Title: 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

Authors: Anna T Rayward[a,b], Beatrice Murawski[a,b], Ronald C Plotnikoff [a,c] , Corneel Vandelanotte[d], Wendy J Brown[e], Elizabeth G Holliday[b], Mitch J Duncan[a,b]

Author affiliations

a. Priority Research Centre for Physical Activity and Nutrition, The University of Newcastle, University Drive, Callaghan NSW 2308, Australia
b. School of Medicine & Public Health, Faculty of Health and Medicine, The University of Newcastle, University Drive, Callaghan NSW 2308, Australia
c. School of Education, Faculty of Education & Arts, The University of Newcastle, Callaghan NSW 2308, Australia
d. Physical Activity Research Group, School for Health, Medical and Applied Sciences, CQUniversity, Rockhampton, QLD, 4702, Australia.
e. School of Human Movement and Nutrition Sciences, The University of Queensland, St Lucia QLD 4072, Australia

Author Email Addresses:

ATR: anna.rayward@newcastle.edu.au

BM: beatrice.murawski@newcastle.edu.au

RCP: ron.plotnikoff@newcastle.edu.au

CV: c.vandelanotte@cqu.edu.au

WJB: wbrown@uq.edu.au

EGH: liz.holliday@newcastle.edu.au

MJD: mitch.duncan@newcastle.edu.au

Corresponding Author: Mitch J Duncan Address: ATC Building, The University of Newcastle, University Drive, Callaghan NSW 2308, Australia.

Email: mitch.duncan@newcastle.edu.au; Phone: +61(2) 49217805

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 30-50% 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~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.

Methods

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

84 "Balanced") and will provide additional support in the form of emails, text messages and a
85 participant handbook. Participants in the intervention groups will use the app to access
86 educational resources, set goals, self-monitor, and receive feedback about the health
87 behaviours. Each intervention group will only receive targeted intervention materials specific
88 to their intervention allocation (both physical activity and sleep behaviours for the PAS
89 group; sleep behaviours only for the SHO group). Participants in the PAS group will also be
90 provided with a pedometer (Yamax SW-200) to facilitate self-monitoring of physical activity.
91 The CON group will be asked not to change their physical activity and sleep behaviours, and
92 will be offered the combined physical activity and sleep health intervention after they have
93 completed the 6-month follow-up survey.
94 The Refresh Study has received approval from the Human Research Ethics
95 Committee, The University of Newcastle, Australia (reference number: H-2016-0267) and is
96 registered with the Australian and New Zealand Clinical Trials Registry
97 (ACTRN12617000680369; Universal Trial number: U1111-1194-2680). All participants will
98 provide informed consent via an online form and will be able to withdraw at any time, for any
99 reason, without prejudice. Participants will be asked to complete online surveys at baseline,
100 three-months, and six-month post-baseline follow-up (Figure 1) assessing sociodemographic
101 information, presence of chronic diseases, sleep and physical activity behaviours, mental
102 health status, and quality of life. The baseline survey will be completed prior to
103 randomisation. Reminders to complete assessments will be sent via email or SMS (short
104 message service) (Table 1). Participants will also receive weekly summary progress reports
105 and email or SMS reminders prompting participants to self-monitor target behaviours using
106 the app if required (Table 1). At the completion of each assessment, participants will be
107 entered into a draw to win one of 5 x $50 Gift Cards.
108

Table 1. Messaging Support Communication Schedule Summary

Type	Purpose	Delivery	Timing
Useful facts	Useful knowledge regarding the benefits of physical activity and sleep for health and well-being.	SMS	Once a week x 12
Weekly Summary Report	A personalised summary of participant's behaviours over the previous week.	Email	Once a week x 12
Tools	One tool every 3 weeks to refresh the information about action planning, goal setting and stress management techniques.	Email	Weeks 3,6 and 9
Prompts	A text message prompt a participant to keep logging if they haven't logged any information for four out of seven days.	SMS & email	As required
	An email message to prompt a participant to keep logging if they haven't logged any information for four out of seven days, on four consecutive weeks.		
	An alert to complete the three-month survey.		
	A reminder to complete the three-month survey if required.		
	An alert to complete the six-month survey.		
	A reminder to complete the six-month survey if required.		

Recruitment

A total of 275 participants were recruited from across all states of Australia using nationwide advertising on social (e.g., Facebook, Instagram) and traditional media, in conjunction with, posters in local businesses and around the University of Callaghan Campus and on community noticeboards. Recruitment took place between May and September 2017.

Interested individuals were directed to an online consent form and eligibility survey which was used to assess eligibility. Ineligible applicants were advised of their ineligibility at the end of the survey and offered the opportunity to use the Balanced app without the need to complete assessments [20].

Figure 1. Flow of participants through the Refresh Study

Eligibility

To be eligible for inclusion in this study, individuals must have satisfied the following inclusion criteria:

- be aged between 40 and 65 years,
- have a BMI between 18.5 and 35,
- participate in less than 30 minutes of moderate or vigorous exercise (such as walking or a sport) on three or more days of the week,
- report fairly bad or very bad sleep quality,
- have access to either an iOS or Android smartphone or tablet that can access the internet.

Exclusion criteria included:

- having a diagnosis of a sleep disorder such as insomnia, restless legs, narcolepsy, obstructive sleep apnoea,
- taking any medication related to assisting sleep,
- pregnancy, or having a child aged less than 12 months,
- having any condition which would contraindicate participation in physical activity or changing sleep,

- being employed as a shift-worker,
- planning to travel to a time zone which is three or more hours different from their usual time zone, once a month or more over the following three months,
- currently using a tracking device for physical activity and/or sleep,

Previous studies, requiring low active participants, have used the single-item physical activity measure 'As a rule, do you engage in at least half an hour of moderate or vigorous exercise (such as walking or a sport) on five or more days of the week (yes/no)?'[21, 22]. Despite participants' apparent eligibility (by answering "no" to this question), approximately 50% of these participants were subsequently found to meet current physical activity guidelines at the more thorough baseline assessment [21, 22]. Therefore, to identify participants who are more likely to be insufficiently active, the screening question for this study was adapted to: 'As a rule, do you engage in at least half an hour of moderate or vigorous exercise (such as walking or a sport) on three or more days of the week (yes/no)?'.

Randomisation

Participants will be randomised to one of the three study groups after their baseline assessment has been completed. A randomisation list to assign participants to either control or one of the two intervention groups in a ratio of 1:2:2 will be generated using SAS V9.4 (SAS Institute, Cary, North Carolina, USA). Permuted block randomisation will be used with random blocks of sizes of 10 and 15. Sequentially numbered, opaque envelopes will be used to conceal group allocations. Participant allocations will be assigned from this list by a research assistant who is independent of the study.

Intervention

The Refresh Study is a multi-component intervention to improve sleep quality. The details of the intervention platform and the specifics for each of the three groups are described below.

Intervention Platform

The intervention will primarily be delivered using the Balanced app, available on both iOS and Android operating systems. The original version of this app and its development is described elsewhere [20] and has been modified for the current study as detailed below.

The app can be tailored to a participant's specific group allocation to provide only the features, functionality and educational resources specific to their group allocation. The Sleep Health Only group will only have access to the sleep component of the app. The Physical Activity and Sleep Health group will receive an identical sleep component in addition to a physical activity component. Participants will be sent login details so they can access the appropriate version of the app and it will be available to the participants for the entirety of the study period (6 months). The app was developed using concepts which operationalise constructs from social cognitive and self-regulatory theories, which have been found to facilitate behaviour change [20, 23, 24]. The theoretical constructs and behaviour change techniques to be operationalised within the study are described in Tables 2a and 2b. There are five sections within the app, described below: 1) *Your Stats*, 2) *Dashboard*, 3) *Progress*, 4) *Resources* and 5) *My Profile*.

Table 2a. *Operationalisation of social cognitive factors and behaviour change strategies for physical activity intervention component*

Table 2b. *Operationalisation of social cognitive factors and behaviour change strategies for sleep intervention component*

Your Stats

The *Your Stats* section of the app (Figure 2), allows participants to enter goals for physical activity (daily moderate-vigorous intensity activity time (minutes), daily step count, and the number of days per week to do muscle strengthening exercises a participant wishes to perform) and sleep (time to go to sleep, time to wake up and the number (out of 10) of sleep hygiene behaviours the participant wishes to try to practice each day). The sleep hygiene behaviours are based on those identified as useful for improving sleep health from a public health perspective [15]. In addition, the *Your Stats* section allows participants to enter data about what they actually achieved daily, for each of these behaviours. It also allows them to enter a subjective rating for sleep quality, although no goal is set for sleep quality, since sleep quality is under less volitional control of an individual relative to other behaviours. The information entered into this section of the app, then produces feedback in the form of the traffic lights on the *Dashboard* and graphs in the *Progress* section. The *Your Stats* section is intended to operationalise the constructs of goal-setting and self-monitoring.

Figure 2.
a. Screenshot of Balanced Your Stats for Activity showing data entry option for daily behaviour and goals.
b. Screenshot of Balanced Your Stats for Sleep showing data entry options for nightly sleep behaviours and a sample of sleep hygiene options (screen extended).

