during sessions 3 and 4, and was reinforced consistently throughout the rest of the program. The second strategy involved cognitive reframing for depression. This involved practicing additional cognitive restructuring exercises (thought diaries) during sessions 6 and 7 to address negative thoughts that exacerbated depressed mood. Finally, positive affirmations designed to increase hopefulness (positive data logs and cue cards) were practiced during sessions 7 and 8. The advanced CBT-I+ sessions also ran for approximately 60-90 minutes, and often went for the full 90-minute duration due to the additional therapeutic content.

3.1.4.8.3 Control

Participants randomly assigned to the psychoeducation control group (PCG) also attended eight 60-90 minute weekly group-based sessions. The therapeutic content in PCG was substantially different from the treatment groups because PCG only included psychoeducation about sleep, insomnia, and depression, and omitted the active cognitive or behavioural change strategies designed to change cycles of insomnia and depression.²⁷ Furthermore, there were no prescribed homework or relapse prevention exercises. Although PCG contained a similar session structure to the experiential conditions, PCG involved a more supportive counselling/socialisation approach. For instance, PCG therapists were instructed to reflect and validate the participants' thoughts and feelings, but allow the participants' to continue their line of conversation. The CBT-I and CBT-I+ therapists were trained to clarify the participants' thoughts and feelings, and utilise CBT techniques (e.g., Socratic questioning, reframing, goal setting, reinforcement, problem-solving) to redirect the conversation back onto practicing the applicable CBT strategy. PCG was considered an active control group as it controlled for non-specific confounding treatment effects (e.g., therapeutic alliance).³⁰

3.1.4.9 Therapeutic Process Considerations

Data from the assessment interviews were reviewed during clinical supervision meetings to construct biopsychosocial insomnia and depression case conceptualizations. In recognition of the increased challenges that older adults can experience during therapy,⁵⁵⁻⁵⁷ several 'process-orientated' strategies were implemented across all conditions to increase therapeutic engagement, adherence, and retention. First, brief breaks were conducted during each therapy session to manage participant fatigue and offer opportunities to model *in situ* behaviour experiments (e.g., techniques to reduce naps). Second, organising transport to participate was an initial barrier for some participants. Therefore, considerable time was devoted to problem-solving transport options to confirm their weekly attendance. Third,

initial telephone reminders were made by therapists to offer encouragement and motivation to attend. Fourth, a 'caring card' was posted to participants if they missed a session, which also included the relevant session information/tasks they had missed. The 'caring cards' were signed by the group participants and stated, "Thinking of you. We look forward to seeing you at our next meeting to continue working through the program". Fifth, each participant was encouraged to nominate a support person (e.g., spouse, child, friend, case manager) to consolidate the weekly session materials. Nominating a support person was completed during the first session of each condition and was regularly reviewed throughout therapy. The role of the support person was to assist the participant with homework application (e.g., reviewing worksheets, implementing strategies) and with weekly session attendance (e.g., providing transport). The support person did not have direct contact with the study (e.g., not present during group sessions). Finally, the therapeutic workbooks with weekly worksheet activities were specifically designed for older adults. For instance, material was written in larger font with case example activities more applicable to older adults. These process-orientated strategies are discussed further in Sadler et al.²⁸

3.1.4.10 Statistical Analyses

Data were entered, screened and analysed using SPSS Version 24. Baseline demographics were calculated with frequency/descriptive analyses and further explored using t-tests/chi-square tests. Quantitative primary and secondary variables were analysed using linear mixed modelling (LMM). LMM enabled testing for the presence of cluster effects due to the group mode of clinical program delivery, and for intra-subject random effects, or equivalently correlation of participants' measures over time. There was no significant evidence of group cluster effects. The best fitting correlation structure was compound symmetry (exchangeable correlation), meaning constant correlation of each participants'

measures over the three time points. The LMM models incorporated differences between the three intervention conditions, longitudinal trends over time, and group-time interactions.

A number of dichotomous variables (e.g., diagnosis) were analysed using longitudinal logistic regression fitted by the method of generalized estimating equations (GEE). Again, the best fitting intra-subject correlation structure was exchangeable correlation. In some cases, longitudinal logistic regression was not possible because of 'non-structural zeros' (e.g., empty cells in the cross-tabulations of diagnosis by time-point due to 0 or 100% of cases having a diagnosis at a particular time). When all participants had the diagnosis at baseline, equality of proportions diagnosed in the three intervention conditions were tested at post and follow-up, using chi-square tests of independence.

Effect sizes (Cohen's *d*) were calculated by dividing the mean difference by the square root of the residual variance of each measure and condition. Power analysis details for this trial are presented in Sadler et al.²⁷

3.1.5 Results

3.1.5.1 Baseline Characteristics

No significant differences between the three conditions (CBT-I, CBT-I+, PCG) were detected at baseline for demographic variables (Table 1, $p > .05$), sleep and mental health characteristics (Table 2, $p > .05$), or participant treatment expectancy (Treatment Credibility Index,⁵⁸ $\chi^2 = 1.19$, $p = .31$), hence no covariate variables were included in the analyses.

Table 5 Demographics at baseline

Variable	CBT-I (<i>n</i> = 24)	CBT-I+ (<i>n</i> = 25)	PCG (<i>n</i> = 23)
Age, mean (SD)	74.7 (7.1)	77.0 (8.4)	72.3 (7.6)
Sex, n (%)			
female	15 (62.5)	13 (52.0)	12 (52.2)
male	9 (37.5)	12 (48.0)	10 (43.5)
transgender	0 (0)	0 (0)	1 (4.3)
Relationship Status, n (%)			
married	10 (41.7)	10 (40.0)	9 (39.1)
widowed	8 (33.3)	9 (36.0)	3 (13.0)
divorced	3 (12.5)	3 (12.0)	5 (21.7)
separated	0 (0)	1 (4.0)	3 (13.0)
single	1 (4.2)	1 (4.0)	3 (13.0)
defacto	2 (8.3)	1 (4.0)	0 (0)
Education Level, n (%)			
primary	3 (12.5)	2 (8.0)	2 (8.7)
secondary	11 (45.8)	13 (52.0)	16 (69.6)
vocational	4 (16.7)	3 (12.0)	1 (4.3)
tertiary	6 (25.0)	7 (28.0)	4 (17.4)
Income, n (%)			
pension	19 (79.2)	20 (80.0)	18 (78.3)
self-funded	3 (12.5)	5 (20.0)	3 (13.0)
veteran's affairs	2 (8.3)	0 (0)	2 (8.7)
Accommodation, n (%)			
house	13 (54.2)	11 (44.0)	13 (56.5)
unit	4 (16.7)	6 (24.0)	5 (21.7)
retirement village	3 (12.5)	2 (8.0)	0 (0)
nursing home	4 (16.7)	6 (24.0)	5 (21.8)

Note: CBT-I, Cognitive Behaviour Therapy for Insomnia; CBT-I+, Cognitive Behaviour Therapy for Insomnia plus; PCG, Psychoeducation Control Group; SD, Standard Deviation.

Table 6 Sleep and mental health characteristics at baseline

Variable	CBT-I (n = 24)	CBT-I+ (n = 25)	PCG (n = 23)
ISI, mean (SD)	17.0 (1.0)	18.2 (1.0)	16.8 (1.0)
GDS, mean (SD)	17.2 (1.2)	18.3 (1.2)	16.5 (1.2)
Sleep Diary, mean (SD)			
SOL (mins)	52.0 (6.9)	65.1 (6.7)	61.0 (7.0)
WASO (mins)	78.2 (12.5)	109.9 (12.2)	81.9 (12.8)
TST (mins)	358.7 (20.1)	358.6 (19.7)	385.3 (20.5)
SE (%)	61.8 (2.9)	60.2 (2.8)	62.5 (2.9)
SQ (0-3)	1.6 (0.1)	1.5 (0.1)	1.6 (0.1)
SLEEP-50, n (%)			
Sleep Apnea (≥ 15)	0 (0)	1 (4.0)	3 (13.0)
Narcolepsy (≥ 7)	1 (4.2)	2 (8.0)	1 (4.3)
Restless Legs (≥ 7)	0 (0)	3 (12.0)	3 (13.0)
Circadian Rhythm (≥ 8)	0 (0)	0 (0)	0 (0)
Sleep Walking (≥ 7)	0 (0)	0 (0)	0 (0)
Nightmares (≥ 9)	4 (16.7)	3 (12.0)	6 (26.1)
CPAP, n (%)	1 (4.2)	0 (0)	2 (8.7)
EQ, mean (SD)			
Health Quality (5-15)	8.3 (1.6)	9.7 (1.7)	9.0 (1.7)
Health Status (0-100)	64.5 (16.2)	51.8 (15.6)	63.9 (14.1)
MMSE, mean (SD)	28.2 (1.6)	27.5 (2.3)	27.8 (1.9)
MINI, n (%)			
Panic	3 (12.5)	6 (24.0)	4 (17.4)
Agoraphobia	4 (16.7)	8 (32.0)	5 (21.7)
Social Anxiety	3 (12.5)	6 (24.0)	2 (8.7)
Generalised Anxiety	9 (37.5)	9 (36.0)	3 (13.0)
Obsessive Compulsive	1 (4.2)	2 (8.0)	1 (4.3)
Post-Traumatic Stress	3 (12.5)	4 (16.0)	5 (21.7)
Substance Dependence	4 (16.7)	2 (8.0)	2 (8.7)
Bipolar Type 2	3 (12.5)	1 (4.0)	2 (8.7)
Schizophrenia	0 (0)	1 (4.0)	1 (4.3)
Psychotropic Medication, n (%)			
Combination of 2 or more	12 (50.0)	11 (44.0)	12 (52.2)
Antidepressant only	6 (25.0)	9 (36.0)	4 (17.4)
Anxiolytic only	1 (4.2)	1 (4.0)	1 (4.3)
Hypnotic only	3 (12.5)	2 (8.0)	2 (8.7)
Antipsychotic only	1 (4.2)	0 (0)	1 (4.3)
Mood stabiliser only	0 (0)	0 (0)	0 (0)
No psychotropics	1 (4.2)	2 (8.0)	3 (13.0)
Prior Psychiatric Inpatient, n (%)	10 (41.7)	9 (36.0)	14 (60.9)

Prior Suicide Attempt, n (%)	3 (12.5)	6 (24.0)	6 (26.1)
Prior ECT, n (%)	4 (16.7)	2 (8.0)	1 (4.3)
Prior Psychotherapy, n (%)	11 (45.8)	13 (52.0)	9 (39.1)
Prior Personality Disorder, n (%)	2 (8.3)	5 (20.0)	4 (17.4)

Note: CBT-I, Cognitive Behaviour Therapy for Insomnia; CBT-I+, Cognitive Behaviour Therapy for Insomnia plus; PCG, Psychoeducation Control Group; ISI, Insomnia Severity Index; GDS, Geriatric Depression Scale; SOL, Sleep Onset Latency; WASO, Wakefulness After Sleep Onset; TST, Total Sleep Time; SE, Sleep Efficiency; SQ, Sleep Quality; SLEEP-50, SLEEP-50 Questionnaire; CPAP, Continuous Positive Airway Pressure; EQ, EuroQol Health Scale; MINI, Mini International Neuropsychiatric Interview; Mins, Minutes; SD, Standard Deviation; MMSE, Mini Mental State Examination; ECT, Electroconvulsive Therapy.

3.1.5.2 Treatment Completion and Missing Data

Treatment completion was defined as attending at least 6 out of the 8 sessions. From the 72 participants who commenced the trial, 69 (96%) completed treatment from pre to post. More specifically, each participant allocated to CBT-I ($n = 24$, 100%) completed treatment. Twenty-three out of 25 (92%) participants completed CBT-I+, and 22 from 23 (96%) completed PCG.

Outcome measure completion rate were high in this trial. From the initial 72 participants, 69 (96%) completed the post assessment measures and 65 (90%) completed the 3-month follow up. The sleep diary completion rate was slightly lower, with 66 (92%) participants completing the post sleep diary and 60 (83%) completing the follow up.

3.1.5.3 Primary Outcomes

Results for the primary outcome variables are shown in Table 3 and Figures 2 and 3.

The CBT-I and CBT-I+ conditions both had significant reductions in insomnia severity (as measured by the ISI) from pre to post ($p < .001$), which were maintained at follow-up. The PCG condition did not have a significant reduction in insomnia severity from pre to post ($p = .144$). CBT-I generated significantly greater reductions in insomnia severity than PCG from pre to post ($p < .001$). This was also found when comparing CBT-I+ and PCG for insomnia severity from pre to post ($p < .001$).

Outcomes were similar for depression severity (as measured by the GDS), with both CBT-I and CBT-I+ having significant reductions in depression severity from pre to post ($p < .001$) that were maintained at follow-up. The PCG condition had no significant changes in GDS scores from pre to post ($p = .153$). CBT-I and CBT-I+ both had significantly greater reductions in depression severity than PCG from pre to post ($p < .001$).

The CBT-I and CBT-I+ conditions were not significantly different at reducing insomnia or depression severity at post or follow-up. Large effect sizes were found for both CBT-I and CBT-I+ on insomnia and depression severity at post and follow-up.

Table 7 Means, standard deviations, and effect sizes for primary measures

Measure	Condition	Pre	Post	d^{wg}	d^{bg}	F/U	d^{wg}	d^{bg}	F/p	F/p	F/p
		Mean (SD)	Mean (SD)			Mean (SD)			Condition	Time	Interaction
ISI (0-28)	CBT-I	17.04 (1.02)	10.21 (1.02)	2.57	1.87	9.54 (1.04)	2.82	2.40	4.01 (.023)	83.26 ($<.001$)	12.24 ($<.001$)
	CBT-I+	18.24 (1.00)	10.94 (1.02)	2.75	1.60	12.01 (1.03)	2.35	1.47	-	-	-
	PCG	16.78 (1.04)	15.19 (1.05)	0.60	-	15.91 (1.06)	0.33	-	-	-	-
GDS (0-30)	CBT-I	17.17 (1.19)	9.92 (1.19)	2.98	2.12	10.64 (1.21)	2.68	2.12	2.03 (.139)	91.13 ($<.001$)	13.66 ($<.001$)
	CBT-I+	18.28 (1.17)	11.86 (1.18)	2.64	1.33	11.57 (1.19)	2.76	1.73	-	-	-
	PCG	16.52 (1.22)	15.08 (1.23)	0.59	-	15.79 (1.23)	0.30	-	-	-	-

Note: ISI, Insomnia Severity Scale; GDS, Geriatric Depression Scale; CBT-I, Cognitive Behaviour Therapy for Insomnia; CBT-I+, Cognitive Behaviour Therapy for Insomnia plus; PCG, Psychoeducation Control Group; SD, Standard Deviation; F/U, Follow-Up; d^{wg} , Cohen's d within groups; d^{bg} , Cohen's d between groups. Follow-up within-group Cohen's d were based on change from Pre to F/U.

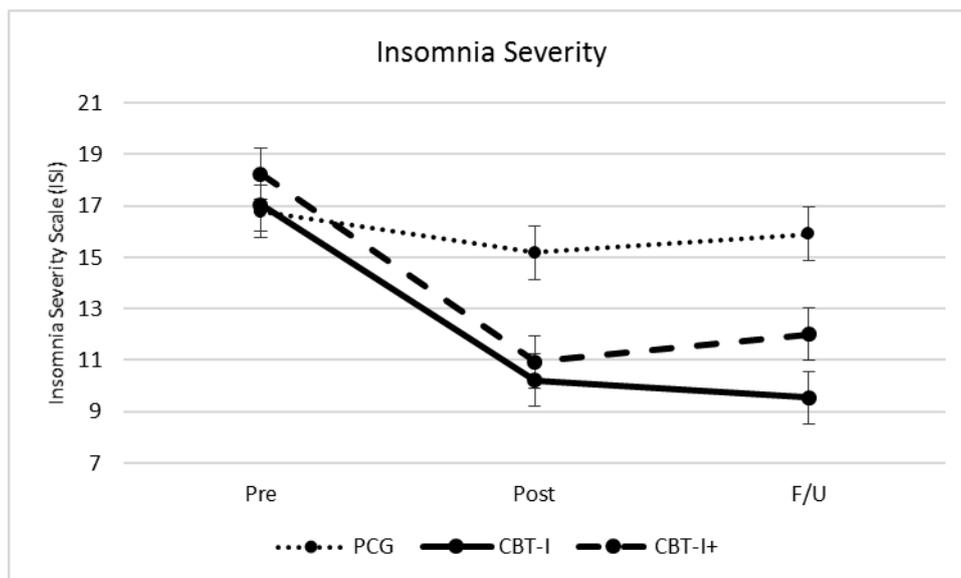


Figure 3 Changes in insomnia severity across conditions and time. CBT-I, Cognitive Behaviour Therapy for Insomnia; CBT-I+, Cognitive Behaviour Therapy for Insomnia plus; PCG, Psychoeducation Control Group.

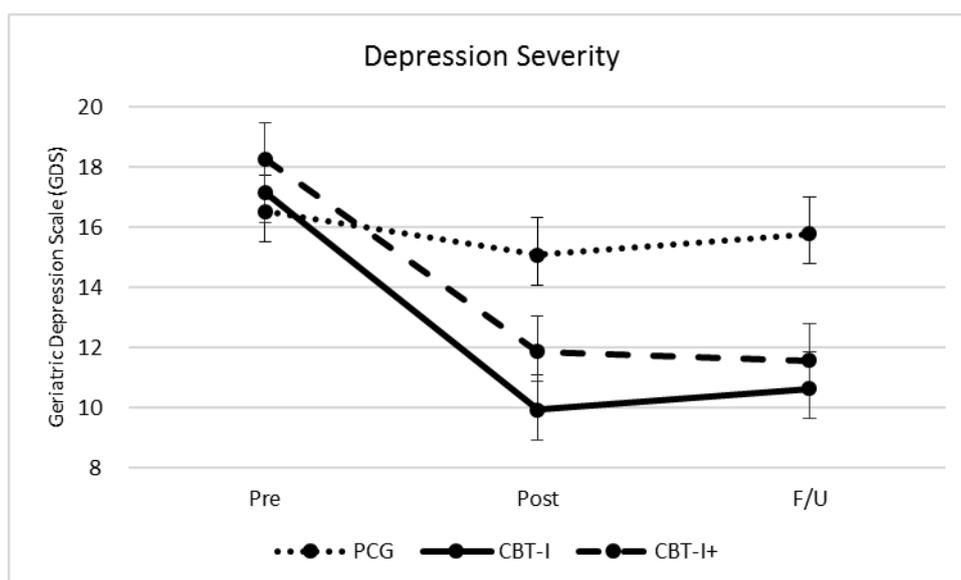


Figure 4 Changes in depression severity across conditions and time. CBT-I, Cognitive Behaviour Therapy for Insomnia; CBT-I+, Cognitive Behaviour Therapy for Insomnia plus; PCG, Psychoeducation Control Group.

3.1.5.4 Remission Rates

Insomnia Disorder and Major Depressive Disorder were assessed at each assessment point (pre, post, follow-up) using *DSM-V* criteria.³⁵ Participants were categorised into

dichotomous variables (yes or no) as either having the diagnosis or not. The same multidimensional assessment process that was conducted during the preliminary eligibility assessment was also conducted at post and follow-up.

In the CBT-I condition, 71% (17 of 24) no longer met *DSM-V* criteria for comorbid insomnia at post, which was maintained at follow-up (68%). Similarly, 78% (18 of 23) who completed CBT-I+ no longer had comorbid insomnia at post, however, this remission rate reduced to 45% at follow up. The PCG condition demonstrated 27% (6 of 22) no longer had comorbid insomnia at post and 14% at follow up.

Eighty eight percent (21 of 24) of participants who completed CBT-I and 78% (18 of 23) who completed CBT-I+ no longer met *DSM-V* criteria for major depression at post. Follow up remission rates were 73% for CBT-I, and 64% for CBT-I+. In the PCG condition, 36% (8 of 22) no longer met depression criteria at post, and 19% at follow up.

3.1.5.5 Secondary Outcomes

Table 4 shows results for the secondary measures. There were significant improvements across each of the sleep diary parameters (SOL, WASO, TST, SE, SQ) for both CBT-I and CBT-I+ from pre to post ($p < .001$). The PCG condition did not show significant improvements in SOL, WASO, or TST from pre to post ($p > .05$), however, there were significant improvements observed for PCG on SE ($p = .041$) and SQ ($p < .001$) from pre to post. No significant changes were found from post to follow-up for the sleep diary metrics across conditions.

No significant differences were found between the CBT-I and CBT-I+ conditions for the secondary outcomes. CBT-I and CBT-I+ each demonstrated significant improvements from pre to post for anxiety ($p < .001$), hopelessness ($p < .001$), dysfunctional beliefs about sleep ($p < .001$), and physical health ($p < .004$), which were all maintained at follow up. For anxiety and physical health, the PCG did not show significant improvements from pre to post

($p > .05$), however, PCG did reveal significant improvements from pre to post for hopelessness ($p = .009$) and dysfunctional beliefs about sleep ($p = .05$) that were each maintained at follow up.

Table 8 Means, standard deviations, and effect sizes for secondary measures

Measure	Condition	Pre	Post	d^{wg}	d^{bg}	F/U	d^{wg}	d^{bg}	F / p	F / p	F / p
		Mean (SD)	Mean (SD)			Mean (SD)			Condition	Time	Interaction
SOL (mins)	CBT-I	51.96 (6.87)	25.78 (6.93)	1.65	1.85	24.50 (7.04)	1.73	2.03	3.36 (.041)	37.84 ($<.001$)	5.60 ($<.001$)
	CBT-I+	65.06 (6.74)	33.86 (6.98)	1.96	1.34	34.15 (7.19)	1.94	1.43	-	-	-
	PCG	60.99 (7.02)	55.11 (7.08)	0.37	-	56.82 (7.14)	0.26	-	-	-	-
WASO (mins)	CBT-I	78.19 (12.5)	41.57 (12.6)	1.07	1.02	40.49 (12.9)	1.10	1.77	2.56 (.085)	12.72 ($<.001$)	5.13 ($<.001$)
	CBT-I+	109.8 (12.2)	63.33 (12.8)	1.36	0.39	73.67 (13.3)	1.06	0.80	-	-	-
	PCG	81.92 (12.7)	76.49 (12.9)	0.16	-	101.0 (13.0)	0.56	-	-	-	-
TST (mins)	CBT-I	358.6 (20.1)	429.7 (20.1)	2.21	0.85	426.9 (20.3)	2.12	1.25	0.31 (.735)	32.99 ($<.001$)	6.74 ($<.001$)
	CBT-I+	358.6 (19.6)	398.7 (20.0)	1.25	0.11	394.4 (20.3)	1.12	0.24	-	-	-
	PCG	385.3 (20.5)	402.2 (20.6)	0.53	-	386.7 (20.6)	0.05	-	-	-	-
SE (%)	CBT-I	61.84 (2.90)	77.56 (2.92)	2.73	1.85	77.20 (2.95)	2.66	2.14	1.80 (.172)	71.34 ($<.001$)	9.13 ($<.001$)
	CBT-I+	60.23 (2.84)	72.19 (2.92)	2.07	0.92	73.17 (2.98)	2.24	1.44	-	-	-
	PCG	62.53 (2.96)	66.88 (2.98)	0.75	-	64.87 (2.99)	0.41	-	-	-	-
SQ (0-3)	CBT-I	1.60 (0.09)	2.21 (0.09)	2.48	0.94	2.25 (0.09)	2.66	1.29	1.09 (.341)	88.51 ($<.001$)	3.48 (.010)
	CBT-I+	1.56 (0.09)	2.11 (0.09)	2.27	0.54	2.07 (0.09)	2.11	0.57	-	-	-
	PCG	1.65 (0.09)	1.98 (0.09)	1.36	-	1.94 (0.09)	1.18	-	-	-	-
GAI (0-5)	CBT-I	3.33 (0.33)	2.04 (0.33)	1.51	0.75	2.14 (0.33)	1.39	0.80	0.38 (.683)	21.04 ($<.001$)	7.07 ($<.001$)
	CBT-I+	3.24 (0.32)	1.82 (0.33)	1.65	1.01	1.97 (0.33)	1.49	1.00	-	-	-
	PCG	2.61 (0.33)	2.69 (0.34)	0.09	-	2.83 (0.34)	0.25	-	-	-	-
DBAS (0-100)	CBT-I	66.21 (3.30)	48.13 (3.30)	2.28	1.45	43.46 (3.35)	2.87	2.38	2.68 (.076)	65.55 ($<.001$)	9.08 ($<.001$)
	CBT-I+	66.12 (3.23)	50.64 (3.23)	1.95	1.13	50.70 (3.32)	1.95	1.47	-	-	-
	PCG	65.39 (3.37)	59.61 (3.40)	0.73	-	62.33 (3.43)	0.39	-	-	-	-
BHS (0-20)	CBT-I	10.38 (0.95)	7.21 (0.95)	1.98	0.86	7.00 (0.96)	2.11	1.66	0.75 (.476)	75.83 ($<.001$)	10.71 ($<.001$)
	CBT-I+	10.96	6.49	2.80	1.31	6.36	2.87	2.06	-	-	-

	PCG	(0.93) 10.04 (0.97)	(0.94) 8.58 (0.97)	0.92	-	(0.94) 9.66 (0.98)	0.24	-	-	-	-
EQ (0-15)	CBT-I	8.33 (0.35)	7.58 (0.35)	0.94	1.19	7.41 (0.35)	1.15	1.75	3.30 (.043)	23.41 (<.001)	3.46 (.010)
	CBT-I+	9.68 (0.34)	8.39 (0.35)	1.61	0.17	8.36 (0.35)	1.66	0.57	-	-	-
	PCG	8.96 (0.36)	8.53 (0.36)	0.53	-	8.81 (0.36)	0.19	-	-	-	-

Note: SOL, Sleep Onset Latency; WASO, Wakefulness After Sleep Onset; TST, Total Sleep Time; SE, Sleep Efficiency; SQ, Sleep Quality; GAI, Geriatric Anxiety Inventory; DBAS, Dysfunctional Beliefs and Attitudes About Sleep Scale; BHS, Beck Hopelessness Scale; EQ, EuroQol Health Scale; CBT-I, Cognitive Behaviour Therapy for Insomnia; CBT-I+, Cognitive Behaviour Therapy for Insomnia plus; PCG, Psychoeducation Control Group; SD, Standard Deviation; F/U, Follow-Up; d^{wg} , Cohen's d within groups; d^{bg} , Cohen's d between groups. Follow-up within-group Cohen's d were based on change from Pre to F/U.

