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Yvonne Kutzer  
*Edith Cowan University*

Lisa Whitehead  
*Edith Cowan University*

Eimear Quigley  
*Edith Cowan University*

Mandy Stanley  
*Edith Cowan University*

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Protocol

The Role of Dysfunctional Sleep Beliefs in Mediating the Outcomes of Web-Based Cognitive Behavioral Therapy for Insomnia in Community-Dwelling Older Adults: Protocol for a Single-Group, Nonrandomized Trial

Yvonne Kutzer¹, MSc, HDip; Lisa Whitehead², PhD; Eimear Quigley³, MPsyhc; Mandy Stanley¹, PhD

¹School of Medical and Health Sciences, Edith Cowan University, Joondalup, Australia
²School of Nursing and Midwifery, Edith Cowan University, Joondalup, Australia
³School of Arts and Humanities, Edith Cowan University, Joondalup, Australia

Corresponding Author:
Yvonne Kutzer, MSc, HDip
School of Medical and Health Sciences
Edith Cowan University
270 Joondalup Drive
Joondalup, 6027
Australia
Phone: 61 8 6304 5656
Email: yvonnek@our.ecu.edu.au

Abstract

Background: Sleeping well is an essential part of good health. Older adult populations report a high rate of sleep problems, with recent studies suggesting that cognitive processes as well as behavioral and hyperarousal-related mechanisms could be important factors in the development and maintenance of insomnia. Individuals who have an asynchronous or uncoupled sleep pattern and sleep appraisal—those who complain about their sleep but do not have poor sleep quality, and vice versa—might show differences in subjective sleep and sleep perceptions and other characteristics that could impact their treatment outcomes following cognitive behavioral therapy for insomnia (CBT-I).

Objective: The purpose of this protocol is to describe the rationale and methods for a nonrandomized, single-arm trial assessing objective and subjective sleep quality in community-dwelling older adults aged 60-80 years with synchronous sleep patterns and sleep appraisal compared to those in older adults with asynchronous sleep patterns and sleep appraisal. The trial will further examine the role of cognitive, behavioral, and hyperarousal processes in mediating the treatment outcomes of web-based CBT-I.

Methods: This trial aims to recruit a sample of 60 participants, who will be assigned to 1 of 4 sleep groups based on their sleep pattern and sleep appraisal status: complaining good sleepers, complaining poor sleepers, noncomplaining good sleepers, and noncomplaining poor sleepers, respectively. The trial will be completed in 2 phases: phase 1 will assess objective sleep (measured via wrist actigraphy) and subjective (self-reported) sleep. Phase 2 will investigate the impact of a web-based CBT-I program on the sleep outcomes of individuals with uncoupled sleep compared to that of individuals without uncoupled sleep, as well as the mediators of CBT-I.

Results: Recruitment began in March 2020, and the last participants were recruited by March 2021. A total of 65 participants completed phases 1 and 2. Data analysis for phase 1 was finished in December 2021, and data analysis for phase 2 was finalized in July 2022. The results for phase 1 were submitted for publication in March 2022, and those for phase 2 will be submitted by the end of December 2022.

Conclusions: This trial will provide guidance on factors that contribute to the variability of sleep in older adults and their sleep outcomes following CBT-I. The outcomes of this study could be valuable for future research attempting to tailor CBT-I to individual needs.

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older adults; insomnia; cognitive therapy; digital literacy; cognitive behavioral therapy for insomnia (CBT-I); online psychological intervention

Introduction

Sleep problems, such as insomnia, are highly prevalent in those older than 60 years of age [1], with age-related changes in sleep architecture appearing from middle age and continuing to remain relatively constant past the age of 60 years [2]. Insomnia is characterized by difficulties with sleep initiation, duration, or quality that are not due to a lack of opportunity to sleep and which results in daytime impairment [3]. It is classified as chronic when it occurs at least 3 times per week and persists for more than 3 months [4]. Furthermore, a diagnosis of insomnia consists of 2 components: sleep quality and sleep appraisal. Sleep quality can be good or poor and sleep appraisal can be characterized by the presence or absence of a sleep complaint. These 2 factors have been described as being independent of each other [5], and in about 25%-35% of individuals, sleep quality and sleep appraisal are asynchronous and uncoupled [6]. It has been proposed that such uncoupling of sleep quality and sleep complaints may be prevalent among older adults [7,8]. In their seminal study examining poor sleepers that do not complain of insomnia, Fichten et al [9] first observed the asynchrony of sleep complaints and sleep patterns in older individuals. They reported that daytime impairment, assessed as sleepiness and daytime fatigue was higher in high-distress poor sleepers than in low-distress poor sleepers, and that low-distress poor sleepers experienced the same levels of daytime impairment as good sleepers.