Dashboard

The *Dashboard* section (Figure 3) provides a visual representation of progress towards goals using a traffic light system and is intended to operationalise the construct of feedback on a behaviour. Activity and Sleep "tiles" are displayed for the Physical Activity and Sleep Health group and a single Sleep "tile" is displayed for the Sleep Health Only group. The colour refers to minutes of activity for the activity tile, and sleep duration for the sleep tile. The colour of the tiles reflects progress of the user-entered data for a behaviour, in

comparison to their goal for that behaviour. A green light indicates a participant is meeting, exceeding or close to their goal; an orange light indicates they are progressing toward their goal although are not close; and a red light indicates they are markedly below their goal. This is based on process evaluation of the original Balanced app, indicating participants preferred progress toward their goals to be displayed, rather than comparison to recommended guidelines for a behaviour [20].

Figure 3

a. Screenshot of the Balanced Dashboard displaying green and orange feedback on Activity and Sleep tiles for the Physical Activity and Sleep Health group.

b. Screenshot of the Balanced Dashboard displaying red feedback on the Sleep tile for the Sleep Health Only group.

Progress

The *Progress* section of the app (Figure 4) provides graphical feedback of the participant's progress in relation to their physical activity (activity time, step count and muscle strengthening sessions) and/or sleep (sleep duration, sleep quality, sleep/wake time consistency and sleep hygiene) behaviours for four time periods (daily, weekly, three months and all). Although participants do not set goals for sleep quality and sleep duration, the feedback regarding these elements of sleep is important. Changes in sleep quality potentially reflect the outcome of practicing good sleep hygiene behaviours [15] and participants essentially set a sleep duration goal by setting goals for time to sleep and time to wake, which can then be used to compare their actual sleep duration with sleep duration recommendations [25]. Consistency in the time to sleep and time to wake is a key component of sleep hygiene recommendations and has been shown to be associated with improved sleep health [26-28]. This section is intended to operationalise the constructs of feedback and self-monitoring.

Figure 4
a. Daily progress summary for sleeping time. b Weekly progress summary for sleeping time. c. Three-month progress summary for sleeping time d. Three-month progress summary for sleep and wake times.

Resources

The *Resources* section provides educational information about "*how much, why and how*" for each behaviour, including national recommendations [25, 29], benefits of these behaviours for health, suggestions for improving these behaviours such as goal setting, action planning and sleep hygiene behaviours [15] and tips for overcoming barriers. The educational strategies are based on existing research and previous interventions [20, 30]. This information will be available for both behaviours for the Physical Activity and Sleep Health group whilst the Sleep Health Only group will only have access to the sleep information. The *Resources* section also includes information explaining the traffic light system. It is intended that the behaviour change techniques of education and action planning will be operationalised in The *Resources* section.

My Profile

The *My Profile* section of the app allows participants to change their email address and password and provides information about the research team involved with app development.

Study Groups

Physical Activity and Sleep Health Group Intervention (PAS)

The Physical Activity and Sleep Health intervention group will use the app to access educational material, set physical activity and sleep goals, self-monitor their physical activity and sleep behaviours and to receive graphical feedback in relation to their progress towards

these goals. In addition to the app, participants in the Physical Activity and Sleep Health intervention group will be mailed a *pedometer,* to assist with self-monitoring step count, and a *participant handbook*, containing information about how to use the app, as well as "*tools*" for setting goals, action planning and stress management techniques.

Participants will also receive content and prompts via emails and text messages during the first 12 weeks of the intervention. These will include a weekly text message containing a brief educational fact about, or tip for overcoming barriers to, physical activity or sleep, and a weekly email, containing a personalised summary of the participant's weekly physical activity and sleep behaviours. The email is created by the research team, summarising the self-monitoring information participants have entered into the app. This summary will provide additional feedback and prompt the setting of new goals if required. Participants with blank entries in their personalised email summary will be encouraged, by text within the email, to enter information into the app. On weeks 3, 6 and 9, in conjunction with their weekly summary, participants will receive a copy of the goal-setting (week 3), action planning (week 6) and stress management tools (week 9) (which they will have received initially with their handbook) to reinforce these strategies over time and promote continued engagement.

Additional text messages may also be sent as required, to prompt a participant to keep logging behaviours if they do not log information for any of the physical activity and/or sleep behaviours on four days or more out of seven in the last week. After four consecutive text messages, participants will be sent an email further encouraging them to log their behaviours. Prompts to re-engage in self-monitoring will be sent, as e-health interventions frequently suffer from non-usage attrition after several weeks [31] and self-monitoring is an important behaviour change technique [32]. Text messages will be sent using an online, web-based text messaging service only accessible to the research team. Table 1 provides a summary of the

messaging support communication schedule. The core components of the intervention are *education*, *self-monitoring*, and *feedback* on performance as detailed below.

Education

Educational content will be provided within the "Resources" section of the app and within the goal-setting, action planning and stress management "tools" mailed and emailed to participants. These will provide information on the health benefits of sufficient physical activity and sleep, inform participants of the national recommendations for physical activity and sleep duration, educate participants about sleep hygiene behaviours they can adopt to promote good sleep and also provide information on stress management and relaxation techniques.

The *Goal Setting Tool* will also provide specific guidance for which physical activity and sleep goals they will be required to set, and how to go about setting these goals. Participants will be encouraged to gradually increase their physical activity levels towards the levels recommended in the national guidelines, including both aerobic and muscle strengthening exercise. Materials will detail strategies to increase daily steps to increase incidental physical activity and reduce sitting time. Participants will also be encouraged to choose and engage in sleep hygiene behaviours and increase the number they engage in over time. A key intervention focus is on the establishment of regular bed-time and wake time, as a larger variation in bed-times have been shown to be associated with poorer sleep [26, 28].

The *Action Planning Tool* will provide insight into the "*how, why, when, where, who with, and what*" of creating an action plan, including examples of action plans and exercise options, from which the participant can model their own. This will include: *aerobic physical activities* (e.g., brisk walking, cycling, swimming) and *resistance training physical activities* (e.g., squats, modified push-ups, planking) as well as *intensity* (e.g., "until you huff and

puff'), *duration* (e.g., at least 30 minutes) and *frequency* (e.g., five days/week *or* two days/week of activity one plus three days/week of activity two) in which they could choose to engage. Participants will be encouraged to develop an action plan for both physical activity and sleep.

The *Stress Management Tool* will provide step-by-step guides to progressive muscle relaxation, deep breathing exercises and mindfulness exercises, adapted from publicly available resources [33-36]. Information about how to use the app and interpret the feedback graphs and traffic light system of goal progress will be provided in the participant handbook.

Self-monitoring and goal setting

To facilitate self-monitoring of physical activity and goal setting, participants in the Physical Activity and Sleep Health intervention group will be provided with a pedometer (Yamax SW200) to measure daily step count, as pedometers have been shown to produce a significant effect on physical activity behaviour change [18]. Goal setting and action planning for both physical activity and sleep hygiene behaviours will be emphasised. The goals will be entered into the *Dashboard* section of the app, reviewed intermittently and updated if necessary.

Goals to be entered into the app for physical activity will include; the daily number of minutes of *moderate to vigorous intensity*, the number of days per week of *resistance training sessions* and daily *step count*, and for sleep: *time to bed* (hh:mm), *time to wake* (hh:mm), the daily number of sleep hygiene behaviours (out of 10) they wish to practice, which is an approach used in previous studies [20]. Participants will be required to self-monitor these behaviours by manually entering information about each of the behaviours for which they set goals (in the "Dashboard" section of the app) and a *sleep quality rating* (using a star rating with five stars indicating excellent quality sleep).

Goal setting and self-monitoring will be essential components for assessing progress and garnering feedback. This is important since it has been shown that interventions which include physical recording of information (e.g., writing activity information down in a logbook) and those that bridge the gap between setting a goal and attaining a goal, by regularly monitoring goal progress, are likely to enhance behaviour change [32].

Feedback

The participant's goals will be compared with the activity and sleep information entered by the participant and used to provide graphical feedback in the *Progress* section of the app as described above. To assist with motivation, at the end of each week, participants will receive a personalised, tabulated, weekly summary (once per week for the first 12 weeks of intervention) of their behaviours. The feedback for physical activity will include: total weekly minutes of activity, daily average minutes of activity, number of days/week activity time goal was reach, number of days/week they were close to activity time goal, total weekly step count, daily average step count, number of days/week step count goal was reach, number of days/week they were close to step count goal, the number of days on which muscle strengthening sessions performed that week and if they met the muscle strengthening goal or not. The feedback for sleep will include: average nightly sleep duration, average sleep quality rating, daily average number of sleep hygiene behaviour performed, average bed time, average wake time and an indication as to whether the participant's bed times and wake times varied by < 60 minutes or > 60 minutes [37]. The participant will be encouraged to use this feedback to evaluate their weekly performance and use this as a guide when reviewing their goals and to determine their goals for the following week.

Sleep Health-Only Group (SHO)

The Sleep Health-Only group will receive the same sleep education, goal setting, action planning and monitoring as the combined Physical Activity and Sleep Health group. They will not receive any of the physical activity components of that intervention group beyond the general advice to "exercise regularly" as part of the overall sleep hygiene recommendations. They will not receive a pedometer.

Wait List Control Group (CON)

The wait list control group will not receive any intervention materials and will be asked not to modify their behaviours regarding physical activity and sleep. They will be asked to complete the assessments at 0, three and six months, after which time they will be offered access to the combined physical activity and sleep health intervention.

