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STUDY PROTOCOL: IMPROVING ADULTS PHYSICAL ACTIVITY AND SLEEP

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Title

A randomised controlled trial using a theory-based m-health intervention to improve physical activity and sleep health in adults: The Synergy Study protocol.

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ABSTRACT

Introduction To decrease chronic disease rates, there is a need to reduce physical inactivity and poor sleep health in the adult population. Given the high prevalence of these unhealthy habits, behavioural interventions with potential for wide reach are needed.

Methods and Analysis The aims of the Synergy Study will be to test the effect of a 3-month personalised mobile app intervention on two main outcomes: minutes of moderate-to-vigorous physical activity and overall sleep quality. In addition, between-group changes in health-related quality of life and mental health status will be assessed as secondary outcomes. The pre-specified mediators and moderators include social cognitive factors, the neighbourhood environment, health (BMI, depression, anxiety, stress) and sociodemographic factors (age, gender, education). Assessments will be conducted after 3 months (primary endpoint) and 6 months (follow-up). The intervention will provide access to a specifically developed mobile app, through which participants can set goals for active minutes, daily step counts, resistance training, sleep times and sleep hygiene practice. The app also allows participants to log their behaviours daily and view progress bars as well as instant feedback in relation to goals. The personalised support system will consist of weekly summary reports, educational and instructional materials, prompts upon disengagement and weekly facts.

Ethics and dissemination The Human Research Ethics Committee of The University of Newcastle, Australia granted full approval: H-2016-0181. This study will assess the efficacy of a combined behaviour intervention, mechanisms of behaviour change and gather high-quality process data, all of which will help refine future trials. Dissemination of findings will include publication in a peer-reviewed journal and presentation at national or international conferences. Participants will receive a plain English summary report of results.

Keywords physical activity, sleep health, behaviour change, m-health, e-health, smartphone, app, intervention, adults, study protocol

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BACKGROUND

Engaging in sufficient physical activity and maintaining good sleep health are two lifestyle behaviours that significantly reduce the risk of all-cause mortality,[1 2] cardiovascular disease,[3 4] and type-2-diabetes.[5 6] *Sufficient physical activity* is the accumulation of at least 150 minutes of moderate-intensity or 75 minutes of vigorous-intensity physical activity per week.[7] *Good sleep health* is characterised by duration, quality and timing of sleep that leaves a person satisfied with their sleep and alert during the day.[8] Internationally, up to 32% of adults are insufficiently physically active,[9] and up to 29% report sleeping <6 hours,[10] 24% report poor quality sleep,[11] and >50% report inconsistent bed and wake times, the latter of which are indicators of poor sleep health.[12] There is no global estimate of the percentage of adults who report both, insufficient physical activity and poor sleep health. However, evidence suggests that individuals with poor sleep health also report lower levels of physical activity.[13 14] Thus, interventions which target both behaviours have the potential to make meaningful contributions to public health.

Multiple lifestyle behaviour interventions produce greater reductions in the risk of poor health than interventions that target a single behaviour.[15] Moreover, physical activity and sleep have a bidirectional relationship,[16] in which physical activity improves indicators of sleep health (e.g., sleep quality) and good sleep health is associated with greater levels of physical activity.[17] Interventions targeting both behaviours simultaneously may capitalise on this reciprocal relationship to produce larger increases in both behaviours.[18] Previous reviews of multiple behaviour interventions however, have not identified any studies that specifically target changes in both physical activity and sleep health and tested the efficacy of this approach in a randomised controlled trial.[19-21]

Non-pharmacological sleep interventions (e.g., Cognitive Behavioural Therapy for Insomnia) frequently promote sleep hygiene,[22] using a set of self-regulatory strategies that help to promote good sleep health, but details of behaviour change techniques (BCT) to support changes in sleep hygiene behaviours, such as regular physical activity or stress management, are usually not reported.[23 24] Without providing the necessary guidance to promote behaviour change, it is unlikely that such education-only interventions are likely to change behaviour, as education-only interventions are known to be less effective than those that are combined with additional self-regulation strategies.[25] Furthermore, multiple health behaviour change interventions need to implement BCT that are specific to each behaviour to produce greater changes in targeted behaviours.[26] Interventions targeting physical activity and sleep in combination therefore need to provide behaviour-specific intervention strategies to maximise change and harness the potentially synergistic effects between physical activity and sleep.

Reviews of the evidence suggest theory-based interventions are more effective in changing behaviour than interventions that do not use a theoretical approach.[27] Theoretical models provide important guidance for the development of behaviour change interventions, aiming for the uniform operationalisation of cognitive and behavioural determinants. Social Cognitive Theory (SCT) is one of the most widely used theories in health behaviour research.[28] It aids the conceptual understanding of behaviour change, as it accounts for the interactions between individual and environmental processes that either facilitate or impede behaviour change[29]. This is particularly relevant when targeting both, physical activity and sleep health, since individual as well as environmental factors are known to influence both behaviours.[30 31] SCT has guided the development of numerous physical activity interventions and its constructs are strongly associated with physical activity.[31 32] However, there is limited understanding of these social cognitive factors in relation to sleep health.[30]

Due to the high prevalence of people who report either being insufficiently active or meeting indicators of poor sleep health, there is a need for broad reaching interventions. Because smartphone ownership is growing steadily, with approximately 80% of the population owning a device,[33] intervention delivery entailing this medium is likely to be accessible, affordable and conveniently integrated into daily life.

This study aims to test: (1) the efficacy of an app-based intervention to improve physical activity and sleep quality (as primary outcomes) and health-related quality of life and mental health status (as secondary study outcomes), relative to a waitlist control; (2) the mediating role of social cognitive factors and app usage in behaviour change; and (3) health (BMI, depression, anxiety, stress), sociodemographic factors (age, gender, education) and the neighbourhood environment as potential moderators of intervention efficacy.

METHODS

This trial was registered prospectively on the Australian New Zealand Clinical Trials Registry (ANZCTR Registration Number: ACTRN12617000376347; Universal Trial Number: U1111-1186-6588). The conduct and reporting of the trial will follow CONSORT guidelines[34], and the CONSORT-EHEALTH checklist.[35] Full ethical approval was obtained from the Human Research Ethics Committee of The University of Newcastle, Australia (Approval Number: H-2016-0181).

Study design

A two-arm randomised controlled trial with a combined physical activity and sleep intervention and a waitlist control group, with assessments conducted at 0 (baseline), 3 months (primary endpoint) and 6 months (follow-up).

Recruitment

Digital and print-based advertising will be used to recruit nationwide in Australia. Recruitment for both intervention arms commenced in May 2017 and will conclude once sample size requirements are achieved (n = 160, refer to power and sample size section). Social media advertising will be used to recruit in social media networks (e.g., Twitter, Facebook) using target audiences that broadly match inclusion criteria (i.e., age). Electronic and print-based advertising will include magazines and newspapers with state-wide reach. All recruitment materials will provide contact details and a link to the consent form and eligibility survey. Due to the remote delivery of the intervention in combination with self-report based assessments, participants will not be required to visit the research centre.

Exclusion criteria

Individuals who meet any of the following criteria will not be eligible to participate:

- not residing in Australia;
- not being between 18 and 55 years old;
- reporting a height and weight that is not consistent with a BMI between 18.5 and 35;
- accumulating more than 90 minutes of moderate/vigorous physical activity per week;
- rating their sleep-quality (over the past month) as *fairly good* or *very good*;
- currently pregnant or having given birth in the past 12 months;
- having a condition that would make it unsafe or limits their ability to increase activity levels or change sleep behaviours;

- having a diagnosed sleep disorder (chronic insomnia, sleep apnoea, sleepwalking, narcolepsy, restless legs syndrome, etc.);
- currently consuming hypnotics (sleep inducing medication);
- being employed in any night shift work;
- planning frequent travel (once a month or more often) to a destination with a shift in time zone by more than three hours during the intervention period;
- currently using a self-monitoring system or device to track or log physical activity or sleep (this includes non-device assisted applications); and
- not having access to an internet-enabled iOS (Apple) or Android smartphone or tablet.

Study procedure

Eligible participants will be contacted via Email and welcomed into the study. Participants will be asked to complete online surveys assessing primary and secondary outcomes, potential mediators/moderators and socio-demographics at three time points. Figure 1 illustrates the flow of participants throughout the trial.

All online surveys will be administered using Qualtrics® (Provo, Utah). If specified screening criteria are not met, participants will be advised via text displayed at the end of their survey and further contact will only be made where ambiguous responses require clarification. Ineligible participants will also receive a link providing free and unlimited access to the public version of the Balanced app.[36]

Participants will receive an Email with a unique password-protected link (URL) to their survey at each assessment point. Each person who has completed their baseline survey will be randomly allocated to one of two groups. Participants allocated to the intervention group

will be mailed a pedometer, tool sheets, login details and instructions for download and installation of the *"Balanced"* smartphone app in the form of a participant handbook. The initial *"Balanced"* app was specifically developed for scientific purposes and is described in more detail elsewhere.[36] As part of the modifications to the previous app, the physical activity component of the app was revised to include daily steps and resistance training in addition to moderate-to-vigorous intensity physical activity; and sleep hygiene in addition to sleep times and sleep quality. Regular app use is supported by an Email and text message-based support system (see Table 1), which is initiated as soon as a participant has gained access to the app. All messaging will follow a standardised protocol that was designed under consideration of the specificity, timeliness and relevance of contents (see Table 1), as those are valued components in mobile apps designed to change health behaviours.[37] Following completion of their 3-month assessment, participants may continue to use the app as much or as little as they like, but the message-based support will no longer be provided.

