

A randomised controlled trial to test the efficacy of an m-health delivered physical activity and sleep intervention to improve sleep quality in middle-aged adults: The Refresh Study Protocol



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ABSTRACT

Introduction: Poor sleep health is common and has a substantial negative health impact. Physical activity has been shown to improve sleep health. Many sleep interventions do not explicitly target physical activity, potentially limiting changes in activity and also sleep. Few intervention target those with poor sleep health but without a diagnosed disorder. This study aims to examine the efficacy of a combined physical activity and sleep intervention to improve sleep quality in middle-aged adults and its effect on physical activity, depression and quality of life.

Methods: A three-arm randomised trial with a three-month primary time-point, will be conducted. Adults (N = 275) aged 40–65 years, who report physical inactivity and poor sleep quality, will be randomly allocated to either a combined Physical Activity and Sleep Health, a Sleep Health-Only or a Wait List Control group. The multi-component m-health intervention will be delivered using a smartphone/tablet “app”, supplemented with email and SMS. Participants will use the app to access educational material, set goals, self-monitor and receive feedback about behaviours. Assessments will be conducted at baseline, three-month primary time-point and six-month follow-up. Generalized linear models using an ANCOVA (baseline-adjusted) approach, will be used to identify between-group differences in sleep quality, following an intention-to-treat principle.

Discussion: This study will determine whether the addition of a physical activity intervention enhances the effectiveness of a sleep intervention to improve sleep quality, relative to a sleep-only intervention, in physically inactive middle-aged adults who report poor sleep health, but without a sleep disorder.

List of abbreviations

AAQ	Active Australia Questionnaire
ACTRN	Australian Clinical Trials Registry Number
ANZCTR	Australian New Zealand Clinical Trial Registry
App	Application
BMI	Body Mass Index
CBTi	Cognitive Behavioural Therapy for Insomnia
CON	Waitlist Control
DASS-21	Depression Anxiety Stress Scale-21

iOS	iPhone Operating System
K6	Kessler 6 Questionnaire
PAS	Physical Activity and Sleep
PSQI	Pittsburgh Sleep Quality Index
Refresh	REsearch FoR Exercise, Sleep and Health
SAS	Statistical Analysis Software
SHO	Sleep Health Only
SMS	Short Message Service
WSQ	Workforce Sitting Questionnaire

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1. Introduction

Good sleep health is characterised by duration, quality, efficiency and timing of sleep that leaves a person satisfied with their sleep and alert during the day. Poor quality sleep increases the risk of many chronic conditions including cardiovascular disease [1], type 2 diabetes [2], and depression [3], as well as negative impacts on self-rated health [4], work productivity [5] and economic output [6]. Between 30 and 50% of the global population report poor quality sleep [7], with only half being attributable to diagnosed sleep disorders [8,9]. Previous research identified that a high proportion of middle-aged adults have both poor physical activity and sleep behaviours [9].

Given the number of people who report poor sleep health, broad reaching and effective interventions are required [10]. Face-to-face cognitive behavioural therapy for insomnia (CBTi), is an effective treatment for poor sleep quality, but accessing CBTi is often limited by a lack of trained therapists and insufficient time and funds [11]. Technology-based interventions can potentially address this problem by offering greater reach and accessibility. Meta-analysis of technology-based sleep interventions have shown significant improvements in sleep quality ($d \sim 0.41$) [12]. These interventions have targeted populations with sleep disorders [12], but little is known about their ability to improve sleep quality amongst people reporting poor sleep quality but without a sleep disorder. Physical activity is known to improve sleep health [13], with meta-analyses indicating that regular exercise has a positive effect on total sleep time ($d = 0.25$, 95% CI 0.07–0.43), sleep efficiency ($d = 0.30$, 95% CI 0.06–0.55), sleep-onset-latency ($d = 0.35$, 95% CI 0.00–0.70) and sleep quality ($d = 0.30$, 95% CI 0.48–1.00) [13]. However, around 23.3% of adults worldwide are physically inactive [14]. “Regular exercise” is a component of sleep hygiene behaviours that are regularly utilised in sleep interventions [15], however, this component is usually not explicitly targeted. In a recent review of interventions using self-help CBTi, none of the 16 studies using sleep hygiene, provided detailed instructions about increasing activity [16]. Additionally, it has been shown that in multiple behaviour interventions, to maximise change, each behaviour must be targeted using behaviour change techniques that are specific to that behaviour [17–19]. Sleep interventions not providing specific behaviour change techniques for physical activity, may not maximise the changes in activity or capitalise on potential flow-on effects that increased activity may have on sleep health. Therefore, combining a physical activity intervention with a sleep intervention has the potential to enhance its efficacy to improve sleep quality.