3.1.6 Discussion

This study had two primary aims. The first involved examining whether CBT-I was effective for older adults with comorbid insomnia and depression within a community mental health setting. The second aim explored whether an advanced form of CBT-I+ generated better outcomes compared to standard CBT-I. As expected, CBT-I produced significantly greater reductions in insomnia and depression severity compared to the control group that were maintained at follow up. The second hypothesis was not supported because the advanced and standard conditions showed similar reductions in insomnia and depression severity at post and follow up; however the study was not sufficiently powered to conclusively test this hypothesis.

The findings from this study add to a growing body of literature that suggest CBT-I is an effective treatment for comorbid insomnia.^{15,22,30} These results are meaningful because comorbid insomnia is highly prevalent among older adults but is often misunderstood and inadequately treated.^{28,52} This can result in poorer clinical outcomes and costly economic consequences.⁸⁻¹⁰ The present study is the first RCT to include a highly diverse clinical sample of older adults with comorbid insomnia and depression. Previous CBT-I trials have focused on younger or middle aged adults and have often excluded older adults with complicated comorbidities.²⁸ Consequently, the results from this trial demonstrate that CBT-I

can significantly benefit heterogeneous psychogeriatric populations presenting with comorbid insomnia and depression.

Recent RCTs have also indicated that CBT-I could have a positive effect onto comorbid depression for individuals with both conditions.^{29,30,59} This RCT supported this proposition, as CBT-I generated significant reductions in depression severity with sustained large effect sizes at post and follow up. This suggests that when insomnia and depression are comorbid, specifically targeting insomnia with CBT-I has an effect onto depression recovery.³¹⁻³⁴ One of the reasons CBT-I could have a positive influence on depression is due to the transferable cognitive and behavioural mechanisms that underpin change during treatment.

There are several possible reasons why reducing insomnia severity through CBT-I could improve comorbid depression. For instance, older adults tend to experience more night time awakenings and are generally lighter sleepers compared to younger adults.¹⁻³ Hence increased early morning awakenings can result in less opportunities for deeper sleep (e.g., rapid eye movements). This means that effectively applying stimulus control (e.g., going to bed later) could increase sleep quality and associated energy levels.¹¹ Another possible mechanism of change could be increasing time-out-of-bed through sleep restriction.^{50,54} Improving the rest-activity ratio could have a mild behavioural activation effect, therefore increasing the likelihood of exposure to additional reinforcers (e.g., morning light, physical activity, socialisation). Researchers have also theorized that insomnia can influence depression via endorsing negative thoughts, such as ‘I don’t get enough sleep’, ‘I should try harder to sleep’, and ‘My sleep will never improve’.^{1,6} Unhelpful sleep-related beliefs have been associated with maladaptive safety behaviours (e.g., daytime napping, staying awake in bed) and physiological complaints (e.g., tension, fatigue).⁶⁰⁻⁶² The increased desire to withdraw from daily activities could increase the individual’s attempts to sleep, which in turn,

could exacerbate psychophysiological arousal and reduce sleep efficiency.⁶⁰⁻⁶² Cycles of negative thinking and behavioural withdrawal could further increase levels of amotivation and hopelessness, perpetuating a state of depressed mood.^{4,6,63} These broad spectrum of cognitive and behavioural mechanisms highlight why making changes through CBT-I could transfer onto improvements in mood and function.

It was anticipated in this trial that specifically targeting depression by adding therapeutic content to CBT-I would boost overall outcomes for older adults with comorbid insomnia and depression. CBT-I+ is based on the 'less of more' treatment principal, whereas CBT-I works from the 'more of less' approach to treatment.²⁸ This means CBT-I+ offers more therapeutic material to target two interrelated problems (insomnia and depression) simultaneously within the one program, whereas CBT-I is more concentrated because it is designed to target one problem (insomnia) with a set of focussed sleep strategies. Although the advanced program showed significant improvements across the primary and secondary measures, the results were similar to the standard program. In addition, although the effect sizes were consistently smaller for CBT-I+ compared to CBT-I, the study was not sufficiently powered to test for equivalence. Nevertheless, these results suggest that further refinement of CBT-I+ may be needed in future studies that test for either superiority or equivalence.

A possible reason why CBT-I+ might not be more effective than CBT-I could be the added level of complexity involved in delivering CBT-I+. The advanced program was likely more complicated to complete for both therapists and participants because of the additional theoretical and therapeutic content to practice within 8 sessions. Standard CBT-I, on the other hand, may have presented a simpler form of treatment because CBT-I involved learning fewer strategies and processes compared to CBT-I+. It is suggested that a longer course of therapy (e.g., 12-16 sessions) and a more specialized training package may be required to strengthen the effect of CBT-I+. Since therapeutic adherence was not psychometrically

evaluated in this study, a future project that quantitatively compares adherence between the two arms would be worthwhile to test the hypothesis that a simpler treatment (e.g., standard CBT-I) may be better suited to older adults with comorbid depression. Furthermore, a qualitative study that explores the experiences of older adults who have participated in CBT-I and CBT-I+ may also help researchers tailor more individualized treatment programs.

Research that identifies which specific CBT strategies are best suited to older adults with comorbid insomnia and depression will likely contribute significantly to improving the application of CBT-I.²⁸ For instance, it is anticipated that comorbid insomnia populations with greater heterogeneity and severity (e.g., psychogeriatric settings) may benefit from a more focussed, simplified, and repetitious form of CBT-I. Conversely, insomnia populations that are more homogeneous (e.g., academic settings) may gain greater benefit from modified CBT-I programs that offer a greater range of strategies. Furthermore, traditional face-to-face modes of CBT-I (e.g., group, individual) will likely remain a central treatment option in geriatric clinical settings, as older adults with low computer literacy and severe comorbidities will unlikely engage in self-directed digital forms of treatment.²⁸ Future studies that expand these program design and delivery ideas among various comorbid insomnia populations will provide an important step in the evolution of CBT-I.

The results from this trial have important implications for community mental health services. Currently therapists and mental health clinicians receive minimal training towards accurately assessing and conceptualizing comorbid sleep-wake disorders.^{26,49,52} In addition, few practitioners are qualified to deliver CBT-I within clinical settings.⁴⁹ The inadequate dissemination of CBT-I has been well publicized and a series of solutions have been recommended by experts in the field.^{29,49,64} For instance, CBT-I training packages could be delivered across disciplines to non-sleep specialists, and ongoing peer-to-peer supervision could be offered to practitioners who are interested in behavioural sleep medicine.⁴⁹ Another

cost effective option could be recruiting provisional psychologists on clinical training placements within mental health services to deliver group-based CBT-I on a continuing basis. This study highlights how relatively inexperienced mental health clinicians can be easily trained to delivery CBT-I and expect large positive effects within a complex clinical setting. Mental health services who implement CBT-I programs will be delivering a cost-effective intervention that supports person-centred recovery principals.

It is worth noting the weaknesses and strengths of this RCT. The limitations involved (1) not employing objective biological measures, such as actigraphy or polysomnography, to validate the subjective sleep measures, (2) the initial target sample size (as discussed in Sadler et al.²⁷) was not achieved in this trial due to timing and resource restraints, resulting in insufficient power to detect possible outcome differences between CBT-I and CBT-I+, (3) having a limited 3 month follow up period, (4) not including CBT for depression as another comparison condition, and (5) amending diagnostic assessment tools to correlate with updated *DSM-V* criteria. Also the CSD measure may have demonstrated questionable reliability because of the 1 week recording period (instead of the recommended 2 weeks). Furthermore, although all co-therapists were at a similar level of clinical experience and received the same training/supervision from the first author (PS), there was a chance the quality of the therapist dyad could have influenced outcomes. Finally, a validated adverse events metric was not utilised in this trial, however, participant wellbeing was closely monitored through a combination of feedback sources (e.g., participants, assessors, therapists, mental health clinicians). No complaints or critical incidents were recorded throughout this RCT, supporting the safe qualities of CBT. It is suggested that a qualitative participant feedback study would be valuable to inform future research of the potential covert limitations involved in delivering CBT-I for older adults.

The notable weaknesses within this trial were offset by its methodological and clinical strengths. This RCT built on previous research by applying *DSM-V* criteria and including two experiential conditions with an active comparison control. The post and follow-up assessors were blinded and the study demonstrated a high retention/completion rate. From a clinical formulation and treatment application perspective, this study provides new evidence that suggests CBT-I and CBT-I+ are beneficial for older adults with interrelated complex comorbidities. Replication of this study is necessary with a larger sample size to conclusively establish whether or not the two interventions have different or equivalent effects. Mental health services that offer and deliver treatment for insomnia with CBT will be providing evidence-based best practice for older adults with comorbid insomnia and depression.

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3.2 Bridge between Quantitative and Qualitative Results

Randomised controlled clinical trials that utilise a mixed-methods (quantitative and qualitative) design are considered the strongest scientific method for the generation of a diverse range of data. This diverse range of data provides multiple dimensions to the results that can better inform future treatments. The quantitative analyses examined the efficacy of CBT-I and CBT-I+ compared to a control condition via an RCT methodology (published in *SLEEP*), whereas the qualitative analyses aimed to explore the participants' experiences of treatment via feedback from focus groups (under review in *Aging and Mental Health*). Quantitative research provides a general overview of the data, but has the potential to omit important individualised accounts of the treatment experience. Considering such individualised accounts in conjunction with quantitative findings provides a more rounded interpretation of the outcomes. The nature of qualitative research is more exploratory, subjective, and open-ended, as researchers seek to interpret trends, themes, or patterns that emerge in the participants' responses. Although quantitative research methods are considered to be more statistically rigorous, qualitative research often provides a novel and more nuanced understanding of the therapeutic effects. Information acquired through qualitative methods contributes a unique perspective when explaining treatment outcomes and plays a pivotal role in tailoring more individualised therapeutic programs. Given that there were several novel aspects to both the therapeutic intervention and the population under study, a qualitative results chapter was undertaken to explore the participants' experiences of treatment with the view to guiding future directions for research.

QUALITATIVE RESULTS

4.1 Focus Groups

4.1.1 Publication Details

Title:

Cognitive behaviour therapy for insomnia and depression: Qualitative reflections from older adults who participated in a randomised controlled trial

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4.1.2 Abstract

Objectives

To explore the experiences of older adults who participated in a randomised controlled trial (RCT) that tested cognitive behaviour therapy for insomnia and depression.

Methods

Focus groups were conducted post treatment for older adults (>65y/o) who participated in a RCT that tested two experiential interventions targeting comorbid insomnia and depression (cognitive behaviour therapy for insomnia, CBT-I; cognitive behaviour therapy for insomnia plus positive mood strategies, CBT-I+). Six semi-structured group interviews ($N = 31$) were analysed using a qualitative thematic analysis.

Results

Interview data were transcribed into 424 sentences and 60 codes were extracted. Thirty-four initial themes emerged, which were transformed into 3 themes and 10 subthemes. The three primary themes were (1) positive experiences, (2) negative experiences, and (3) suggested modifications. The positive subthemes were (1a) therapists, (1b) togetherness, (1c) use of strategies reduced symptoms, and (1d) acceptance. The negative subthemes were (2a) persistent symptoms, (2b) program too condensed, and (2c) attendance obstacles. The suggested modifications were (3a) lengthen program, (3b) multi-dimensional learning, and (3c) multi-modal delivery options.

Conclusion

The experiences and suggestions identified in this study strengthen the foundation to advance therapeutic program development for older adults with comorbid insomnia and depression.

Future CBT-I programs for older adults may be improved by increasing the length of therapy (e.g., 8 sessions to 12 sessions), adding multi-dimensional learning opportunities (e.g.,

visual/audio/mentorship), and offering various modes of treatment delivery (e.g., group, individual, internet, telephone).

4.1.3 Introduction

Insomnia is a highly prevalent sleep problem occurring in up to 80% of older adults (>65y/o) with mental health problems (Foley et al., 2004). Although the presence of insomnia (difficulties initiating or maintaining sleep) increases substantially with advancing age, insomnia is often misdiagnosed and poorly treated (Sadler et al., 2018a; Vitiello et al., 2013). Research has established a strong link between sleep and mood, with higher levels of insomnia correlating with higher levels of depression (Sadler et al., 2013). For older adults with comorbid insomnia and depression, treatment options typically focus on dispensing psychotropic medicines and recovery plans usually concentrate on treating depression rather than simultaneously treating comorbid insomnia (Sadler et al., 2018a). This treatment conceptualisation can be misleading because insomnia often remains a significant issue during and after pharmacotherapy (Morin, 2006), and insomnia poses a significant risk for depressive relapse and suicide ideation if left untreated (McCall et al., 2010). Fortunately, the cognitive behavioural approach to treating insomnia and depression can complement the limitations inherent with the medical approach.

Cognitive behaviour therapy for insomnia (CBT-I) is a first line treatment program that produces positive and sustainable effects for older adults (Belanger et al., 2012; Rybarczyk et al., 2013). This course of treatment aims to provide psychoeducation and targeted practical strategies to correct unhelpful cognitive and behavioural insomnia patterns (Morin et al., 2006; Morin & Benca, 2012). CBT-I can be delivered in different formats (Edinger, 2015). Group therapy has proven to be particularly beneficial for older adults, as this format can increase socialisation and motivation to change, and is also cost effective (Koffel et al., 2015; Rybarczyk et al., 2013). Although various digital forms of CBT-I (e.g., internet-based) are beginning to show promising results for comorbid insomnia and depression (e.g., Blom et al., 2015, 2016), older adults who have severe psychopathology

and/or low computer literacy will require face-to-face therapy as a primary mode of treatment (Sadler et al., 2018a).

A small but growing body of randomised controlled trials (RCT) have investigated the effect of CBT-I on comorbid insomnia and depression (for review see Sadler et al., 2018a). The only RCT in this field that specifically investigated older adults was recently conducted by a team of researchers from Victoria, Australia (Sadler et al., 2018b). This study recruited a heterogeneous sample of 72 older adults with diagnosed comorbid insomnia and depression from community mental health services. Participants were randomised to one of three group therapy conditions; cognitive behaviour therapy for insomnia (CBT-I, standard treatment), cognitive behaviour therapy for insomnia plus positive mood strategies (CBT-I+, advanced treatment), or a psychoeducation control group (PCG). Quantitative outcome measures (e.g., Insomnia Severity Index and Geriatric Depression Scale) were collected at pre treatment (week 0), post treatment (week 8), and three month follow up (week 20). It was found that the experiential cognitive behaviour therapy conditions generated significantly greater reductions in insomnia and depression severity compared to the control group from pre to post, which were maintained at follow-up. The standard and advanced conditions showed similar reductions and effects on insomnia and depression severity at post and follow up. Despite these positive findings, one of the important limitations from Sadler et al.'s (2018b) trial was its sole reliance on quantitative-based outcomes (e.g., questionnaires, clinical interviews).

The results from RCTs are often restricted by quantitative analyses because this methodology provides an overview of the data, and has the potential to omit important individualised results that need to be considered when constructing case formulation and treatment. Qualitative studies use different research methods of evaluating treatment outcomes compared to traditional quantitative research, mainly through interpreting data that is transcribed from interviews or focus groups (Braun & Clarke, 2006; Savin-Baden & Major,

2013). The nature of this type of research is more exploratory, subjective, and open-ended, as researchers seek to interpret trends, themes, or patterns that emerge in the participants' responses (Braun & Clarke, 2006; Savin-Baden & Major, 2013). Although quantitative research methods are considered to be more statistically rigorous, qualitative research can provide a nuanced understanding of the results (Braun & Clarke, 2006). Consequently, information that is acquired through qualitative analyses contributes a valuable perspective to explaining treatment outcomes and may play a pivotal role in developing innovative CBT-I programs.

Insomnia experts have suggested more qualitative-based research is needed to help develop a better understanding of the effects of CBT-I among various populations and settings (Blom et al., 2016; Vitiello, 2016). For example, a systematic review was recently conducted to investigate 22 insomnia-related qualitative studies (Araujo, Jarrin, Leanza, Vallieres, & Morin, 2017). The authors divided the articles into 3 categories: experience of insomnia, management of insomnia, and medicalisation of insomnia. Their key findings included (1) insomnia is experienced as a 24 hour problem, (2) individuals with insomnia often feel frustrated and misunderstood by health professionals, (3) the subjective experiences of insomnia are often discounted by health professionals, and (4) treatment delivery typically focusses on sleep hygiene and medication. Although this systematic review provided valuable insights into the experiences of individuals with insomnia, the analysis did not include any RCTs that had collected feedback from older adults with insomnia and depression who had completed a course of group-based CBT-I.

A comparative study was recently conducted by Blom and colleagues (2016) who carried out a follow up qualitative analysis to investigate factors that may have facilitated or hindered the participants' treatment response to internet-based CBT for insomnia (iCBT-I) and internet-based CBT for depression (iCBT-D). Blom et al.'s feedback interviews were

conducted via telephone six months post treatment ($N = 35$). Blom et al. found that participants who received the iCBT-I condition were more positive about their treatment experience and reported fewer hindering factors compared to participants who received the iCBT-D condition. Increased use of iCBT-I treatment content for both conditions was positively associated with better outcomes. Symptoms of insomnia, depression, and other comorbidities were perceived as more hindering for iCBT-D than for iCBT-I. This indicated that participants may have been more ready to correct their sleep patterns than their depression, and therefore found more benefit from iCBT-I as opposed to iCBT-D. Blom et al.'s findings provide further evidence that focussing on addressing insomnia first may be an important step in providing more effective treatment for depression.

The aim of the current study was to qualitatively explore the experiences of older adults who recently participated in a clinical trial that tested the effects of group-based cognitive behaviour therapy for insomnia and depression (Sadler et al., 2018b). The results from reflective focus groups could provide unique insights into treatment development and capture a sense of what was most beneficial to instigate change among this age group. This feedback could play an important role in improving future therapeutic programs for older adults with comorbid insomnia and depression.

4.1.4 Methodology

4.1.4.1 Design

This study was conducted in parallel with the post treatment data collection point of an RCT that explored the effects of group-based CBT-I and CBT-I+ for older adults diagnosed with comorbid insomnia and depression (Sadler et al., 2018b). This study occurred within community mental health services across Victoria, Australia, between 2014 and 2016. The RCT was registered with the Australian and New Zealand Clinical Trials Registry (ID:

ACTRN12615000067572), and ethics approval was granted for the current reflective study by three Human Research Ethics Committees (Federation University Australia, Latrobe Regional Hospital, and Peninsula Health). Participants were eligible to participate in the feedback focus groups if they had completed one of the two experiential conditions in Sadler et al.'s (2018b) trial.

4.1.4.2 Participants and Procedure

At the end of each group treatment program (following session eight), participants (>65y/o) were invited to provide their reflections and feedback from participating in treatment. The group interviews were conducted in community mental health clinics. Thirty-seven of the 42 eligible participants agreed to participate in the semi-structured group interviews. The data from one group ($n = 6$, CBT-I+ condition) was lost due to a technical recording error, and another CBT-I+ group declined to participate due to transport commitments ($n = 5$). As a result, thirty-one participants ($n = 21$ CBT-I; $n = 10$ CBT-I+) were available for data analysis (M age 75 years, 61% female). Demographic details of this sample are shown in Table 9.

Table 9 Participant demographics

Variable	CBT-I (<i>n</i> = 21)	CBT-I+ (<i>n</i> = 10)	TOTAL (<i>n</i> = 31)
Age, mean (SD)	74.5 (7.2)	75.6 (7.4)	74.8 (7.1)
Sex, n (%)			
Female	13 (61.9)	6 (60.0)	19 (61.2)
Male	8 (38.1)	4 (40.0)	12 (38.8)
Relationship Status, n (%)			
Married	7 (33.3)	5 (50.0)	12 (38.8)
Widowed	8 (38.1)	4 (40.0)	12 (38.8)
Divorced	3 (14.3)	1 (10.0)	4 (12.9)
Single	1 (4.8)	0 (0.0)	1 (3.2)
Defacto	2 (9.5)	0 (0.0)	2 (6.3)
Education Level, n (%)			
Primary	3 (14.3)	0 (0.0)	3 (9.7)
Secondary	9 (42.9)	6 (60.0)	15 (48.4)
Vocational	3 (14.3)	1 (10.0)	4 (12.9)
Tertiary	6 (28.6)	3 (30.0)	9 (29.0)
Income, n (%)			
Pension	16 (76.1)	8 (80.0)	24 (77.5)
Self-funded	3 (14.3)	2 (20.0)	5 (16.1)
Veteran's affairs	2 (9.5)	0 (0)	2 (6.3)
Accommodation, n (%)			
House	12 (57.1)	7 (70.0)	19 (61.2)
Unit	3 (14.3)	2 (20.0)	5 (16.1)
Retirement village	2 (9.5)	0 (0.0)	2 (6.3)
Residential Aged Care Facility	4 (19.1)	1 (10.0)	5 (16.1)

Note: CBT-I, Cognitive Behaviour Therapy for Insomnia; CBT-I+, Cognitive Behaviour Therapy for Insomnia plus; SD, Standard Deviation.

The interviews were completed face-to-face in small focus groups and were recorded with an audio device. All interviews began with a central question, “What was your overall experience from participating in this program?” After the group participants had responded to this initial question, the interviewer was free to follow whatever the participants brought up, trying to validate their responses and use open-ended questions to allow for variation in their experiences of treatment. Each participant in each group was encouraged to contribute their unique perspectives. If the interview came to a natural pause, the interviewer raised

additional concepts for the participants to consider, these included (1) strengths and weaknesses of the program, (2) effects of strategies/interventions, (3) therapeutic workbook, (4) length of program, (5) group size, and (6) co-therapists. On average, the group interviews went for approximately 20 minutes in length.

Each focus group was facilitated by the first author (PS). PS is a registered clinical psychologist with a Master of Clinical Psychology and Master of Applied Science. He has been studying and working in community mental health services since 2006 and is in the final stage of completing a PhD. PS was actively involved in the original RCT on which this report is based (Sadler et al., 2015; Sadler et al., 2018b). His experiences in supervising the trial influenced the design and analysis of this qualitative-based study.

4.1.4.3 Qualitative Analysis

This study applied thematic analysis to interpret the focus group reflective data. Thematic analysis aims to understand how an individual or small group makes sense of a given phenomenon (Braun & Clarke, 2006). Thematic analysis was implemented to review the data that were collected during the reflective focus groups. The group interviews were transcribed verbatim into text by the first author (PS). The text transcripts were read several times to extract emerging codes, which were transformed into themes and subthemes by PS and later reviewed by the co-authors. Themes and subthemes identify both something of importance to the participants, and also convey a meaning of their reflections (Braun & Clarke, 2006). These themes have formed the basis for the qualitative results. Direct quotes from the participants were also identified to highlight the thematic findings.

4.1.5 Results

Data from the six focus group interviews were transcribed into 424 sentences and 60 codes were extracted. Thirty-four initial themes emerged, which were finally transformed

into 3 themes and 10 subthemes. Table 1 demonstrates an example of the thematic analysis process.

Table 10. Example of the thematic analysis process

Quote	Code	Theme	Subtheme
“From what I’ve done here, you know, it’s like I know I’m not the only one. And it’s great being able to sit around with people and talk about it all. And people have got similar problems and different problems. And you get little handy hints on what they’re doing, and something else to give a try.”	Insight and skills from peers within the group	Positive experience	Togetherness

The three primary themes were (1) positive experiences, (2) negative experiences, and (3) suggested modifications. The positive subthemes were (1a) therapists, (1b) togetherness, (1c) use of strategies reduced symptoms, and (1d) acceptance. The negative subthemes were (2a) persistent symptoms, (2b) program too condensed, and (2c) attendance obstacles. The suggested modifications were (3a) lengthen program, (3b) multi-dimensional learning, and (3c) multi-modal delivery options. Figure 1 depicts a summary of the final thematic map.