Table 1.
Overview and content of message-based support service

Delivery	Content	Frequency		
		weekly	monthly	as required
Email	General communication, survey reminders, notifications (eligibility, group allocation)			x
	Personalised weekly summary	x		
	Tool sheets (sent separately at weeks 3, 6 and 9)		x	
	App usage reminder (Condition: if 3 consecutive SMS prompts were unsuccessful in motivating participants to re-engage), only if applicable	x		
SMS	Fact of the week	x		
	Usage prompt (Condition: if non-usage occurred on at least 4/7 days per week)	x		
App-based Prompts	If enabled, a daily on-screen notification prompts participants to log data, if app has not been used to self-monitor behaviour in >24h			x

Note. The message-based support system will be delivered for the first 12 weeks of the intervention only.

Intervention

The intervention is composed of app and non-app components, with non-app components referring to any content of the intervention that is delivered via participant handbook, text message or Email.

App components consist of educational resources, self-monitoring, goal-setting and feedback. Participants will have continuous access to the app throughout the intervention period. For the first 3 months, which is the time between baseline and the primary endpoint, these components will be complemented by a messaging system providing personalised feedback on progress towards goals, prompting goal review and prompting practice of the target behaviours. The messaging component will cease at the 3-month assessment, but participants will have continued access to the app. Following completion of the study, participants will be able to continue to access and use the app for an indefinite period, however will not be required to complete any further assessments as part of this study. The app will be available on both, Android and Apple based operating systems. Table 2 provides an overview of intervention strategies used to operationalise the social cognitive constructs in the intervention.

Educational resources

App resources will consist of educational information about the importance of the two behaviours, basic instructions on how to change each behaviour and guidance for app use (e.g., how to interpret traffic lights and progress graphs). Educational content will provide participants with knowledge on the health benefits of each behaviour, the current national guidelines for physical activity and sleep and the importance of resistance training and incidental physical activity in addition to aerobic exercise, as well as the importance of all

dimensions of sleep health (i.e., sleep duration, sleep quality, sleep timing). Educational content will consist of a comprehensive range of stimulus control and sleep hygiene recommendations based on summaries of the evidence.[22] In addition to app content, participants will receive a total of three tool sheets (enclosed in the handbook), one tool sheet including goal-setting strategies,[38] for each behaviour (one for physical activity, and one for sleep), one that emphases action planning (again, one for each behaviour) and one tool sheet with information and instructions adapted from publicly available resources for the practice of stress management techniques (i.e., progressive muscle relaxation, deep breathing and mindfulness).[39-41] All tool sheets will be distributed along with the participant handbook at outset (participants in the intervention group will receive their materials following completion of their baseline assessment and waitlist controls will receive an identical package following their 6-month assessment). In addition, during each month of the intervention, one tool will be promoted (via Email) to encourage utilisation of these resources (goal-setting at week 3, followed by action planning at week 6 and stress management at week 9). Individuals are instructed to set goals that are personally relevant and meaningful to them, but the goal-setting information provided will advise participants that their overarching goal should be to gradually progress towards achieving the recommended minimum of 150 minutes of moderate-intensity physical activity per week,[7] and sleeping between 7 and 9 hours per night.[42] Furthermore, participants will receive a weekly text message containing 1 of 12 educational and motivational facts relating to physical activity and sleep for better health (i.e., the consequences of poor sleep health). Each factoid message will also refer to the resources section available in the app and encourage people to use it.

Self-monitoring

Participants will be asked to recall minutes of moderate to vigorous physical activity, and participation in resistance training, and manually enter this into the app every day. Daily steps will be objectively measured using the pedometer (Yamax SW200) provided and manually entered by participants into the app. Participants will not be asked to return their pedometer.

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Table 2.
Operationalisation of social cognitive factors and behaviour change strategies

SCT constructs	BCT[1]	Components	Description of intervention components
Self-efficacy	▪ Graded tasks ▪ Self-monitoring ▪ Goal review ▪ Feedback on performance ▪ Praise/rewards ▪ Relapse prevention/ coping ▪ Barrier identification/ problem solving ▪ Stress management	App log	Participants will be asked to recall and enter their activity and sleep behaviours. The daily log will allow entries for active minutes, daily steps, resistance training sessions, sleep and wake times, a sleep quality rating, as well a checklist of 10 sleep hygiene goals. Participants will be asked to tick off those sleep hygiene goals they implemented the previous day.
		App progress charts	Bar charts will provide a history for daily, weekly and 3-month progress in relation to goals per behaviour (for each of the items data are logged for).
		App dashboard traffic light	The activity dashboard produces a traffic light colour relating to total active minutes, while the colour of the sleep dashboard relates to total sleep duration. Goals can be adjusted at any time, which will determine the colours on the dashboard traffic light. This is dynamically updated as soon as a self-monitoring entry is made: 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.
		Tool sheets	A series of tool sheets delivered at weeks 3, 6, and 9 will promote goal-setting and action planning and give detailed guidance on how to set SMART goals and follow through with an action plan in the face of barriers (i.e., by being prepared).
		Weekly summary (Email)	This support feature will provide an overview of weekly totals and averages per behaviour (if sufficient data are available) and prompt participants to review goals, if needed.
		Prompts (SMS)	If participants fail to log any data on more than 4 days per week, they will receive a message prompting them to resume logging.
Behavioural capability	▪ Information on where and when to be active/engage in in sleep promoting behaviours ▪ Instructions on how to be active and engage in sleep promoting behaviours	App resources	The resources section will provide the current national guidelines on how much physical activity per week and how much sleep (hours) per night adults need. This section also includes brief content on the when, the where, who with and how of being active and sleeping well (e.g., sleep hygiene practices).
		Weekly facts (SMS)	Each week, participants will receive a short text message with educational content on activity and/or sleep and health to reinforce the importance of both behaviours.
		Tool sheets	Tool sheets provide more detailed information that enable a person to make positive changes to their physical activity and sleep levels and include action plan templates and examples of exercises. These materials will also include stress management techniques, such as PMR and controlled breathing.

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Outcome expectations/ expectancies	▪ Information about the behaviour in relation to health	Tool sheets	As part of the goal-setting tool sheet, participants will be asked to think about the reasons for wishing to improve their health behaviours and what they anticipate as personal benefits, following improved levels of activity and sleep (examples will be provided).
		App resources	This section will include information on why activity and sleep are important and how they contribute to health and wellbeing.
		App log personal goals	Participants will be asked to personalise their goals, but work towards recommended minima (150 MVPA/week; 7-9h sleep/night); goals are carried forward from previous entries unless adjusted
Intentions/goals	▪ Goal-setting ▪ Action Planning ▪ Self-monitoring ▪ Prompt practice ▪ Time Management ▪ Teach use of prompts ▪ Time management	App dashboard traffic light	Participants will be encouraged to put equal effort into improving both PA and sleep. This means 2 amber lights are better than one green and one red light.
		Tool sheets	Participants will receive goal-setting strategies and example action plans for guidance (per behaviour) as part of the tool sheets described above. One of 3 tools will be promoted specifically via Email at week 3, 6 and 9, respectively.
		Reminders	Participants are advised to set a daily bedtime reminder (optional) on their phone, which is intended to prompt a person's bedtime routine and will promote regular bed times.
		App resources	Environmental restructuring as part of good SH will be highlighted in the resource section and include details on *how to* manage the bedroom environment. Also includes information on activity & sleep in the social context and seeking support from those in the same household (housemates, partner, family members).
Sociostructural factors (social support & environment)	▪ Use of prompts ▪ Environmental restructuring ▪ Barrier identification ▪ Plan social support	Tool sheets	This will include short examples on how to identify and manage barriers around being active and getting good sleep and how to utilise one's social support and environment in favour of activity and sleep.

Note. [1]Behaviour changes techniques were specified in accordance with the 40-item taxonomy of behaviour change techniques by Michie et al.[43]; MVPA = moderate-to-vigorous intensity physical activity; PA = physical activity; PMR = progressive muscle relaxation; SH = sleep hygiene;

Self-monitoring of sleep in the app will also be manually entered by participants. The sleep log consists of: *bedtime* (time of going to sleep), *wake time* (time of waking) and *sleep quality* (rating scale from 0 to 5 where 5 indicates high sleep quality). As an additional feature, this section of the app allows participants to log which sleep hygiene behaviours they practiced the previous day (Figure 2). These include consumption of caffeine, alcohol, nicotine, excessive intake of fluids or heavy meals before bedtime, regulation of the impact of light, noise and temperature in the bedroom, use of light-emitting devices, regular exercise, maintenance of consistent sleep and wake times, having and following a bedtime routine, creating comfort (e.g., proper pyjamas and bedding) and managing stress.[22] Participants can self-monitor these behaviours at any time of the day and update this information as many times per day as they prefer.