This study aims to examine the efficacy of a combined physical activity and sleep health intervention with a sleep health-only intervention and a wait list control, to improve sleep quality in middle-aged adults *without* a sleep disorder. The intervention groups will be compared on the secondary outcomes of sleep characteristics (sleep onset latency, sleep duration, sleep efficiency, sleep disturbance, use of sleep medication and daytime dysfunction), physical activity, depressive symptoms and quality of life. The study will also assess physical activity, sleep hygiene, insomnia severity, sleep timing, morningness-eveningness and app usage as mediators and moderators of sleep health.

2. Methods

2.1. Study design

The intervention will be implemented in a three-armed randomised controlled trial, the Refresh Study (REsearch FoR Exercise, Sleep and Health), with a three-month primary time point and six-month post-baseline follow-up. The aim is to compare sleep quality between a combined Physical Activity and Sleep Health group (PAS), a Sleep Health Only group (SHO) and a Waitlist Control group (CON). The multi-component intervention will be delivered remotely using a

mobile device (smart-phone or tablet) application “app” (called “Balanced”) and will provide additional support in the form of emails, text messages and a participant handbook. Participants in the intervention groups will use the app to access educational resources, set goals, self-monitor, and receive feedback about the health behaviours. Each intervention group will only receive targeted intervention materials specific to their intervention allocation (both physical activity and sleep behaviours for the PAS group; sleep behaviours only for the SHO group). Participants in the PAS group will also be provided with a pedometer (Yamax SW-200) to facilitate self-monitoring of physical activity. The CON group will be asked not to change their physical activity and sleep behaviours, and will be offered the combined physical activity and sleep health intervention after they have completed the 6-month follow-up survey.

The Refresh Study has received approval from the Human Research Ethics Committee, The University of Newcastle, Australia (reference number: H-2016-0267) and is registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12617000680369; Universal Trial number: U1111-1194-2680). All participants will provide informed consent via an online form and will be able to withdraw at any time, for any reason, without prejudice. Participants will be asked to complete online surveys at baseline, three-months, and six-month post-baseline follow-up (Fig. 1) assessing sociodemographic information, presence of chronic diseases, sleep and physical activity behaviours, mental health status, and quality of life. The baseline survey will be completed prior to randomisation. Reminders to complete assessments will be sent via email or SMS (short message service) (Table 1). Participants will also receive weekly summary progress reports and email or SMS reminders prompting participants to self-monitor target behaviours using the app if required (Table 1). At the completion of each assessment, participants will be entered into a draw to win one of 5 x \$50 Gift Cards.

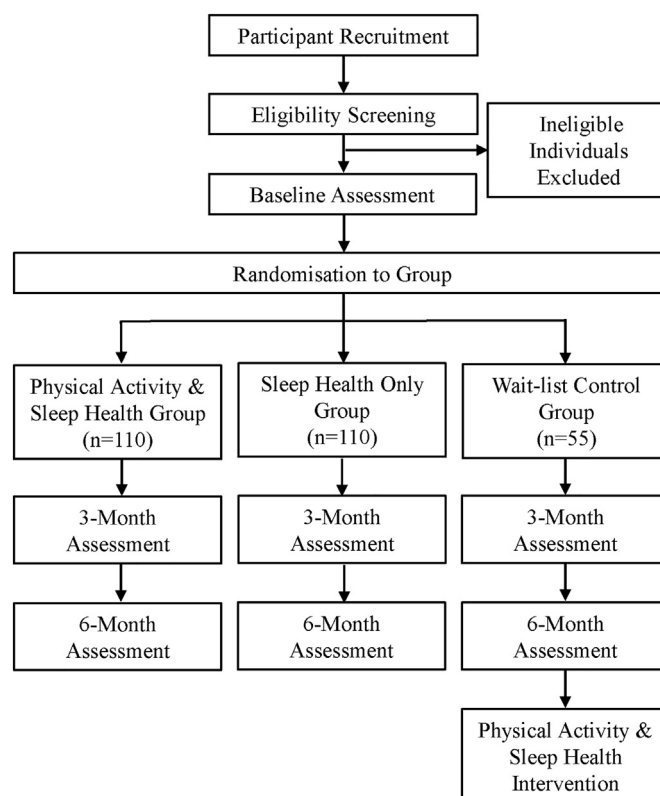


Fig. 1. Flow of participants through the Refresh Study.

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