Measures

All outcomes except sociodemographic characteristics will be measured using an online survey at baseline, 3 months and 6 months. In addition, the 3-month survey will include measures to assess app usage for the intervention groups. Table 3 provides an overview of the outcome measures and timing of measurement.

402 Table 3. Overview of outcome measures and timing of measurement

		Time point of assessment		
Outcome	**Measure**	**Baseline**	**3 months**	**6 months**
Primary Outcome				
Sleep quality (past 30 days)	The Pittsburgh Sleep Quality Index (PSQI)	x	x	x
Secondary Outcomes				
Minutes of moderate- and vigorous intensity physical activity (per week)	The Active Australia Questionnaire (AAQ	x	x	x
Self-reported resistance training	Two item questionnaire asking number of days and time spent in resistance training	x	x	x
Sleep characteristics	Sub-components of The Pittsburgh Sleep Quality Index (PSQI)	x	x	x
Sitting time	The Workforce Sitting Questionnaire	x	x	x
Mental Health	The Kessler 6 (K6)	x	x	x
	The Depression Anxiety and Stress Scale (DASS-21)	x	x	x
Quality of life	The 12-Item Short Form Health Survey	x	x	x
Energy and fatigue	The 3-item subscale of the Rand 36	x	x	x
Sample Characteristics				
Sociodemographics	Age, gender, ethnicity, education, income, marital status, occupation, employment status	x		
Lifestyle and health factors	Height, weight, alcohol and caffeine consumption, smoking status, chronic disease status, working hours	x	x	x
Mediators/Moderators				
Sleep hygiene practices	The Sleep Hygiene index (SHI)	x	x	x
Insomnia severity	Sleep Condition Indicator (SCI)	x	x	x
	The Insomnia Severity Index (ISI)	x	x	x
Sleep Timing	The Sleep Timing Questionnaire (STQ)	x	x	x
Morningness-Eveningness	The Morningness-Eveningness Questionnaire (MEQ)	x	x	x
Process evaluation (intervention groups only)				
App usage & engagement	The Balanced App database		x	
Assessment of App Usability and Usage Statistics	The System Usability Scale		x	

403

404

405

406

Primary outcomes

Sleep quality will be assessed using the Pittsburgh Sleep Quality Index (PSQI) at 0, three and six months. The PSQI assesses sleep disturbances and sleep quality over the preceding month using a seven component, 19-item survey assessing various components of sleep, including times to bed and to wake, duration, sleep onset latency, subjective quality and other problems. The scores (0-3) of the seven components are summed (range 0-21) and scores above five indicate poor quality sleep, with poorer sleep signified by a higher number. The PSQI has been found to have good validity [38] and reliability (α=0.83) [39].

Secondary Outcomes

Physical Activity

Self-reported physical activity will be assessed using the Active Australia Questionnaire (AAQ), which assesses time spent in walking, moderate and vigorous intensity activity during the previous 7 days. It has acceptable test re-test reliability and validity [40] and is sensitive to changes in physical activity during interventions [41]. Physical activity will be reported as the total minutes of walking, moderate and vigorous (weighted by two) intensity physical activity. Self-reported resistance training will be assessed using two items adapted from items in previous studies which assessed participation in resistance training [42, 43]. These items assess the number of days that resistance training was performed and the amount of time engaged in resistance training each day. Physical activity will also be assessed as a mediator and moderator.

Sleep Characteristics

The following individual sub components of the PSQI will be also reported: sleep onset latency, sleep duration, sleep efficiency, sleep disturbance, use of sleep medication and daytime dysfunction [39].

Sitting Time

Sitting time will be assessed using the Workforce Sitting Questionnaire (WSQ) which assesses total and domain specific (whilst travelling, working, watching TV, using the computer at home and at other times of the day) time spent sitting on week days and on weekends. The (WSQ) has acceptable test-retest reliability (ICC = 0.46-0.90) and acceptable criterion validity compared to accelerometry (r = 0.18-0.46) [44].

Mental Health

Mental health will be assessed using the Kessler 6 (K6) and Depression Anxiety Stress Scale-21 (DASS-21) questionnaires. The Kessler 6 is a validated measure of non-specific psychological distress derived from a short, six item psychological screening questionnaire [45]. DASS-21 is a valid and reliable instrument for assessing the presence of depression, anxiety and stress (α = 0.88, 0.82 and 0.90 respectively); [46].

Quality of Life

Health-related quality of life will be assessed using the 12-Item Short Form Health Survey which measures self-reported physical and mental health components over the previous four week period [47]. In addition, energy and fatigue will be measured using the 3-item subscale of the Rand 36 (Version 1.0) [48]. This will allow any changes in energy and fatigue over the intervention period to be measured.

457

458 *Sociodemographics and Chronic Disease Status*

459 Information regarding participants' age, sex, weight, height, marital status, income, years of
460 educational, employment status, occupational level, work hours, ethnicity, alcohol [49] and
461 caffeine consumption and smoking status will be assessed. Participants will be asked to report
462 chronic health conditions including: heart/coronary disease, cerebrovascular disease,
463 hypertension, hypercholesterolaemia, type 1 and type 2 diabetes, asthma, chronic obstructive
464 pulmonary disease/, cancer, kidney disease, irritable bowel disease, arthritis, osteoporosis,
465 sleep apnoea, insomnia, rest less legs syndrome, depression, anxiety or other mental illness.

466

467 ***Mediators and Moderators***

468 *Physical Activity*

469 The same measures of physical activity described above will be assessed.

470

471 *Sleep Hygiene Practices*

472 Sleep hygiene practices will be assessed using the Sleep Hygiene Index (SHI), a 13-
473 item survey which assesses the frequency (always, frequently, sometimes, rarely, never) of
474 sleep hygiene behaviours. The SHI has good test-retest reliability ($r = 0.71$) and internal
475 consistency ($\alpha = 0.66$) and is positively correlated with the Pittsburgh Sleep Quality Index (r
476 $= 0.48$) and the Epworth Sleepiness Scale ($r = 0.244$); [50].

477

478 *Insomnia Severity*

479 To evaluate the presence of symptoms of insomnia amongst participants, the Sleep
480 Condition Indicator (SCI), an eight item survey identifying the presence, frequency and
481 duration of symptoms of insomnia, will be used [51]. The SCI is sensitive to change, has

internal consistency and strongly correlates with other clinically sensitive instruments (PSQI and ISI); [51]. To assess the severity of insomnia, the Insomnia Severity Index (ISI), a seven-item self–report questionnaire which assesses the nature, severity and night-time and daytime impact of insomnia, will be used. The ISI is a reliable and valid instrument with high internal consistency ($\alpha = 0.90$) and a strong correlation with the PSQI ($r = 0.80$); [52].

Sleep Timing

Self-reported sleep timing will be assessed using the Sleep Timing Questionnaire (STQ) which assesses the earliest, latest and usual time to bed and time to wake as well as week day and weekend variation of these times. The STQ has reasonable test-retest reliability ($r = 0.71$) and validity correlating well with both wrist actigraphy ($r = 0.59 – 0.77$) and sleep diary ($r = 0.84 – 0.86$) [53].

Morningness-Eveningness

To assess a participants' predilection for morningness or eveningness the reduced scale Morning/Evening Questionnaire, a five-item survey will be used. The reduced form correlates very closely with the full questionnaire which has good internal consistency ($\alpha = 0.83$) and test-retest reliability ($r = 0.77$) [54].

Assessment of App Usability and Usage Statistics

Usability of the app will be assessed using the System Usability Scale which is a reliable tool used to assesses the usability of websites [55]. The questionnaire will be adapted to refer to usability of the app. Ten items used in a previous study [56] will be added to assess the usefulness of the app in terms of its ability to improve self-efficacy regarding physical activity and sleep behaviours, to set goals and overcome barriers to be active and practice

sleep hygiene behaviours, to stay active and keep up good sleep hygiene behaviours and remain motivated to be active and practice good sleep behaviours. Usage statistics (number, frequency and timing of self-monitoring entries) captured by the app database will be used to assess engagement with and use of the intervention platform using app usage tracking software similar to previous studies [57, 58].

Power and Sample Size

The study is powered on change in the primary outcome of sleep quality measured by the Pittsburgh Sleep Quality Index, at the three-month primary time point. Based on meta-analyses and pilot data, and accounting for a sub-clinical population, we hypothesise that both the Sleep Health-Only (d=0.30) and combined Physical Activity and Sleep Health interventions (d = 0.65) will significantly improve sleep quality relative to the control group [16, 20, 59, 60]. The assumed baseline-follow-up correlation was 0.60, based on the correlation found in preliminary data from a trial which targeted and measured changes in sleep (r=0.60) [20]. A step-wise gateway approach will be applied to control family-wise error rate for analysis of the primary outcome. First, both intervention groups pooled will be compared with the control group (mean PSQI = 6.845 and 8.0 for pooled intervention groups and control group respectively; SD = 2.42: $\alpha = 0.05$ (two-sided); power = 0.80) assuming an allocation ratio of 4:1 (sample size required for the first comparison, Pooled Intervention Groups = 112, Control group = 28). If this test is significant, the two intervention groups will then be compared with each other (mean PSQI = 6.42 and 7.27 for Combined Physical Activity and Sleep Health and Sleep Health-Only groups respectively; SD = 2.42; $\alpha = 0.05$ (two-sided); power = 0.80) (sample size for the second comparison, intervention groups = 82 per group). The sample size for the study is based on the difference between intervention groups as this is the smallest difference between groups. Internet-based interventions are

known for high drop-out rates [20, 61] so to allow for 25% loss to follow-up, the size of each group was inflated accordingly (Combined Physical Activity and Sleep Health = 110, Sleep Health Only = 110, Control = 45). The control group number was further adjusted (Control = 55) to allow for random block allocation using a 2:2:1 ratio, resulting in a total sample of 275 participants.