Self-regulation

App feedback on behaviour will be provided using graphical displays of logged behaviour in relation to the goals set by the participant (Figure 3). Two types of graphical feedback are provided. There will be separate graphs for moderate-to-vigorous intensity physical activity, steps, resistance training, sleep duration, sleep quality, sleep timing and sleep hygiene. This information will provide a breakdown in the form of daily, 1-week and 3-month bar charts. The second graphical feedback to participants is via the dashboard which changes to one of three colours - green, orange and red in a traffic light system - to provide immediate feedback on participants' behaviour to in relation their goals on a daily basis (Figure 3). The comparison of actual behaviour to goals based on a percentage of the goal achieved allows the use of consistent criteria across behaviours. This differs to the traffic light system originally used in Balanced, since process data from that study alluded to participants preferring to see this feedback based on goals rather than guidelines for each behaviour.[36]

As part of the goal review strategies, participants will be encouraged to evaluate their achievements in relation to goals and adjust their goals whenever needed. This will be facilitated by a personalised weekly summary of the previous week, delivered via Email, so that any reviews and adjustments of goals align with the most recent progress and foster self-efficacy. If a participant has logged data on less than 4 days per week (per behaviour), a text message will be sent to prompt practice.

Waitlist control group

Upon enrolment and allocation, the waitlist control group will not receive any intervention materials and only be required to complete their baseline, 3-month and 6-month assessments. After the 6-month assessment is completed, participants in this group will receive full access to the intervention.

Randomisation

Participants will be randomly allocated to 2 groups (intervention or control) after having completed their baseline assessment. Opaque sealed envelopes (n = 80 per group) will be prepared by BM using permuted block randomization with block sizes of 4 and 8, following the procedures suggested by Doig et al.[44] Once a participant has completed their baseline assessment, a researcher not associated with the study who is responsible for group allocation will open the envelope that is next in sequence and inform the project leader about the allocation outcome. Participants will be informed by the project leader and be sent a package containing study materials (i.e., handbook and pedometer), if they have been allocated to the intervention group (participants in the waitlist control group will receive their study materials after completing their 6-month assessment). The only exception for contravention with the

allocation sequence will be made if family members or couples living in the same household enrol in the study, which would pose a high risk of contamination, especially between groups. For this reason, all individuals who are identified as members of the same household will be allocated to the same group. Neither the trial participants, nor the project lead (BM) will be blinded to group assignment.

Outcome measures

All measures will be assessed via online survey at baseline, 3 months, and 6 months, except for socio-demographics which will only be collected at baseline. The 3-month survey will further include process evaluation items that measure system usability and participant satisfaction (intervention group only). The two primary outcomes will be total minutes of moderate-to-vigorous physical activity and sleep quality. To increase adherence to scheduled assessments, participants who complete their survey will be entered into a draw for 1 of 5 $50 shopping vouchers. This information will not be provided prior to enrolment and is not intended to function as an incentive for individuals to sign up to participate, but merely to promote adherence to assessment requirements. Table 3 provides a summary of outcome measures and assessment time points. All online surveys will be pilot-tested and locked prior to study commencement to prevent any changes from being made once the study is underway. All survey forms will be hosted on Qualtrics®.

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Table 3.
Overview of outcome measures and assessment time points

Variables	Measure	Instrument	Time point of assessment		
			Baseline	3 months	6 months
Primary outcomes	Minutes of moderate- and vigorous intensity physical activity (last week)	The Active Australia Questionnaire (AAQ)	x	x	x
	Overall sleep quality (past 30 days)	The Pittsburgh Sleep Quality Index (PSQI)	x	x	x
Secondary outcomes	Health-related quality of life	The RAND-12 plus 3 items assessing energy/fatigue (RAND-36)	x	x	x
	Depression, Anxiety, Stress	The DASS-21	x	x	x
	Resistance training	Number of sessions per week and duration per session	x	x	x
	Sitting behaviour	The Workforce Sitting Questionnaire	x	x	x
	Sleep timing	The Sleep Timing Questionnaire	x	x	x
	Insomnia symptom severity	The Insomnia Severity Index (ISI)	x	x	x
	Daytime sleepiness	The Epworth Sleepiness Scale (ESS)	x	x	x
Process evaluation items (intervention group only)	Self-efficacy using a mobile app	The Internet Self-Efficacy Scale		x	
	User satisfaction	The Cognitive-Affective Model of Perceived User Satisfaction (CAMPUS)		x	
	App usage & engagement	The Balanced App database	Continuous recording		
	App usability	The System Usability Scale		x	
	Utility, advice acceptability & relevance	Semi-structured telephone interviews		x	
Sample characteristics	Demographics	Age, gender, height, weight, chronic disease status	x		
	Socioeconomic factors	Education, income, marital status, occupation, working hours	x		
	Morningness-Eveningness	The Morningness-Eveningness Questionnaire (MEQ)	x		
Moderators/ Mediators	Sleep hygiene behaviours	The Sleep Hygiene index (SHI)	x	x	x
	Environment	Perceived Neighbourhood Disorder	x	x	x
	Social cognitive factors	Social cognitive factors relating to physical activity Social cognitive factors relating to sleep hygiene behaviour	x	x	x
	Habit	The Automaticity Scale	x	x	x
	App usage & engagement	The Balanced App database	Continuous recording		

Primary outcomes

Physical activity

The Active Australia Questionnaire (AAQ has demonstrated acceptable reliability),[45 46] is sensitive to change in interventions,[47] and provides a measure of both the frequency and duration of moderate- and vigorous-intensity physical activity during the last week. This includes the total time spent in recreational walking and transport, moderate-intensity physical activity (e.g., swimming, golfing), aerobic activity (e.g., cycling, jogging) and vigorous gardening or yard work. Total minutes of moderate- and vigorous-intensity physical activity will be created by summing minutes of walking, moderate and vigorous (weighted by 2) intensity physical activity.

Sleep quality

The Pittsburgh Sleep Quality Index (PSQI) consists of 19 items and 7 component scores with scores ranging from 0 to 21.[48] Items refer to sleep disturbances over the last 30 days and higher scores indicate poorer sleep quality and a score above 5 is commonly used to indicate poor sleep quality. The current study will use the PSQI as a continuous score. The PSQI is the most frequently used self-report instrument in sleep research.[49-51] The PSQI has demonstrated good reliability ($\alpha = 0.83$), is sensitive to change and has strong psychometric properties.[48 52] All of the 7 component scores (e.g., sleep efficiency and total sleep duration) will be reported in addition to the total score.

Secondary outcomes

Health-related quality of life

Poor sleep quality and inadequate sleep duration are independently associated with low health-related quality of life.[53] The RAND-12 is a reliable and widely used instrument that

assesses multiple concepts of health such as physical functioning, role limitations due to physical and emotional problems, social functioning, emotional wellbeing, energy/fatigue, pain as well as general perceptions of health. In addition to the RAND-12 scale, 3 additional items that make up the energy/fatigue subscale in the 36-item version of the RAND will be asked, so that this domain can be evaluated separately. This will allow improvements in energy and fatigue during the course of the intervention to be assessed.

Depression, anxiety, and stress

The effect of changes in physical activity and sleep on participants' severity of depression, anxiety and stress symptoms will be assessed using the Depression-Anxiety-Stress Scale (DASS-21). The DASS-21 is reported to have satisfactory levels of internal consistency for its total scale (r = 0.93) as well as for its individual scales for depression (r = 0.88), anxiety (r = 0.82) and stress (r = 0.90).[54] In addition, DASS-21 scores will be examined as a potential moderator of intervention efficacy.

Resistance training

Since the AAQ does not capture resistance training and because the Synergy Study will promote regular resistance training, the number and duration of resistance training sessions per week will be assessed using two items adapted from previous studies that assessed resistance training.[55] One item will ask participants: "In the last week, on how many days have you participated in muscle strengthening activities (including weight/resistance training)?" and "What do you estimate was the total time (in hours/minutes) that you spent doing muscle strengthening activities (incl. weight/resistance training) in the last week?" The original items were adapted by changing the recall period from the previous month to the last week to align with the recall period used in the AAQ.

Sitting time

The Workforce Sitting Questionnaire (WFSQ) will provide a self-report measure of total domain-specific sitting time (over the last week), on workdays and non-workdays.[56] Domains include sitting time accumulated at work, watching TV, using a computer, using transport and doing other leisure activities. The WFSQ captures sitting time across several domains with acceptable validity (r = 0.45) and reliability (ICC = 0.63). Possible reductions in total sitting time may be a result of increased amounts of time allocated to light/incidental or moderate-to-vigorous physical activity.[57]

Sleep timing

A modified version of the validated Sleep Timing Questionnaire will be used to assess the variability in sleep and wake times on working days as well as non-working days.[58] To minimise participant burden, the instrument used will only include items on the stability of *usual* bed and wake times, and the *usual* bed and wake times per se. Response options are categorical and scored on a scale from 1-11 with lower scores indicating less variability in bed or wake times (e.g., 1 = 0-15 min; 2 = 16-30 min; 11 = >4 hours).