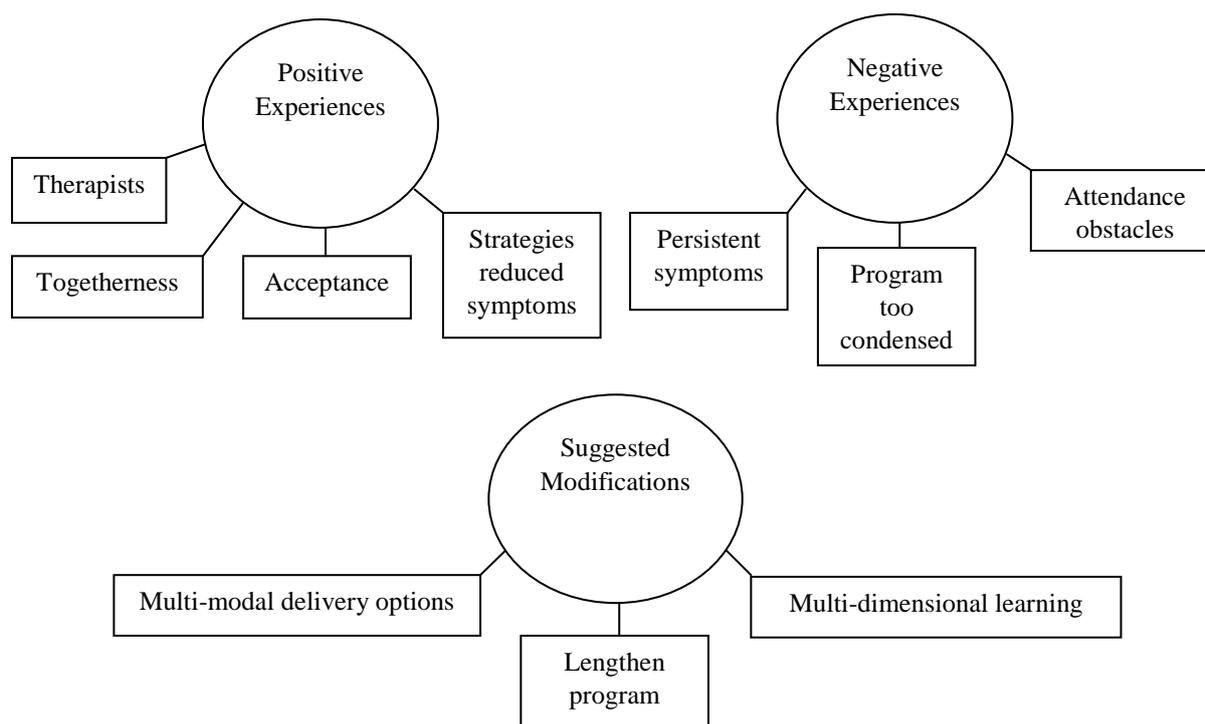


Figure 5. Final thematic map

4.1.5.1 Positive Experiences

4.1.5.1.1 Therapists

The strongest theme that emerged from the group reflections was the positive therapeutic alliance that was established between the participants and co-therapists. Each of the six feedback groups consistently reported the co-therapists were skilful and demonstrated positive qualities that improved their therapeutic experience. The majority of participants each made separate statements that supported the positive experience they felt from the therapists' co-facilitation of the groups. For example,

"I felt like I was in the right place at the right time. I felt at every turn they (co-therapists) respected our perspectives. They were considering our comfort at all times. We could ask them questions that they could explain it." (66y/o, female, CBT-I)

4.1.5.1.2 Togetherness

Another strong positive experience that was reported by each group was the concept of togetherness. Participants reported they experienced a heightened sense of belonging and connectedness whilst sharing their sleep and mood experiences together. Participants also reported they felt understood and appreciated by their peers.

“Everyone was so different...but I found we all had similar problems. I found because we are in a group there are people that are in the same boat as I am. I think that helped because I thought I was the only one. But apparently I wasn’t...I found that was really good.” (77y/o, female, CBT-I)

4.1.5.1.3 Use of strategies reduced symptoms

Participants in each group reported implementing cognitive and behavioural change skills helped reduce their insomnia and depression severity. The focus groups highlighted offering a variety of strategies in the programs were important. The most frequent beneficial strategies reported were the relaxation-based skills, such as diaphragmatic breathing, imagery and muscle relaxation.

“I’ve learnt how to relax properly. I know I’m not supposed to lie on the bed, but I can’t help that because of my bad back. But I am sleeping better now. Um...when I wake up, I’m not taking as long to get back to sleep. I mean I still have my nights...but on the whole, I’m going back to sleep quicker. I listen to the tape you made for us in the daytime and evening, and then I sleep at night.” (74y/o, female, CBT-I)

A combination of additional cognitive and behavioural interventions were also discussed by participants during the group reflections. Examples of these are reflected in the following statements,

“Well I have improved...now I’m going to bed a bit later.” (84y/o, male, CBT-I+)

“The main one for me was not looking at the clock all night. I’ve got rid of the clock...not really (laughter), but now I don’t see it at night. Because I was watching it and it was 3

o'clock in the morning, and next it was 2 minutes past 3, and then it was 2 ½ minutes past 3, and then I never got back to sleep again. I think that would be the major one.” (81y/o, male, CBT-I)

“It’s given me a more positive outlook...if I have trouble sleeping, I can have some positive thoughts to counteract it.” (76y/o, male, CBT-I+)

“That’s invaluable (points to the therapeutic workbook). If I ever feel confused, I go back to the bible...my sleep bible.” (88y/o, female, CBT-I)

4.1.4.1.4 Acceptance

Developing a deeper attitude of acceptance was the final positive theme that emerged from the groups. Several participants made statements that demonstrated a greater sense of acceptance about their mental health.

“I find I am more at peace now because I think what they (co-therapists) taught us is very calming. I am very short fused...and I’m not like that anymore. I think of things now before I do my lolly (laughter). I don’t know...I have learned to accept.” (77y/o, female, CBT-I)

“Ya know...I think perhaps not worrying about the amount of sleep I think I should have. Just focussing on the amount of sleep I do get...is satisfactory (smiling).” (65y/o, male, CBT-+)

4.1.5.2 Negative Experiences

4.1.5.2.1 Persistent symptoms

Despite the overall positive experiences from this study and significant positive outcomes from the original RCT (Sadler et al., 2018b), two out of the six focus groups discussed having persistent insomnia and depression symptoms post treatment. For example, two participants reported persistent symptoms despite completing treatment. They each reported,

“I’m not sure whether I’ve changed very much, it’s hard to say, I still feel tired.” (68y/o, female, CBT-I+)

“I could sleep on a barb wire fence years ago, and never have any trouble sleeping, and now I’m still a real night owl...it’s just me personally, because, I’m just a non-sleeper.” (72y/o, female, CBT-I)

4.1.5.2.2 Attendance obstacles

Participants reported it was difficult to attend therapy sessions for a range of reasons, including (1) the initial symptom severity of their comorbid conditions (e.g., tiredness, amotivation, anxiety, pain), (2) the distance that some participants had to travel to attend the community mental health clinic, and (3) having to organise/depend on others for transport if the participant did not drive. For example,

“Distance was a problem, a lot of travelling to get here.” (68y/o, female, CBT-I)

“Some weeks I just couldn’t concentrate on what people were saying. It was all going over my head. And I was dreading (the therapist) would ask me something...and he did sometimes (laughter).” (79y/o, female, CBT-I+)

Of note, Sadler et al.’s clinical trial was conducted within rural and regional areas of Victoria, Australia. Despite the geographic obstacles for some participants, the overall attendance/completion rate throughout the trial was high. Sadler et al. (2018b) reported each participant allocated to CBT-I completed treatment (n = 24, 100%), and 23 out of 25 participants (92%) completed CBT-I+ (see Sadler et al. 2018b for further details).

4.1.5.2.3 Program too condensed

One of the challenges inherent within delivering multicomponent CBT-I programs is balancing the amount of interventions offered with the length of treatment. A reported criticism of the treatment programs was the volume of therapeutic content that was compacted into 8 weekly sessions. Although most participants reported having a variety of

available strategies was a strength of treatment, some participants found learning multiple skills over 8 weekly sessions was difficult to comprehend, for example,

“This sort of thing (pointing to cognitive reframing worksheet exercises)...I had trouble with this. I’d like to go over that again. And you know...some of the things that were done a few weeks ago, I can’t bring them back into my head now.” (66y/o, male, CBT-I+)

4.1.5.3 Suggested Modifications

4.1.5.3.1 Lengthen program

Participants suggested future CBT-I programs could be improved by extending the length of treatment (e.g., from 8 sessions to 12 sessions). This could provide more opportunities to personalise cognitive and behavioural changes and strengthen their relapse prevention skills.

“I think it could have been a bit longer because there were a few different concepts I couldn’t quite grasp straight away.” (86y/o, male, CBT-I+)

“You’re coming into a group of people you don’t know. You start to feel comfortable in about 2 to 3 weeks. I think you’d have to extend the program to allow for that. I mean, you’ve got to feel comfortable with the people in the room to start and speak...you know...what’s really on your mind.” (67y/o, male, CBT-I+)

4.1.5.3.2 Multi-dimensional learning

It was also suggested that CBT-I programs could be improved by utilising a variety of learning methods. Instead of primarily focussing on completing traditional handwritten worksheets during therapy, participants suggested applying multi-dimensional learning methods (e.g., videos and/or audio clips of implementing strategies; use of senior mentors during a group) could cater to everyone’s learning needs and strengths. This could make the

therapeutic experience easier to comprehend and increase the application of CBT-I interventions. One participant reported,

“Perhaps a video to show at the groups would make a big difference. One of the things that stuck in my mind, always, was when I was in the army. They showed us two films in our training...they’ve always been in my mind...it’s never left my mind. Some people are auditory, and some are visual.” (70y/o, male, CBT-I)

4.1.5.3.3 Multi-modal delivery options

Although participants greatly benefitted from participating in the CBT-I group therapy format, offering a range of therapeutic modalities (e.g., individualised, internet-based, telephone) could potentially enhance the personalised experience of treatment. Participants’ stated,

“I really valued the one-on-one time I got early on when I was upset...that helped me come to the group.” (72y/o, female, CBT-I)

“I think it would be beneficial to have some phone review sessions...if that could be organised, that would be good.” (79y/o, female, CBT-I+)

4.1.6 Discussion

The aim of this study was to explore the experiences of older adults who completed group-based forms of CBT for insomnia and depression within community mental health services (Sadler et al., 2018b). Sadler et al.’s original clinical trial demonstrated that both standard CBT-I and advanced CBT-I+ conditions significantly reduced participants’ level of insomnia and depression, however, the results were limited by the reliance on quantitative outcome measures. Hence the current exploratory study built on Sadler et al.’s research by offering a qualitative perspective to interpreting the results. Thematic analysis revealed the

participants underwent both positive and negative experiences during Sadler et al.'s trial, with associated suggested modifications to improve future CBT-I programs.

The current investigation followed recommendations from CBT-I experts (e.g., Araujo et al., 2017; Blom et al., 2016; Vitiello, 2016), who suggested qualitative-based research is required to assist in developing new frontiers of treatment for people with comorbid insomnia. Since this is the first study to analyse focus group reflections from older adults who completed group-based CBT-I and CBT-I+, there's minimal research to compare the current results. This exploration extended Blom et al.'s (2016) qualitative study by taking note of their methodological weaknesses. Blom et al.'s feedback interviews were conducted via telephone six months post treatment, which made it difficult for participants to recall specific details of their therapeutic experiences. The current study addressed this issue by completing face-to-face focus group interviews on the same day of the final treatment sessions. Another methodological problem in Blom et al.'s analysis involved the division of their sample into four subgroups. This resulted in very low statistical power and meant their comparative findings should be interpreted with considerable caution. Finally, Blom et al.'s research targeted young to middle age adults who were able to self-direct internet-based treatment for insomnia and depression. This restricts the generalisability of their results, as pertinent matters that can affect older adults with multiple comorbidities were not discussed.

The results from the current thematic analysis provide contemporary implications for practitioners, researchers, and community mental health services who are interested in improving treatment for older adults with insomnia and depression. The positive themes that emerged confirmed that this cohort of older adults value and benefit from face-to-face treatment in a group therapy format. This supports well known theoretical principals of CBT, which suggest establishing rapport, providing opportunities for peer validation, and building group cohesion are central mechanisms to positive therapeutic outcomes (Beck, 2011; Koffel

et al., 2015). The participants reported a strong therapeutic alliance with the co-therapists during Sadler et al.'s (2018b) trial. This is of particular significance because the co-therapists who delivered the programs were provisional psychologists who had minimal expertise in assessing or treating comorbid insomnia prior to commencing their clinical gero-psychology placement. This suggests CBT-I and CBT-I+ can be effectively delivered by novice co-therapists who undertake a structured clinical supervision and training plan (Manber et al., 2012; Sadler et al., 2018b). Furthermore, the increased sense of togetherness and companionship that the participants reported may have been a partial mechanism for change, as sharing their experiences with like-minded peers seemed to assist their motivation and ability to implement the CBT-I strategies. These combined positive findings have cost-effective implications for community mental health services, which indicate that offering CBT-I group programs to older adults with comorbid insomnia and depression will likely enhance recovery outcomes. Although this study revealed the majority of participants underwent positive experiences during Sadler et al.'s (2018b) RCT, some participants also encountered negative experiences.

An unfortunate reality of any psychological treatment trial is not all participants reach remission. This qualitative analysis discovered that some participants had persistent insomnia and/or depressive symptoms post treatment. This is not uncommon, as previous comorbid insomnia CBT research have reported up to 50% of participants' still experience psychopathology post treatment (e.g., Manber et al., 2008). Participants who took part in the current focus groups also reported the program was too condensed. This meant that some older adults believed there was too much therapeutic content to comprehend and practice within the eight sessions. Consequently, participants suggested that extending the program to include more sessions could provide additional opportunities to review and consolidate the interventions, which could in turn, strengthen sleep and mood outcomes.

Attending face-to-face group therapy can be a confronting process, particularly for older adults with insomnia and depression who are in strong patterns of withdrawal or avoidance. A number of participants in the reflective focus groups reported it was initially difficult to attend therapy due to various obstacles, such as symptom severity and transport issues. These obstacles could be improved by implementing the following measures: (1) professionals who provide sustained encouragement and positive reinforcement before and during therapy will likely increase the participants' positive experiences (Sadler et al., 2018a), (2) mental health services that offer a therapy bus or facilitate transport will likely increase therapy attendance and retention, and (3) CBT-I programs could be improved by utilising a variety of multi-dimensional learning methods and multi-modal delivery options. Future clinical trials could test whether adding visual and audio CBT-I content (e.g., video clips highlighting stimulus control behaviour changes) via modified modalities (e.g., group, individualised, internet, smartphone) creates a greater personalised therapeutic experience.

Since this is the first study to qualitatively analyse feedback from older adults who participated in CBT for comorbid insomnia and depression, the results have set new foundations for research to advance. A pivotal strength and weakness of qualitative research is the reliance on the analyst's biases and abilities to interpret data accurately. The current study relied on the first author to conduct the interviews and interpret the data, therefore, including an independent co-facilitator and/or co-analyst could have provided an additional perspective. Another limitation in this study related to the sample size. The two treatment conditions were not compared to explore whether different themes emerged due to the low and variable sample sizes, hence data from the 31 participants were pooled together for analysis. This meant that the collective experiences of participants were more likely reflective of standard CBT-I rather than advanced CBT-I+. Future researchers that qualitatively explore

the experiences of participants who have completed CBT-I+ will possibly detect novel findings that add to the emerging hybrid forms of therapy for comorbid insomnia.

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5. CONCLUSION

Sleep and mood are important interrelated factors that influence an older adult's daily functioning. The specific relationship between insomnia and depression is particularly relevant for older adults because the prevalence of comorbid insomnia increases substantially with older age. Although pharmacotherapy remains the most common form of treatment offered to older adults with comorbid insomnia and depression, medication alone is often insufficient to treat both conditions and has the potential to exacerbate sleep and mood problems. Hence researchers have begun to explore how safer and more cost-effective forms of treatment impact comorbid insomnia and depression among older adults.

Cognitive behaviour therapy is the most effective form of psychological treatment for comorbid insomnia. Although several trials have shown CBT-I to have a positive impact on comorbid insomnia and depression, these studies possessed significant methodological weaknesses and primarily focussed on younger adult homogenous populations. These gaps in the research raised two important clinical questions that were tested during this thesis: (1) Could the effects of CBT-I be generalised to a heterogenous sample of older adults with comorbid insomnia and depression within a community mental health setting, and (2) could redesigning CBT-I to include positive mood-enhancing strategies produce stronger effects than standard CBT-I treatment?

This RCT implemented appears to be the first of its kind. The primary results from this trial demonstrated that specifically treating comorbid insomnia with CBT had positive effects for improving depression for older adults with complex comorbidities. The advanced CBT-I+ condition revealed similar reductions in insomnia and depression severity compared to the standard CBT-I condition. Both treatments demonstrated large effect sizes, high retention, and strong remission rates among older adults with insomnia and depression. It is important to note that this trial had inadequate power to detect non-equivalence using a mixed

model analysis. It would have been more appropriate to use one primary measure (e.g., insomnia severity) instead of both insomnia and depression severity. Replication of this study is necessary with a larger sample size to conclusively establish whether the two interventions have different or equivalent effects on these measures. Replication with other age groups and settings is also required to establish generalisability. It was concluded CBT-I and CBT-I+ were both effective at reducing insomnia and depression severity for older adults. Mental health services that deliver treatment for comorbid insomnia with cognitive behaviour therapy may improve recovery outcomes for older adults with depression.

The evidence presented within this thesis generates operational opportunities for clinical practice. Firstly, mental health clinicians who treat older adults receive little or no training in behavioural sleep medicine. Clinicians could be provided with regular professional development training to learn how to initially assess and diagnose comorbid insomnia, and secondly learn how to deliver CBT-I as part of a client's recovery plan for depression. Constructing a tailored training package within aged persons' mental health services will enable CBT-I to become a safe and viable treatment option for clients with insomnia and depression. When mental health service resources are limited, psychology students on clinical placement could implement cost-effective CBT-I programs.

This thesis demonstrated that both CBT-I and CBT-I+ were efficacious treatments that could be offered to older adults with insomnia and depression. The quantitative results suggested there was no need to add depression treatment strategies to a standard course of CBT-I. Although this trial was not powered to test for superiority, the qualitative analyses provided a novel dimension to the RCT results that have set foundations for future research. Feedback from the focus groups identified four positive and three negative experiences for participants in the intervention conditions. The positive themes consolidated the benefits of a group therapy approach for this cohort, and the negative themes highlighted the need for

flexible and personalised approaches to treatment delivery. The qualitative results provide a pathway to design a better combined CBT treatment for insomnia and depression. This could involve (1) extending the program length (e.g., from 8 to 12 sessions) to allow more time to practice the depression interventions, (2) adding multi-dimensional learning methods (e.g., visual/audio/mentorship) to cater for each participant's needs/strengths, and (3) offering various modes of treatment delivery (e.g., group, individual, internet, telephone) to increase participants' motivation to engage in their treatment of choice. These suggestions provide clear directions to test more innovative treatment options for older adults with comorbid insomnia and depression.

APPENDIX A

Evidence of Literature Review Publication

COGNITIVE BEHAVIOUR THERAPY, 2018
VOL. 47, NO. 2, 139–154
<https://doi.org/10.1080/16506073.2017.1359206>



Advancing cognitive behaviour therapy for older adults with comorbid insomnia and depression

Paul Sadler^a , Suzanne McLaren^a , Britt Klein^{a,b} and Megan Jenkins^a

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ABSTRACT

Insomnia and depression are two of the most common mental health problems that negatively impact older adults. The burden associated with these highly comorbid conditions requires an innovative approach to treatment. There have been significant advancements in the field of cognitive behaviour therapy for insomnia (CBT-I) over recent years. CBT-I has evolved from targeting homogenous insomnia samples to now showing promising results for comorbid insomnia. CBT-I is not only effective at treating comorbid insomnia, but can also have a positive impact on depression severity. Despite these important clinical developments, limited research has explored whether modifying CBT-I programmes to specifically target comorbid depression could improve outcomes for older populations. This paper reviews recent literature and provides therapeutic recommendations to advance CBT-I for older adults with comorbid insomnia and depression.

ARTICLE HISTORY

Received 19 November 2016
Accepted 20 July 2017

KEYWORDS

Cognitive behaviour therapy; comorbid insomnia; depression; older adults

Introduction

Insomnia and depression share a strong bidirectional relationship that is highly prevalent among older adults (Pigeon et al., 2008; Sadler, McLaren, & Jenkins, 2013). Throughout this article, the term “older adults” refers to a mean age of 65 years and older, whereas “adults” refers to a mean age between 18 and 64 years. Approximately, twice as many older adults experience insomnia compared to adults (Crowley, 2011; Ohayon, Zulley, Guilleminault, Smirne, & Priest, 2001), and insomnia is typically more complex among older adults due to increased multiple comorbidities (Foley, Ancoli-Israel, Britz, & Walsh, 2004; Weissman, Greenwald, Niño-Murcia, & Dement, 1997). Studies have reported that the majority of older adults with depression experience significant comorbid insomnia symptoms (Foley et al., 2004; Pigeon et al., 2008). Furthermore, evidence indicates that insomnia often precipitates the onset of depression and can increase the chance of depressive relapse if inadequately treated (Baglioni et al., 2011; Breslau, Roth, Rosenthal, & Andreski, 1996; Franzen & Buysse, 2008; Perlis et al., 2006). A meaningful understanding of insomnia and depression also

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APPENDIX B

Evidence of Protocol Publication

Sadler et al. *Trials* (2015) 16:538
 DOI 10.1186/s13063-015-1066-6

Trials

STUDY PROTOCOL

Open Access



Cognitive behaviour therapy for older adults experiencing insomnia and depression in a community mental health setting: Study protocol for a randomised controlled trial

Paul Sadler^{1*}, Suzanne McLaren¹, Britt Klein^{1,2,3}, Megan Jenkins¹ and Jack Harvey¹

Abstract

Background: Cognitive behaviour therapy for insomnia (CBT-I) is a well-established treatment; however, the evidence is largely limited to homogenous samples. Although emerging research has indicated that CBT-I is also effective for comorbid insomnia, CBT-I has not been tested among a complex sample of older adults with comorbid insomnia and depression. Furthermore, no study has explored whether modifying CBT-I to target associated depressive symptoms could potentially enhance sleep and mood outcomes. Therefore, this study aims to report a protocol designed to test whether an advanced form of CBT for insomnia and depression (CBT-I-D) is more effective at reducing insomnia and depressive symptoms compared to a standard CBT-I and psychoeducation control group (PCG) for older adults in a community mental health setting.

Methods/Design: We aim to recruit 150 older adults with comorbid insomnia who have presented to community mental health services for depression. Eligible participants will be randomly allocated via block/duster randomisation to one of three group therapy conditions: CBT-I, CBT-I-D, or PCG. Participants who receive CBT-I will only practice strategies designed to improve their sleep, whereas participants who receive CBT-I-D will practice additional strategies designed to also improve their mood. This trial will implement a mixed-methods design involving quantitative outcome measures and qualitative focus groups. The primary outcome measures are insomnia and depression severity, and secondary outcomes are anxiety, hopelessness, beliefs about sleep, comorbid sleep conditions, and health. Outcomes will be assessed at pre-intervention (week 0), post-intervention (week 8), and 3-month follow-up (week 20).

Discussion: This CBT study protocol has been designed to address comorbid insomnia and depression for older adults receiving community mental health services. The proposed trial will determine whether CBT-I is more effective for older adults with comorbid insomnia and depression compared to a PCG. It will also establish whether an advanced form of CBT-I-D generates greater reductions in insomnia and depression severity compared to standard CBT-I. The results from the proposed trial are anticipated to have important clinical implications for older adults, researchers, therapists, and community mental health services.

(Continued on next page)

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Full list of author information is available at the end of the article



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APPENDIX C

Evidence of Randomised Controlled Trial Publication



SLEEPJ, 2018, 1–12

doi: 10.1093/sleep/zyy104

Advance Access publication Date: 24 May 2018

Original Article

ORIGINAL ARTICLE

Cognitive behavior therapy for older adults with insomnia and depression: a randomized controlled trial in community mental health services

Paul Sadler^{1,*}, Suzanne McLaren^{1,2}, Britt Klein^{1,2}, Jack Harvey^{1,3} and Megan Jenkins¹

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*Corresponding author. Paul Sadler, School of Health Sciences & Psychology, Faculty of Health, Federation University Australia, PO Box 663, Ballarat 3353, Victoria, Australia. Email: paulsads@hotmail.com.

Abstract

Study Objectives: To investigate whether cognitive behavior therapy was effective for older adults with comorbid insomnia and depression in a community mental health setting, and explore whether an advanced form of cognitive behavior therapy for insomnia produced better outcomes compared to a standard form of cognitive behavior therapy for insomnia.

Methods: An 8-week randomized controlled clinical trial was conducted within community mental health services, Victoria, Australia. Seventy-two older adults (56% female, M age 75 ± 7 years) with diagnosed comorbid insomnia and depression participated. Three conditions were tested using a group therapy format: cognitive behavior therapy for insomnia (CBT-I, standard), cognitive behavior therapy for insomnia plus positive mood strategies (CBT-I+, advanced), psychoeducation control group (PCG, control). The primary outcomes were insomnia severity (Insomnia Severity Index) and depression severity (Geriatric Depression Scale). Primary and secondary measures were collected at pre (week 0), post (week 8), and follow-up (week 20).

Results: CBT-I and CBT-I+ both generated significantly greater reductions in insomnia and depression severity compared to PCG from pre to post ($p < .001$), which were maintained at follow-up. Although the differences between outcomes of the two treatment conditions were not statistically significant, the study was not sufficiently powered to detect either superiority of one treatment or equivalence of the two treatment conditions.

Conclusion: CBT-I and CBT-I+ were both effective at reducing insomnia and depression severity for older adults. Mental health services that deliver treatment for comorbid insomnia with cognitive behavior therapy may improve recovery outcomes for older adults with depression.

Trial Registration: Australian and New Zealand Clinical Trials Registry (ANZCTR); URL: <http://www.anzctr.org.au>; Trial ID: ACTRN1261500067572; Date Registered: December 12, 2014.

Statement of Significance

This is the first randomized controlled clinical trial to demonstrate that specifically treating insomnia with cognitive behavior therapy has a positive effect onto improving depression for older adults with multiple comorbidities. Standard and advanced cognitive behavior therapy programs revealed similar reductions in insomnia and depression severity, however, this trial had inadequate power to detect nonequivalence. Both active treatments demonstrated large effect sizes, high retention, and strong remission rates among older adults with insomnia and depression. Replication of this study is necessary with a larger sample size to conclusively establish whether or not the two interventions have different or equivalent effects. Replication with other age groups and settings is also required to establish generalizability of results.

Key words: insomnia; depression; comorbidity; cognitive behavior therapy; older adults; mental health

Submitted: 13 December, 2017; Revised: 17 April, 2018

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APPENDIX D

Evidence of Focus Group Manuscript Submission

Aging and Mental Health



**Cognitive behaviour therapy for insomnia and depression:
Qualitative reflections from older adults who participated in
a randomised controlled trial**

Journal:	<i>Aging and Mental Health</i>
Manuscript ID	CAMH-2018-0441
Manuscript Type:	Original Article
Keywords:	Depression < Mood Disorders, Anxiety and Trauma related disorders, Sleep problems < Mood Disorders, Anxiety and Trauma related disorders, Cognitive Behavioural Therapy < Psychosocial Interventions, Group Therapy < Psychosocial Interventions, Qualitative methods

SCHOLARONE™
Manuscripts

APPENDIX E

Ethics Approval from Federation University Australia

Approval

Human Research Ethics Committee



The approval of the Latrobe Regional Hospital Human Research Ethics Committee has been noted by the Federation University HREC

Principal Researcher:	Suzanne McLaren	
Other/Student Researcher/s:	Paul Sadler Britt Klein	Megan Jenkins
School/Section:	SHS	
Project Number:	E14-042	
Project Title:	Cognitive Behaviour Therapy for Older Adults Experiencing Insomnia and Depression in a Community Mental Health Setting: A Randomised Controlled Trial.	
For the period:	28/02/2014 to 31/12/2015	

Please quote the Project No. in all correspondence regarding this application.