Analyses

To examine differences between intervention groups at three and six months, generalized linear models (GLM) and generalized linear mixed models (GLMM) using an ANCOVA (baseline-adjusted) approach, will be used respectively. Analysis of three-month outcomes will include a fixed effect for group to estimate treatment effects. Analysis of six-month outcomes will use a random intercept to account for repeated measures on individuals and treatment effects will be estimated by including fixed effects for group, time and the group x time interaction. GLM and GLMM will also include the baseline value of the outcome as a covariate. Secondary outcomes will be assessed using a similar GLM and GLMM approaches. The proposed mediators will be examined using established approaches to conducting mediation analysis [62, 63]. Generalized linear mixed models and time-to-event analysis will be used to examine differences in usage patterns. All analyses will be conducted according the intention-to-treat principle including all available data. Sensitivity analyses such as multiple imputation will be undertaken to investigate the robustness of conclusions to different assumed missing data mechanisms.

Data Management

Data will be collected using the Qualtrics® survey platform, exported as a text file and imported into Stata for analysis on a password protected computer. Throughout the trial, a database will be kept to track participants' progress and will be used to generate communications with participants regarding the delivery of intervention components and scheduling of the 3-month and 6-month assessments in the form of emails and text messages. Participant engagement with the intervention will be monitored by ATR and MJD, usage data from the app is stored on password protected servers. Participants will be sent email/text messages of encouragement to re-engage with the intervention if required. The members of the research team who are based in Newcastle Australia (ATR, BM, MJD, EGH and RCP) will have access to all identified and de-identified data. Given the nature of the trial and the data being collected, a Data Management Committee is not required.

Identifiable electronic information will be kept on a networked computer which will be password protected. Only the researchers and the company that conducts maintenance on the app, will have access to this material. De-identified data will be kept for a minimum of fifteen years at the University of Newcastle after which time the paperwork will be shredded or electronically deleted.

Findings of the research will not allow the identification of participants and will be published in scientific literature, ATR's doctoral thesis and presented at scientific conferences.

Roles and Responsibilities

The ICMJE criteria for authorship have been met by all authors [64]. ATR, BM, RCP, CV, WJB, EGH and MJD contributed to the intervention development and design. ATR, MJD and EGH conducted and developed the data analysis plan. All authors edited the manuscript and approved the final version prior to submission. ATR will be primarily

responsible for recruitment, data collection and delivery of the intervention, under the supervision of MJD, RCP and EGH. BM will undertake these responsibilities when required. ATR, MJD, BM and RCP conceptualised the study and led all aspects of study design and CV, WJB and EGH provided critical review of the study methodology. ATR drafted the manuscript. All authors (ATR, BM, RCP, CV, WJB, EGH and MJD) will be involved with the interpretation of results and the dissemination of the research findings.

Any changes to the trial protocol will be submitted for approval by the Human Research Ethics Committee (HREC) and updated with ANZCTR. Any adverse events, related or un-related to participation in the trial will be reported to HREC. Participants will be advised to seek medical assistance as soon as possible if they experience any shortness of breath, chest pains or other potentially significant health symptoms. Participants will be provided with contact details for Lifeline and BeyondBlue in case they find the nature of any questions in the surveys distressing.

Discussion

Poor sleep health is associated with a considerable burden of illness including increased risk of non-communicable diseases [65], depression, decreased work productivity and high health care costs [6]. Approximately 30-50% of adults worldwide report poor sleep quality [7]. Only about half of these people have a diagnosable sleep disorder [8], yet many interventions to date are targeted at those with a sleep disorder. Additionally, although physical activity has been shown to improve sleep quality [13], none of the studies included in a review of sleep health interventions provided participants with specific strategies and behaviour change techniques to foster changes in physical activity [16]. This is important, as previous studies have shown education-only physical activity interventions are not effective

606 [66]. This is particularly important in the context of multiple behaviour interventions where,
607 to maximise change in a behaviour, specific intervention strategies need to be provided for a
608 behaviour [17]. Consequently, sleep health interventions that do not provide participants with
609 targeted strategies to change physical activity may not maximise change in physical activity,
610 nor the resulting flow on effects that physical activity may have on sleep health. Given the
611 large numbers who report poor sleep health [7] as well as large proportion of the population
612 who are insufficiently active [14], including the large proportion of middle aged adults who
613 report both poor sleep and insufficient activity [9] these factors are likely to have a
614 detrimental impact on health. Therefore, there is a clear need for the development of broad-
615 reaching, effective interventions to improve sleep quality for this population of adults who
616 experience poor sleep quality but do not have a sleep disorder [67, 68]. Although participants
617 will be excluded from this study if they report diagnosed sleep disorders, they will not be
618 screened for undiagnosed conditions and as such will be a study limitation. This study will
619 also allow the evaluation of the effectiveness of the intervention to improve physical activity
620 behaviour and the exploration of any associated effects of the interventions on depressive
621 symptoms and quality of life, which are both known to be adversely impacted by poor sleep
622 health and low levels of physical activity [3, 70-72].

623 To achieve this, a technology-based approach which allows participants access to the
624 intervention at a time and place convenient to them can be used [73]. An important feature of
625 this study includes the use of behaviour change strategies using constructs from
626 psychological theories known to facilitate behaviour change and which are likely to enhance
627 the effect of the intervention [74]. Another important element is the inclusion of a specific
628 physical activity component within the sleep intervention, since physical activity has been
629 shown to improve sleep [13, 75]. A review of the effects of physical activity on sleep found
630 that regular exercise produced comparable results to pharmacological and behavioural

631 therapy interventions for insomnia for sleep-onset-latency, sleep duration and sleep quality
632 [13]. Another review examining the influence of exercise on sleep quality and insomnia in
633 middle-aged women, found that, although there was no significant effect on insomnia
634 severity, exercise improved sleep quality [76]. However, sleep interventions to date have
635 largely not harnessed this potential effect by specifically targeting physical activity. The
636 three-arm design will allow us to directly compare the relative efficacy of the physical
637 activity and sleep health intervention to the sleep only intervention to determine whether the
638 addition of physical activity enhances the effectiveness of a sleep health intervention to
639 improve sleep quality. The combination of a physical activity intervention with a sleep
640 intervention is likely to further reduce the risk of chronic diseases associated with poor sleep
641 such as cardiovascular disease and type 2 diabetes, by synergistically enhancing the
642 effectiveness of the sleep intervention [4, 77], and may guide multiple health behaviour
643 change strategies and policies in the future.

644

645

646 **List of abbreviations**

647	AAQ	Active Australia Questionnaire
648	ACTRN	Australian Clinical Trials Registry Number
649	ANZCTR	Australian New Zealand Clinical Trial Registry
650	App	Application
651	BMI	Body Mass Index
652	CBTi	Cognitive Behavioural Therapy for Insomnia
653	CON	Waitlist Control
654	DASS-21	Depression Anxiety Stress Scale-21
655	iOS	iPhone Operating System
656	K6	Kessler 6 Questionnaire

PAS	Physical Activity and Sleep
PSQI	Pittsburgh Sleep Quality Index
Refresh	**Re**search **f**o**r** **E**xercise, **S**leep and **H**ealth
SAS	Statistical Analysis Software
SHO	Sleep Health Only
SMS	Short Message Service
WSQ	Workforce Sitting Questionnaire

Declarations

Ethics Approval and consent to participate

Ethical approval for this study was provided by the Human Research Ethics Committee, The University of Newcastle, Australia (reference number H-2016-0267). Participants provided informed consent.

Trial Registration: Australian New Zealand Clinical Trial Registry: ACTRN12617000680369; Universal Trial number: U1111-1194-2680

Consent for publication

Not applicable.

Availability of data and material

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing Interests

The authors declare that they have no competing interests.

Funding

ATR is supported by a Wests Scholarship (ID G1201152). MJD (ID 100029) and CV (ID 100427) are supported by a Future Leader Fellowship from the National Heart Foundation of Australia. This project was supported in part by Vanguard Grant (ID 100629) from the National Heart Foundation of Australia. The project is sponsored by the University of Newcastle. The project is independent of all sponsors and funders for all aspects of study design, data collection, management, analysis and interpretation, writing of articles and decisions regarding publication of these articles.

Authors' contributions

ATR, MJD and BM conceptualised the study and led all aspects of study design. ATR drafted the manuscript. ATR, MJD, BM, RCP, CV, WJB and EGH contributed to the intervention development and design. ATR, MJD and EGH conducted and developed the data analysis. All authors edited the manuscript and approved the final version prior to submission.

Acknowledgments

Not applicable.