Insomnia severity

The Insomnia Severity Index (ISI) is a valid and reliable instrument for measuring insomnia severity.[59] It can be used to classify individuals as having no insomnia (0-7), sub-threshold insomnia (8-14), moderate clinical insomnia (15-21) or severe clinical insomnia (22-28). This index will measure the proportion of the sample with potentially severe, yet undiagnosed insomnia symptoms.

Daytime sleepiness

Daytime sleepiness is a component of sleep health. It will be measured using the Epworth Sleepiness Scale (ESS), which assesses daytime sleepiness. This scale has demonstrated high internal consistency (Crohnbach's *alpha* = 0.88) and good reliability (*r* = 0.82). [60]

Process outcomes

Internet self-efficacy

Participants' confidence in using the smartphone app will be assessed using an adaptation of the Internet Self-Efficacy Scale to capture participants' overall understanding of app software, confidence in gathering information (educational resources) using the app and learning to use the app, as well as the ability to troubleshoot and resolve app problems.[61] Participants will rate their agreement with a total of eight statements on a seven-point scale from *strongly disagree* to *strongly agree*.

Perceived user satisfaction

The Cognitive-Affective Model of Perceived User Satisfaction (CAMPUS) will be used to ask participants about thoughts and feelings associated with using the mobile app (Balanced). A total of 23 items enquire about participant opinion on the effects and aesthetics as part of the app design (15 items), its effectiveness and efficiency (5 items) and the level of satisfaction experienced when using the app (3 items) with the following anchors: *frustrated – contented*, *unhappy – gratified* and *sad – joyful*. Items will be adapted to refer specifically to the Balanced app, for example "I would consider my experience with using the Balanced app as innovative". This instrument has demonstrated adequate levels of reliability and validity.[62]

App usage

Overall interaction with the app will be measured continuously throughout the study period by the app database, which records the time and date a self-monitoring entry was made and the actual value or response entered into the app. Analysis of usage patterns will include the number of self-monitoring entries made and the duration of self-monitoring throughout the intervention, similar to previous research.[63 64] These data will also be considered as a mediator of behaviour change in the intervention group.

Usability of the App

App usability will be assessed using the 10-item System Usability Scale,[65] a valid and reliable tool that assesses participant satisfaction relating to the utility of the websites on a 5-point scale (items will be reworded for smartphone app usability). Higher total scores (range 1-100) relate to better usability.

Utility, Advice Acceptability and Relevance of the App

A participant sub-sample (10%) will be determined by random selection for semi-structured telephone interviews, which will take place once all participants have completed their 6-month assessments. These interviews will contribute valuable information for process evaluation and include general personal feedback, desirable improvements and preferences relating to future use. As part of these interviews, participants will be asked about their perception of the app's usefulness to improve changes in self-efficacy levels (confidence) toward physical activity and sleep health, coping with potential impediments (barriers) to being more active and sleeping better, maintaining new routines/action plans and keeping it a priority to be more active and sleeping better. Finally, advice acceptability and relevance in terms of the content will be examined based on a previously used questionnaire.[66]

Mediators and moderators

Social Cognitive Factors

The testing of social cognitive factors as potential mediators of intervention efficacy may provide insights into some of the underlying mechanisms involved in behaviour change, as observed in previous behaviour change interventions.[67] Constructs from Social Cognitive Theory will be assessed based on items from previously developed scales, with separate items for each of the two behaviours relating to the person's projections towards their occurrence *over the next three months.* For each behaviour, items (as adapted from previous studies) will be probing the constructs of self-efficacy,[66 68] perceived behavioural capability,[69] outcome expectations and expectancies,[68 70] environment,[71] social support,[72] implementation intentions/goals,[73] and action planning.[73] Table 3 summarises, for physical activity and sleep hygiene behaviours, the number of items per construct and the response options for each item (See Table 4).

For physical activity, a total of 34 items will be used to assess the social cognitive factors. Items will be framed around the statement "Regular physical activity is defined as doing at least 150 minutes of moderate intensity physical activity each week. Moderate intensity can be described as any type of aerobic activity performed at a level where a person begins to lightly sweat, but can still carry on a conversation. This may feel different from one person to another." These items will be scored by using the sum of items per construct. For sleep, a total of 72 items will be used to assess the eight social cognitive factors. Each social cognitive item will be based on each of the following nine sleep hygiene behaviours: (1) avoiding caffeinated beverages (coffee, tea, energy drinks, etc.) in the late afternoon or right before bedtime, (2) avoiding nicotine right before bedtime, (3) avoiding alcohol right before

bedtime, (4) exercising regularly, (5) reducing stress levels, (6) reducing the impact of noise and nuisance in the bedroom, (7) keeping sleep and wake times consistent, (8) avoiding daytime naps and (9) avoiding the use of technological devices (e.g., phone, TV, laptop, etc.) right before bedtime or in bed. To avoid overburdening participants, each construct will be assessed using a single item per sleep hygiene behaviour (nine in total). Thus, each social cognitive construct will have nine items. For example, the self-efficacy construct will be assessed by participants indicating their self-efficacy to perform each of the nine sleep hygiene behaviours. Each construct will be scored as the sum of the nine sleep hygiene items; however, the environment construct will not be included for sleep hygiene behaviours, as this is already captured as part of the perceived neighbourhood disorder questionnaire.

Table 4.
Social cognitive factors related to physical activity and sleep hygiene behaviours

Construct	Items	Response anchors
Physical Activity		
Self-efficacy	10	(1) not at all confident (5) extremely confident
Perceived behavioural capability	3	(1) never (5) always
Outcome expectations	5	(1) strongly disagree (7) strongly agree
Outcome expectancies	5	(1) not at all important (4) extremely important
Environment	3	(1) strongly disagree (5) strongly agree
Social support	2	(1) strongly disagree (5) strongly agree
Implementation intentions (goals)	2	(1) no, not really (7) strongly intend; and (1) not at all motivated (7) extremely motivated
Action planning	4	(1) no detailed plans (7) detailed plans
Sleep Hygiene Behaviours (k = 9)		
Self-efficacy	9	(1) not at all confident

		(5) extremely confident
Perceived behavioural capability	9	(1) never (5) always
Outcome expectations	9	(1) strongly disagree (7) strongly agree
Outcome expectancies	9	(1) not at all important (4) extremely important
Environment	9	(1) strongly disagree (5) strongly agree
Social support	9	(1) strongly disagree (5) strongly agree
Implementation intentions	9	(1) no, not really (7) strongly intend and
Action planning	9	(1) no detailed plans (7) detailed plans

Note. Each item per construct will refer to one of nine different sleep hygiene behaviours

Automaticity

Habits relating to lifestyle behaviours are non-conscious processes, which can act as determinants of behaviour and may even regulate behaviour independently of changes in conscious processes such as intention.[74] The role that behavioural automaticity plays in the context of physical activity and sleep behaviours, respectively, will be taken into account using 1 item from the Automaticity Index per sleep hygiene behaviour (9 items),[75] and all 4 items of the index relating to physical activity (13 items in total), for example: "Reducing the impact of noise in my bedroom is something *I do automatically*.", "Exercise is something I do without thinking.".

Sleep hygiene

Sleep hygiene will be assessed to measure changes in in sleep hygiene behaviour using the 13-item Sleep Hygiene Index (SHI) developed by Mastin et al.[76] Higher global scores indicate poorer sleep hygiene behaviour, but there is no cut-off to label categories of sleep hygiene engagement. This instrument demonstrates acceptable internal consistency ($\alpha =$

0.66) and test-retest reliability ($r = 0.71$, $p < 0.01$).[76] Importantly, the SHI shows positive correlations ($r = 0.48$) with both, the global scores ($p < 0.01$) and the component scores ($p < 0.05$ or less) of the Pittsburgh Sleep Quality Index.[76] Items are answered using a 5-point Likert scale from *never* (0) to *always* (4).

Environment

Perceptions about the order or disorder within a person's physical and/or social environment (i.e., neighbourhood peacefulness, safety, cleanliness) can have a significant influence on physical activity levels and the quality and duration of sleep.[77-79] A person's neighbourhood environment can also negatively affect mental health and participation in other health behaviours.[80] Based on an existing scale of neighbourhood disorder, which demonstrated good levels of construct validity and internal consistency/reliability,[81] 4 items will assess each of the following characteristics of neighbourhood disorder: *physical disorder* and *physical order, social disorder* and *social order*. These are assessed using the following items: (1) "My neighbourhood is noisy", (2) "My neighbourhood is clean", (3), "There is a lot of crime in my neighbourhood" and (4) "My neighbourhood is safe" These items will be answered on a 5-point scale from strongly disagree (1) to strongly agree (5) and the average responses across the four items will be calculated.