REPORTS TO HREC:

Annual reports for this project must be submitted to the Ethics Officer on:
28 February 2015

A final report for this project must be submitted to the Ethics Officer on:
31 January 2016

This report can be found at:

<http://federation.edu.au/research-and-innovation/research-support/ethics/human-ethics/human-ethics3>

Mrs Fiona Koop

Ethics Officer
20 May 2014

Please see attached 'Conditions of Approval'.

Ethics Approval from Federation University Australia

Extension Approval

Human Research Ethics Committee



Principal Researcher:	Professor Suzanne McLaren
Other/Student Researcher/s:	Mr Paul Sadler Professor Britt Klein Megan Jenkins
School/Section:	SHS
Project Number:	E14-042
Project Title:	Cognitive behaviour therapy for older adults experiencing insomnia and depression in a community mental health setting: A randomised controlled trial.
Original Approval Dates	28/02/2014 to 31/12/2015
Extension Period:	01/01/2016 to 30/06/2016

Quote the Project No. **E14-042** in all correspondence regarding this application.

Please note: Ethics Approval is contingent upon the submission of a **Final Project Report** at the completion/discontinuation of the project. **Annual Project Reports** must also be submitted if the duration of the project exceeds twelve months. It is the responsibility of researchers to take note of the following dates and submit these reports in a timely manner, as reminders may not be sent out. Failure to submit reports will result in your ethics approval lapsing.

REPORTS TO HREC:

A final report for this project must be submitted to the Ethics Officer on:
30 July 2016

These report forms can be found at:

<http://federation.edu.au/research-and-innovation/research-support/ethics/human-ethics/human-ethics3>

Fiona Koop

Ethics Officer
27 January 2016

Please see attached 'Conditions of Approval'.

APPENDIX F

Ethics Approval from Latrobe Regional Hospital



Human Research Ethics Committee Certificate of Approval

PO Box 424
Traralgon, Latrobe City
Victoria 3844 Australia
Telephone +613 5173 8000
Facsimile +613 5173 8444
Also trading as Gippsland Health
ABN 18 128 843 652

This is to certify that

Project No: 2014-02 - LNR

Project Title: Cognitive Behaviour Therapy for Older Adults Experiencing Insomnia and Depression in a Community Mental Health Setting: A Randomised Controlled Trial

Principal Researchers: Professor McLaren; Mr Paul Sadler

has been given approval by the Human Research Ethics Committee from:

Approval date: 28/02/2014 **Expiry date:** 31/12/2015

It is the Principal Researcher's responsibility to ensure that all researchers associated with this project are aware of the conditions of approval. A copy of the approved ethics application and supporting documents must be kept on your files for audit purposes.

The Principal Researcher is required to notify the Human Research Ethics Committee in relation to the following.

- Any significant changes to the project and the reason for that change, including an indication of ethical implications (Amendment Form on LRH Research website)
- Adverse Event Reports regarding participants;
- Any other unforeseen events or unexpected developments that merit notification;
- The inability of the Principal Researcher to continue in that role, or any other change in research personnel involved in the project;
- Commencement date of the project (form on LRH Research website); and
- Termination or closure of the project.

Additionally, the Principal Researcher is required to submit

- A Progress Report every 12 months for the duration of the project (form are available on the LRH Research website);
- A Request for Extension of the project prior to the expiry date, if applicable; and,
- A detailed Final Report at the conclusion of the project (form are available on the LRH Research website).

The Human Research Ethics Committee may conduct an audit at any time.

All research subject to the Latrobe Regional Hospital Human Research Ethics Committee review must be conducted in accordance with the *National Statement on Ethical Conduct in Human Research (2007)*.

The Latrobe Regional Hospital Human Research Ethics Committee is constituted in accordance with the *National Statement on Ethical Conduct in Human Research (2007)*.

SPECIAL CONDITIONS

Nil

4/3/14

Amanda Cameron
Acting Chief Executive

Please quote Project No and Title in all correspondence

Ethics Approval from Latrobe Regional Hospital



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 Also trading as Gippsland Health
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Human Research Ethics Committee Certificate of Approval of Amendments

This is to certify that amendment(s) to

Project 2014-02 LNR

Cognitive Behaviour Therapy for Older Adults Experiencing Insomnia and
 Depression in a Community Mental Health Setting: A Randomised Controlled Trial

Principal Researcher: Paul Sadler

Amendment No:

Amendment Request 08/12/15

- Extension of completion date to 30 June 2016

have been approved in accordance with your amendment application on the understanding that you observe the *National Statement on Ethical Conduct in Research Involving Humans (2007)*.

It is your responsibility to ensure that all people associated with this particular research project are made aware of what has been approved in relation to any special conditions set down by the Human Research Ethics Committee.

Any further change to the application which is likely to have an impact on the ethical aspects of this project will require an application for amendment and subsequent approval from the Human Research Ethics Committee before a change to the project can be made.

SPECIAL CONDITIONS

- Nil

Peter Craighead
 Chief Executive

Date: 5 Jan 2016

All research subject to the Latrobe Regional Hospital Human Research Ethics Committee review must be conducted in accordance with the National Statement on Ethical Conduct In Human Research (2007).

APPENDIX G

Ethics Approval from Peninsula Health



*Premier's Award
Metropolitan
Health Service
of the Year
2007, 2009*

**RESEARCH
PROGRAM**

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Peninsula Health

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Frankston Victoria 3199 Australia
Telephone 03 9784 7777

HUMAN RESEARCH ETHICS COMMITTEE

Full Approval

19 October 2015

Mr Paul Sadler
Federation University Australia
PO Box 633
BALLARAT VIC 3353

Dear Mr Sadler

PROJECT: HREC/15/PH/4

TITLE: Effect of Cognitive Behaviour Therapy on symptom severity in older adults experiencing insomnia and depression in a community mental health setting: a randomised controlled trial

Thank you for submitting the above project which was first considered by the Peninsula Health Human Research Ethics Committee on Wednesday 18 March 2015 in accordance with the National Statement on Ethical Conduct in Human Research (2007). Following review of resubmitted documents I am pleased to advise that full approval to commence has now been granted.

The documents approved include:

Application:

NEAF:	29 March 2015
VSM:	21 January 2015
Protocol:	12 March 2015
Participant Information and Consent Form:	Version 2: 27 March 2015
Tools:	
Participant Invitation:	Version 2: 27 March 2015
Questionnaire Package:	Version 1: 21 January 2015
M.I.N.I.	Version 6.0.0
Sleep Diary:	Version 1: 21 January 2015

*At Peninsula Health we value:
Service Integrity Compassion Respect Excellence*

APPENDIX H

Ethics Final Report

Annual/Final Project Report



Human Research Ethics Committee

Please indicate the type of report	<input type="checkbox"/> Annual Report <input checked="" type="checkbox"/> Final Report
Project No:	E14-042
Project Name:	Cognitive behaviour therapy for older adults experiencing insomnia and depression in a community mental health setting: A randomised controlled trial.
Principal Researcher:	Paul Sadler
Other Researchers:	Prof Suzanne McLaren, Prof Britt Klein, Dr Megan Jenkins
Date of Original Approval:	20/5/14
School / Section:	Psychology
Phone:	0400 590 896
Email:	paulsads@hotmail.com

Please note: For HDR candidates, this Ethics annual report is a separate requirement, in addition to your HDR Candidature annual report, which is submitted mid-year to research.degrees@federation.edu.au.

1) Please indicate the current status of the project:		
1a) Yet to start		<input type="checkbox"/>
1b) Continuing		<input type="checkbox"/>
1c) Data collection completed		<input checked="" type="checkbox"/>
1d) Abandoned / Withdrawn:		<input type="checkbox"/>
1e) If the approval was subject to certain conditions, have these conditions been met? (If not, please give details in the comments box below)	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Comments:		

1f) Data Analysis	<input type="checkbox"/> Not yet commenced	<input type="checkbox"/> Proceeding	<input checked="" type="checkbox"/> Complete	<input type="checkbox"/> None
1g) Have ethical problems been encountered in any of the following areas:				
Study Design			<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Recruitment of Subjects			<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Finance			<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Facilities, Equipment			<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
(If yes, please give details in the comments box below)				
Comments:				

2a) Have amendments been made to the originally approved project?	
<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes
2b) If yes, was HREC approval granted for these changes?	
<input checked="" type="checkbox"/> Yes	Provide detail: <input type="checkbox"/> Yes Application for Amendment to an Existing Project <input type="checkbox"/> Yes Change of Personnel <input checked="" type="checkbox"/> Yes Extension Request
<input checked="" type="checkbox"/> No	If you have made changes, but not had HREC approval, provide detail as to why this has not yet occurred:
2c) Do you need to submit any amendments now?	
<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes Application for Amendment to an Existing Project <input type="checkbox"/> Yes Change of Personnel <input type="checkbox"/> Yes Extension Request * NB: If 'Yes', download & submit the appropriate request to the HREC for approval: Please note: Extensions will not be granted retrospectively. Apply well prior to the project end date, to ensure continuity of HRE approval.

3a) Please indicate where you are storing the data collected during the course of this project: (Australian code for the Responsible conduct of Research Ch 2.2.2, 2.5 – 2.7)
Data is stored in a locked filing cabinet, in a locked office, in a locked mental health clinic.
3b) Final Reports: Advise when & how stored data will be destroyed (Australian code for the Responsible conduct of Research Ch 2.1.1)
In 7 years via a professional shredding company.

4) Have there been any events that might have had an adverse effect on the research participants OR unforeseen events that might affect continued ethical acceptability of the project?

No

Yes * NB: If 'yes', please provide details in the comments box below:

Comments:

5a) Please provide a short summary of results of the project so far (no attachments please):

The experiential CBT conditions both generated significantly greater reductions in insomnia and depression severity compared to PCG from pre to post, which were maintained at follow-up.

5b) Final Reports: Provide details about how the aims of the project, as stated in the application for approval, were achieved (or not achieved). (Australian code for the Responsible conduct of Research 4.4.1)

The two central aims were achieved and the supplementary aim was also achieved by successfully implementing a RCT and analysing the participant experiences of treatment via feedback focus groups. Articles representing the lit review, methodology, and results are in the process of being published.

6) Publications: Provide details of research dissemination outcomes for the previous year resulting from this project: eg: Community seminars; Conference attendance; Government reports and/or research publications

Sadler et al. (2015). Protocol published in journal Trials.
Latrobe Regional Hospital research conference 2016

7) The HREC welcomes any feedback on:

- Difficulties experienced with carrying out the research project; or
- Appropriate suggestions which might lead to improvements in ethical clearance and monitoring of research.

APPENDIX I

Participant Plain Language Statement

**PARTICIPANT PLAIN LANGUAGE STATEMENT**

Short Title	Cognitive Behaviour Therapy for Insomnia Among Older Adults with Depression
Protocol Number	E14-042
Project Sponsor	Federation University Australia
Coordinating Principal Investigator Principal Investigator	Professor Suzanne McLaren Mr Paul Sadler
Location	Community Mental Health Service

What does my participation involve?**1 Introduction**

Thank you for considering to take part in this trial. You have been invited to participate in this project because you are being supported by a health service to improve and maintain a healthy mood.

The purpose of this study is to see if we can help older adults receiving mental health care improve their sleep. The study aims to test a treatment program which is specifically designed for older adults with insomnia. The program is called Cognitive Behaviour Therapy.

This participant information sheet tells you about the project and what is involved with participation. Knowing what is involved will help you decide if you want to take part. Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend, or health professional.

Participation in this study is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care by your mental health team whether or not you decide to take part. If you decide you would like to take part in this trial, you will be asked to sign the attached consent form. By signing the consent form you are telling us that you:

- Understand what you have read
- Consent to take part in this research project
- Consent to participate in the assessment and treatment sessions
- Understand that even if you sign the consent form, you are free to withdraw from this study at anytime

2 What is the purpose of this research?

People who experience insomnia (such as difficulties falling to sleep or staying asleep) often experience associated problems with their mood. Cognitive Behaviour Therapy is a well-established treatment for insomnia, however, no study has investigated whether this form of therapy is effective for older adults with insomnia and depression who are being supported by a rural mental health service. The project aims to explore how Cognitive Behaviour Therapy influences a person's sleep and mood. The information gained from this research may help us improve the delivery of future treatments for older adults with insomnia and depression receiving community mental health services.

This research has been initiated by the study's principal investigators, Paul Sadler and Suzanne McLaren. The results of the research will be used by Paul Sadler to obtain a Doctor of Philosophy in Psychology degree from Federation University Australia. This research has been funded by Federation University Australia, and no commercial sponsors have provided additional funds for this study. This research is being conducted in collaboration with Latrobe Regional Hospital's Aged Persons Community Mental Health Service.

3 What does participation in this research involve?

If you would like to participate in this study, the consent form needs to be signed and returned prior to participation. Once the consent form is completed, one of the research team will contact you via phone to ask you some brief questions about your current sleep difficulties. This initial phone call is expected to take 5 to 10 minutes.

The next step involves arranging an appointment for you to meet with one of the research team at your local mental health service. This consultation will involve asking questions about your sleep, physical and mental health. Your answers will help determine whether you are eligible to participate in this study. This appointment will take approximately 60 minutes.

If you are eligible for the study, you will be asked to complete a questionnaire package about your sleep and mood on three separate occasions; at the beginning of the trial, at the end of the trial, and 3 months after the trial has finished. The questionnaire package will take approximately 30 minutes to complete each time.

You will also be financially compensated \$20 on three separate occasions throughout the trial, at week 1, week 8, and three month follow up. Therefore, if you remain involved throughout the entire trial you will receive a total of \$60. There are no costs for you that are associated with participating in the project. All therapeutic strategies and interventions required as part of this research will be provided to you free of charge.

You will be participating in a randomised controlled treatment trial. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better than the other. To try to make sure the groups are the same, each participant is put into a group by chance (random). You will have a two in three chance of receiving a Cognitive Behaviour Therapy group.

You will also be participating in a blind study. In a blind study, you do not know which of the treatments you are receiving, however, the research team will know which treatment you are receiving. This is to ensure that your previous knowledge about the treatment groups doesn't bias the results.

This project will take place over 8 consecutive weeks. Once you are randomly allocated to participate in one of the treatment groups, you will attend 8 weekly 60-90 minute treatment sessions. The treatment programs will be run in small groups of approximately 5 participants and be co-facilitated by two therapists. The final session will provide participants with a chance to reflect on the strengths of the program and suggest areas of improvement. This research project will be supervised each week by the principal researchers. This will involve overseeing the project to ensure a professional and ethical standard of care is maintained.

4 What do I have to do?

There are three groups being tested in this study, so your level of participation during this project will depend on what group you are randomly assigned to.

If you are randomly allocated to receive the Cognitive Behaviour Therapy for insomnia group, you will be asked to attend 8 weekly treatment sessions that involve learning more about your sleep, and identifying unhelpful habits that may be contributing towards your sleep difficulties. You will learn several skills that aim to change your sleep pattern and sleep quality. You will also be provided with information and worksheets during the program which are designed to help you improve your sleep pattern. Participating in this form of therapy requires time and commitment. It will take perseverance to make sustainable changes to your sleep habits, and therefore the strategies that you will learn need to be practiced each day during the trial. Participants in this group will be supported by two qualified therapists who have received specialised training in this therapy. The 8 treatment sessions will be provided in small groups at the local mental health service venue. This will give you an opportunity to meet other people who are experiencing similar problems and support each other in making changes to your sleep habits. The sessions will be led by the two therapists and regular opportunities for group discussion will be made available. Food and beverages will be provided during each session free of charge.

If you are randomly allocated to the Cognitive Behaviour Therapy for insomnia and depression group, you will receive the same program as the group described above. This group, however, will include additional strategies that are specifically designed to also improve your mood. This will involve assisting you to increase your level of daily activity and help you to refocus your attention on positive thoughts rather than negative thoughts.

Finally, if you are randomly allocated to the Sleep Education group, you will be asked to attend 8 weekly sessions that will involve learning more detailed information about sleep and sleep disorders. This program will provide you with resources to assist in building your knowledge about sleep.

You are able to continue taking your regular medication during this project. It is important that the dosage of your medications is not changed during the trial. This is to ensure that any changes in your sleep or mood are likely to be attributable to the treatment being tested in this trial. Also, if you are currently participating in another form of psychological therapy with a psychologist, you will be asked to temporarily cease this treatment whilst you are participating in this project. If you would like to continue being treated by your current psychologist, you will be ineligible for this research project.

It is desirable that your local doctor or psychiatrist be advised of your decision to participate in this research project. If you have a local doctor, we recommend that you inform them of your participation in this project.

5 Other relevant information about the research project

This research team aims to recruit approximately 60 people to participate in the project. This study will be made available to older adults with insomnia and depression who are being case managed by Latrobe Regional Hospital's Aged Persons Mental Health Service. The therapists who implement the assessment and treatment sessions will be registered provisional psychologists who are completing their final clinical psychology placement with Latrobe Regional Hospital. These therapists will be supervised each week by the principal investigator to ensure a high standard of professionalism is maintained. Some of the treatment sessions will be audio tape recorded for both supervision purposes and analysis of results.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part in this project, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. If you do decide to take part, you will be given this Participant Information Sheet to keep. Your decision whether to take part or not to take part, or to take part and then withdraw will not affect your routine mental health treatment, your relationship with those treating you, or your relationship with Latrobe Regional Hospital's Mental Health Service.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. Other options are available; these include support from your case manager, medication advice from your psychiatrist, and health care from your local doctor. You can discuss these options with the research team before you decide whether or not to take part in this research project. You can also discuss alternative treatment options with your local doctor.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, several possible benefits may include:

- Better knowledge about sleep
- Better understanding of what is maintaining your insomnia problem
- Added skills to better manage insomnia
- Improved sleep patterns and better sleep quality
- More constructive thoughts and beliefs about sleep
- Improvements in mood and functioning
- Increased hope for the future

9 What are the possible risks or disadvantages of taking part?

It is important to identify possible risks or disadvantages that are involved in participating in this study.

Since Cognitive Behaviour Therapy for insomnia is designed to change problematic patterns of behaviour and beliefs that may have been present for several months or years, it can take up to 4 to 6 weeks for your sleep to show genuine sustained signs of improvement. Also, one of the treatment strategies involves restricting your time spent in bed, which may cause temporary increased tiredness. Therefore, it is recommended that you limit activities that require high levels of alertness or concentration (for example, working heavy machinery) during the first 4 to 6 weeks of the trial.

It is anticipated that the main inconvenience to you during this project will be your time. Consequently every effort has been made to source the shortest assessment measures and most effective interventions to minimise your time investment in the study. There may be additional side effects or disadvantages that the researchers do not expect or do not know about. Please tell your therapist or mental health service immediately about any new or unusual symptoms that you experience so this can be addressed by the research team.

If you become upset or distressed as a result of your participation in the research, the therapists will be able to provide support and/or arrange for other appropriate supports, such as contacting your case manager or local doctor. Any additional counselling or treatment that is needed will be provided by qualified staff who are not members of the research project team. This counselling can be provided free of charge by your local mental health service.

10 What if new information arises during this research project?

Sometimes during the course of a research project new information becomes available about the treatment that is being studied. If this happens, your therapist will tell you about it and discuss with you whether you want to continue in the project. If you decide to withdraw, your therapist will make arrangements for your regular mental health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

11 Can I have other treatments during this research project?

Whilst you are participating in this research project, you may not be able to make changes to your medications or other treatments. It is important to tell a member of the research team about any treatments or medications you are taking, including over-the-counter medicines, vitamins, or alternative therapies. You should also tell a study staff member about any changes to these during your participation in the trial. A therapist will explain to you which treatments or medications need to stay the same for the time you are involved in the project.

12 What if I withdraw from this research project?

You can withdraw from this project at any time. Your withdrawal will not jeopardise your ongoing care from the mental health service. You will continue to receive the best possible care by your mental health team after your withdrawal. If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

13 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include:

- Unacceptable side effects
- The treatment being shown not to be effective
- The treatment being shown to need further alterations or testing
- Decisions made by Federation University Australia or Latrobe Regional Hospital
- Unforeseen personal circumstances to the research team

14 What happens when the research project ends?

Once the trial ends after the eighth week you can continue receiving support by your local mental health team. This ongoing support will be provided free of charge. If you feel that you do not require ongoing mental health treatment after the trial has finished, you can discuss this with your case manager or psychiatrist, and arrange your future mental health care to be transferred back to your local doctor.

If you would like to learn more about Cognitive Behaviour Therapy for your sleep or mood after this project has ended, please ask your case manager and they will assist you with accessing these resources.

You will be contacted 3 months after the trial finishes by a member of the research team to monitor your progress. A summary of the results from this research project will be made available around June 2015. Please contact the principal investigator named at the end of this document if you would like a summary of the results and this information will be posted to you.

How is the research project being conducted?

15 What will happen to information about me?

By signing the consent form you consent to the principal investigator and research staff collecting and using personal information about you for the research project. Any information obtained in connection with this project that can identify you will remain confidential. Information will be securely stored and kept in a locked filing cabinet at your local mental health service office. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except in exceptional circumstances required by law. Information from this research project will be stored for 7 years and then be shredded by Federation University Australia staff.

Information about you may be obtained from your mental health records held at this service for the purpose of this research project. By signing the consent form, you agree to the study team accessing your records if they are relevant to your participation in this project.

It is anticipated that the results of this study will be published. In any publication or presentation, information will be provided in such a way that you cannot be identified. Your anonymity will be maintained by not providing any of your personal details, such as name, date of birth, or address.

In accordance with relevant Australian and Victorian privacy laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree with be corrected. Please contact the principal investigator named at the end of this document if you would like to access your information.

16 Complaints

If you suffer any complications as a result of this research project, you should contact a research team member as soon as possible, and you will be assisted with arranging appropriate support. If you are registered with Medicare, you can receive medical or psychiatric treatment free of charge as a public patient in any Australian public hospital. Contact details are located at the end of this document if you wish to register a complaint about this project.

17 Who is organising and funding the research?

This research project is being conducted by the principal investigator, Paul Sadler, and it is being funded by Federation University Australia. The participant financial incentives will be funded by Federation University Australia. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

18 Who has reviewed the research project?

All research in Australian involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Federation University Australia and Latrobe Regional Hospital. This project will be carried out according to the National Statement of Ethical Conduct in Human Research (2007).

19 Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project, or if you have any problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal investigator, Paul Sadler.

Clinical contact person

Name	Mr Paul Sadler
Position	Principal Investigator & Clinical Psychologist
Telephone	5671 4515 or 5624 3600
Email	psadler@lrh.com.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Complaints contact person

Latrobe Regional Hospital	Patient Liaison Manager
Telephone	5173 8530
Email	inquiry@lrh.com.au

If you need to urgently contact a mental health professional or support person outside of working hours, you can phone the below services, 24 hours a day 7 days a week:

Emergency contacts

Mental Health Triage Team	1300 363 322
Lifeline	13 11 14
Beyond Blue	1300 224 636
Police or Ambulance	000

Once again, thank you for taking the time to read this information and considering to take part in this study. If you would like to participate in this project, please read and sign the attached Consent Form.

APPENDIX J

Informed Consent Form

CONSENT FORM

Short Title	Cognitive Behaviour Therapy for Insomnia Among Older Adults
Protocol Number	LRH - LNR - 2014
Project Sponsor	Federation University Australia
Coordinating Principal Investigator Principal Investigator	Professor Suzanne McLaren Mr Paul Sadler
Location	Community Mental Health Service

Declaration by Participant

I have read the Participant Plain Language Statement or someone has explained it to me in a language that I understand.

I understand the purposes, procedures, and risks of the research described in the project.

I give permission for my doctors or other health professionals to release information to the researchers concerning my health conditions and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I can be given a photocopy of this document to keep for my records.

I am aware that is project has been approved by the Latrobe Regional Hospital and Federation University Human Research Ethics Committees.