The distinction between high- and low-distress, or asynchronous, good and poor sleepers could also be relevant for the treatment of sleep problems, as it could signify differences in how individuals respond to insomnia treatment. Cognitive behavioral therapy for insomnia (CBT-I) is the recommended first-line treatment method to address insomnia in any age group [10]. It contains several core components such as psychoeducation, cognitive therapy, and behavior therapy [11,12]. However, despite a widespread recommendation for the use of CBT in the treatment of insomnia, the provision of pharmacotherapy remains the dominant approach to address sleep problems in older adults. This is in part due to a lack of trained clinicians [13]. The pharmaceutical treatment of insomnia can lead to polypharmacy, the concurrent use of multiple medicines, which is an identified issue for older individuals [14]. Polypharmacy can result in interaction effects or side effects, for example, an increased fall risk, in older adults [15,16]. CBT-I’s effectiveness and safety on the other hand have been well established, demonstrating moderate to large effects on improving sleep continuity [17]. CBT-I is also an effective treatment option for older adults, with recent research suggesting that even brief interventions can improve sleep onset latency, wake-after-sleep onset, sleep efficiency, and sleep quality [18,19], making it a viable alternative for older individuals at risk of polypharmacy.

The exact mechanisms by which such improvements are achieved remain unknown, and it is not fully understood why some individuals respond to CBT-I and others do not. It is estimated that 20%-30% of individuals with insomnia do not have a treatment response to CBT-I [20]. Cognitive processes are important factors in the development and maintenance of insomnia [5,20-27], particularly in older adults [28-30]. Discrepancies in subjective sleep perception and objectively measured sleep are also common [31]. In order to scrutinize sleep quality in older adults and the role that dysfunctional beliefs and other cognitive or behavioral factors play in mediating the outcomes of CBT-I, this study will examine both subjective and objective sleep quality in older adults aged 60-80 years in Western Australia. The age category of 60 years and older has been selected as it is the United Nations’ agreed cutoff for the classification of older persons in high-income nations [32]. The upper cutoff of 80 years was chosen based on an American Academy of Sleep Medicine report highlighting that the sleep variability in adults aged 80 years and older is either significantly higher or significantly lower than that in adults under 65 years [33,34]. Consequently, adults aged older than 80 years will be excluded.

The concurrent measurement of objective and subjective sleep quality will be used to determine the prevalence of individuals with asynchronous sleep patterns and sleep appraisal in this sample (phase 1). Phase 2 will assess the impact of a web-based CBT-I program on the sleep outcomes of individuals with synchronous sleep patterns and sleep appraisal and those with asynchronous sleep patterns and sleep appraisal. It is anticipated that complaining good sleepers and complaining poor sleepers will show improved sleep outcomes following CBT-I, compared with noncomplaining good and poor sleepers. We further hypothesize that individuals with a sleep complaint but without poor sleep quality (complaining good sleepers) experience higher levels of dysfunctional sleep cognitions and distress than persons with poor sleep in the absence of a sleep complaint (noncomplaining poor sleepers). We expect that additional factors such as hyperarousal [35], sleep effort [36], sleep-related self-efficacy [37], sleep locus of control [38], sleep-related behaviors [39], and chronotype [40] mediate the relationship between web-based CBT-I and sleep outcomes in older adults; therefore, these processes will also be examined.

Since our planned study is likely to generate a considerable amount of data, we aim to reduce publication bias and improve the reproducibility of our research by publishing this research protocol.

Methods

Ethics Approval

Ethical approval for this study has been granted by the Edith Cowan University Human Research Ethics Committee.
The Insomnia Severity Index [44,45] is a brief self-report questionnaire used to measure the severity of insomnia, impairment of daytime functioning, and worry about sleep over the past 2 weeks. It examines both nighttime and daytime components of insomnia and is increasingly used in research as an instrument to examine treatment response. The Insomnia Severity Index has been shown to have excellent internal consistency in community samples (Cronbach \( \alpha = 0.90 \)).