Sample characteristics

A range of demographic and socioeconomic factors such as age, gender, height and weight, education, income, marital status, occupation, working hours, etc. will be assessed. Participants will be asked to also indicate (allowing multiple selection) whether they have been told by a doctor that they have any of the following chronic diseases: arthritis, asthma, cancer, cerebrovascular disease (stroke), chronic obstructive pulmonary disease

(emphysema), coronary heart disease (heart attack, angina), type-1 diabetes, type-2 diabetes, high blood pressure, kidney disease, mental illness (depression, anxiety, etc.), osteoporosis, irritable bowel syndrome, high cholesterol, or any other disease (to be specified by the participant). In addition, participants will be assessed for *morningness* or *eveningness* type,[82] as eveningness types are thought to be more prone to engage in activities that cause social jetlag, due to misalignments between times of sleep and times of social activity.[83]

Power and sample size

Meta-analyses of physical activity interventions typically report small to moderate increases in physical activity (Cohen's $d = 0.14 – 0.68$).[84 85] Moreover, poor sleep health, specifically the duration or quality of sleep, has small to moderate magnitude associations with lower physical activity levels.[86] Meta-analyses of non-pharmacological sleep interventions report small to medium effect sizes for changes in sleep quality (Hedge's $g = 0.35$ and Cohen's $d = 0.41$) in clinical populations,[87 88] and medium to large effect sizes ($d = 0.74$) in studies using exercise to improve sleep.[89] Therefore, based on these observations and feasibility data from the combined intervention,[36] it was assumed that a 3-month combined physical activity and sleep intervention that specifically targets both behaviours and leverages the bi-directional relationship between behaviours is likely to produce moderate increases in physical activity ($d = 0.45$) and moderate to large increases in sleep quality ($d = 0.65$). Pre-post correlations were based on preliminary data taken from a trial targeting and measuring changes in physical activity and sleep,[36] which showed correlations of $r = 0.57$ and $r = 0.60$ for physical activity and sleep quality, respectively; therefore a pre-post correlation of 0.60 was assumed in the current study. Assuming an alpha of 0.025 (due to measuring two primary outcomes; MVPA and sleep quality), power of 0.80, a moderate effect size ($d = 0.45$ for physical activity; $d = 0.65$ for sleep) and a pre-post correlation of 0.60, a total of 60 participants per

group will be required for physical activity and 35 per group for sleep quality, the larger sample of which will be used.

Meta-analyses of physical activity and sleep interventions report average drop-out rates of 20%,[85 87] however the majority of web-based trials report drop-out rates that are higher than that,[84] thus the sample size for this study will be inflated to account for a 25% drop-out in the current study. Therefore, the total sample size is 80 participants per group or 160 in total. A sample of this size will also be adequately powered to detect mediated effect sizes of small (β = 0.14) magnitude.[90] The participant recruitment phase will conclude once 160 complete baseline responses have been obtained.

Analyses

Analyses will apply the *intention-to-treat* principle. Analysis of primary outcomes will be blinded to group allocation and overseen by an independent statistician. The primary aim of this study will be to examine differences in physical activity and sleep quality between the intervention group and the control group at the 3-month primary time point. Between-group differences in physical activity (AAQ minutes) and sleep quality (PSQI) will be estimated using Generalised Linear Mixed Models (GLMM) adjusting for baseline measures of the outcome, including all available data in the analysis. The model will include fixed effects for group, time and their interaction. A random intercept will be used to account for repeated measures on individuals. Separate GLMM will be used to examine changes in physical activity and sleep.

Sensitivity analyses using Pattern Mixture Modelling will be conducted to examine the impact of missing data on outcomes. Where the GLMM assumes data are missing at random,

Pattern Mixture Modelling is robust to the assumed pattern of missing data. Group differences in secondary outcome measures will be estimated using the same linear mixed modelling approach, setting an alpha of 0.025 for each outcome. Potential mediators and moderators of intervention efficacy will be examined using established approaches.[91] Generalised linear mixed models and survival analysis will be used to examine differences in usage patterns.

Data monitoring

Survey data will be exported directly from Qualtrics® as a text file and imported into Stata for scoring and analysis. A detailed database will track participants' progress through the trial including the scheduling of assessments and reminders to complete assessments. Intervention usage will be monitored throughout the trial by BM and MJD by way of the password-protected app database. Given the purpose of the trial, the data to be collected as well as the nature of the intervention, no *Data Monitoring Committee* will be established. Detailed strategies, including Email/text message reminders will be used to remind participants about upcoming assessments. All Newcastle-based members of the research team (BM, MJD, ATR, RCP) and other associated personnel will have access to the information in both identified and re-identifiable forms. Should statistical analysis advice be sought, access to the data will be granted in re-identifiable form using unique numerical identifiers and access approved by the relevant Ethics Committee.

Print data will be stored in locked filing cabinets accessible only to the research team. Electronic data will be stored on password-protected computers or servers only accessible to the research team. Data will be retained for 15 years in accordance with section 3.1.1 of the *Australian Code for the Responsible Conduct of Research* and all (paper and electronic)

records will be disposed of in accordance with the requirements of the *Australian Code for the Responsible Conduct of Research*.

Results from the outcome measures will not be presented in a way that adversely affects the confidentiality of participants. The description of participants will not allow identification of individual participants, and individual results and individual names will not be revealed. Final reports and publications will only consist of aggregated results. At the completion of the study, participants will receive a plain English summary of study results.

Study sponsorship, funding and organisation

This study was supported in part by funds from a Future Leader Fellowship from the National Heart Foundation of Australia awarded to MJD (ID 100029) as well as a Vanguard Grant from the National Heart Foundation of Australia awarded to MJD (ID 100629).

The trial is sponsored by the University of Newcastle and will be coordinated independently of the study sponsor and funder by the Priority Research Centre for Physical Activity and Nutrition, University of Newcastle, Australia and managed by project lead BM and overseen by chief investigator MJD. The study funder and sponsor will have no role in the conducting or evaluation of the trial, nor did the study funder and sponsor have any authority over the study design, collection, management, analysis and interpretation of data, the preparation of manuscripts or the submission of reports.

Declaration of interests

The authors and principal investigators of this study protocol declare no conflict of interest.

Roles and responsibilities

Any amendments to the study protocol will be submitted to the Human Research Ethics Committee (HREC) and updated on the trial register (ANZCTR) once full ethical approval has been obtained. All authors meet ICMJE criteria for authorship in that they have contributed substantially to the conceptual design; or the processes of data collection, analysis or interpretation; the drafts and revisions of the study protocol and manuscript; granted approval of the final version of the study protocol; and acknowledged their accountability with regards to the integrity and accuracy of this study protocol.[92] In detail, the first author of this protocol (BM) will be responsible for administrative and managerial procedures related to all phases of the trial, which will be supervised by MJD and RCP. ATR will fulfil this role, in the case of BM's temporary illness or absence. BM, MJD, ATR and RCP contributed to the development of study materials, MJD, CV and WJB have contributed to the conceptual design of the trial and all authors (BM, RCP, ATR, CV, WJB and MJD) contributed to the writing of the protocol and will be involved in the interpretation of results, the evaluation of the trial and dissemination of study findings.

Any type of adverse events reported by study participants, whether they be due to their participation or due to an unrelated cause will be recorded and reported to the HREC. This may include events reported by participants, including musculoskeletal injuries associated with the uptake or increase in physical activity or emotional distress due to any survey items of sensitive nature. Great care will be taken to avoid and prevent adverse events and the research team will provide every possible assistance to remediate those events, should they occur. The participant information statement interested individuals will have access to prior to consenting to participate details any potential risks of discomfort associated with

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participation in the study and provides contact details and information of national support services (e.g., Black Dog Institute, Lifeline, etc.).

DISCUSSION

It is advised that adults accumulate a weekly minimum of 150 minutes of moderate intensity physical activity, combined with muscle strengthening activities on two days per week,[7] and also achieve 7-9 hours of sleep per night.[93] Achieving the recommended levels of physical activity and sleep contribute and maintain optimal health and wellbeing through risk reductions associated with chronic diseases such as heart disease and type-2-diabetes.[3-6] Engaging in optimal levels of physical activity and sleep health can also positively contribute to long-term weight management, mental health and overall quality of life.[94-96] Notwithstanding this wide spectrum of benefits, a large proportion of the population does not accumulate sufficient physical activity and/or achieve optimal sleep.