Name of Participant (please print)	Date:
Signature	Your Phone Number:

APPENDIX K

Assessment Package

Geriatric Depression Scale (GDS)

1.	Are you basically satisfied with life?	YES	NO
2.	Have you dropped many of your activities and interests?	YES	NO
3.	Do you feel that your life is empty?	YES	NO
4.	Do you often get bored?	YES	NO
5.	Are you hopeful about the future?	YES	NO
6.	Are you bothered by thoughts you can't get out of your head?	YES	NO
7.	Are you in good spirits most of the time?	YES	NO
8.	Are you afraid that something bad is going to happen to you?	YES	NO
9.	Do you feel happy most of the time?	YES	NO
10.	Do you often feel helpless?	YES	NO
11.	Do you often get restless or fidgety?	YES	NO
12.	Do you prefer to stay at home rather than go out and do things?	YES	NO
13.	Do you frequently worry about the future?	YES	NO
14.	Do you feel you have more problems with memory than most?	YES	NO
15.	Do you think it is wonderful to be alive now?	YES	NO
16.	Do you feel downhearted and blue?	YES	NO
17.	Do you feel pretty worthless the way you are now?	YES	NO
18.	Do you worry a lot about the past?	YES	NO
19.	Do you find life exciting?	YES	NO
20.	Is it hard for you to get started on new projects?	YES	NO
21.	Do you feel full of energy?	YES	NO
22.	Do you feel that your situation is hopeless?	YES	NO
23.	Do you think that most people are better off than you are?	YES	NO
24.	Do you frequently get upset over little things?	YES	NO
25.	Do you frequently feel like crying?	YES	NO
26.	Do you have trouble concentrating?	YES	NO
27.	Do you enjoy getting up in the morning?	YES	NO
28.	Do you prefer to avoid social occasions?	YES	NO
29.	Is it easy for you to make decisions?	YES	NO
30.	Is your mind as clear as it used to be?	YES	NO
TOTAL Score 1 point for each symptom of depression (SHADED BOXES)			

Beck Hopelessness Scale (BHS)

1	I look forward to the future with hope and enthusiasm	T	F
2	I might as well give up because there is nothing I can do about making things better for myself	T	F
3	When things are going badly, I am helped by knowing that they cannot stay that way forever	T	F
4	I can't imagine what life would be like in ten years	T	F
5	I have enough time to accomplish the things I want to do	T	F
6	In the future, I expect to succeed in what concerns me most	T	F
7	My future seems dark to me	T	F
8	I happen to be particularly lucky, and I expect to get more of the good things in life than the average person	T	F
9	I just can't get the breaks and there's no reason I will in the future	T	F
10	My past experiences have prepared me well for the future	T	F
11	All I can see ahead of me is unpleasantness rather than pleasantness	T	F
12	I don't expect to get what I really want	T	F
13	When I look ahead to the future, I expect I will be happier than I am now	T	F
14	Things just won't work out the way I want them to	T	F
15	I have great faith in the future	T	F
16	I never get what I want, so it's foolish to want anything	T	F
17	It's very unlikely that I will get any real satisfaction in the future	T	F
18	The future seems vague and uncertain to me	T	F
19	I can look forward to more good times than bad times	T	F
20	There's no use in really trying to get anything I want because I probably won't get it	T	F

Dysfunctional Beliefs and Attitudes About Sleep Scale (DBAS-10)

1. I need 8 hours sleep to feel refreshed and function well during the day.

Strongly Disagree _____ Strongly Agree
0 1 2 3 4 5 6 7 8 9 10

2. When I don't get the proper amount of sleep on a given night, I need to catch up on the next day by napping or on the next night by sleeping longer.

Strongly Disagree _____ Strongly Agree
0 1 2 3 4 5 6 7 8 9 10

3. I am concerned that chronic insomnia may have serious consequences on my physical health.

Strongly Disagree _____ Strongly Agree
0 1 2 3 4 5 6 7 8 9 10

4. When I have trouble getting to sleep, I should stay in bed and try harder.

Strongly Disagree _____ Strongly Agree
0 1 2 3 4 5 6 7 8 9 10

5. I am worried that I may lose control over my abilities to sleep.

Strongly Disagree _____ Strongly Agree
0 1 2 3 4 5 6 7 8 9 10

6. After a poor nights sleep, I know that it will interfere with my daily activities on the next day.

Strongly Disagree _____ Strongly Agree
0 1 2 3 4 5 6 7 8 9 10

7. When I feel irritable, depressed, or anxious during the day, it is mostly because I did not sleep well the night before.

Strongly Disagree _____ Strongly Agree
0 1 2 3 4 5 6 7 8 9 10

8. When I sleep poorly on one night, I know it will disturb my sleep schedule for the whole week.

Strongly Disagree _____ Strongly Agree
0 1 2 3 4 5 6 7 8 9 10

9. When I feel tired, have no energy, or just seem not to function well during the day, it is generally because I did not sleep well the night before.

Strongly Disagree _____ Strongly Agree
0 1 2 3 4 5 6 7 8 9 10

10. I get overwhelmed by my thoughts at night and often feel I have no control over this racing mind.

Strongly Disagree _____ Strongly Agree
0 1 2 3 4 5 6 7 8 9 10

Geriatric Anxiety Inventory Short Form (GAI-SF)

1.	I worry a lot of the time	YES	NO
2.	Little things bother me a lot	YES	NO
3.	I think of myself as a worrier	YES	NO
4.	I often feel nervous	YES	NO
5.	My own thoughts often make me nervous	YES	NO
TOTAL Score 1 point for each endorsed 'yes' for anxiety			

The EuroQol Health Scale (EQ-VD-3L)

Please Tick

Mobility

- I have no problems in walking around
- I have some problems in walking around
- I am confined to bed

Personal Care

- I have no problems with personal care
- I have some problems washing or dressing myself
- I am unable to wash or dress myself

Usual Activities (*e.g. work, housework, family or leisure activities*)

- I have no problems with performing my usual activities
- I have some problems with performing my usual activities
- I am unable to perform my usual activities

Pain/Discomfort

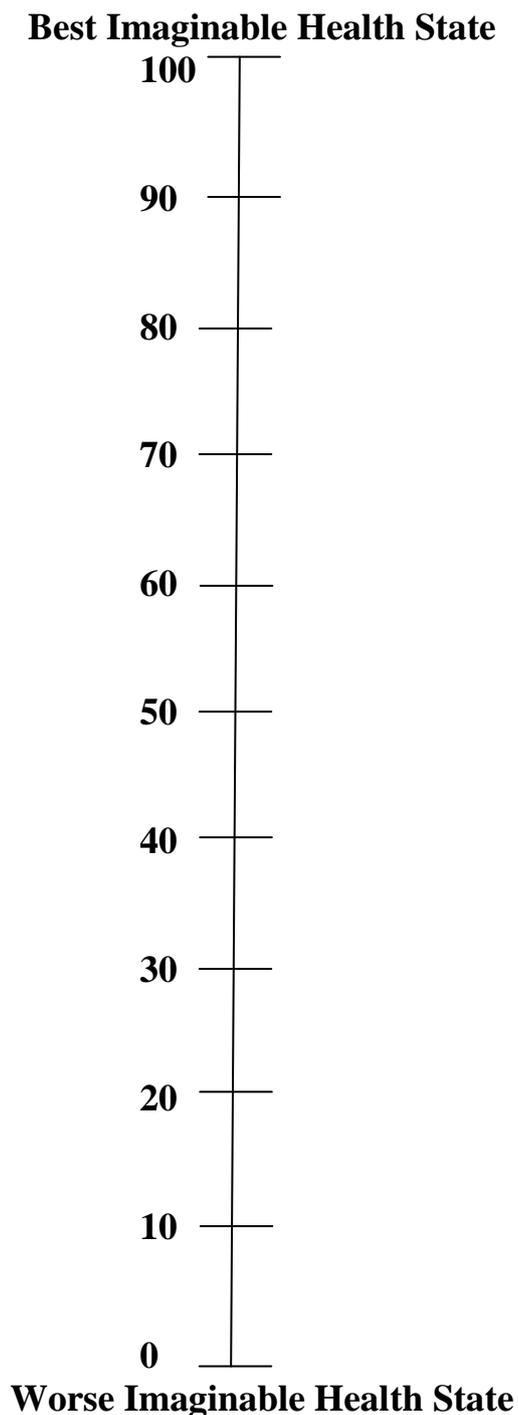
- I have no pain or discomfort
- I have moderate pain or discomfort
- I have extreme pain or discomfort

Anxiety/Depression

- I am not anxious or depressed
- I am moderately anxious or depressed
- I am extremely anxious or depressed

To help people say how good or bad their health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please draw a cross (X) on the scale to indicate how good or bad your health state is today.



SLEEP-50 Scale

	Not At all	A Little	Rather Much	Very Much
1. I am told that I snore.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. I sweat during the night.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. I am told that I hold my breath when sleeping.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. I am told that I wake up gasping for air.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. I wake up with a dry mouth.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. I wake up during the night while coughing/being short of breath.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. I wake up with a sour taste in my mouth.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. I wake up with a headache.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. I have difficulty in falling asleep.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. Thoughts go through my head keep me awake.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. I worry and find it hard to relax.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. I wake up during the night.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. After waking up during the night, I fall asleep slowly.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. I wake up early and cannot get back to sleep.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15. I sleep lightly.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16. I sleep too little.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
17. I see dreamlike images when falling asleep or waking up.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
18. I sometimes fall asleep on a social occasion.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
19. I have sleep attacks during the day.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

	Not At all	A Little	Rather Much	Very Much
20. With intense emotions, my muscles sometimes collapse during the day.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
21. I sometimes cannot move when falling asleep or waking up.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
22. I am told that I kick my legs when I sleep.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
23. I have cramp or pain in my legs during the night.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
24. I feel little shocks in my legs during the night.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
25. I cannot keep my legs at rest when falling asleep.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
26. I would rather go to bed at a different time.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
27. I go to bed at different times (more than 2 hours difference).	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
28. I do shift work.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
29. I sometimes walk when I am sleeping.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
30. I sometimes wake up in a different place than where I fall asleep.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
31. I sometimes find evidence of having performed an action during the night I do not remember.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
32. I have frightening dreams (if not, go to 37).	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
33. I wake up from these dreams.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
34. I remember the content of these dreams.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
35. I can orientate quickly after these dreams.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
36. I have physical symptoms during or after these dreams (e.g. sweating, heart palpitations, shortness of breath).	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
37. It is too light in my bedroom during the night.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
38. It is too noisy in my bedroom during the night.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

	Not At all	A Little	Rather Much	Very Much
39. I drink alcoholic beverages during the evening.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
40. I smoke during the evening.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
41. I use other substances during the evening (e.g. sleep or other medications).	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
42. I feel sad and depressed.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
43. I have no pleasure or interest in daily occupations.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
44. I feel tired at getting up.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
45. I feel sleepy during the day and struggle to remain alert.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
46. I would like to have more energy during the day.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
47. I am told that I am easily irritated.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
48. I have difficulty in concentrating on tasks.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
49. I worry whether I sleep enough.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
50. Generally, I sleep poorly.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Mini International Neuropsychiatric Interview (Version 6.0)**M.I.N.I.****MINI INTERNATIONAL NEUROPSYCHIATRIC INTERVIEW****(High Prevalence Disorders)****English Version 6.0****DSM-IV***(Edited to align with DSM-V)***USA: D. Sheehan¹, J. Janavs, K. Harnett-Sheehan, M. Sheehan, C. Gray.**¹University of South Florida College of Medicine- Tampa, USA**EU: Y. Lecrubier², E. Weiller, T. Hergueta, C. Allgulander, N. Kadri, D. Baldwin, C. Even.**²Centre Hospitalier Sainte-Anne – Paris, France

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DISCLAIMER

Our aim is to assist in the assessment and tracking of patients with greater efficiency and accuracy. Before action is taken on any data collected and processed by this program, it should be reviewed and interpreted by a licensed clinician.

This program is not designed or intended to be used in the place of a full medical and psychiatric evaluation by a qualified licensed physician – psychiatrist. It is intended only as a tool to facilitate accurate data collection and processing of symptoms elicited by trained personnel.

Insomnia Diagnostic Interview

- | | |
|---|----------|
| A. (1) Do you currently have difficulties falling asleep? | Yes / No |
| A. (2) Do you currently have difficulties staying asleep? | Yes / No |
| A. (3) Do you wake up in the early hours of the morning and can't get
back to sleep? | Yes / No |
| A. (4) Are you dissatisfied with the current quality of your sleep? | Yes / No |
| B. Does your sleep problem affect your functioning during the day? | Yes / No |
| C. Does your sleep problem occur at least 3 nights per week? | Yes / No |
| D. Has your sleep problem lasted for more than 3 months? | Yes / No |
| E. Have you been previously diagnosed with other sleep problems? | Yes / No |
| 1. Would you like to improve your sleep? | Yes / No |
| 2. On a scale of 1 to 10, where 10 is very important and 1 is not important at all, how
important is it to improve your sleep on a scale of 1 to 10? | /10 |
| 3. Would you be willing to consider making changes to your current
sleep routine? | Yes / No |

1. During your lifetime, when did you first notice experiencing problems with your sleep?

2. Were there any possible life circumstances or triggering events that contributed towards the beginning of your sleep problem?

3. When did your most recent bout of sleep problems start?

4. Did your sleep problem gradually get worse or did it suddenly become a problem?

5. Have you previously tried any treatments or strategies to improve your sleep? If so, what were they and what was your response?

6. Describe, in detail, your typical night time routine prior to going to bed?

7. What time do you typically hop into bed?

8. How long does it typically take you to fall asleep?

9. What time do you typically wake up in the morning?

10. Do you have a short nap during the day? If so, frequency, length, where and when?

11. Do you drink tea or coffee? If so, frequency, amount, where and when?

12. Do you wake up during the night? If so, approximately how many times, how long, and what do you do?

13. Do you worry or experience negative thoughts before going to bed? If so, what do you worry about?

14. What type of activity do you typically do during the day?

Mini Mental State Examination (MMSE)

Orientation to Time

What is the? Year? Season? Date? Day? Month? /5

Orientation to Place

Where are we? Country? State? Suburb? Street? Building? /5

Registration

I am going to name 3 words. After I have said all 3, I want you to repeat them. /3

(Ball, Car, Man)

(1 point for each correct reply on the first attempt)

Remember what they are because I am going to ask you to name them again in a few minutes.

Name the 3 words several more times (maximum 5 times) if needed, for the patient to report correctly. (Record number of trials_____)

Attention and Calculation

/5

Spell WORLD backwards (D L R O W)

or Serial Sevens. Ask the patient to count backwards by 7 from 100 (100,93,86,79,72,65)

Stop after five answers (1 point for each correct answer) use higher of the 2 scores

Recall

Do you recall the three words I asked you to remember?

(give 1 point for each correct answer) /3

Language

What is this called? (show WATCH, then PEN) /2

I'd like you to repeat a phrase after me: "No ifs, ands, or buts." /1

Visio Spatial

Have the patient read and do the following "Close your eyes" /1

Write any complete sentence (subject, object, verb) /1

Copy this design (intersecting pentagons), 10 completed angles. /1

Give pt paper, ask them to take into their R/L hand, fold the paper in half once with both hands, and put the paper down on the floor. /3

MMSE SCORE ____/30

Treatment Credibility Index (TCI)

Please read the paragraph below about a treatment program called ‘Cognitive Behaviour Therapy for Insomnia’, and then using the following scales please rate each question.

Cognitive Behaviour Therapy for Insomnia is designed to help people change unhelpful patterns of behaviour and thinking that contribute towards sleep problems. This program is delivered over 8 consecutive sessions, with a one week break between sessions to consolidate learning and practice new skills. Each session takes approximately 60 minutes to complete, and is conducted in small groups led by qualified therapists. Throughout the program, participants learn about sleep and what factors maintain their insomnia problems. At the end of each session, participants are provided with worksheets and practical tasks to complete and discuss the following week to help improve their sleep. The first 4 sessions provide guidelines to help make changes to your sleep routine. This part of the program also provides relaxation training to reduce tension and worry. The final 4 sessions are dedicated towards identifying unhelpful beliefs about sleep that contribute towards insomnia, and works on adjusting these thoughts to make them more balanced and constructive. The program concludes with a reflection activity to summarise the most important skills that have been useful throughout the program. Participants are also provided with an opportunity to provide feedback to assist with improving future treatment programs that target insomnia among older adults.

1. How logical does this Cognitive Behaviour Therapy program seem to you?

1	2	3	4	5	6	7	8	9	10
not at all			somewhat				very much		

2. How successfully do you think this treatment will be in reducing your insomnia problems?

1	2	3	4	5	6	7	8	9	10
not at all			somewhat				very much		

Demographic Information

1. Name _____ 2. Date of Birth _____

3. Address _____ 4. Phone Number _____

5. Relationship Status _____ 6. Past Occupation _____

7. Level of Education _____ 8. Religion _____

9. Income Source _____ 10. Accommodation Type _____

11. Next of Kin Details _____

Medical Information:

1. What medical conditions do you have? _____

2. Who is your current General Practitioner? _____

3. What medications are you currently taking? _____

4. *Would you be willing to stay on the same dose of your medications throughout the trial?* _____

Depression History:

1. Have you experienced bouts of depression throughout your lifetime, or has it only been only more recent your problems with depression? _____

2. Have you previously been admitted to a mental health hospital, such as the Macalister Ward at Latrobe Regional Hospital? _____

3. Have you previously received electroconvulsive therapy (ECT)? _____

4. Have anyone in your family experienced mental illness or problems with depression? _____

5. *Are you currently participating in any form of psychological therapy, or currently working with a psychologist?* _____

APPENDIX L

Cognitive Behaviour Therapy for Insomnia Program:

Session Protocols with Worksheets

Cognitive Behaviour Therapy for Insomnia

Therapist Session Protocol

Session 1:

Introduction and Psychoeducation

1. Welcome as entering (10 mins)

- Prepare drinks/food/socialise
- Provide **Name Badges**

2. Official welcome once all seated (5 mins)

- Thank participants for participating and their interest in improving sleep
- Acknowledge Federation University and LRH for supporting program
- Officially introduce yourselves
- Housekeeping (toilets, food/drinks, temperature, confidentiality, aim to create a comfortable and respectful atmosphere where we value each other, encourage team support, and provide regular opportunities for feedback to improve the program)

3. Wool Icebreaker (5-10 mins)

- *“Just before we provide an overview of the program, we have a light and playful activity to get us started to release the nerves”*
- Ask all to stand up
- Toss this piece of wool around the group. As the wool comes around, state your name and how long it took you to get here. Keep holding a piece of wool as it gets tossed to another person
- Can anyone guess what this wool represents?
- Connection between us, work as a team, support/value each other
- Pull tight and ask someone to let go
- This represents a missing link in the team, which can be felt by all
- Encourage importance of weekly attendance and value their input

4. Program Overview and Today’s Agenda (5 mins)

- Today’s agenda (Learn about program and more about your sleep)
- Go through the **‘Cognitive Behaviour Therapy’** and **‘Sleep Health’** worksheet
- Provide each participant with their **Sleep Toolbox and Incentive**

5. Psycho-Education Group Discussion (30-40mins)

- Rationale – ‘It’s important to understand the facts about sleep, as this can create a strong platform to build from and empower us to makes changes if necessary’
- Review concept of learning from recent baseline sleep diary
- Go through the ‘**Cognitive Behaviour Therapy**’ and ‘**Sleep Health Facts**’ worksheet
- Use recent participant examples to highlight CBT model in action
- Use open ended questions to the group; Encourage group discovery
- When the group is unable to identify answers, provide hints from the worksheets

6. Summary and assign Task for this week (10 mins)

- Summarise today’s session
- Go round the group and ask ‘What one new thing you’ve learnt today?’
- Provide two worksheets to participants to place in toolbox

Tasks for this week:

1. Read worksheets at least once to consolidate learning about sleep
2. Encourage participants to consider **one specific sleep goal** they’d like to achieve throughout the program, such as taking less time to fall asleep, feeling more relaxed prior to bedtime, or increasing satisfaction with their sleep quality.

Cognitive Behaviour Therapy

What is Cognitive Behaviour Therapy?

Cognitive Behaviour Therapy is designed to help people learn more helpful ways of thinking and behaving to produce better sleep. It involves changing unhelpful patterns that contribute towards our sleep problems.

The program provides guidelines and strategies to help make practical changes to your sleep routine. The second part of the program is dedicated towards identifying unhelpful beliefs that contribute towards insomnia, and works on adjusting these thoughts to make them more balanced and constructive.

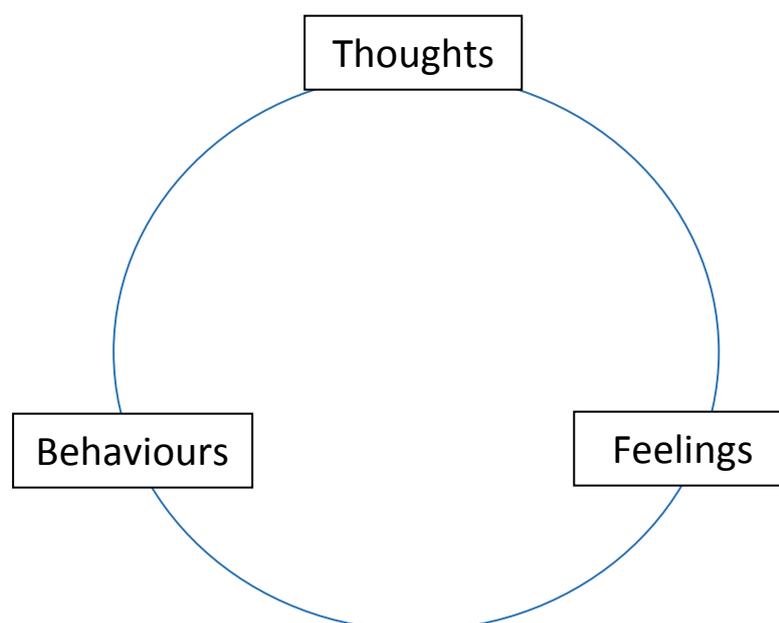
This program finishes by reflecting on the most useful strategies that have been effective for improving your sleep to maximise long term progress.

What does Cognitive Behaviour Therapy mean?

Cognitive refers to our thoughts, attitudes, or beliefs which influence our interpretations and experiences of specific situations.

Behaviour means our physical actions, habits, or routines.

Therapy involves a collaborative process of discussing problems with a mental health professional to develop more positive and sustainable solutions.



Cognitive Behaviour Therapy

What to Expect?

1. This program is delivered over 8 consecutive group sessions, with a one week break between sessions to consolidate learning and practice new skills.
2. Each session will take 60 to 90 minutes and is led by qualified therapists who have been trained and supervised by a senior clinical psychologist.
3. Receive education to enhance your awareness and understanding about what maintains insomnia problems.
4. Learn new strategies to make changes to your sleep pattern. The more you practice these strategies the more likely your sleep will improve.
5. Complete worksheets each week between sessions to correct unhelpful patterns of behaviour and thinking. You can complete these by yourself or you can consider involving a **supportive person** to help you each week.
6. Sessions will involve group discussions to support and motivate each other.
7. This program is not a quick fix or perfect sleep remedy. It can often take up to 4 to 6 weeks to start making permanent changes to your sleep pattern.
8. The program requires commitment and perseverance. The more sessions you attend the more you will get out of the program. Try your best to attend each session, as your involvement is valued by the group.
9. You will be provided with regular opportunities to provide feedback to assist with improving future treatment programs.
10. Food, beverages, and therapeutic resources will be provided each session. You will also be provided with financial vouchers to thank you for your time and commitment.

Sleep Health Facts

What is Sleep?

1. Sleep is one of our most basic human needs, similar to oxygen and water.



2. One of the main purposes of sleep is to restore the mind and body. For instance, sleep assists with restoring energy, consolidating learning, repairing injuries, and stabilising psychological wellbeing.

3. Sleep usually consists of lying down with closed eyes; having a slow breathing rhythm with relaxed muscles; and being in an unconscious state that can be woken.

4. Sleep needs vary widely from person to person. Although the average amount of sleep for adults is approximately 8 hours per night, some people function well with much less sleep and others require much more each night.

Are there different stages of Sleep?

5. Previous researchers believed sleep was a passive state where our brain shut down overnight. Scientists have now proven that our brains are very active whilst asleep.

6. Sleep changes across the night in 90 minute cycles. There are two types of sleep that occur during each cycle:

- Rapid eye movement (REM) sleep consists of increased electrical brain activity, vivid dreaming, very relaxed muscles, and rapid eye movements under closed eyelids. REM is in every sleep cycle, even if only for short period.

- Non rapid eye movement (NREM) sleep consists of 4 stages. Stage 4 is the deepest and most restorative sleep stage, also known as 'delta sleep'.

Sleep Health Facts

Does Sleep change with age?

7. Children and pregnant women need much more sleep compared to the adult population, for instance, a new baby may sleep up to 16 hours each day.

8. The amount of sleep a child needs continues to decrease throughout adolescence, but stops changing and stabilises in early adulthood.

9. In older adulthood, sleep can become less efficient and the sleep/wake cycle can shift forwards. For instance, older adults tend to become 'lighter' sleepers, go to bed and rise earlier, and experience more night-time awakenings than younger adults. This doesn't mean that the sleep of older adults is necessarily disturbed or of poor quality.

10. *Myth: We need less sleep when we are older.* Scientists suggest that we generally need about the same amount of sleep as we needed in younger adulthood. Therefore, an adult's sleep needs are stable throughout their life.

What are some possible effects of ongoing poor Sleep?

11. People who experience ongoing poor sleep are more likely to experience:

- Poorer concentration, attention, and memory
- More intense or rigid patterns of thinking
- More challenges with completing daily activities
- Increased levels of depression and anxiety, such as tiredness, irritability, and worry
- Poorer physical health

What is classified as 'Healthy Sleep'?

12. People with healthy sleep patterns generally:

- fall asleep within 20-30 minutes,
- experience brief arousals throughout the night and can fall back asleep,
- can be flexible and adapt to a poor night's sleep, and
- create the right conditions for sleep in their mind and environment.

Cognitive Behaviour Therapy for Insomnia

Therapist Session Protocol

Session 2:

Understanding Insomnia & Sleep Reinforcement Strategies

1. Socialise (5 mins)

- Prepare drinks/food and provide name badges
- Encourage participants to use and bring their growing 'toolbox' each week

2. Summarise last week's Session One (5 mins)

- Completed a '*Playful*' activity together to introduce each other, encourage team work, connection, and respect. We greatly value each person's attendance and input.
- Discussed 'Cognitive Behaviour Therapy' worksheet to learn what to expect from the 8 week program.
- Discussed 'Sleep Health Facts' worksheet to learn the basics behind sleep

3. Today's Agenda Overview (5 mins)

- Group check-in to review their understanding of the two previous worksheets
- Learn factors that maintain insomnia problems (Understanding Insomnia) worksheet
- Learn how starting to change our behaviour or routine may improve sleep (Sleep Reinforcement) worksheet
- Set tasks to practice over the next week to start changing your sleep pattern

4. Group Check-In and Review Homework (15 mins)

- Ask '*Does anyone have questions/comments about the two worksheets from last week?*' (Cognitive Behaviour Therapy and Sleep Facts)
- Revise information as comments arise and clarify for participant comprehension
- *Hint:* Remember to thank participants for their feedback, and you can put questions to the group for group discovery.