Table 2a. *Operationalisation of social cognitive factors and behaviour change strategies for physical activity intervention component*

Theoretical Construct	Behaviour Change Technique	Physical Activity Intervention Component	Description	Intervention Delivery Method
Self-efficacy				
Confidence in one's ability to engage in a behaviour (physical activity or sleep) (task self-efficacy) and to overcome barriers to engaging in these behaviours (barrier self-efficacy)	Setting graded tasks/ incremental challenges	Setting achievable goals and regular revision of goals	Participants will be encouraged to gradually increase the number of sessions, duration and intensity of physical activity.	App Goal setting tool
	Self-monitoring/ self-re-evaluation	Daily logging of activity into Balanced app	Participants will log: - Minutes of daily physical activity - Daily step count - Muscle strengthening sessions – 'yes' or 'no' each day. Graphical feedback in the form of bar charts and a colour coded traffic light display relating to their progress towards set goals will be provided.	App Pedometer
	Goal review/feedback/ positive reinforcement	Dashboard - Traffic lights	The dashboard will be divided into tiles. The physical activity tile will relate to minutes of physical activity based on daily entries (24h); A green light indicates a participant is meeting, exceeding or close to their goal; an orange light indicates they are progressing toward their goal although are not close; and a red light indicates they are markedly below their goal.	App

		Bar graphs	Bar Graphs will show progress in relation goals for minutes of physical activity, step count and days including muscle strengthening sessions, over four time points; daily, weekly, three-month and all.	App
		Email messages	Weekly personalised summary email with information about personal activity goal progress will be sent to participants.	Email
	Relapse prevention	Use of prompts	Participants will receive text prompts to remind and encourage them to log physical activities if they have not logged for any four of seven consecutive days.	Text message reminder
			Text messages including useful facts about physical activity and information about overcoming barriers.	Text message fact
	Normative behaviours	Information in the "Resources" section of the Balanced app	Information regarding the health benefits of, national recommendations for, and strategies to achieve physical activity will be provided.	App
	Knowledge/ education	Educational information in the "Resources" section of the Balanced app and the Goal Setting and	Australian physical activity recommendations will be provided.	App
			Health benefits of physical activity (e.g., reducing the risk of heart disease, diabetes, depression and anxiety as well as feel more energised) will be provided.	App Goal Setting Tool Action Planning Tool

		Action Planning Tools	Overcoming barriers; participants will be provided with information about overcoming barriers.	App Goal Setting Tool Action Planning Tool
			Social support; participants will be encouraged to find friends and family to be physically active with.	App Goal Setting Tool Action Planning Tool
			Tips for creating an action plan outlining type of activity, intensity, duration, where, when, who with and some problem-solving strategies, will be provided to inform participants how to go about being physically active.	App Action Planning Tool
Outcome Expectations/Expectancies				
An individual's anticipated outcome of physical activity behaviours and the value they place upon that outcome	Information on consequences of behaviour	Educational information in the "Resources" section of the Balanced app	Health benefits of physical activity (e.g., reducing the risk of heart disease, diabetes, depression and anxiety as well as feel more energised) will be provided.	App Handbook
		Action Planning Tool	As part of the intervention materials, reasons why they wish to improve their physical activity and what they anticipate as personal benefits, following improved physical activity (examples will be provided).	App Action Planning Tool
Socio-structural				
The creation of supportive relationships which	Mobilise social support	Information in the "Resources" section of the Balanced app	Participants will be encouraged to engage with family members, friends and peers to assist them achieve their	App

reduce vulnerability to stress		Example action plan	physical activity goals by joining in or encouraging them to do so.	Action Planning Tool
	Environmental restructuring	Educational information in the Action Planning tool.	The example action plan will provide ideas to assist participants make the most of their environment to improve their physical activity such as: "I'll park the car further away so I can walk.", "Use the steps and the bench in the park".	Action Planning Tool
Intentions and Goals				
Intentions and goals refer to what a person proposes to do	Use of prompts	Text messages	Participants will receive text prompts to remind them to log physical activities if have not logged for any 4 of 7 consecutive days.	Text message reminder
	Action plan	Development of action plan	The Action Planning Tool will assist in the creation of an action plan, outlining type of activity, intensity, duration, where, when, who with and some problem-solving strategies, will be provided to inform participants how to go about being physically active.	Action Planning Tool
	Graded tasks	Action plan revision	Participant's action plans will be revised/updated as required intermittently	App Action Planning Tool
	Goal setting	Setting of proximal and distal goals	Participants will set daily goals with an action plan. Additionally, participants will be asked to set a longer term goal to keep in mind for the end of the intervention (e.g., "I will run a Park Run without stopping").	App Goal Setting Tool

	Review of goals	Graphical feedback: bar charts	Participants will receive on-screen feedback on their progress in the form of a bar chart which displays their progress towards their goals.	App
		Graphical feedback: traffic lights	Participants will receive graphical on-screen feedback on their progress in relation to their goals in the form of a traffic light system display; within 20%, meeting or exceeding goals will generate a green light; entries between 20% and 35% of goal will generate an orange light; entries more than 35% below goal will generate a red light. This feedback will be used to assist participants in reviewing their goals.	App
	Time management	Educational information in the Action Planning tool.	Participants will be provided with information about scheduling physical activity sessions in the example action plan.	Action Planning Tool

1 **Table 2b.** *Operationalisation of social cognitive factors and behaviour change strategies for sleep intervention component*

2

Theoretical Construct	Behaviour Change Technique	Sleep Intervention Component	Description	Intervention Delivery Method
Self-efficacy				
Confidence in one's ability to engage in a behaviour (physical activity or sleep) (task self-efficacy) and to overcome barriers to engaging in these behaviours (barrier self-efficacy)	Setting graded tasks/ incremental challenges	Setting achievable goals and regular revision of goals	Participants will be encouraged to set realistic sleep goals (Bed time, wake time and sleep hygiene goals) which can be adjusted at any time.	App Goal setting tool
	Self-monitoring/ self-re-evaluation	Daily logging of sleep into Balanced app	Participants will log: - Sleep start time - Sleep end time - Sleep hygiene goals achieved (from checklist of 10) - Sleep quality rating (1-5 stars) Graphical feedback in the form of bar charts and a colour coded traffic light display relating to their progress towards set goals will be provided.	App
	Goal Review/feedback/ positive reinforcement	Traffic lights	The dashboard will be divided into tiles. The sleep tile will relate to nightly sleep duration; A green light indicates a participant is meeting, exceeding or close to their goal; an orange light indicates they are progressing toward their goal although are not close; and a red light indicates they are markedly below their goal.	App

		Bar graphs	Bar Graphs will show progress in relation goals for bed time/wake time, sleep duration, sleep hygiene and sleep quality over four time points; one day, week, three-months and all.	App
		Email messages	Weekly personalised summary email with information about personal sleep goals progress will be sent to participants.	Email
	Relapse prevention	Use of prompts	Participants will receive text prompts to remind them to log sleep behaviours if they have not logged for any four of seven consecutive days.	Text message reminder
			Text messages including useful facts about sleep and information about overcoming barriers.	Text message fact
	Knowledge/ education	Educational information in the "Resources" section of the Balanced app and the Goal Setting and Action Planning Tools	Advice including national recommendations for sleep duration and about the how much, why and how of engaging in sleep promoting behaviours (sleep hygiene) will be provided.	App Goal Setting Tool Action Planning Tool
			Health benefits of good sleep (e.g., reducing the risk of heart disease, diabetes, depression and anxiety as well as feel more energised) will be provided.	App Goal Setting Tool Action Planning Tool
			Information about environmental restructuring and how to manage the bedroom environment as part of	App Goal Setting Tool

			good sleep hygiene will be provided.	Action Planning Tool
		Action planning Tool	The action planning tool will provide information about the how, why, when, where, who with and what of achieving sleep goals.	Action planning Tool
		Stress Management Tool	The stress management tool will provide links to relaxation podcasts and videos, as well as step-by-step guides to progressive muscle relaxation, deep breathing exercises and mindfulness exercises which are commonly accepted techniques incorporated into interventions for sleep.	Stress Management Tool
	Problem solving	Educational information in the mid-week text message	Tips for overcoming obstacles in changing sleep behaviour will be provided amongst the mid-week text messages.	Text message fact
Outcome Expectations/Expectancies				
An individual's anticipated outcome of sleep behaviours and the value they place upon that outcome	Information on consequences of behaviour	Educational information in the "Resources" section of the Balanced app	Health benefits of good sleep (e.g., reducing the risk of heart disease, diabetes, depression and anxiety as well as feel more energised) and the current national guidelines on how much sleep is needed, will be provided.	App Handbook
		Action planning tool	As part of the intervention materials, reasons why they wish to improve their sleep behaviour and what they anticipate as personal	App Action Planning Tool