Wide reaching behavioural programmes, such as those offered through m-health interventions, have the potential to elicit the much needed shift of relatively large groups of the population toward levels of physical activity and sleep that meet recommendations.[97] To yield positive changes in health behaviour, such interventions need to include educational information, incorporate behaviour change techniques and deliver a level of guidance that endorse the initiation and maintenance of health behaviour change.[29 98] Systematic reviews of the effectiveness of multiple health behaviour interventions suggested that those targeting related behaviours (e.g., diet and physical activity) produced greater behaviour change than those targeting unrelated behaviours (e.g., smoking and physical activity),[99] and that specific intervention techniques are necessary for each behaviour.[26] Physical activity and sleep are suggested to have a bi-directional relationship,[16] yet no previous RCTs have combined

physical activity and sleep in one intervention and therefore have not utilised the synergistic relationship between physical activity and sleep. The Synergy Study addresses this by targeting both physical activity and sleep, simultaneously, using specific intervention techniques to enhance participants' self-regulatory skills in relation to the two health behaviours and thus, leverages the potential for synergistic improvements in both behaviours. An advantage of this study lies in its mode of delivery, which involves mobile technology and therefore blends into day-to-day life. A key intervention strategy is the use of goal-setting and feedback to promote behaviour change. It seeks to achieve this through the promotion of dynamic goals and action plans, the implementation of a personalised support system further addresses potential barriers (i.e., low levels of self-efficacy) that can increase the gap between participant intentions and behavioural outcomes,[100] and contribute to long-term behaviour maintenance. This includes knowledge on how to set attainable goals and having strategies in place that facilitate the occurrence of healthy behaviours, despite challenging situations or unfavourable environmental factors.[29] The structured promotion of goal-setting strategies, combined with action plans that define in detail how an individual will implement the intended behaviour, is known to be effective in changing health behaviours.[98]

Additional strengths of this study include its randomised waitlist controlled study design, which will allow making inferences about the causal links between the intervention and changes in behaviour, including participants from the wider public. While it is the first aim of this study to test the intervention's efficacy to produce changes in two primary outcomes, the pre-specified secondary outcomes (mental health, quality of life) will give insight into changes in parameters of health and wellbeing that may be very meaningful to the participant. And finally, this study will generate knowledge on social cognitive determinants of behaviour change relating to sleep health and explore how these factors differ between physical activity

and sleep. This will enhance the understanding of underlying mechanisms associated with successful behaviour change in both behaviours and also further the application of social cognitive theories in the multi health behaviour context. The limitations of this study include the study duration, which, although at 6 months is longer than many studies,[84] does not provide insight into longer term changes and behaviour maintenance; and the lack of a comparator condition receiving only the sleep or the physical activity programme to determine the magnitude each intervention component has on its own. It is beyond the scope of this study to test long-term efficacy exceeding 6 months, but future trials may be encouraged to do this, provided the Synergy Study proves efficacious in the short term with indications of effect retention at the 6-month time point.

CONCLUSION

This study protocol provides the rationale and methods associated with the implementation and evaluation of the Synergy Study, a theory-based m-health intervention including personalised support, with the aim to improve physical activity and sleep health in Australian adults. To the authors' knowledge, this study will be the first to simultaneously target changes in these two behaviours, using a sophisticated combination of technologies and evidence-based strategies and test the efficacy of this approach in a randomised controlled trial. Findings from this trial will provide valuable knowledge pertaining to the design of m-health interventions that combine behaviours in a format with wide reach.

LEGEND OF TABLES

Table 1. *Overview and content of message-based support service*

Table 2. *Operationalisation of social cognitive factors and behaviour change strategies*

Table 3. *Overview of outcome measures and assessment time points*

Table 4. *Social cognitive factors related to physical activity and sleep hygiene behaviours*

LEGEND OF IMAGES/FIGURES

Figure 1. *Flow of participants in the Synergy Study*

Figure 2. *Sleep hygiene log items*

Figure 3. *Screenshots of app screens for self-monitoring and feedback relative to goals*

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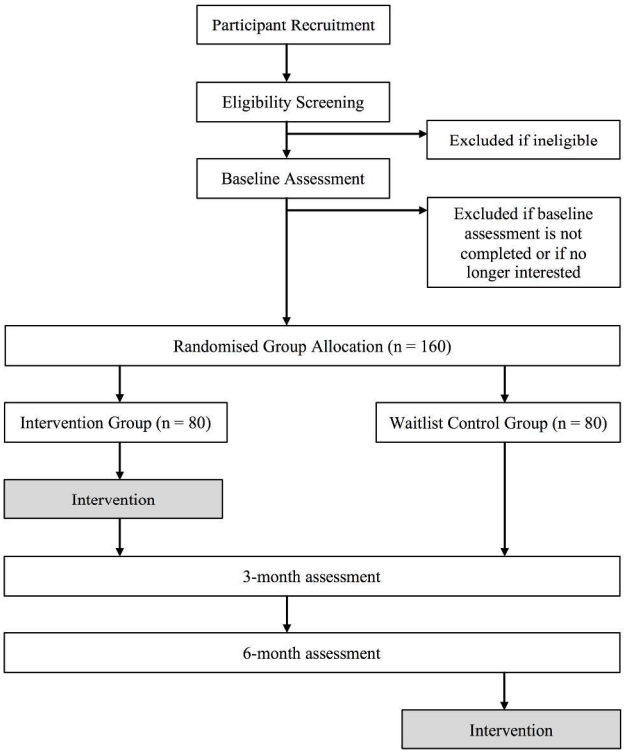

Figure 1. Flow of participants in the Synergy Study

296x420mm (300 x 300 DPI)

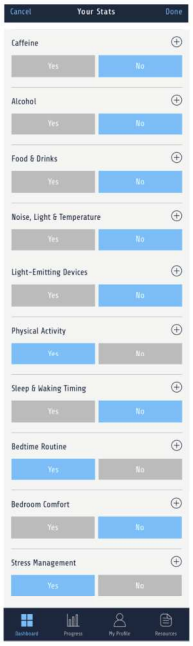

Figure 2. Sleep hygiene log items.

Figure 2. Sleep hygiene log items

296x420mm (300 x 300 DPI)

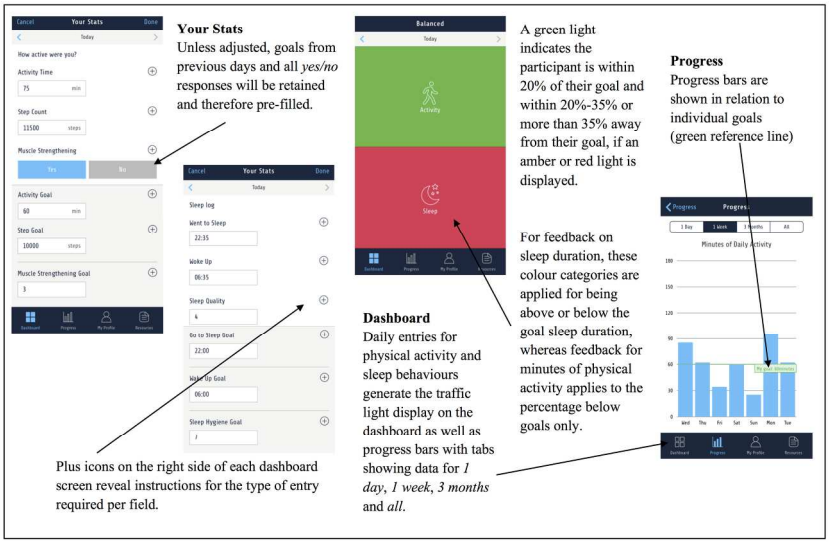

Figure 3. Screenshots of app screens for self-monitoring and feedback relative to goals

209x148mm (300 x 300 DPI)

STUDY PROTOCOL: IMPROVING ADULTS PHYSICAL ACTIVITY AND SLEEP

Appendix 1.
WHO Trial Registration Data Set (Version 1.2.1)

1. **Primary Registry and Trial Identifying Number**
   Australia New Zealand Clinical Trial Registry (ANZCTR): ACTRN12617000376347

2. **Date of Registration in Primary Registry**
   13/03/2017

3. **Secondary Identifying Numbers**
   Universal Trial Number (UTN): U1111-1186-6588 (obtained on 19/08/2016)

4. **Source(s) of Monetary or Material Support**
   National Heart Foundation of Australia – This project is supported by Vanguard Grant (ID 100629) and also by a Future Leader Fellowship (ID 100029) from the National Heart Foundation of Australia.

5. **Primary Sponsor**
   The University of Newcastle

6. **Secondary Sponsor(s)**
   None

7. **Contact for Public Queries**
   Associate Prof Mitch Duncan, ATC Building Level 3, The University of Newcastle, University Drive, Callaghan NSW 2308, Australia *Email:* Mitch.Duncan@newcastle.edu.au Phone: +61 2 4921 7805

8. **Contact for Scientific Queries**
   Associate Prof Mitch Duncan, ATC Building Level 3, The University of Newcastle, University Drive, Callaghan NSW 2308, Australia *Email:* Mitch.Duncan@newcastle.edu.au Phone: +61 2 4921 7805

9. **Public Title**
   Testing the effectiveness of a mobile device delivered program to improve physical activity and sleep among inactive Australian adults with poor sleep.

10. **Scientific Title**
    A randomised controlled trial using a theory-based m-health intervention to improve physical activity and sleep health in adults: The Synergy Study protocol.

11. **Countries of Recruitment**
    Australia

12. **Health Condition(s) or Problem(s) Studied**
    Physical inactivity and poor sleep health will be targeted to promote the prevention of chronic diseases such as type-2 diabetes, heart disease and obesity through greater levels of physical activity and better sleep health (characterised by optimal sleep duration, good sleep quality and consistent bed and wake times).