The Glasgow Sleep Effort Scale [36] reviews sleep effort. Sleep effort is a concept that explains a person’s voluntary effort to control a partially involuntary process, namely falling asleep. The Glasgow Sleep Effort Scale consists of 7 items, for example, “I put too much effort into sleeping when it should come naturally,” rated on a 3-point scale (“very much”, “to some extent”, and “not at all”). Internal consistency was reported as fair, with Cronbach \( \alpha = 0.77 \) [36].

The Sleep Efficacy for Sleep Scale [37] assesses the “belief people have in their ability to participate in certain behaviors needed to promote their health” [46,47]. The Self-Efficacy for Sleep Scale is a 9-item measure of how confident an individual is to carry out a variety of behaviors related to sleep, for example, “fall asleep at night in less than 30 minutes.” Items are scored on a 5-point scale, with higher scores being indicative of increased sleep self-efficacy. The SES has fair internal consistency (Cronbach \( \alpha = 0.71 \)) [48].

The Sleep Locus of Control Scale [38] is an 8-item measure that examines the internal sleep locus of control, the belief that sleep outcomes are dependent on one’s behavior on a 6-point Likert scale. The Sleep Locus of Control Scale contains 2 subscales, internal locus of control and chance sleep locus, and is reported to have internal consistency of Cronbach \( \alpha = 0.72 \) (internal locus of control) and \( \alpha = 0.59 \) (chance sleep locus) [38].

Hyperarousal will be assessed using the Pre-Sleep Arousal Scale (PSAS) [35]. The PSAS measures cognitive and somatic symptoms of arousal before falling asleep using 2 subscales. The 2 subscales each consist of 8 items. The items are rated using a 5-point Likert scale, with scores ranging from 1 to 5. The internal consistency of the PSAS has been reported as Cronbach \( \alpha = 0.67 \) for the cognitive and \( \alpha = 0.84 \) for the somatic subscales in normal sleepers and \( \alpha = 0.76 \) and \( \alpha = 0.81 \), respectively, for individuals with insomnia.

The Morningness-Eveningness Questionnaire [40] assesses the chronotype. The 19-item scale was developed to examine individuals’ alertness at specific times of the day. The 19-item scale examines preferences in sleep and wake times and what times of the day subjects feel most alert. The Morningness-Eveningness Questionnaire has shown sufficient internal consistency for the original (Cronbach \( \alpha = 0.82 \)) as well as for the reduced version [49].

The Sleep-Related Behaviors Questionnaire [39] is a 32-item instrument that assesses safety behaviors relating to sleep; for example, “I miss or cancel appointments (daytime or evening).” Items are rated on a 5-point scale ranging from 0 (meaning “almost never”) to 4 (meaning “almost always”). The questionnaire has high internal consistency (Cronbach \( \alpha = 0.92 \)).
Participants will wear an actigraph and complete a sleep diary over 96 hours (72 hours plus an additional 24 hours to account for nonadherence wear time). Actigraphic sleep assessment will assess sleep onset latency, wake-after-sleep onset, total sleep time, and the number of nighttime awakenings. The Actigraph model wGT3X-BT activity monitor (ActiGraph) will be used. Actigraphy has been recognized by the American Academy of Sleep Medicine as an appropriate method for assessing sleep. However, when compared with polysomnography, actigraphy has lower accuracy in detecting wake periods; especially in individuals with poor sleep quality [50]. The actigraphy data will be manually scored along with a sleep diary. This process was recommended by Boyne et al [51] to optimize agreement with polysomnography-measured sleep-wake. Additionally, the Choi algorithm will be used to differentiate between wear and nonwear times, which more accurately estimates time spent sedentary than other algorithms [52]. The sleep diary is a modified version of the Consensus Sleep Diary [53], which, in addition to the questions covered by the Consensus Sleep Diary, records the total duration of all daytime naps, how many times the study participant got up during the night, what time they had planned to wake up at, and whether they took any sleep medication.

Participants will be grouped into 4 sleep groups: noncomplaining good sleepers, complaining good sleepers, noncomplaining poor sleepers, and complaining poor sleepers. Participants will be grouped based on their actigraphy results and sleep complaint status (complaining versus noncomplaining sleepers), with participants appraised as poor sleepers if their sleep onset latency or wake-after-sleep onset is ≥31 minutes, 3 times or more during the recording period (as per actigraph recording). A participant will be considered a complaining sleeper if they report having had a sleep problem (eg, trouble falling asleep) for a minimum of 6 months at baseline data collection [5,54].