			benefits, following improved sleep (examples will be provided).	
Socio-structural				
The creation of supportive relationships which reduce vulnerability to stress	Mobilise social support	Information in the Action Planning Tool	Information on seeking support from those in the same household (housemates, partner, and family members) will be provided.	App Action Planning Tool
	Environmental restructuring	Educational information in the "Resources" section and the Action Planning Tool.	Environmental restructuring as part of good sleep hygiene will be highlighted in the resource section and include details on how to manage the bedroom environment.	App Action Planning Tool
Intentions and Goals				
Intentions and goals refer to what a person proposes to do	Use of prompts	Text Messages	Participants will receive text prompts to remind them to log sleep if not logged for any 4 of 7 consecutive days.	Text message reminder
	Action plan	Development of action plan	Participants will receive a guide to assist them develop action plan based on sleep hygiene recommendations, which fosters engagement in sleep promoting behaviours.	Action Planning Tool
	Graded tasks	Action plan revision	Participant's action plans will be revised/updated as required intermittently	App Action Planning Tool
	Goal setting	Setting of proximal goals	Participants will set personal bedtime and wake time goals; number of sleep hygiene	App Goal Setting Tool

			behaviours will be set as a sleep hygiene goal.	
	Review of goals	Graphical feedback: bar charts	Bar Graphs will show progress in relation goals for bed time/wake time, sleep duration, sleep hygiene and sleep quality over four time points; one day, one week, three-months and all.	App
		Graphical feedback: traffic lights	The dashboard will be divided into tiles. The sleep tile will relate to nightly sleep duration; entries within 20%, meeting or exceeding goals will generate a green light; entries between 20% and 35% of goal will generate an orange light; entries more than 35% below goal will generate a red light.	App
	Barrier Identification/ problem solving	Educational information in the mid-week text message	Tips for overcoming obstacles in changing sleep behaviour will be provided amongst the mid-week text messages.	Text message fact
Socio-structural				
The creation of supportive relationships which reduce vulnerability to stress	Mobilise social support	Information in the Action Planning Tool	Information on seeking support from those in the same household (housemates, partner, and family members) will be provided.	App Action Planning Tool
	Environmental restructuring	Educational information in the "Resources" section and the	Environmental restructuring as part of good sleep hygiene will be highlighted in the resource section and include details on how to manage the bedroom environment.	App Action Planning Tool

		Action Planning Tool.		
Intentions and Goals				
Intentions and goals refer to what a person proposes to do	Use of prompts	Text Messages	Participants will receive text prompts to remind them to log sleep if not logged for any 4 of 7 consecutive days.	Text message reminder
	Action plan	Development of action plan	Participants will receive a guide to assist them develop action plan based on sleep hygiene recommendations, which fosters engagement in sleep promoting behaviours.	Action Planning Tool
	Graded tasks	Action plan revision	Participant's action plans will be revised/updated as required intermittently	App Action Planning Tool
	Goal setting	Setting of proximal goals	Participants will set personal bedtime and wake time goals; number of sleep hygiene behaviours will be set as a sleep hygiene goal.	App Goal Setting Tool
	Review of goals	Graphical feedback: bar charts	Bar Graphs will show progress in relation goals for bed time/wake time, sleep duration, sleep hygiene and sleep quality over four time points; one day, one week, three-months and all.	App
		Graphical feedback: traffic lights	The dashboard will be divided into tiles. The sleep tile will relate to nightly sleep duration; entries within 20%, meeting or exceeding goals will generate a green light;	App

			entries between 20% and 35% of goal will generate an orange light; entries more than 35% below goal will generate a red light.	
	Barrier Identification/ problem solving	Educational information in the mid-week text message	Tips for overcoming obstacles in changing sleep behaviour will be provided amongst the mid-week text messages.	Text message fact

References

[1] Hoevenaar-Blom MP, Spijkerman AMW, Kromhout D, van den Berg JF, Verschuren WMM: Sleep Duration and Sleep Quality in Relation to 12-Year Cardiovascular Disease Incidence: The MORGEN Study. Sleep 2011, 34(11):1487-92.

[2] Shan Z, Ma H, Xie M, Yan P, Guo Y, Bao W *et al*: Sleep duration and risk of type 2 diabetes: a meta-analysis of prospective studies. Diabetes care 2015, 38(3):529-37.

[3] Baglioni C, Battagliese G, Feige B, Spiegelhalder K, Nissen C, Voderholzer U, Lombardo C, Riemann D: Insomnia as a predictor of depression: A meta-analytic evaluation of longitudinal epidemiological studies. J Affect Disorders 2011, 135(1–3):10-9.

[4] Duncan MJ, Kline CE, Vandelanotte C, Sargent C, Rogers NL, Di Milia L: Cross-Sectional Associations between Multiple Lifestyle Behaviors and Health-Related Quality of Life in the 10,000 Steps Cohort. PLoS ONE 2014, 9(4):e94184.

[5] Guertler D, Vandelanotte C, Short C, Alley S, Schoeppe S, Duncan MJ: The association between physical activity, sitting time, sleep duration, and sleep quality as correlates of presenteeism. J Occup Environ Med 2015, 57(3):321-8.

[6] Hafner M, Stepanek M, Taylor J, Troxel WM, van Stolk C: Why sleep matters–the economic costs of insufficient sleep. 2016.

[7] Léger D, Poursain B, Neubauer D, Uchiyama M: An international survey of sleeping problems in the general population. Curr Med Res Opin 2008, 24(1):307-17.

[8] Mansfield DR, Hillman DR, Antic NA, McEvoy RD, Rajaratnam S: Sleep loss and sleep disorders. Med J Aust 2013, 199(8):5-6.

[9] Rayward AT, Duncan MJ, Brown WJ, Plotnikoff RC, Burton NW: A cross-sectional cluster analysis of the combined association of physical activity and sleep with sociodemographic and health characteristics in mid-aged and older adults. Maturitas 2017, 102:56-61.

[10] Mukherjee S, Patel SR, Kales SN, Ayas NT, Strohl KP, Gozal D, Malhotra A: An Official American Thoracic Society Statement: The Importance of Healthy Sleep. Recommendations and Future Priorities. Am J Resp Crit Care 2015, 191(12):1450-8.

[11] Cunnington D, Junge MF, Fernando AT: Insomnia: prevalence, consequences and effective treatment. Med J Aust 2013, 199(8):S36-40.

[12] Cheng SK, Dizon J: Computerised cognitive behavioural therapy for insomnia: a systematic review and meta-analysis. Psychother Psychosom 2012, 81(4):206-16.

[13] Kredlow MA, Capozzoli M, Hearon B, Calkins A, Otto M: The effects of physical activity on sleep: a meta-analytic review. J Behav Med 2015, 38(3):427-49.

[14] Sallis JF, Bull F, Guthold R, Heath GW, Inoue S, Kelly P *et al*: Progress in physical activity over the Olympic quadrennium. Lancet 2016, 388(10051):1325-36.

[15] Irish LA, Kline CE, Gunn HE, Buysse DJ, Hall MH: The role of sleep hygiene in promoting public health: A review of empirical evidence. Sleep Med Rev 2015, 22:23-36.

[16] Ho FY-Y, Chung K-F, Yeung W-F, Ng TH, Kwan K-S, Yung K-P, Cheng SK: Self-help cognitive-behavioral therapy for insomnia: a meta-analysis of randomized controlled trials. Sleep Med Rev 2015, 19:17-28.

[17] Mc Sharry J, Olander EK, French DP: Do single and multiple behavior change interventions contain different behavior change techniques? A comparison of interventions targeting physical activity in obese populations. Health Psychol 2015, 34(9):960-5.

[18] McEwan D, Harden SM, Zumbo BD, Sylvester BD, Kaulius M, Ruissen GR, Dowd AJ, Beauchamp MR: The effectiveness of multi-component goal setting interventions for changing physical activity behaviour: a systematic review and meta-analysis. Health Psychol Rev 2016, 10(1):67-88.