    If the study is conducted in healthy human volunteers belonging to the target population

of the intervention (e.g. preventive or screening interventions), enter the particular health condition(s) or problem(s) being prevented.

13. **Intervention(s)**

Intervention Group: The intervention group will receive a combined physical activity and sleep intervention using a mobile app and personalised support for 3 months

Intervention Description: The mobile app will operationalise goal-setting, self-monitoring and feedback strategies in relation to physical activity and sleep health. The message-based support service (Email and text messaging) will provide feedback on progress towards goals, prompts to practice the two behaviours and review/adjust goals, daily reminders (optional) and tool sheets on goal-setting, action planning and stress management. Participants will be asked to self-monitor their daily physical activity and sleep behaviours and set personal goals for both behaviours within the app. We will advise participants to log both behaviours on a daily basis, whereas goals can be reset at any time (if need be) or otherwise will remain unchanged. A summary report, which is sent to participants once weekly will assist with the process of goal review. Goal achievement is considered successful, if participants are within 20% of their goal. For example, if a participant aimed for 30 min of activity, their feedback dashboard (traffic light) will display a green light and their goal is reached, if the participant logged at least 24 min of activity or more for that day. Multiple entries per day are possible. A pedometer will be shipped to participants to facilitate the logging of a daily step count. Participants will be asked to set relevant and achievable goals (guidance provided); however, we will encourage individuals to gradually work towards the recommended minimum of physical activity (PA) and sleep as per national guidelines, which is 150 min/week (plus 2 days of resistance training) for PA and 7-9 hours of sleep per night. The app and all other components are informed by social cognitive theories and follow behaviour change taxonomies to ensure consistency with implementation standards and reporting. Participants will be given continuous access to the app.

Waitlist Control Group:
Following the 6-month follow-up assessment, thee waitlist control group will receive full access to the intervention

14. **Key Inclusion and Exclusion Criteria**

Interested individuals meeting any of the following criteria are not eligible to participate:

- not residing in Australia;
- not between 18 and 55 years old;
- reporting a height and weight that is not consistent with a BMI between 18.5 and 35;
- accumulating more than 90 minutes of moderate/vigorous physical activity per week;
- rating their sleep-quality (over the past month) as *fairly good* or *very good*;
- currently pregnant or having given birth in the past 12 months;
- having a condition that would make it unsafe or limits their ability to increase activity levels or change sleep behaviours;
- having a diagnosed sleep disorder (chronic insomnia, sleep apnoea, sleepwalking, narcolepsy, restless legs syndrome, etc.);
- currently consuming hypnotics (sleep inducing medication);

- being employed in any night shift work;
- planning frequent travel (once a month or more often) to a destination with a shift in
- time zone by more than three hours during the intervention period;
- currently using a self-monitoring system or device to track or log physical activity or
- sleep (this includes non-device assisted applications); and
- not having access to an internet-enabled iOS (Apple) or Android smartphone or tablet.

14. **Study Type**
Study type consists of:
- Type of study: interventional
- Study design: 2-arm RCT with a waitlist control group
  - Method of allocation: randomized
  - Masking: unmasked
  - Assignment: intervention group vs. waitlist control group
  - Purpose: to determine causal effect of the intervention
- Phase: n/a
- Allocation concealment and sequence: Opaque envelopes (k = 80 per group) using permuted block randomization with block sizes of 4 and 8. A researcher not associated with the study who is responsible for group allocation will open the envelope that is next in sequence and inform the project leader about the allocation outcome.

15. **Date of First Enrolment**
01/06/2017

16. **Target Sample Size**
n = 160 (80 per group)

17. **Recruitment Status**
Recruiting (participants are currently being recruited and enrolled)

18. **Primary Outcome(s)**
Two primary outcomes have been specified for this study

- **Physical Activity**
- The Active Australia Questionnaire
- 0, 3 and 6 months

- **Sleep Quality**
- The Pittsburgh Sleep Quality Index
- 0, 3 and 6 months

19. **Key Secondary Outcomes**
- **Health-related quality of life**
- RAND-12 plus 3 items from the RAND-36 assessing energy/fatigue
- 0, 3 and 6 months

- **Mental Health (depression, anxiety, stress)**
- Depression-Anxiety-Stress Scale (DASS-21)
- 0, 3 and 6 months

- **Resistance training**
- Number of sessions per week and duration per session
- 0, 3 and 6 months

- **Sitting time**
- Workforce Sitting Questionnaire
- 0, 3 and 6 months

- **Sleep timing**
- Sleep Timing Questionnaire
- 0, 3 and 6 months

- **Insomnia symptom severity**
- Insomnia Severity Index
- 0, 3 and 6 months

- **Daytime sleepiness**
- Epworth Sleepiness Scale
- 0, 3 and 6 months

STUDY PROTOCOL: IMPROVING ADULTS PHYSICAL ACTIVITY AND SLEEP

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	5
	2b	All items from the World Health Organization Trial Registration Data Set	Appendix 1
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	32
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1;32
	5b	Name and contact information for the trial sponsor	1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	32
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	32
Introduction			

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3ff
	6b	Explanation for choice of comparators	n/a
Objectives	7	Specific objectives or hypotheses	5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6f
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9ff
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	17
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	16; 18
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	19ff
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	8

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	28f
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	6
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	17
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	17
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	17
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	17
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	18ff
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	18

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	30
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	30
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	30
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	30
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	31
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	33
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	n/a
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	32

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	6
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	31
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	32
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	31
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	10
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	31
	31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Appendix 2
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

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A randomised controlled trial using a theory-based m-health intervention to improve physical activity and sleep health in adults: The Synergy Study protocol.

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STUDY PROTOCOL
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Title

A randomised controlled trial using a theory-based m-health intervention to improve physical activity and sleep health in adults: The Synergy Study protocol.

Authors

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STUDY PROTOCOL: IMPROVING ADULTS PHYSICAL ACTIVITY AND SLEEP

ABSTRACT

Introduction To decrease chronic disease rates, there is a need to reduce physical inactivity and poor sleep health in the adult population. Given the high prevalence of these unhealthy habits, behavioural interventions with potential for wide reach are needed.

Methods and Analysis The aims of this 2-arm RCT will be to test the effect of a 3-month personalised mobile app intervention on two main outcomes: minutes of moderate-to-vigorous physical activity and overall sleep quality. In addition, between-group changes in health-related quality of life and mental health status will be assessed as secondary outcomes. The pre-specified mediators and moderators include social cognitive factors, the neighbourhood environment, health (BMI, depression, anxiety, stress) and sociodemographic factors (age, gender, education). Assessments will be conducted after 3 months (primary endpoint) and 6 months (follow-up). The intervention will provide access to a specifically developed mobile app, through which participants can set goals for active minutes, daily step counts, resistance training, sleep times and sleep hygiene practice. The app also allows participants to log their behaviours daily and view progress bars as well as instant feedback in relation to goals. The personalised support system will consist of weekly summary reports, educational and instructional materials, prompts upon disengagement and weekly facts.

Ethics and dissemination The Human Research Ethics Committee of The University of Newcastle, Australia granted full approval: H-2016-0181. This study will assess the efficacy of a combined behaviour intervention, mechanisms of behaviour change and gather high-quality process data, all of which will help refine future trials. Dissemination of findings will include publication in a peer-reviewed journal and presentation at national or international conferences. Participants will receive a plain English summary report of results.

Trial registration number ACTRN12617000376347

Keywords physical activity, sleep health, behaviour change, m-health, e-health, smartphone, app, intervention, adults, study protocol

Strengths and limitations of this study

- No previous studies have tested the efficacy of a mobile intervention targeting physical activity and sleep in combination in a randomised waitlist-controlled trial in physically inactive adults reporting poor quality sleep, who do not have a sleep disorder.
- Outcome data will contribute to the knowledge relating to chronic disease prevention through multi health behaviours using a mobile intervention with wide reach.
- Findings will facilitate the future design of technology-based multi health behaviour change interventions.
- Limitations include the lack of an intervention arm which receives only the physical activity or only the sleep intervention.
- Remotely delivered (mobile) interventions are known to have high attrition rates.

STUDY PROTOCOL: IMPROVING ADULTS PHYSICAL ACTIVITY AND SLEEP

BACKGROUND

Engaging in sufficient physical activity and maintaining good sleep health are two lifestyle behaviours that significantly reduce the risk of all-cause mortality,[1 2] cardiovascular disease,[3 4] and type-2-diabetes.[5 6] *Sufficient physical activity* is the accumulation of at least 150 minutes of moderate-intensity or 75 minutes of vigorous-intensity physical activity per week.[7] *Good sleep health* is characterised by duration, quality and timing of sleep that leaves a person satisfied with their sleep and alert during the day.[8] Internationally, up to 32% of adults are insufficiently physically active,[9] and up to 29% report sleeping <6 hours,[10] 24% report poor quality sleep,[11] and >50% report inconsistent bed and wake times, the latter of which are indicators of poor sleep health.[12] There is no global estimate of the percentage of adults who report both insufficient physical activity and poor sleep health. However, evidence suggests that individuals with poor sleep health also report lower levels of physical activity.[13 14] Thus, interventions which target both behaviours have the potential to make meaningful contributions to public health.