Procedure

Participants who express an interest in participating will be contacted to make an appointment for a screening call. During the screening call, potential participants will be provided with information about the study and will be assessed against the eligibility criteria. Once a potential participant is confirmed to be eligible, they will complete, sign, and return the consent form. Upon study commencement, potential participants will be provided with an individual web-based link to the Qualtrics questionnaire battery (Qualtrics XM Platform software, Qualtrics). Once the questionnaire has been completed, actigraphs will be posted to participants using a courier service. Delivery and collection times will be arranged before dispatch at a time convenient for the participant. Where courier services are not available, the sleep watches will be posted by registered express mail, including a prepaid self-addressed return envelope. Study participants will be required to wear an actigraph on their nondominant wrist for 96 hours, except when they take a bath, have a shower, go swimming, or undergo any other activity that would result in them submerging the actigraph in water. They will also be instructed to record the exact time when they remove the actigraph and, subsequently, when they reattach the actigraph to their wrist in their sleep diary. This allows for accurate matching of the actigraph-estimated wear and nonwear times with the sleep diary. The sleep diary will be completed concurrently to record bedtimes, sleep and wake times, frequency and duration of nocturnal awakenings, rise times, daytime naps, and nonwear times, and will be returned with the actigraph after the measurement has been completed. A printed copy of the sleep diary will allow the participant to keep the diary on their bedside table so the relevant sections can be completed upon going to bed and waking up in the morning. Following the baseline assessment, including the recording of demographic information and sleep complaints, the administration of the questionnaires, and actigraphy measurement, all groups will receive identical instructions for the web-based CBT-I program. Participants will be required to complete the 4 sessions plus homework of the program within 4 weeks. Participants will receive weekly email reminders from the principal investigator to confirm the completion of each of the 4 CBT-I modules. Once the completion of the CBT-I program has been confirmed with the participant, actigraphy, sleep diary, and questionnaire measurements will be repeated posttreatment. The study process is shown in Figure 1.
Figure 1. Study process flowchart. CBT: cognitive behavioral therapy; CG: complaining good; CP: complaining poor; NG: noncomplaining good; NP: noncomplaining poor; SOL: sleep onset latency; WASO: wake-after-sleep onset.

**Description of Intervention**

There are a variety of web-based CBT-I courses, mostly developed in the United Kingdom or the United States. One exception is the “This Way Up—Managing Insomnia” program [55,56]. This treatment course was created by a team of clinical psychologists and psychiatrists at the Clinical Research Unit for Anxiety and Depression, which is run by the University of New South Wales and St Vincent’s Hospital in Sydney. The free self-help program consists of 4 lessons in a comic-based format. Lesson 1 provides background knowledge about sleep and insomnia and which factors are conducive to good sleep and which ones are related to insomnia (sleep hygiene). Lessons 2 and 3 address the management of thoughts and behaviors that interfere with sleep (sleep restriction, stimulus control, and cognitive therapy). The sleep restriction protocol aims at...
decreasing nighttime awakenings by limiting the time a person
spends in bed [57]. Initially, the prescribed time in bed
corresponds with the average total sleep time as measured in
the week prior to initiating the sleep restriction protocol, with
a minimum time in bed of 5.5 hours. Time in bed is then
gradually increased until the amount of nighttime sleep achieved
is sufficient for individual requirements. Lesson 4 focuses on
relaxation techniques. The program cannot be individually
tailored to the patient’s specific sleep difficulties but provides
broad topic coverage of the most common factors present in
insomnia (eg, waking too early), and program participants are
advised that not all themes covered may be relevant to their
circumstances.

Each lesson takes about 20 minutes to complete, with additional
compulsory homework. A unit only registers as completed once
the homework has been downloaded. It is recommended that a
user completes 1 lesson every 1-2 weeks. However, the system
will not grant access for less than 5 days between modules.
Reminders are emailed or sent by text message automatically
once a new session becomes available, and there is also the
option to set a web-based appointment for the next course
module. In addition to the course unit and homework,
participants are required to complete a sleep diary. Upon
completion of the course, an extra 12 months’ access is made
available for additional practice. The program is available only
to individuals who live in Australia.

The program’s easy-to-access platform makes it suitable even
for individuals with low eHealth literacy. This could be
important when providing web-based CBT-I to older
populations, even though older adults are increasingly familiar
with using the internet and social media. A recent report
exploring the attitudes and behaviors of adults aged 70 years
and older pointed out that 99% of individuals have searched for
information on the internet, 65% of them post on or read from
social media, and 82% of them who are on social media use
Facebook [46].