[19] Williams S, French D: What are the most effective intervention techniques for changing physical activity self-efficacy and physical activity behaviour—and are they the same? Health Educ Res 2011, 26(2):308-22.
[20] Duncan M J, C. V, Trost S G, Rebar A L, N. R, Burton N W *et al*: Balanced: a randomised trial examining the efficacy of two self monitoring methods for an app-based multi-behaviour intervention to improve physical activity, sitting and sleep in adults. . BMC Public Health 2016.
[21] Caperchione CM, Duncan MJ, Rosenkranz RR, Vandelanotte C, Van Itallie AK, Savage TN *et al*: Recruitment, screening, and baseline participant characteristics in the WALK 2.0 study: a randomized controlled trial using Web 2.0 applications to promote physical activity. Contemp Clin Trials Commun 2016, 2:25-33.
[22] Vandelanotte C, Reeves MM, Brug J, De Bourdeaudhuij I: A randomized trial of sequential and simultaneous multiple behavior change interventions for physical activity and fat intake. Prev Med 2008, 46(3):232-7.
[23] Luszczynska A, Schwarzer R: Social cognitive theory, vol. 2. England: Open University Press; 2005.
[24] Bandura A: Health Promotion by Social Cognitive Means. Health Educ Behav 2004, 31(2):143-64.
[25] Hirshkowitz M, Whiton K, Albert SM, Alessi C, Bruni O, DonCarlos L *et al*: National Sleep Foundation's updated sleep duration recommendations: final report. Sleep Health 2015, 1(4):233-43.
[26] Duncan MJ, Kline CE, Rebar AL, Vandelanotte C, Short CE: Greater bed- and wake-time variability is associated with less healthy lifestyle behaviors: a cross-sectional study. J Public Health 2016, 24(1):31-40.
[27] Stepanski EJ, Wyatt JK: Use of sleep hygiene in the treatment of insomnia. Sleep Med Rev 2003, 7(3):215-25.
[28] Buysse DJ, Cheng Y, Germain A, Moul DE, Franzen PL, Fletcher M, Monk TH: Night-to-night sleep variability in older adults with and without chronic insomnia. Sleep Med 2010, 11(1):56-64.
[29] Australia's Physical Activity and Sedentary Behaviour Guidelines [http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pubhlth-strateg-phys-act-guidelines#apaadult]. Accessed,5 April 2016
[30] Duncan M, Vandelanotte C, Kolt GS, Rosenkranz RR, Caperchione CM, George ES *et al*: Effectiveness of a Web- and Mobile Phone-Based Intervention to Promote Physical Activity and Healthy Eating in Middle-Aged Males: Randomized Controlled Trial of the ManUp Study. J Med Internet Res 2014, 16(6):e136.
[31] Guertler D, Vandelanotte C, Kirwan M, Duncan MJ: Engagement and nonusage attrition with a free physical activity promotion program: the case of 10,000 Steps Australia. Journal of medical Internet research 2015, 17(7):e176.
[32] Harkin B, Webb TL, Chang BP, Prestwich A, Conner M, Kellar I, Benn Y, Sheeran P: Does monitoring goal progress promote goal attainment? A meta-analysis of the experimental evidence. Psychol Bull 2016, 142(2):198.
[33] Zachariae R, Lyby MS, Ritterband LM, O'Toole MS: Efficacy of internet-delivered cognitive-behavioral therapy for insomnia – A systematic review and meta-analysis of randomized controlled trials. Sleep Med Rev 2016, 30:1-10.
[34] Relaxation techniques for stress relief [https://www.healthdirect.gov.au/relaxation-techniques-for-stress-relieve]. Accessed,01/04/2017
[35] Mindfulness in Everyday Life (wtih GP notes) [https://www.blackdoginstitute.org.au/docs/default-source/psychological-toolkit/7-mindfulnessineverydaylife-(with-gp-notes).pdf?sfvrsn=6]. Accessed,01/04/2017

[36] Mindfulness in Everyday Life [https://www.blackdoginstitute.org.au/docs/default-source/factsheets/mindfulnessineverdaylife.pdf?sfvrsn=6]. Accessed,01/04/2017
[37] Kline CE, Irish LA, Buysse DJ, Kravitz HM, Okun ML, Owens JF, Hall MH: Sleep hygiene behaviors among midlife women with insomnia or sleep-disordered breathing: the SWAN sleep study. J Women's Health 2014, 23(11):894-903.
[38] Backhaus J, Junghanns K, Broocks A, Riemann D, Hohagen F: Test–retest reliability and validity of the Pittsburgh Sleep Quality Index in primary insomnia. J Psychosom Res 2002, 53(3):737-40.
[39] Buysse DJ, Reynolds Iii CF, Monk TH, Berman SR, Kupfer DJ: The Pittsburgh sleep quality index: A new instrument for psychiatric practice and research. Psychiat Res 1989, 28(2):193-213.
[40] Timperio A, Salmon J, Crawford D: Validity and reliability of a physical activity recall instrument among overweight and non-overweight men and women. J Sci Med Sport 2003, 6(4):477-91.
[41] Reeves MM, Marshall AL, Owen N, Winkler EAH, Eakin EG: Measuring physical activity change in broad-reach intervention trials. J Phys Act Health 2010, 7.
[42] Short CE, James EL, Girgis A, D'Souza MI, Plotnikoff RC: Main outcomes of the Move More for Life Trial: a randomised controlled trial examining the effects of tailored-print and targeted-print materials for promoting physical activity among post-treatment breast cancer survivors. Psycho-Oncology 2015, 24(7):771-8.
[43] Bampton EA, Johnson ST, Vallance JK: Profiles of resistance training behavior and sedentary time among older adults: Associations with health-related quality of life and psychosocial health(). Prev Med Reports 2015, 2:773-6.
[44] Chau JY, van der Ploeg HP, Dunn S, Kurko J, Bauman AE: A tool for measuring workers' sitting time by domain: the Workforce Sitting Questionnaire. Brit J Sport Med 2011:bjsports-2011-090214.
[45] Prochaska JJ, Sung H-Y, Max W, Shi Y, Ong M: Validity Study of the K6 Scale as a Measure of Moderate Mental Distress based on Mental Health Treatment Need and Utilization. Int J Meth Psych Res 2012, 21(2):88-97.
[46] Henry JD, Crawford JR: The short-form version of the Depression Anxiety Stress Scales (DASS-21): Construct validity and normative data in a large non-clinical sample. Brit J Clin Psychol 2005, 44(2):227-39.
[47] Ware J, Kosinski M, Keller SD: A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. Med Care 1996, 34.
[48] Ware Jr JE, Sherbourne CD: The MOS 36-item short-form health survey (SF-36): I. Conceptual framework and item selection. Med Care 1992:473-83.
[49] Bradley KA, DeBenedetti AF, Volk RJ, Williams EC, Frank D, Kivlahan DR: AUDIT-C as a brief screen for alcohol misuse in primary care. Alcohol Clin Exp Res 2007, 31(7):1208-17.
[50] Mastin DF, Bryson J, Corwyn R: Assessment of Sleep Hygiene Using the Sleep Hygiene Index. J Behav Med 2006, 29(3):223-7.
[51] Espie CA, Kyle SD, Hames P, Gardani M, Fleming L, Cape J: The Sleep Condition Indicator: a clinical screening tool to evaluate insomnia disorder. BMJ Open 2014, 4(3):e004183.
[52] Morin CM, Belleville G, Bélanger L, Ivers H: The Insomnia Severity Index: psychometric indicators to detect insomnia cases and evaluate treatment response. Sleep 2011, 34(5):601-8.
[53] Monk T, Buysse D, Kennedy K, Potts J, DeGrazia J, Miewald J: Measuring sleep habits without using a diary: The sleep timing questionnaire (STQ). Sleep 2003, 26(2):208-12.

[54] Anderson MJ, Petros TV, Beckwith BE, Mitchell WW, Fritz S: Individual Differences in the Effect of Time of Day on Long-Term Memory Access. Am J Psychol 1991, 104(2):241-55.
[55] Brooke J: SUS-A quick and dirty usability scale, vol. 189. Great Britain: Taylor & Francis; 1996.
[56] Vandelanotte C, Short C, Plotnikoff RC, Hooker C, Canoy D, Rebar A *et al*: TaylorActive--Examining the effectiveness of web-based personally-tailored videos to increase physical activity: a randomised controlled trial protocol. BMC Public Health 2015, 15(1):1-14 p.
[57] Guertler D, Vandelanotte C, Kirwan M, Duncan MJ: Engagement and nonusage attrition with a free physical activity promotion program: The case of 10,000 Steps Australia. J Med Internet Res 2015, 17(7).
[58] Kolt GS, Rosenkranz RR, Savage TN, Maeder AJ, Vandelanotte C, Duncan MJ *et al*: WALK 2.0-using Web 2.0 applications to promote health-related physical activity: a randomised controlled trial protocol. BMC Public Health 2013, 13(1):1.
[59] Cheng SK, Dizon J: Computerised cognitive behavioural therapy for insomnia: a systematic review and meta-analysis. Psychotherapy and psychosomatics 2012, 81(4):206-16.
[60] Kredlow MA, Capozzoli MC, Hearon BA, Calkins AW, Otto MW: The effects of physical activity on sleep: a meta-analytic review. J Behav Med 2015, 38(3):427-49.
[61] Ritterband LM, Thorndike FP, Ingersoll KS, et al.: Effect of a web-based cognitive behavior therapy for insomnia intervention with 1-year follow-up: A randomized clinical trial. JAMA Psychiatry 2017, 74(1):68-75.
[62] Imai K, Keele L, Tingley D: A general approach to causal mediation analysis. Psychol Methods 2010, 15(4):309.
[63] Hayes AF, Preacher KJ: Statistical mediation analysis with a multicategorical independent variable. Brit J Math Stat Psy 2014, 67(3):451-70.
[64] Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals [www.icmje.org].
[65] Cappuccio FP, D'Elia L, Strazzullo P, Miller MA: Quantity and quality of sleep and incidence of type 2 diabetes: a systematic review and meta-analysis. Diabetes care 2010, 33(2):414-20.
[66] Marshall AL, Leslie ER, Bauman AE, Marcus BH, Owen N: Print versus website physical activity programs: A randomized trial. Am J Prev Med 2003, 25(2):88-94.
[67] Kline CE: The bidirectional relationship between exercise and sleep: Implications for exercise adherence and sleep improvement. Am J Lifestyle Med 2014, 8(6):375-9.
[68] Buman MP, King AC: Exercise as a Treatment to Enhance Sleep. Am J Lifestyle Med 2010, 4(6):500-14.
[69] Young T, Evans L, Finn L, Palta M: Estimation of the clinically diagnosed proportion of sleep apnea syndrome in middle-aged men and women. Sleep 1997, 20(9):705-6.
[70] Mammen G, Faulkner G: Physical Activity and the Prevention of Depression: A Systematic Review of Prospective Studies. Am J Prev Med 2013, 45(5):649-57.
[71] Magee CA, Caputi P, Iverson DC: Relationships between self-rated health, quality of life and sleep duration in middle aged and elderly Australians. Sleep Med 2011, 12(4):346-50.
[72] Davies CA, Vandelanotte C, Duncan MJ, van Uffelen JGZ: Associations of physical activity and screen-time on health related quality of life in adults. Prev Med 2012, 55(1):46-9.
[73] Kohl LF, Crutzen R, de Vries NK: Online prevention aimed at lifestyle behaviors: a systematic review of reviews. J Med Internet Res 2013, 15(7):e146.
[74] Michie S, Prestwich A: Are interventions theory-based? Development of a theory coding scheme. Health Psychol 2010, 29(1):1.