5. 'Understanding Insomnia' Group Discussion (30 mins)

- '*It's important to understand more about insomnia, as this knowledge can create a strong platform to build from and empower us to make changes to our sleep pattern*'
- Go through and discuss the '**Understanding Insomnia**' worksheet.
- Use recent participant specific examples to highlight CBT model in action
- Use open ended questions to the group; Encourage group discovery.
- When the group is unable to identify answers, provide hints from the worksheets

6. 'Sleep Reinforcement Strategies' Group Discussion (30 mins)

- *'Over the next few weeks, we are going to start learning how changing our behaviour may improve our sleep'*
- Acknowledge these strategies are challenging to implement and requires daily practice and commitment to gradually take effect
- Start going through '**Sleep Reinforcement**' worksheet
- Be aware of probable unhelpful sleep beliefs and defensive responses. Reflect and validate their point of view.
- Highlight we're all here to try new strategies, support each other, and acknowledge previous research has found these guidelines have been effective if practiced routinely over time.

7. Summarise Session and assign Task for this week (5-10 mins)

- Summarise today's session
- Go round the group and ask *'What's one important thing you've taken from today?'*

Participant Tasks for this week:

1. Read 'Understanding Insomnia' worksheet at least once to consolidate learning.
2. Start practicing the relevant 'Sleep Reinforcement Strategies' each day to continue working on next week.

Understanding Insomnia

What is Insomnia?

1. Insomnia can include the following problems with sleep:

- Difficulty falling asleep
- Difficulty maintaining sleep throughout the night
- Waking up too early and not being able to return to sleep
- Unsatisfactory sleep quality

2. Insomnia is more than just a fleeting sleep difficulty, it is a persistent problem that impairs our day-to-day functioning.

3. Insomnia is the most common sleep problem, and is one of the most common health complaints.

4. Insomnia can affect up to 50% of older adults. Studies have also shown that the rate of insomnia is much higher among people with depression.

5. Insomnia rarely occurs by itself. It usually occurs in the context of other physical and mental health conditions.

What causes Insomnia?

6. There are many possible reasons why insomnia can develop. These include:

- Biological factors, such as having a physical health problem or infection, medical operation, hormone change, incontinence, pain, or medication side effect.
- Psychological factors, such as bereavement, increased stress/worry, depressed mood, excessive napping, negative thinking patterns, substance use, experiencing a major loss or period of adjustment.
- Social factors, such as moving house, jet lag, financial stress, retirement.

7. Although certain factors may be associated with the initial cause of insomnia, other factors are usually responsible for maintaining insomnia.

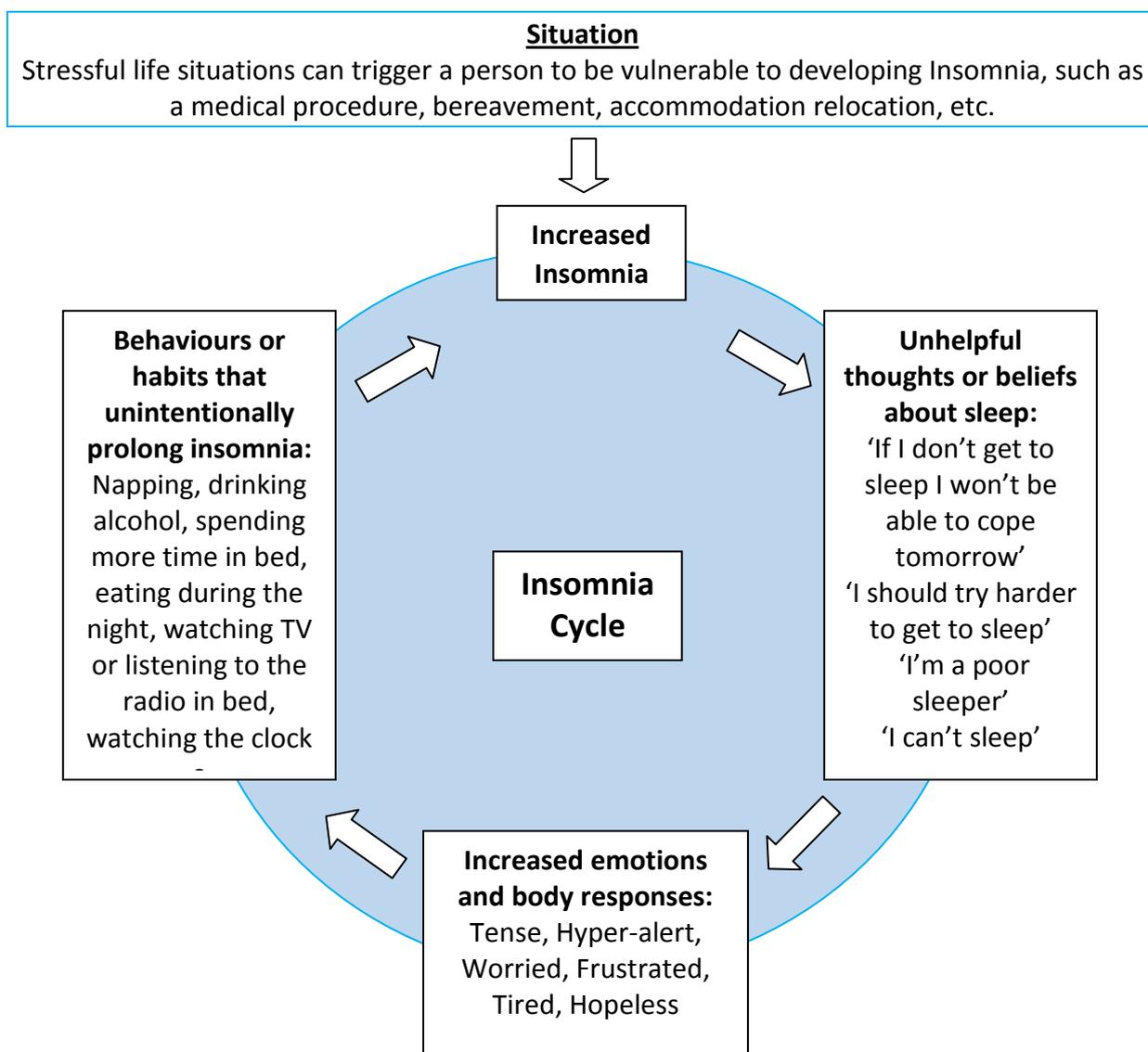
Understanding Insomnia

What maintains Insomnia?

8. People with insomnia develop habits that unintentionally keep their sleep problem going.

9. People with insomnia tend to feel 'stuck' or 'hopeless' because the sleep problem continues despite their best efforts to improve their sleep.

10. There are several common Cycles of Insomnia, which involve unproductive ways of thinking and behaving that keeps the sleep problem going beyond the original cause or stressful life situation. For example,



Sleep Reinforcement Strategies

People with insomnia often use their bed or bedroom for purposes other than sleep, such as reading, watching TV, eating, or listening to the radio. This can create an unhelpful relationship between *sleep and bed*.

Sleep Reinforcement Strategies are designed to help people strengthen the association between their bed with sleep, and to re-establish a more consistent sleep-wake schedule.

The below guidelines have been found to be very effective for people with insomnia. Each strategy needs to be practiced daily over 4 to 6 weeks to maximise sustained better sleep patterns.

Sleep Reinforcement consists of the following instructions:

1. Go to bed only when sleepy

Learn to '*Catch the wave of sleepiness*'. This means waiting until you start to feel very tired and sleepy before hopping into bed. You may have to go to bed *much later* than your current bedtime to achieve this.

2. Use the bed/bedroom only for sleep

This involves significantly reducing the amount of time spent reading, watching TV, listening to the radio, or eating in the bed/bedroom. This strategy helps your body and mind re-learn that bed is for sleep.

3. Get out of bed when unable to fall asleep within 20-30 minutes

If you are unable to fall asleep within 30 minutes after turning out the light, get up and go to another room and do something boring or relaxing to help you '*Catch the next wave of sleepiness*'.

4. Rise at the same time every morning

Getting up at the same time each day helps in developing a better sleep pattern. Do this regardless of how much you have slept the night before.

5. Reduce napping during the day

Napping during the day can make you less tired at night and decrease the depth of your sleep throughout the night. Learn when you are most likely to nap, and instead, do something active to refresh your alertness during that period.

Sleep Reinforcement Strategies

6. Restrict time spent in bed

People with insomnia often spend excess time in bed not sleeping. Therefore, sleep restriction is designed to limit the amount of time in bed to the amount of time spent actually sleeping.

For example, if you stay in bed for approximately 10 hours per night but only sleep for approximately 7 hours per night, you are asked to limit the time you spend in bed to 7 hours per night. As your sleep gradually becomes more efficient, you can begin increasing your time spent in bed by 15 minutes each night.

Important Note:

It is important to note that in the first week or so of practicing these Strategies, you will be creating a mild state of sleep deprivation during the day to create better and deeper sleep over time. While this increased tiredness is normal and temporary, you should be extra careful not to undertake activities that put you at risk of having an accident.

Group Activity:

- ✓ Carefully consider how each Sleep Reinforcement Strategy may apply to you.
- ✓ Once you are clear on which strategies apply to you, begin **practicing these strategies every day/night** to create sustained improvements to your sleep quality.
- ✓ Consider what you may need to begin changing to start practicing these guidelines.

Cognitive Behaviour Therapy for Insomnia

Therapist Session Protocol

Session 3:

Sleep Reinforcement Skills; Introduce Sleep Hygiene Guidelines

1. Socialise (5 mins)

- Prepare drinks/food and provide name badges
- Encourage participants to use and bring their growing 'toolbox' each week

2. Summarise last week's Session Two (5 mins)

- Discussed 'Understanding Insomnia' worksheet
- Introduced 'Sleep Reinforcement Strategies' worksheet (6 guidelines)

3. Today's Agenda Overview (5 mins)

- Group check-in to review their understanding of the two previous worksheets
- Review progress and implementation of their Sleep Reinforcement Skills
- Introduce Sleep Hygiene Guidelines that assist sleep, (Sleep Hygiene) worksheet
- Set tasks to practice over the next week to continue changing your sleep pattern
- Review group boundaries/expectations

4. Group Check-In and Review Homework (30 mins)

- Review group boundaries/expectations (respect, speaking one at a time, working as a team, being supportive and non-judgement towards each other, focussing of sleep, being open to trying new things)
- Review group boundaries (respect, speaking one at a time, working as a team, being supportive, non-judgement towards each other, staying focussed on improving sleep)
- Ask '*Does anyone have questions/comments about the two worksheets from last week?*' (Understanding Insomnia and Sleep Reinforcement Strategies)
- Reflect their content/problems and clarify for participant comprehension
- Be aware of probable unhelpful sleep beliefs and defensive responses. Reflect and validate their point of view.
- Troubleshooting – provide psycho education and rationalisation for prescribed changes, solve problems together.
- *Hint:* Remember to thank participants for their feedback, and you can put questions to the group for group discovery.
- Once you feel participants are more familiar with practicing Sleep Reinforcement Skills, introduce Sleep Hygiene Guidelines.

5. 'Sleep Hygiene Guidelines' Group Discussion (20-30 mins)

- Start going through '**Sleep Hygiene**' worksheet and Group Activity
- Highlight we're all here to try new strategies, support each other, and acknowledge previous research has found these guidelines have been effective if practiced routinely over time.

6. Summarise Session and assign Tasks for this week (5-10 mins)

- Summarise today's session
- Go round the group and ask '*What's one important thing you've taken from today?*'

Participant Tasks for this week:

3. Continue practicing relevant Sleep Reinforcement Strategies
4. Start practicing the relevant 'Sleep Hygiene Guidelines' each day to continue working on next week.

Sleep Hygiene Guidelines

What is Sleep Hygiene?

Sleep hygiene refers to the health and environmental factors that *promote* or *interfere* with your sleep quality. Sleep hygiene also includes a set of rules or guidelines that can assist people improve their sleep pattern.

If one or more of the below guidelines applies to you, it is important to practice these changes **daily** to maximise the chance of improving your sleep quality.

Group Activity:

Carefully consider the questions on both sides of this worksheet together, and **tick** the guidelines that may apply to you.

Do I watch TV or listen to the radio whilst in bed during the day or at night?

Change television or radio use at night

Do I drink tea or coffee at night or during the night?

Reduce tea or coffee intake at night

Do I smoke cigarettes after dinner or during the night?

Reduce cigarette use

Do I regularly drink alcohol during the day or night?

Reduce alcohol use

Do I eat food close to going to bed or do I eat food during the night?

Reduce food intake before bed and overnight

Do I go to the toilet several times overnight?

Limit drinks after dinner, go to the toilet before bed, and discuss with GP

Is my bed or pillows too old or uncomfortable?

Consider purchasing new bed or pillows

Is the temperature in my bedroom too cold or too hot?

Review blankets/linen or nightwear

Sleep Hygiene Guidelines

- Do I watch the clock or regularly look at the time during the night?
Don't look at the clock overnight; Remove clock from sight overnight

- Could I be doing more physical activity during the day?
Increase physical activity in the morning or mid/late afternoon

- Could my night time routine be improved to assist getting to sleep?
Change night time routine to be more relaxing

- Do I get exposed to enough light in the morning?
Increase morning light exposure

Group Task:

- ✓ Once you have realised which Sleep Hygiene Guidelines apply to you, discuss ways you can start following these strategies each day over the next 4 to 6 weeks.

Cognitive Behaviour Therapy for Insomnia

Therapist Session Protocol

Session 4:

Review Sleep Reinforcement & Sleep Hygiene

Introduce Relaxation Skills & CD

1. Socialise (5 mins)

- Prepare drinks/food and provide name badges
- Encourage participants to use and bring their growing 'toolbox' each week

2. Summarise last week's Session Three (5 mins)

- Discussed practicing Sleep Reinforcement Strategies
- Introduced 'Sleep Hygiene Guidelines' worksheet

3. Today's Agenda Overview (5 mins)

- Review their understanding/progress/implementation of the sleep behavioural strategies
- Introduce Relaxation worksheets for group discussion
- Set tasks to practice over the next week

4. Group Check-In and Review Homework (30 mins)

- Ask '*Does anyone have reflections about the tasks from last week?*' (Sleep Reinforcement and Sleep Hygiene Strategies)
- Reflect their content/problems and clarify for participant comprehension
- Be aware of probable unhelpful sleep beliefs and defensive responses. Reflect and validate their point of view.
- Troubleshooting – provide psycho education and rationalisation for prescribed changes, solve problems together.
- *Hint:* Remember to thank participants for their feedback, and you can put questions to the group for group discovery.
- *Once you feel participants are more familiar with continuing to practice Sleep Reinforcement and Sleep Hygiene, introduce Relaxation worksheets*

5. 'Relaxation' Group Discussion (30 mins)

- Start going through the two '**Relaxation**' worksheets
- Use the open ended questions on the worksheet for group discussion
- Encourage participants to consider increasing forms of relaxation they find useful
- Provide participants with the Relaxation CD to listen to each day for homework

6. Summarise Session and assign Tasks for this week (5-10 mins)

- Summarise today's session
- Go round the group and ask '*What's one important thing you've taken from today?*'

Participant Tasks for this week:

5. Continue practicing relevant Sleep Reinforcement and Hygiene strategies
6. Start practicing a form of Relaxation each day and record on the Schedule over the next week. Encourage use of Relaxation CD.

Relaxation

What is Relaxation?

Relaxation is a process of allowing tension to be released from the mind and body. Relaxation can involve learning to slow ourselves down and manage intense emotions (like stress or worry) more effectively. This can be achieved by practicing various relaxation skills to help us unwind, feel more in control, and develop an openness to embracing the present moment.

Why is Relaxation important for sleep?

People with insomnia often experience increased physical and psychological tension that interferes with sleep. This tension is the body's natural response to feeling worried or stressed, which is part of the body's alarm system to deal with perceived danger. Our breathing rate can increase, as can our blood pressure, heart rate, muscle tension, mental arousal, and adrenaline flow. Although this response is helpful in very specific situations, most of the time we don't need these survival responses, so practicing relaxation helps to decrease the fight/flight response and release tension in a controlled way.

How can Relaxation help people with insomnia?

For people who have trouble falling asleep or frequently wake up from 'lighter sleep' overnight, relaxation is often one of the most important skills to improve sleep. Research has shown that people with insomnia who practice a form of relaxation each day over 4 to 6 weeks are more likely to:

- Report less tiredness during the day
- Take less time to fall asleep
- Stay asleep for longer periods overnight
- Have less awakenings overnight
- Go back to sleep more quickly overnight
- Manage muscle tension and pain more effectively
- Report less stress or irritability

Important Note:

Relaxation strategies are not designed to specifically make you sleep. They are designed to improve your ability to release tension and feel more relaxed, which can have a by-product of increasing your likelihood to fall asleep at night or maintain deeper sleep overnight.

Relaxation Skills

What are useful Relaxation Strategies to improve sleep?

Research has shown that learning to slow our breathing rate and learning to release muscle tension can assist in establishing better sleep.

Diaphragmatic Breathing

Diaphragmatic Breathing (otherwise known as deep, slow, or controlled breathing), is a central calming technique that involves slowing your breathing rate by learning to consciously breathe from your diaphragm.

Muscle Relaxation

One method of releasing tension is through Muscle Relaxation. This involves learning to focus on particular muscle groups and slowly allowing the tension in that area to be released. Common parts of the body that hold muscle tension include shoulders, eyes, forehead, jaw, hands, and feet.

Relaxation Tips:

- ✓ There are several additional ways to relax. Consider what forms of relaxation work best for you and begin practicing these more regularly.
- ✓ When practicing deep breathing or muscle relaxation, make sure you are sitting or lying down in a comfortable position, eyes closed, with open body posture. Ensure you are using a 'stomach breathing style' rather than a 'shallow chest breathing style'. You can practice this by placing one hand at the base your stomach, which should rise each time you breathe in.
- ✓ Avoid practicing relaxation after a heavy meal or in distracting surroundings.
- ✓ Practicing a form of relaxation at least **twice a day for 5-10 minutes** will maximise the benefits. Consider scheduling in times to practice and tick them off each day.
- ✓ If you haven't practiced Relaxation before, it can seem daunting at first, especially when intense thoughts or feelings may surface. Like any new skill, relaxation takes perseverance and will likely help you better adapt to these challenging moments with sustained practice.

Cognitive Behaviour Therapy for Insomnia

Therapist Session Protocol

Session 5:

Review ongoing Sleep Behaviour Change progress

Review Relaxation homework (worksheet and CD)

Introduce concept of Beliefs About Sleep

1. Socialise (5 mins)

- Prepare drinks/food and provide name badges
- Encourage participants to use and bring their growing 'toolbox' each week

2. Summarise last week's Session Four (1-2 mins)

- Discussed ongoing changes to our sleep behaviours
- Introduced concept of Relaxation and practicing Relaxation skills

3. Today's Agenda Overview (1-2 mins)

- Review their understanding/progress/implementation of the sleep behavioural strategies and relaxation
- Introduce the concept of how our thoughts can impact our sleep
- Set tasks to practice over the next week

4. Group Check-In and Review Homework (30 mins)

- Ask *'Does anyone have reflections about the tasks from last week?'* (Sleep Behaviour Change strategies and Relaxation)
- Reflect their content/problems and clarify for participant comprehension
- Be aware of probable unhelpful sleep beliefs and defensive responses. Reflect and validate their point of view.
- Troubleshooting – provide psycho education and rationalisation for prescribed changes, solve problems together.
- *Hint:* Remember to thank participants for their feedback, and you can put questions to the group for group discovery.

- *Once you feel participants are more familiar with continuing to correct sleep behaviours and practice regular relaxation, introduce 'Beliefs' worksheet*

5. 'Beliefs About Sleep' Group Discussion (30 mins)

- Start going through the '**Beliefs About Sleep**' worksheet
- Open ended questions to ask for group discussion include:

What thoughts or beliefs may contribute towards sleep problems?

Are there specific situations when you feel more worried about your sleep?

Are there any habits that you're finding difficult to change? If so, this may be due to certain beliefs about sleep that require reflection to test their accuracy.

What strategies could be useful to help someone better manage thinking and worrying in bed?

6. Summarise Session and assign Tasks for this week (5-10 mins)

- Summarise today's session
- Go round the group and ask '*What's one important thing you've taken from today?*'

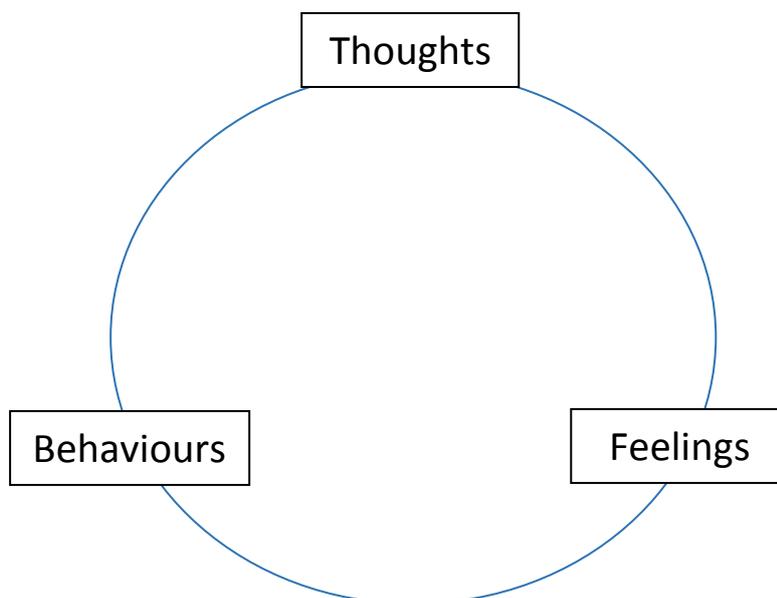
Participant Tasks for this week:

7. Continue practicing sleep behavioural strategies and a form of regular relaxation. Encourage use of Relaxation CD.
8. Read 'Beliefs About Sleep' worksheet. Encourage participants to consider begin implementing guidelines for reducing thinking and worrying about not sleeping.

Beliefs About Sleep

What are Thoughts or Beliefs?

1. Our thoughts or beliefs can involve words, images, memories, or sensations that occur in our mind. Our thoughts play a vital role in influencing how we feel and behave.
2. Thoughts are often automatic. They can pop into our head without us noticing or being aware of them.
3. We tend to automatically believe our thoughts, and usually don't stop to question their accuracy. Some of our thoughts or beliefs are not always true, balanced or helpful.
4. Thoughts can become persistent and develop into unhelpful patterns of thinking.
5. People can experience the same event and interpret it from many different perspectives. Some perspectives are more balanced and flexible, while other perspectives can be more rigid and unhelpful.
6. While many behaviours can maintain poor sleep, several unhelpful beliefs or unrealistic expectations about sleep can strengthen these behaviours.



Beliefs About Sleep

Thinking and Worrying

Many people with insomnia experience excessive time thinking and worrying in bed. Research has also found that people who endorse strong or rigid beliefs about sleep are more likely to experience ongoing sleep problems. Common examples of unhelpful beliefs about sleep include:

"I can't control my thoughts. I can't stop thinking. It can't switch off"

"I need to try harder to fall asleep"

"I'm worried about not getting enough sleep to function properly"

"I should be getting 8 hours of sleep like everyone else"

"I should be sleeping through the night without waking up"

"I've got to sleep now or I won't survive tomorrow"

Group Discussion:

- Does anyone have difficulties with thinking or worrying about not sleeping?
- Are there any specific situations during the day or night when you feel more worried about your sleep?
- What thoughts or beliefs may contribute towards sleep problems?

Important Note:

Experiencing strong or intense beliefs about sleep usually keeps us awake. Therefore, we need to learn more flexible and balanced ways to manage them. Practicing new strategies to better manage our thoughts will increase our chance of falling asleep and staying asleep.

Beliefs About Sleep

Strategies to better manage Thinking and Worrying About Sleep

If you experience problems with thinking or worrying about sleep, the below strategies can be helpful to begin practicing. Don't expect that all these strategies will work for you all the time, it's up to you to try them out and learn which strategies are most useful at various times.

1. Some of the thoughts or worries we experience in bed are relevant to our day to day life. Therefore, instead of worrying in bed, devote a time during the day (5-10 minutes before or after dinner) to write down these thoughts or ideas. Then when the thoughts or worries come when you are in bed, practice thinking to yourself:

"I thought about this today, I'll think about it again tomorrow, I'm just going to rest now" or "It's on the list, I'll think about it tomorrow."

2. Worrying in bed about not sleeping keeps us awake. Instead say to yourself:

"What's the worst thing that could happen if I don't fall asleep? I'll be very tired tomorrow. This will be unpleasant, but I won't die from this. In fact, I'll probably make it through the day just as I've always done in the past. Worrying about it now will only make it worse. **I'll just lie here and rest now, and as long as it is peaceful rest, that will be nearly as restorative as sleep anyway.**"

3. Many people wake up overnight and find it difficult to return to sleep. Practice thinking to yourself:

"It's normal to wake up a couple of times overnight. I'll just allow myself to sleep now" or "Oh good. It's not time to get up yet. I've still got a few hours of rest to go."

4. It's not helpful to 'try' to fall asleep. What is needed is for our mind to let go and relax. Instead of thinking you have to fall asleep, practice thinking:

"There's nothing more I can do today and there's nothing I can do until tomorrow. I'm just going to let go now and focus on slowing my breathing."

Beliefs About Sleep

Strategies to better manage Thinking and Worrying About Sleep

5. People with insomnia can form a habit of putting pressure on themselves to sleep. So it is important to learn a new approach of being more gentle and kind to ourselves about sleep. This can be achieved by practicing saying:

“It’s not the end of the world if I have a bad night’s sleep, it just means I’m going to feel tired the next day” or “I’ve accepted I’ll have a challenging night every now and then, and I will be ok” or “I’m willing to trust that gradually I am learning to sleep better.”

6. Sometimes people with insomnia focus on negative or unpleasant thoughts or memories whilst in bed. Therefore, it is important to change this pattern of thinking and focus on more pleasant thoughts.

Consider making a personal list of pleasant thoughts, memories, or sensations that you can learn to re-focus on when unhelpful thoughts enter your mind in bed. For instance, this could involve a holiday, a movie/TV program, a song, being somewhere peaceful like the beach or garden.