Participants with moderate to extremely severe total scores on
any scale of the DASS-21 (Depression, Anxiety, and Stress
Scale-21) will receive a letter outlining the results and will be
encouraged to discuss these with their health care professionals.
This is considered an advisable measure of duty of care.
However, while the DASS-21 measures the emotional states of
anxiety, stress, and depression over the previous week, it is
considered an advisable measure of duty of care. This could be
important when providing web-based CBT-I to older
populations, even though older adults are increasingly familiar
with using the internet and social media. A recent report
exploring the attitudes and behaviors of adults aged 70 years
and older pointed out that 99% of individuals have searched for
information on the internet, 65% of them post on or read from
social media, and 82% of them who are on social media use
Facebook [46].

Agitation measures will be scored using the Cole-Kripke
algorithm, which is suitable for use with older populations [63]
and using ActiLife software (ActiLife 6 software, Version
6.13.1, ActiGraph). The autoscored data will be manually
compared with the sleep diary to determine any incongruence
between the actigraph measurements and the sleep diary.

Results

Study recruitment was completed in March 2021, with a total
of 65 participants. In addition, a feasibility study to assess
whether the study format was acceptable for participants aged
60-80 years was conducted from October 2019 to 2020.

Data analysis for phase 1 was finished in December 2021, and
data analysis for phase 2 was finalized in July 2022. The results
for phase 1 have been submitted for publication in March 2022,
and those for phase 2 will be submitted by the end of December
2022.
Discussion

Expected Findings

We anticipate that our study will highlight the variability of sleep patterns in older adults and the factors that impact their sleep outcomes following CBT-I. Since the mid-1990s, the need to examine the asynchronous sleep pattern characterized by a mismatch between objective sleep quality and subjective sleep complaint has been highlighted in the literature [7-9,64]. Research to date has indicated that higher levels of distress and maladaptive cognitions, particularly as displayed by complaining sleepers with a subjective sleep complaint, show a stronger correlation with daytime impairment than with objective sleep disruption, and that individuals with subjectively poor sleep report lower sleep quality even if their objective sleep is within acceptable parameters [65]. In addition, the prevalence of complaining good sleepers appears to be high in older adults [26].

The COVID-19 pandemic and its associated impact on mental and physical health outcomes add an additional dimension to the need to investigate sleep health and the role sleep perceptions play in insomnia. Sella et al [66] stressed in their recent paper that during the COVID-19 pandemic, changes in self-reported sleep quality in older adults were predominantly associated with changes in dysfunctional sleep beliefs. Furthermore, the pandemic has brought the need for web-based health services, such as digital CBT-I, to the forefront. Recent systematic reviews suggest that CBT-I reduces dysfunctional sleep beliefs, which contributes to the improvement of insomnia symptoms [27,67].

In our study, we will use actigraphy to measure objective sleep outcomes. Actigraphic sleep assessment can provide an accurate estimate of sleep and wake patterns, even when compared with the gold standard of sleep measurement, polysomnography. It has been recommended for the estimation of sleep parameters in adults with insomnia [68], but the limitation of actigraphy is that it underestimates total sleep time [69]. However, research has also indicated that actigraphy is sensitive in detecting treatment effects [70], making it suitable for assessing the sleep outcomes following CBT-I.

This study will add to the knowledge base regarding CBT-I outcomes in an older adult population and will help ascertain whether asynchronous sleep patterns and sleep appraisal as well as associated maladaptive sleep beliefs, high arousal, and other cognitive factors play a role in this process.

Conclusions

It is crucial to examine sleep quality in older adults as this age group shows a high rate of sleep disturbances. The relatively high prevalence of older adults who are complaining good sleepers is of particular concern. Individuals with a subjective sleep complaint often report worse outcomes regardless of how well they sleep, which suggests that insomnia might not arise from sleep deprivation but could be associated with how sleep quality is perceived by the individual.

To address these concerns and examine the prevalence of uncoupled sleepers specifically in the Western Australian context, this study will assess subjective and objective sleep quality in community-dwelling older adults aged 60-80 years and examine the role of cognitive processes, such as dysfunctional sleep beliefs, in mediating the treatment outcomes of a digital cognitive behavioral therapy program for insomnia.

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Authors’ Contributions

YK designed the study protocol and wrote the initial manuscript draft. MS, LW, and EQ contributed to the study design. All authors made substantial contributions to revising the initial manuscript and read and approved the final manuscript.

Conflicts of Interest

None declared.

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