[75] Rayward AT, Burton NW, Brown WJ, Holliday EG, Plotnikoff RC, Duncan MJ: Associations between Changes in Activity and Sleep Quality and Duration over Two Years. Medicine and science in sports and exercise 2018.
[76] Rubio-Arias JÁ, Marín-Cascales E, Ramos-Campo DJ, Hernandez AV, Pérez-López FR: Effect of exercise on sleep quality and insomnia in middle-aged women: a systematic review and meta-analysis of randomized controlled trials. Maturitas 2017, 100:49-56.
[77] Chennaoui M, Arnal PJ, Sauvet F, Leger D: Sleep and exercise: a reciprocal issue? Sleep Med Rev 2015, 20:59-72.

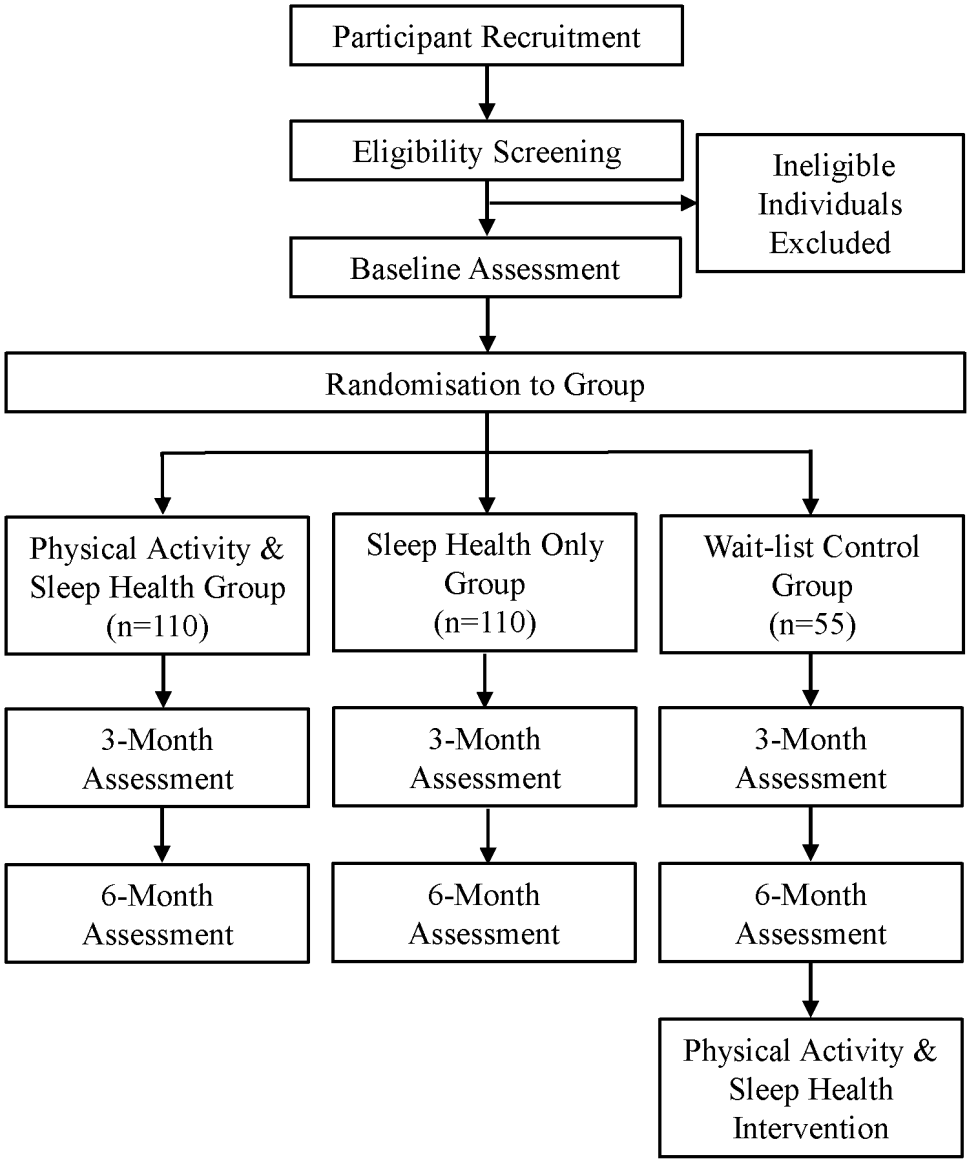

Figure 1. Flow of participants through the Refresh Study

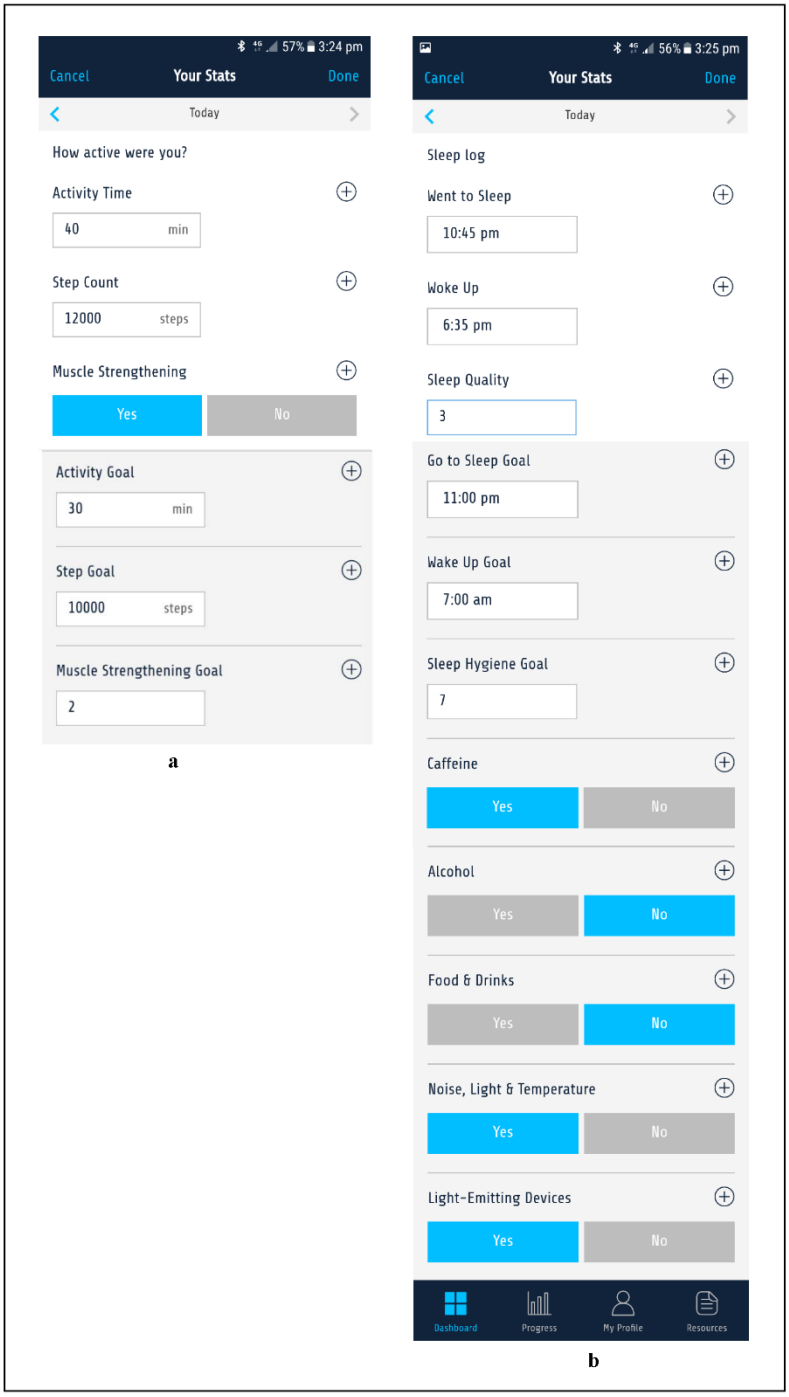

Figure 2.

a. Screenshot of Balanced Your Stats for Activity showing data entry option for daily behaviour and goals.

b. Screenshot of Balanced Your Stats for Sleep showing data entry options for nightly sleep behaviours and a sample of sleep hygiene options (screen extended).

Figure 3

a. Screenshot of the Balanced Dashboard displaying green and orange feedback on Activity and Sleep tiles for the Physical Activity and Sleep Health group.

b. Screenshot of the Balanced Dashboard displaying red feedback on the Sleep tile for the Sleep Health Only group.

Figure 4

a. Daily progress summary for sleeping time. b Weekly progress summary for sleeping time. c. Three-month progress summary for sleeping time d. Three-month progress summary for sleep and wake times.