Final Key Message:

Having several strategies to manage thinking and worrying in bed is important because they may not work all the time. If one strategy worked for a while, but now isn’t useful, don’t throw it away. Keep it in your Sleep Better Toolbox and pick up another strategy that may be useful. Maybe it will work again when you try it another time. Learning to better manage thinking and worrying in bed takes time, practice and perseverance, just like learning any other new skill.

Cognitive Behaviour Therapy for Insomnia

Therapist Session Protocol

Session 6:

Review Beliefs About Sleep and ongoing Behaviour Change progress

Introduce Flexible Thinking About Sleep

1. Socialise (5 mins)

- Prepare drinks/food and provide name badges
- Encourage participants to use and bring their growing 'toolbox' each week

2. Summarise last week's Session Four (1-2 mins)

- Discussed ongoing helpful changes to our sleep behaviours
- Reviewed Relaxation strategies
- Introduced concept of beliefs about sleep and better managing worry

3. Today's Agenda Overview (1-2 mins)

- Review their understanding/progress/implementation of the sleep behavioural strategies
- Review previous strategies to reduce worrying about sleep
- Introduce importance of flexible thinking about sleep

4. Group Check-In and Review Homework (30 mins)

- Ask *'Does anyone have reflections about the tasks from last week?'* (Sleep Behaviour Change strategies and Beliefs About Sleep)
- Reflect their content/problems and clarify for participant comprehension
- Be aware of probable unhelpful sleep beliefs and defensive responses. Reflect and validate their point of view.
- Troubleshooting – provide psycho education and rationalisation for prescribed changes, solve problems together.
- *Hint:* Remember to thank participants for their feedback, and you can put questions to the group for group discovery.
- *Once you feel participants are more familiar with continuing to correct sleep behaviours and have an understanding about beliefs about sleep, introduce concept of 'Flexible Thinking'*

5. 'Flexible Thinking' Group Discussion (30 mins)

- Start going through the '**Flexible Thinking**' content
- Provide education and examples about the process of reframing
- Go through the Thought Record examples
- Encourage group discussion – use reflection, clarification, validation and summaries

6. Summarise Session and assign Tasks for this week (5-10 mins)

- Summarise today's session
- Go round the group and ask '*What's one important thing you've taken from today?*'

Participant Tasks for this week:

Encourage participants to continue practicing the previous strategies that are helping them correct their sleep patterns (will be different among individuals).

Read through the 'Flexible Thinking' worksheets. Encourage participants to consider completing a Thought Record for homework.

Flexible Thinking

People with insomnia often have unrealistic expectations about sleep. These expectations can develop into rigid and strong beliefs, which contribute towards ongoing sleep difficulties.

One effective strategy to better manage insomnia involves learning to become more flexible and balanced in our beliefs about sleep.

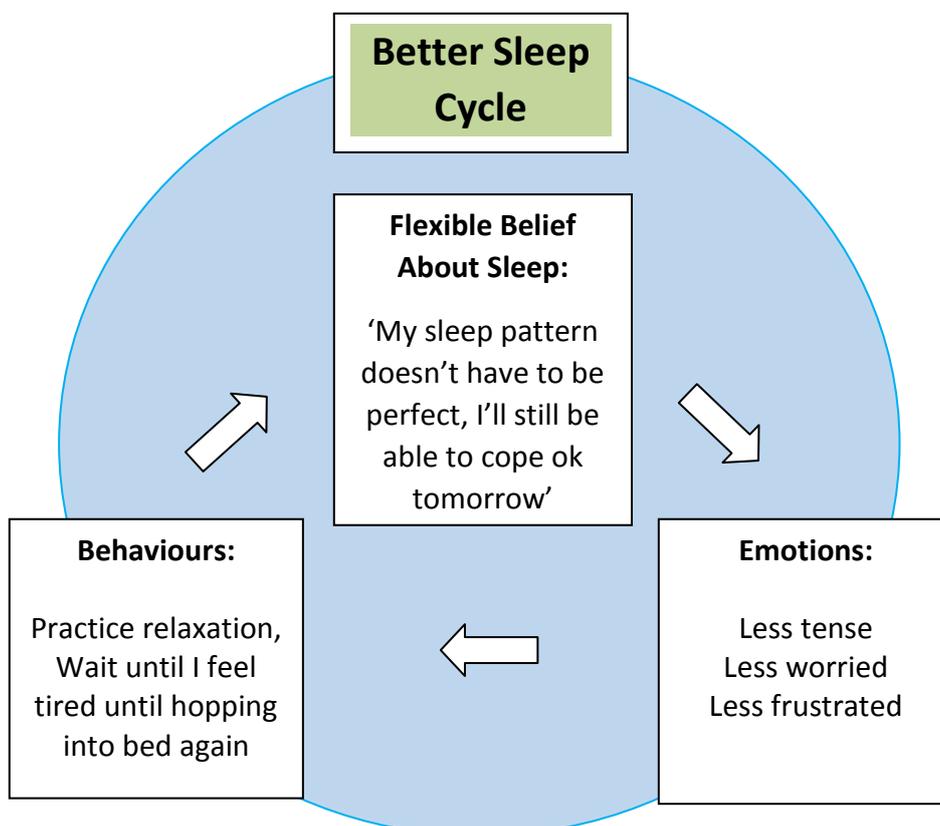
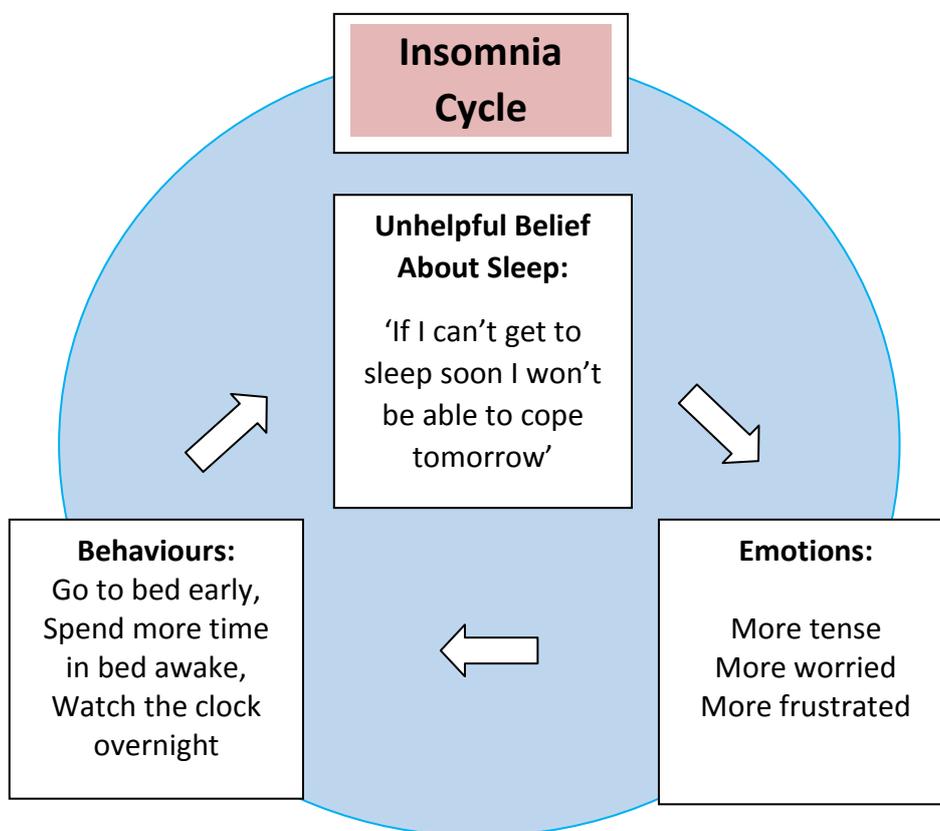
The first step in becoming better at flexible thinking is discovering certain situations that possibly trigger unhelpful beliefs about sleep. Below shows some common examples of how everyday situations can trigger unhelpful beliefs about sleep and unpleasant emotions:

Situation	Unhelpful Belief About Sleep	Emotions
Lying awake in bed at 10pm after 30 minutes of being in bed	'I have to sleep now or I won't get through the day tomorrow'	Worried
Having lunch with a friend who is talking about their sleep	'I should be getting 8 hours of sleep like everyone else'	Embarrassed
Lying awake in bed at 2am after going to the toilet	'I need to try harder to fall asleep'	Frustrated
Just woken up at 7am after having 3 hours of broken sleep overnight	'My sleep is never going to improve'	Hopeless

The purpose of flexible thinking is to learn to stop, think, and refocus onto a more helpful thought or perspective, which can assist with reducing the intensity of unpleasant emotions.

The two diagrams on the next page highlight how changing our beliefs about sleep can improve our sleep patterns.

Flexible Thinking



Flexible Thinking

People who start to sleep better generally begin to develop helpful and balanced beliefs about sleep.



Below contains some real life examples of Flexible Beliefs About Sleep:

- ✓ “I experience a poor night sleep from time to time but overall my sleep pattern is gradually getting better”
- ✓ “I don’t try to fall asleep anymore or put pressure on myself to sleep. Now I create better conditions to catch the wave of sleepiness”
- ✓ “My sleep pattern doesn’t have to be perfect. I can still function ok after a poor night’s sleep”
- ✓ “Oh good. It’s not time to get up yet. I’ve still got a few hours of rest to go.”
- ✓ “I’ll just lie here and rest now, and as long as it is peaceful rest, that will be nearly as restorative as sleep anyway”
- “I’m willing to trust that gradually I am learning to sleep better.”
- ✓ “I’m working on making positive changes to my sleep pattern, but I’m not placing too much importance on it.
- ✓ “If I have a bad night I’ll feel tired tomorrow, but it’s not the end of the world. I’ll likely sleep better tomorrow night.”

Activity:

Explore and discuss the attached *Flexible Thinking Records*. These will help you develop a more helpful and balanced perspective about sleep.

Flexible Thinking Record

Instructions:

1. Consider various expectations, attitudes, or beliefs that may contribute towards maintaining sleep problems.
2. Complete the below Record when you experience a problematic situation related to your sleep.
3. Practice replacing the original sleep belief with a more balanced or realistic belief.
Use the below questions to help complete each column.

Situation	Unhelpful Sleep Beliefs	Emotions (0 to 100%)	Balanced Sleep Beliefs	Re-Rate Emotions (0 to 100%)
<p><u>Catch</u></p> <p>What happened? When? Where? Who with?</p>	<p><u>Check</u></p> <p>What automatic thoughts or images went through my mind during the situation? How did I initially react?</p>	<p>What emotions did I feel at the time? How intense were the feelings?</p>	<p><u>Correct</u></p> <p>Stop, think, and refocus. Is there another way of seeing this? What's a more positive perspective? What advice would I give a friend?</p>	<p>Once I have re-focused on the balanced belief, re-rate the emotion and see whether it has changed.</p>

Cognitive Behaviour Therapy for Insomnia

Therapist Session Protocol

Session 7:

Review recent Flexible Thinking examples

Commence Program Reflection and Relapse Prevention

1. Socialise (5 mins)

- Prepare drinks/food and provide name badges
- Encourage participants to use and bring their growing 'toolbox' each week

2. Summarise last week's Session Six (1-2 mins)

- Reviewed concept of beliefs about sleep and better managing worry
- Discussed flexible thinking skills and process (Thought Record)

3. Today's Agenda Overview (1-2 mins)

- Review the participants understanding of flexible thinking about sleep and the reframing process via thought records.
- Introduce Sleep Program Reflection

4. Group Check-In and Review Homework (30 mins)

- Ask *'Does anyone have reflections about the tasks from last week?'* (Beliefs About Sleep and Flexible Thinking)
- Reflect their content/problems and clarify for participant comprehension
- Be aware of probable unhelpful sleep beliefs and defensive responses. Reflect and validate their point of view.
- Troubleshooting – provide psycho education and rationalisation for prescribed changes, solve problems together.
- *Hint:* Remember to thank participants for their feedback, and you can put questions to the group for group discovery.

- *Once you feel participants are familiar with continuing to correct sleep behaviours and practice flexible thinking about sleep, commence program reflection and summary.*

5. 'Sleep Program Reflection' Group Discussion (30 mins)

- Summarise CBT-I program:

CBT Model - Understanding Insomnia Cycle
Sleep Reinforcement Skills (Stimulus Control/Sleep Restriction)
Sleep Hygiene Guidelines
Relaxation
Flexible Thinking

Group Discussion:

“Ask participants what they can recall about each strategy, assist if needed”

- Introduce '**Reflection**' **worksheet** to aid group discussion.

Participant Tasks for this week:

Encourage participants to continue practicing the strategies that are helping their sleep patterns (will be different among individuals).

Read through their Sleep Program Toolbox (they can do this by themselves or preferably with a supportive person)

Start completing the Reflection worksheet, to finalise next week in Session 8.

Reflection & Maintaining Progress

This **Reflection Activity** is designed to help maintain your positive progress into the future. Carefully consider the below questions and list as many answers as you can. Please begin completing this activity with your support group. It may also be helpful to discuss your responses with a supportive person, such as a friend, family, or staff member.

1. Prior to participating in this program, what unhelpful behaviours or thoughts were negatively impacting my sleep?

2. What useful strategies have I learnt during this program that I would like to continue practicing to further assist my sleep?

3. When I have a poor night's sleep in the future, what can I do or think to protect myself from the insomnia cycle returning?

Cognitive Behaviour Therapy for Insomnia

Therapist Session Protocol

Session 8:

Reflection Activity

Certificates & Closure

1. Socialise (10 mins)

- Prepare drinks/food and provide name badges

2. Summarise previous Session Seven (1-2 mins)

- Learnt about flexible thinking process

3. Today's Agenda Overview (1-2 mins)

- Reflection Activity and Relapse Prevention
- Closure of Program

4. Group Check-In and Review Homework (30 mins)

- Highlight each participant's salient skills learnt from the program
- Reflect their content/problems and clarify for participant comprehension
- Be aware of probable unhelpful sleep beliefs and defensive responses. Reflect and validate their point of view.
- Troubleshooting – provide psycho education and rationalisation for prescribed changes, solve problems together.
- *Hint:* Remember to thank participants for their feedback, and you can put questions to the group for group discovery.

5. 'Reflection Activity' Group Discussion 30 mins)

- Provide rationale for the importance of reflecting on what has been helpful and continuing to practice these changes into the future
- Assist group to start completing the **'Reflection Activity' worksheet**. Encourage each person to finalise this at home.

6. Thank you and Close Program

- Provide completion 'Certificates' and 'Thankyou Voucher'
- **Remind participants of upcoming outcome measure assessments**

7. Feedback Focus Group

- The principal researcher will complete an independent reflection exercise to gain qualitative data regarding the participants' experiences from taking part in the trial.

APPENDIX M

Cognitive Behaviour Therapy for Insomnia and Depression Program:

Additional Worksheets

Be Active

When we feel tired or down, we tend to engage in less meaningful daily activities. This decreased pattern of behaviour can turn into an unhelpful downward spiral and prolong symptoms of insomnia and depression. One important way to improve your sleep and mood is to prescribe daily activities that could increase your sense of **achievement** and **pleasure** each day.

Instructions:

Each day over the next week, record an activity you completed in the table below. When planning an activity, make sure it is realistic and achievable.

Consider activities you've previously enjoyed or would like to do.

Use the below 0 to 10 rating scale to record your sense of *achievement* and sense of *pleasure* **before** and **after** each activity.

0  1 2 3 4 5  6 7 8 9 10 			
Date & Activity		Achievement	Pleasure
	Before		
	After		
	Before		
	After		
	Before		
	After		
	Before		
	After		
	Before		
	After		
	Before		
	After		

*Did your **Sense of Achievement** or **Pleasure** change after completing an activity?*

Flexible Thinking

People with insomnia or depression often have unrealistic expectations about sleep or experience negative thoughts that trigger depressive feelings. These thoughts or attitudes can develop into rigid and strong beliefs, which contribute towards ongoing sleep and mood problems.

One effective strategy to better manage insomnia and depression involves learning to become more flexible and balanced in our thinking patterns.

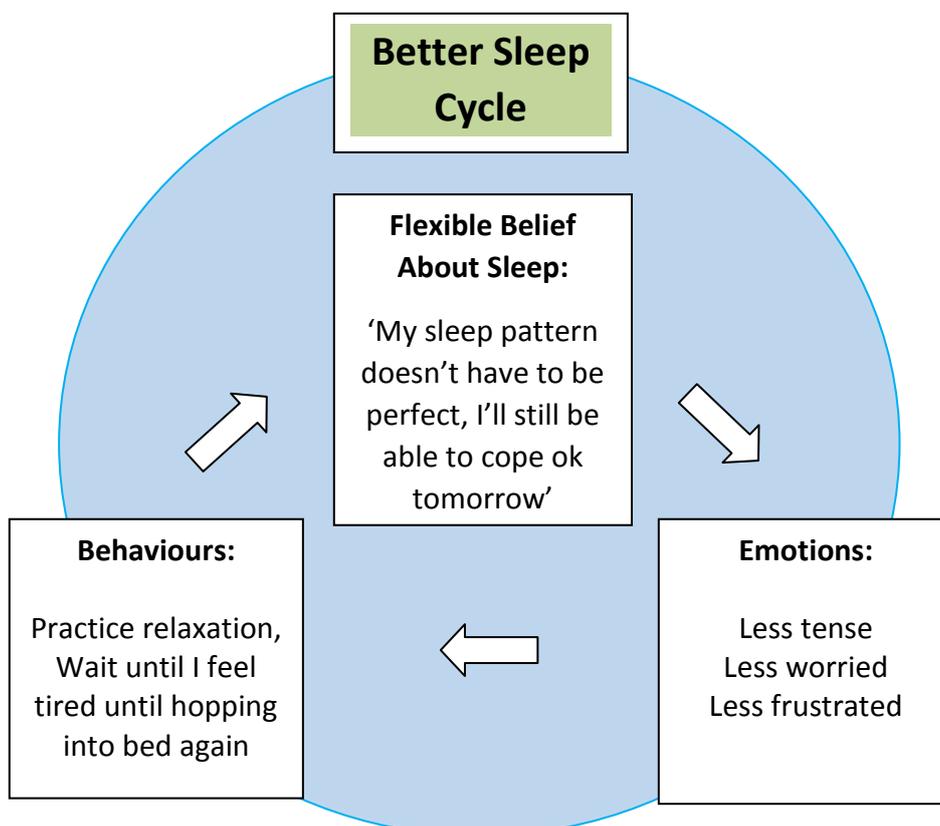
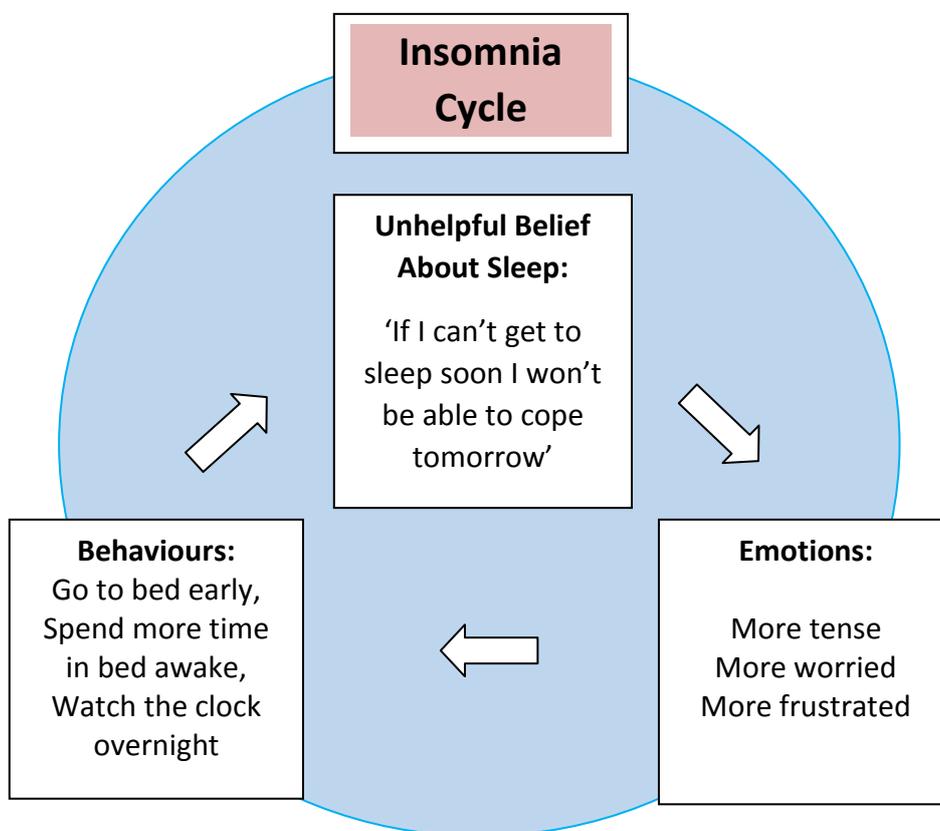
The first step in becoming better at flexible thinking is discovering certain situations that possibly trigger negative or strong beliefs. Below shows some common examples of how everyday situations can trigger unhelpful thoughts and unpleasant emotions:

Situation	Unhelpful Beliefs	Emotions
Lying awake in bed at 10pm after 30 minutes of being in bed	'I have to sleep now or I won't get through the day tomorrow'	Worried
Having lunch with a friend who is talking about their sleep	'I should be getting 8 hours of sleep like everyone else'	Embarrassed
Lying awake in bed at 2am after going to the toilet	'I can't sleep - My sleep is never going to improve'	Hopeless
Just woken up at 7am after having 3 hours of broken sleep overnight	'I'm always tired and can't be bothered'	Depressed

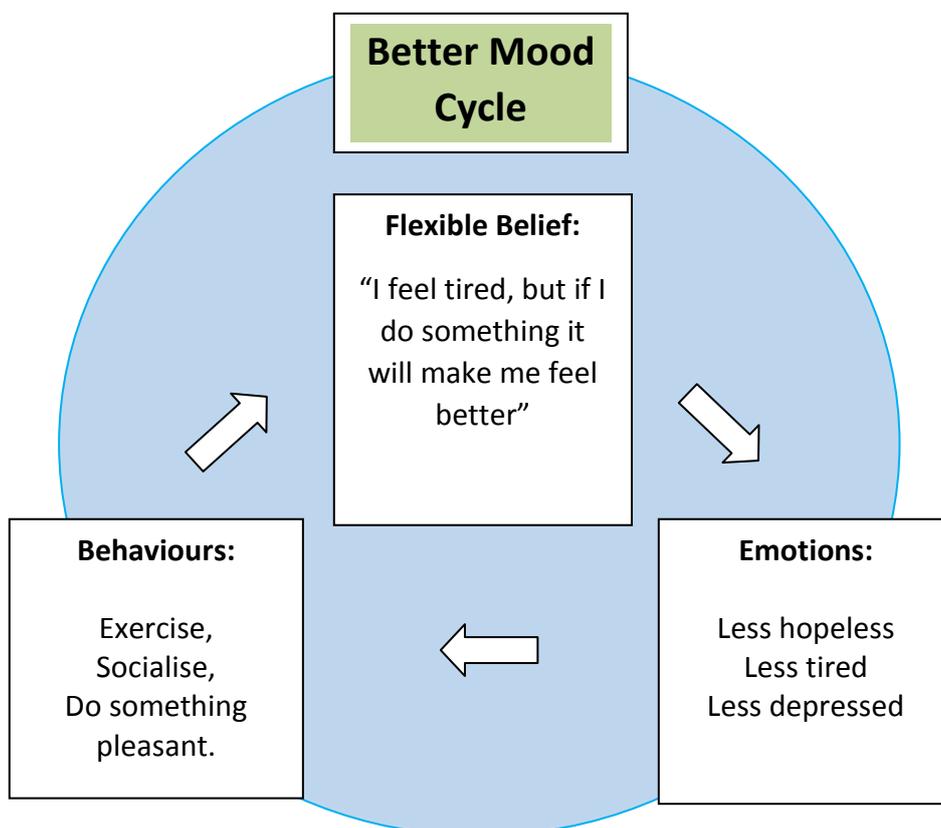
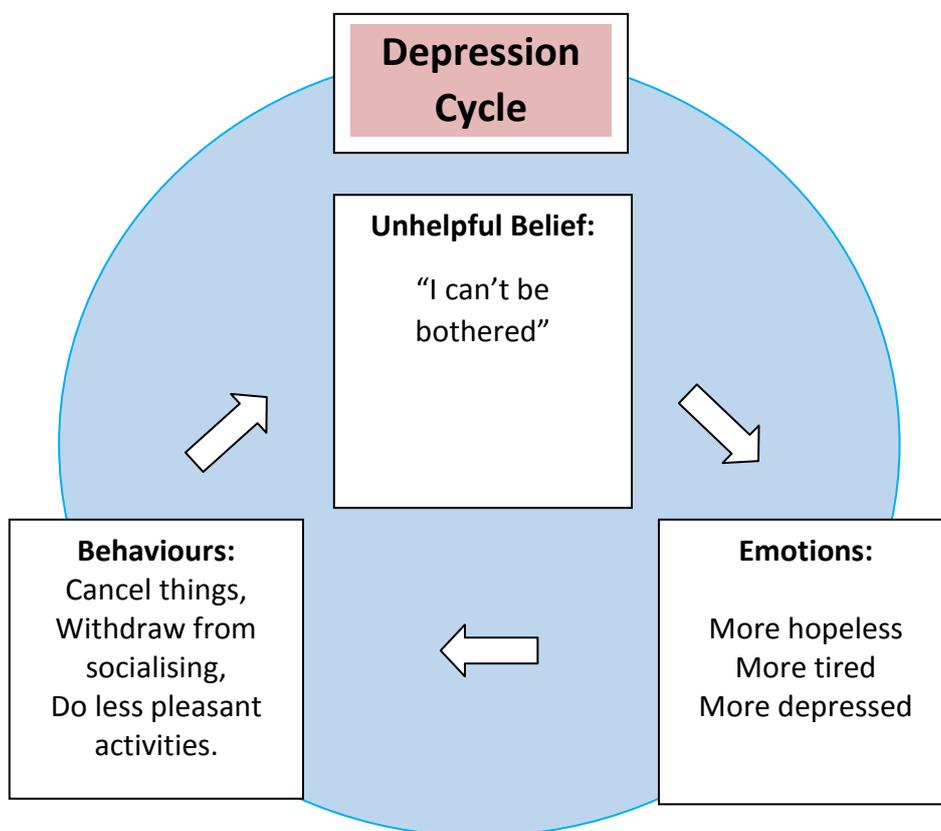
The purpose of flexible thinking is to learn to **catch it, check it, and correct** onto a more helpful thought or perspective, which can assist with reducing the intensity of unpleasant emotions.

The two diagrams on the following pages highlight how changing our thoughts can improve our sleep and mood.

Flexible Thinking



Flexible Thinking



Flexible Thinking

People who start to sleep and feel better generally begin to develop more helpful patterns of thinking.



Below contains some real life examples of Flexible Beliefs About Sleep:

- ✓ “I experience a poor night sleep from time to time, but overall my sleep pattern is gradually getting better”
- ✓ “I don’t try to fall asleep anymore or put pressure on myself to sleep. Now I create better conditions to catch the wave of sleepiness”
- ✓ “My sleep pattern doesn’t have to be perfect. I can still function ok after a poor night’s sleep”
- ✓ “If I have a bad night I’ll feel tired tomorrow, but it’s not the end of the world. I’ll likely sleep better tomorrow night”

Below contains some real life examples of Flexible Beliefs About Mood:

- ✓ “I still have bad days but I’m starting to manage these more effectively”
- ✓ “Sometimes I feel really tired but there’s also other times I feel better”
- ✓ “Life can be extremely painful but I’m not alone. There’s many people like me that are learning new ways to cope better”
- ✓ “This might not work but there’s a chance it could make me feel better”

Group Activity:

Explore and discuss the attached *Flexible Thinking Records*. These will help you develop more helpful and balanced perspectives about sleep and mood.

Positive Affirmations

A *Positive Affirmation* is a belief or coping statement that helps us focus each day on a positive aspect of our self. When we feel vulnerable or are recovering of a period of insomnia or depression, we are less likely to focus on our positive qualities. Therefore, choosing an affirmation to focus on (that is meaningful to you) can assist in developing a more positive frame of mind and increase hope for the future.

My Positive Affirmation = _____

Using the below table, collect a specific experience each day that supports your positive affirmation. This will assist in increasing your belief that this affirmation is true. You can also write your affirmation on the attached cue card to help reinforce your positive focus.

Date	Experiences that support the above positive affirmation:

- ✓ **Write your affirmation on an attached Cue Card to act as a daily positive reminder.**

APPENDIX N

Psychoeducation Control Group Program:

Session Protocols with Worksheets

Psycho-education Control Group

Therapist Session Protocol

Session 1:

Introduction

1. Welcome as entering (10-15 mins)

- Prepare drinks/food/socialise
- Provide **Name Badges, Incentives**

2. Official welcome once all seated (5 mins)

- Thank participants for participating and their interest in improving sleep
- Acknowledge Federation University and LRH for supporting program
- Officially introduce yourselves
- Housekeeping (toilets, food/drinks, temperature, confidentiality, aim to create a comfortable and respectful atmosphere where we value each other, encourage team support, and provide regular opportunities for feedback to improve the program)

3. Today's Agenda (5 mins)

- **"Playful activity** to get us started" (Ice-breaker)
- What to expect from the program, **'Cognitive Behaviour Therapy'** worksheet
- Group discussion about their sleep difficulties

4. Wool Icebreaker (5-10 mins)

- *"Just before we provide an overview of the program, we have a light and playful activity to get us started to release the nerves"*
- Ask all to stand up
- Toss this piece of wool around the group. As the wool comes around, state your name and where you were born. Keep holding a piece of wool as it gets tossed to another person
- Can anyone guess what this wool represents?
- Connection between us, work as a team, support/value each other
- Pull tight and ask someone to let go
- This represents a missing link in the team, which can be felt by all
- Encourage importance of weekly attendance and value their input

5. CBT Worksheet (15-20mins)

- Go through the '**Cognitive Behaviour Therapy**' worksheet
- Encourage group discussion
- Focus psycho-education element (e.g., building knowledge and learning more about sleep) rather than behavioural and cognitive change.

6. Group Sleep Problems Discussion (15-20mins)

- Use open ended questions to the group; Encourage group discovery; Validate responses but contain discussion content to sleep.
- Review recent sleep diary

7. Summary (5-10 mins)

- Summarise today's session
- Go round the group and ask '**What one new thing you've learnt today?**'

Psycho-education Control Group

Therapist Session Protocol

Session 2:

Sleep Health Facts Worksheet Group Discussion

Understanding Insomnia Group Discussion

1. Welcome as entering (10 mins)

- Prepare drinks/food/socialise
- Provide **Name Badges**

2. Today's Agenda (1-2 mins)

- Review and Summarise Session 1
- Group discussion of **Sleep Health Facts** Worksheet
- Group discussion of **Understanding Insomnia** Worksheet

3. Review and Summarise Session 1 (10-15 mins)

- Housekeeping/Boundaries
- Icebreaker Activity – creating a fun and supportive environment
- Placebo CBT Program Overview (Aim to build our knowledge and understanding of sleep and mood problems)
- Discussed each participants sleep problems

4. Group Discussion of Sleep Health Facts (20-30 mins)

- Use worksheet as your therapist guide
- Use open ended questions to the group from the worksheet; Encourage group discovery; Validate responses but contain discussion content to sleep; Assist with answers when needed to encourage flow

5. Group Discussion of Understanding Insomnia (20-30 mins)

- Use worksheet as your therapist guide
- Use open ended questions to the group from the worksheet; Encourage group discovery; Validate responses but contain discussion content to sleep; Assist with answers when needed to encourage flow

6. Summary (5 mins)

- Summarise today's session & provide worksheets
- Go round the group and ask '**What one new thing you've learnt from today?**'

Psycho-education Control Group

Therapist Session Protocol

Session 3:

- Review Session 2 (Sleep Health Facts & Understanding Insomnia)
- Discuss Sleep Hygiene Education

1. Welcome as entering (10 mins)

- Prepare drinks/food/socialise
- Provide **Name Badges**

2. Today's Agenda (1-2 mins)

- Review and Summarise Session 2
- Group discussion/review of **Sleep Health Facts & Understanding Insomnia** Worksheet
- Discuss and complete **Sleep Hygiene** worksheet

3. Review and Summarise Session 2 (10mins)

- Housekeeping/Boundaries
- Reviewed each participants sleep problems
- Learnt about sleep health facts
- Learnt about cycles of insomnia
- Aim of program is to increase our knowledge, awareness, understanding.

4. Group Discussion of Sleep Health Facts and Understanding Insomnia (20 mins)

- Use worksheet as your therapist guide
- Clarify their understanding; Use open ended questions to the group from the worksheet; Encourage group discovery; Validate responses but contain discussion content to sleep; Assist with answers when needed to encourage flow

5. Sleep Hygiene worksheet (20-30 mins)

- Use worksheet as your therapist guide
- Use open ended questions to the group from the worksheet; Encourage group discovery; Validate responses but contain discussion content to sleep; Assist with answers when needed to encourage flow

6. Summary (5 mins)

- Summarise today's session & provide worksheets
- Go round the group and ask **'What one new thing you've learnt from today?'**

Sleep Hygiene Education

What is Sleep Hygiene?

Sleep hygiene refers to the health and environmental factors that *promote* or *interfere* with sleep quality. Sleep hygiene aims to enhance our awareness and provide education that can assist peoples sleep pattern.

Group Activity:

Carefully consider the questions on both sides of this worksheet, and tick the sleep hygiene factors that may apply to you.

- Do I watch TV or listen to the radio whilst in bed during the day or at night?
- Do I drink tea or coffee at night or during the night?
- Do I smoke cigarettes after dinner or during the night?
- Do I regularly drink alcohol during the day or night?
- Do I eat food close to going to bed or do I eat food during the night?
- Do I go to the toilet several times overnight?
- Is my bed or pillows too old or uncomfortable?
- Is the temperature in my bedroom too cold or too hot?
- Do I regularly have naps during the day?
- Do I watch the clock or regularly look at the time during the night?
- Could I be doing more physical activity during the day?

Group Task:

- ✓ **Discuss which Sleep Hygiene factors apply to you.**

Psycho-education Control Group

Therapist Session Protocol

Session 4:

Review Session 3 (Sleep Hygiene Education)

Relaxation & Sleep

1. Welcome as entering (10 mins)

- Prepare drinks/food/socialise
- Provide **Name Badges**

2. Today's Agenda (1-2 mins)

- Review and Summarise Session 3
- Group discussion/review of **Sleep Hygiene** worksheet
- Introduce discussion and education about **Relaxation and Sleep**

3. Review and Summarise Session 3 (10 mins)

- Housekeeping/Boundaries
- Review each participants sleep problems
- Learnt about cycles of insomnia
- Learnt about sleep hygiene factors
- Aim of program is to increase our knowledge, awareness, and understanding.

4. Group Revision of Sleep Hygiene Factors (20 mins)

- Use worksheet as your therapist guide
- Clarify their understanding; Use open ended questions to the group from the worksheet; Encourage group discovery; Validate responses but contain discussion content; Assist with answers when needed to encourage flow

5. Group Discussion Relaxation and Sleep (20-30 mins)

- Use open questions on worksheet to aid group discussion
- Use worksheet as your guide to assist answers
- Go slowly, clarify, reconsolidate, and put questions back to group

6. Summary (5 mins)

- Summarise today's session & provide worksheet
- Go round the group and ask **'What's one new thing you've learnt from today?'**

Relaxation & Sleep

What is Relaxation?

Relaxation is a process of allowing tension to be released from the mind and body. Relaxation can involve learning to slow ourselves down and manage intense emotions (like stress or worry) more effectively. This can be achieved by practicing various relaxation skills to help us unwind, feel more in control, and develop an openness to embracing the present moment.

Why is Relaxation important for sleep?

People with insomnia often experience increased physical and psychological tension that interferes with sleep. This tension is the body's natural response to feeling worried or stressed, which is part of the body's alarm system to deal with perceived danger. Our breathing rate can increase, as can our blood pressure, heart rate, muscle tension, mental arousal, and adrenaline flow. Although this response is helpful in very specific situations, most of the time we don't need these survival responses, so practicing relaxation helps to decrease the fight/flight response and release tension in a controlled way.

How can Relaxation help people with insomnia?

For people who have trouble falling asleep or frequently wake up from 'lighter sleep' overnight, relaxation is often one of the most important skills to improve sleep. Research has shown that people with insomnia who practice a form of relaxation each day over 4 to 6 weeks are more likely to:

- Report less tiredness during the day
- Take less time to fall asleep
- Stay asleep for longer periods overnight
- Have less awakenings overnight
- Go back to sleep more quickly overnight
- Manage muscle tension and pain more effectively
- Report less stress or irritability

Psycho-education Control Group

Therapist Session Protocol

Session 5:

Review Session 4 (Relaxation Education)

Introduce Beliefs About Sleep

1. Welcome as entering (10 mins)

- Prepare drinks/food/socialise
- Provide **Name Badges**

2. Today's Agenda (1-2 mins)

- Review and Summarise Session 4
- Group discussion/review of **Relaxation** worksheet
- Introduce discussion and education about **Beliefs About Sleep**

3. Review and Summarise Session 4 (10 mins)

- Review each participants sleep problems/progress
- Have learnt about cycles of insomnia and sleep hygiene factors
- Learnt about relaxation and impact on sleep
- Aim of program is to increase our knowledge, awareness, and understanding.

4. Group Revision of Relaxation and Sleep (20 mins)

- Use worksheet as your therapist guide
- Clarify their understanding; Use open ended questions to the group from the worksheet; Encourage group discovery; Validate responses but contain discussion content; Assist with answers when needed to encourage flow

5. Group Discussion involving Beliefs About Sleep (20-30 mins)

- Use open questions on worksheet to aid group discussion:
 - *What thoughts or beliefs may contribute towards maintaining sleep problems?*
 - *Are there specific situations when you feel more worried about your sleep?*
 - *Are there any habits that you're finding difficult to change? If so, this may be due to certain beliefs about sleep that require reflection to test their accuracy.*
 - *What strategies could be useful to help someone better manage thinking and worrying in bed?*
- Use worksheet as your guide to assist answers
- Go slowly, clarify, reconsolidate, and put questions back to group

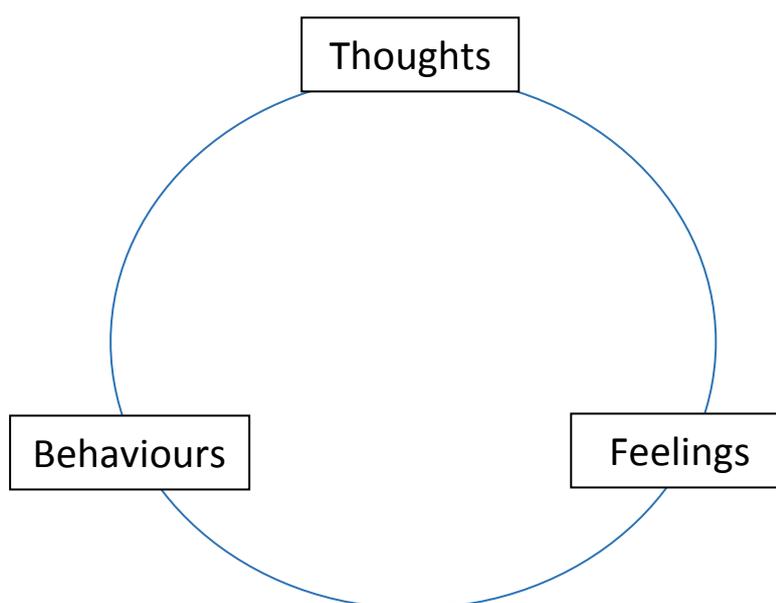
6. Summary (5 mins)

- Summarise today's session & provide worksheet
- Go round the group and ask **'What's one new thing you've learnt from today?'**

Beliefs About Sleep

What are Thoughts or Beliefs?

1. Our thoughts or beliefs can involve words, images, memories, or sensations that occur in our mind. Our thoughts play a vital role in influencing how we feel and behave.
2. Thoughts are often automatic. They can pop into our head without us noticing or being aware of them.
3. We tend to automatically believe our thoughts, and usually don't stop to question their accuracy. Some of our thoughts or beliefs are not always true, balanced or helpful.
4. Thoughts can become persistent and develop into unhelpful patterns of thinking.
5. People can experience the same event and interpret it from many different perspectives. Some perspectives are more balanced and flexible, while other perspectives can be more rigid and unhelpful.
6. While many behaviours can maintain insomnia, several unhelpful beliefs or unrealistic expectations about sleep can strengthen these behaviours.



Beliefs About Sleep

Thinking and Worrying About Sleep

Many people with insomnia experience excessive time thinking and worrying in bed. Research has also found that people who endorse strong or rigid beliefs about sleep are more likely to experience ongoing sleep problems. Common examples of unhelpful beliefs about sleep include:

"I can't control my thoughts. I can't stop thinking. It won't switch off"

"I need to try harder to fall asleep"

"I'm worried about not getting enough sleep to function properly"

"I should be getting 8 hours of sleep like everyone else"

"I should be sleeping through the night without waking up"

"I've got to sleep now or I won't survive tomorrow"

"My sleep will never improve. I'm a bad sleeper"

Group Discussion Points:

- Does anyone have difficulties with thinking or worrying about not sleeping?
- What feelings or emotions are usually triggered by these sleep beliefs?
- Are there any specific situations during the day or night when you feel more worried about your sleep?
- What other thoughts or beliefs may contribute towards sleeping problems?
- Can anyone think of more balanced sleep beliefs that could increase your chance of sleeping better?

Psycho-education Control Group

Therapist Session Protocol

Session 6:

- Review Session 5 (Beliefs About Sleep)
- Introduce second Beliefs About Sleep (2) worksheet

1. Welcome as entering (10 mins)

- Prepare drinks/food/socialise
- Provide **Name Badges & Encourage Use of Toolbox**

2. Today's Agenda (1-2 mins)

- Review and Summarise Session 5
- Group discussion/review of **Beliefs About Sleep** worksheet
- Introduce discussion and education about second **Beliefs About Sleep 2**

3. Review and Summarise Session 5 (10 mins)

- Review each participants sleep problems/progress
- Have learnt about cycles of insomnia and sleep hygiene factors
- Learnt about relaxation and impact on sleep
- Commenced learning about how beliefs can influence sleep
- Aim of program is to increase our knowledge, awareness, and understanding.

4. Group Revision of last week's Beliefs About Sleep discussion (20 mins)

- Use worksheet as your therapist guide
- Clarify their understanding; Use open ended questions to the group from the worksheet; Encourage group discovery; Validate responses but contain discussion content; Assist with answers when needed to encourage flow

5. Group Discussion involving second Beliefs About Sleep worksheet (20-30 mins)

- Use open questions on worksheet to aid group discussion
- Use worksheet as your guide to assist answers
- Go slowly, clarify, reconsolidate, and put questions back to group
- Less directive approach and more supportive/unstructured group discovery

6. Summary (5 mins)

- Summarise today's session & provide worksheet
- Go round the group and ask **'What's one new thing you've learnt from today?'**

Beliefs About Sleep (2)

People with insomnia often have unrealistic expectations about sleep. These expectations can develop into rigid and strong beliefs, which contribute towards ongoing sleep difficulties.

One strategy to better manage insomnia involves learning to become more flexible and balanced in our beliefs about sleep.

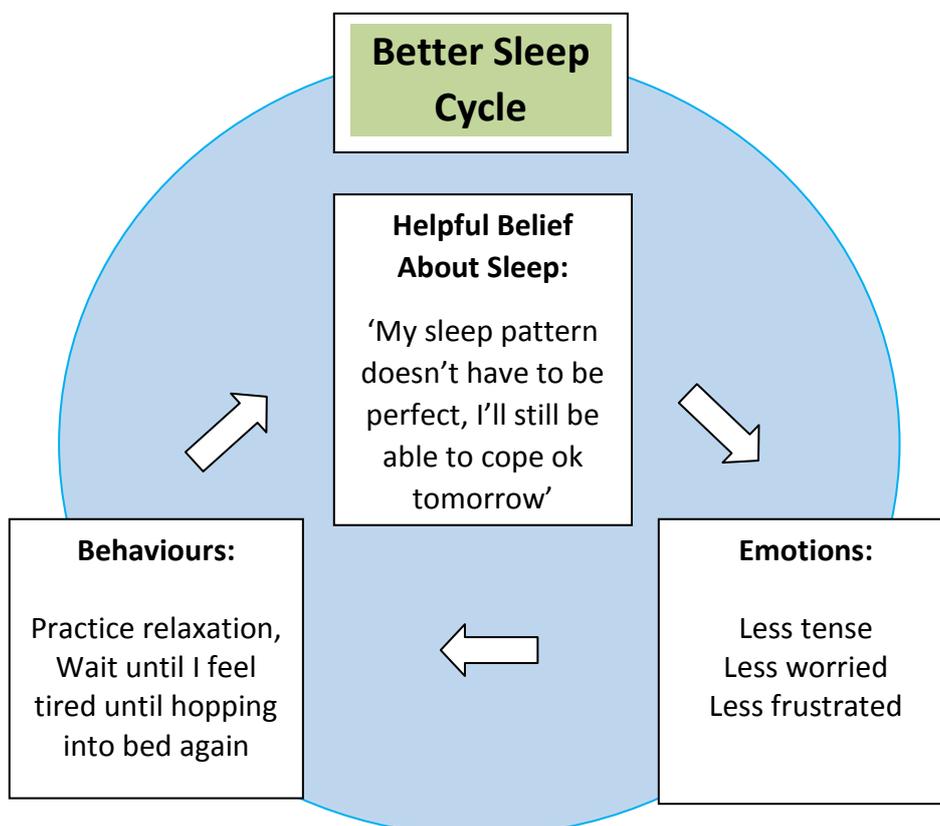
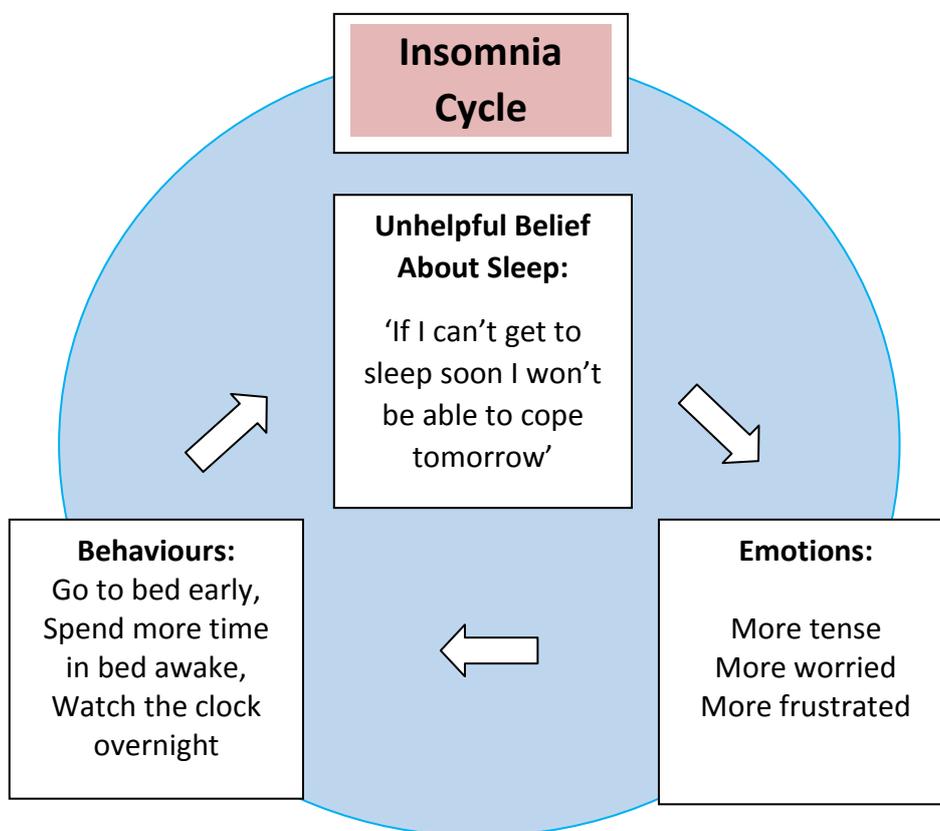
The first step in becoming better at flexible thinking is discovering certain situations that possibly trigger unhelpful beliefs about sleep. Below shows some common examples of how everyday situations can trigger unhelpful beliefs about sleep and unpleasant emotions:

Situation	Unhelpful Belief About Sleep	Emotions
Lying awake in bed at 10pm after 30 minutes of being in bed	'I have to sleep now or I won't get through the day tomorrow'	Worried
Having lunch with a friend who is talking about their sleep	'I should be getting 8 hours of sleep like everyone else'	Embarrassed
Lying awake in bed at 2am after going to the toilet	'I need to try harder to fall asleep'	Frustrated
Just woken up at 7am after having 3 hours of broken sleep overnight	'My sleep is never going to improve'	Hopeless

The purpose of flexible thinking is to learn to stop, think, and refocus onto a more helpful thought or perspective, which can assist with reducing the intensity of unpleasant emotions.

The two diagrams on the next page highlight how reviewing our beliefs about sleep can improve our sleep patterns.

Beliefs About Sleep (2)



Psycho-education Control Group

Therapist Session Protocol

Session 7:

Review Session 6 (Beliefs About Sleep 1 & 2)

Commence Program Summary

1. Welcome as entering (10 mins)

- Prepare drinks/food/socialise
- Provide **Name Badges & Encourage Use of Toolbox**

2. Today's Agenda (1-2 mins)

- Review and Summarise Session 6
- Group discussion/review of **Beliefs About Sleep** worksheets 1 & 2
- Conduct **Program Summary** and group discussion

3. Review and Summarise Session 6 (5-10 mins)

- Review each participants sleep problems/progress
- Commenced discussion about how beliefs can influence sleep (worksheet 2)
- Aim of program is to increase our knowledge, awareness, and understanding.

4. Group Revision of last week's Beliefs About Sleep discussion (15 mins)

- Use worksheet as your therapist guide
- Clarify their understanding; Use open ended questions to the group from the worksheet; Encourage group discovery; Validate responses but contain discussion content; Assist with answers when needed to encourage flow

5. Program Reflection and Group Discussion (30 mins)

- Briefly review each worksheet
- Use open questions on worksheets to aid group discussion
- Use worksheet as your guide to assist answers
- Go slowly, clarify, reconsolidate, and put questions back to group
- Less directive approach and more supportive/unstructured group discovery

6. Summary (5 mins)

- Summarise today's session
- Go round the group and ask **'What's one new thing you've learnt from today?'**

Psycho-education Control Group

Therapist Session Protocol

Session 8:

Program Summary Socialise/Luncheon

1. Welcome as entering (10-15 mins)

- Prepare drinks/food/socialise
- Provide **Name Badges & Encourage Use of Toolbox**

2. Today's Agenda (1-2 mins)

- Review and Summarise Session 7
- Conduct **Program Summary** and group discussion
- Celebratory luncheon

3. Review and Summarise Session 7 (10 mins)

- Review each participants sleep problems/progress
- Commenced discussion about how beliefs can influence sleep (worksheet 2)
- Aim of program is to increase our knowledge, awareness, and understanding.

4. Program Reflection and Socialise (30 mins)

- Briefly review each worksheet
- Use open questions on worksheets to aid group discussion
- Use worksheet as your guide to assist answers
- Go slowly, clarify, reconsolidate, and put questions back to group
- Less directive approach and more supportive/unstructured group discovery

APPENDIX O

Relaxation CD

Track 1 – Introduction (2.53)



1. Introduction.m4a

Track 2 – Getting Comfortable (1.48)



2. Getting Comfortable.m4a

Track 3 – Diaphragmatic Breathing (6.03)



3. Breathing.m4a

Track 4 – Progressive Muscle Relaxation / Guided Imagery (8.01)



4. Muscle Relaxation.m4a