Multiple lifestyle behaviour interventions produce greater reductions in the risk of poor health than interventions that target a single behaviour.[15] Moreover, physical activity and sleep have a bidirectional relationship,[16] in which physical activity improves indicators of sleep health (e.g., sleep quality) and good sleep health is associated with greater levels of physical activity.[17] Interventions targeting both behaviours simultaneously may capitalise on this reciprocal relationship to produce larger increases in both behaviours.[18] Previous reviews of multiple behaviour interventions however, have not identified any studies that specifically target changes in both physical activity and sleep health and tested the efficacy of this approach in a randomised controlled trial.[19-21]

Non-pharmacological sleep interventions (e.g., Cognitive Behavioural Therapy for Insomnia) frequently promote sleep hygiene,[22] using a set of self-regulatory strategies that help to promote good sleep health, but details of behaviour change techniques (BCT) to support changes in sleep hygiene behaviours, such as regular physical activity or stress management, are usually not reported.[23 24] Without providing the necessary guidance to promote behaviour change, it is unlikely that such education-only interventions are likely to change behaviour, as education-only interventions are known to be less effective than those that are combined with additional self-regulation strategies.[25] Furthermore, multiple health behaviour change interventions need to implement BCT that are specific to each behaviour to produce greater changes in targeted behaviours.[26] Interventions targeting physical activity and sleep in combination therefore need to provide behaviour-specific intervention strategies to maximise change and harness the potentially synergistic effects between physical activity and sleep.

Reviews of the evidence suggest theory-based interventions are more effective in changing behaviour than interventions that do not use a theoretical approach.[27] Theoretical models provide important guidance for the development of behaviour change interventions, aiming for the uniform operationalisation of cognitive and behavioural determinants. Social Cognitive Theory (SCT) is one of the most widely used theories in health behaviour research.[28] It aids the conceptual understanding of behaviour change, as it accounts for the interactions between individual and environmental processes that either facilitate or impede behaviour change[29]. This is particularly relevant when targeting both physical activity and sleep health, since individual as well as environmental factors are known to influence both behaviours.[30 31] SCT has guided the development of numerous physical activity interventions and its constructs are strongly associated with physical activity,[31 32] but there is only limited understanding of social cognitive factors in relation to sleep health.[30] However, it may be

useful to apply social cognitive frameworks to better understand mechanisms of adult sleep health, since sleep is affected by factors at both the individual (e.g., self-efficacy to change sleep hygiene behaviours) and environmental level (e.g., sleep environment, neighbourhood factors).

Due to the high prevalence of people who report either being insufficiently active or meeting indicators of poor sleep health, there is a need for broad reaching interventions. Because smartphone ownership is growing steadily, with approximately 80% of the population owning a device,[33] intervention delivery entailing this medium is likely to be accessible, affordable and conveniently integrated into daily life.

This study aims to test: (1) the efficacy of an app-based intervention to improve physical activity and sleep quality (as primary outcomes) and health-related quality of life and mental health status (as secondary study outcomes), relative to a waitlist control; (2) the mediating role of social cognitive factors and app usage in behaviour change; and (3) health (BMI, depression, anxiety, stress), sociodemographic factors (age, gender, education) and the neighbourhood environment as potential moderators of intervention efficacy.

METHODS

This trial was registered prospectively on the Australian New Zealand Clinical Trials Registry (ANZCTR Registration Number: ACTRN12617000376347; Universal Trial Number: U1111-1186-6588). The conduct and reporting of the trial will follow CONSORT guidelines[34], and the CONSORT-EHEALTH checklist.[35] Full ethical approval was obtained from the Human Research Ethics Committee of The University of Newcastle, Australia (Approval Number: H-2016-0181).

Study design

A two-arm randomised controlled (superiority) trial with a combined physical activity and sleep intervention and a waitlist control group, with assessments conducted at 0 (baseline), 3 months (primary endpoint) and 6 months (follow-up).

Recruitment

Digital and print-based advertising will be used to recruit nationwide in Australia. Recruitment for both intervention arms commenced in May 2017 and will conclude once sample size requirements are achieved (n = 160, refer to power and sample size section). Social media advertising will be used to recruit in social media networks (e.g., Twitter, Facebook) using target audiences that match inclusion criteria (i.e., age, living in Australia). Electronic and print-based advertising will include magazines and newspapers with state-wide reach. All recruitment materials will provide contact details and a link to the consent form and eligibility survey. Due to the remote delivery of the intervention in combination with self-report based assessments, participants will not be required to visit the research centre.

Exclusion criteria

Individuals who meet any of the following criteria will not be eligible to participate:

- not residing in Australia;
- not being between 18 and 55 years old;
- reporting a height and weight that is not consistent with a BMI between 18.5 and 35;
- accumulating more than 90 minutes of moderate/vigorous physical activity per week;
- rating their sleep-quality (over the past month) as *fairly good* or *very good*;

- currently pregnant or having given birth in the past 12 months;
- having a condition that would make it unsafe or limits their ability to increase activity levels or change sleep behaviours;
- having a diagnosed sleep disorder (chronic insomnia, sleep apnoea, sleepwalking, narcolepsy, restless legs syndrome, etc.);
- currently consuming hypnotics (sleep inducing medication);
- being employed in any night shift work;
- planning frequent travel (once a month or more often) to a destination with a shift in time zone by more than three hours during the intervention period;
- currently using a self-monitoring system or device to track or log physical activity or sleep (this includes non-device assisted applications); and
- not having access to an internet-enabled iOS (Apple) or Android smartphone or tablet.

Interested participants who indicated already using a self-monitoring system or tracking device were excluded to avoid the potentially confounding effect that the use of a self-monitoring system or device may have on behaviour, as most popular health apps or the trackers themselves frequently implement a variety of behaviour change strategies.[36 37]

Study procedure

Eligible participants will be contacted via Email and welcomed into the study. Participants will be asked to complete online surveys assessing primary and secondary outcomes, potential mediators/moderators and socio-demographics at three time points. Figure 1 illustrates the flow of participants throughout the trial.

All online surveys will be administered using Qualtrics® (Provo, Utah). If specified screening criteria are not met, participants will be advised via text displayed at the end of their survey and further contact will only be made where ambiguous responses require clarification. Ineligible participants will also receive a link providing free and unlimited access to the public version of the Balanced app.[38]

Participants will receive an Email with a unique password-protected link to their survey at each assessment point. Each person who has completed their baseline survey will be randomly allocated to one of two groups. Participants allocated to the intervention group will be mailed a pedometer, tool sheets, login details and instructions for download and installation of the *"Balanced"* smartphone app in the form of a participant handbook. The initial Balanced app was specifically developed for scientific purposes and is described in more detail elsewhere.[38] It originally consisted of three separate categories, one for physical activity (active minutes), one for inactivity (hours and minutes of sitting) and one for sleep (bed and wake times and sleep quality rating). As part of the modifications to the previous app, the physical activity component of the app was revised to include daily steps and resistance training in addition to minutes of moderate-to-vigorous intensity physical activity; and the sleep component was revised to include sleep hygiene in addition to sleep times and sleep quality. The sitting behaviour category was removed for use in the Synergy study, as no specific strategies to reduce sitting time will be provided in this study and because the objective will be to promote improvements in moderate-to-vigorous intensity physical activity and sleep health. App content was modified based on participant feedback (process evaluation and semi-structured interviews) as part of the Balanced study, [38] whilst design and aesthetics from the original version were retained. The main advance of the modified version lies in its increased level of tailoring using personal as opposed to the previously standardised

goals, which makes feedback on progress towards goals and goal achievement more personalised and meaningful for those in need to get engaged in healthy behaviour. [39]

Regular app use will be supported by an Email and text message-based support system (see Table 1), which is initiated as soon as a participant has gained access to the app. All messaging will follow a standardised protocol that was designed under consideration of the specificity, timeliness and relevance of contents (see Table 1), as those are valued components in mobile apps designed to change health behaviours.[40] Following completion of their 3-month assessment, participants may continue to use the app as much or as little as they like, but the message-based support will no longer be provided.

Table 1.
Overview and content of message-based support service

Delivery	Content	Frequency		
		weekly	monthly	as required
Email	General communication, survey reminders, notifications (eligibility, group allocation)			x
	Personalised weekly summary	x		
	Tool sheets (sent separately at weeks 3, 6 and 9)		x	
	App usage reminder (Condition: if 3 consecutive SMS prompts were unsuccessful in motivating participants to re-engage), only if applicable	x		
SMS	Fact of the week	x		
	Usage prompt (Condition: if non-usage occurred on at least 4/7 days per week)	x		
App-based Prompts	If enabled, a daily on-screen notification prompts participants to log data, if app has not been used to self-monitor behaviour in >24h			x

Note. The message-based support system will be delivered for the first 12 weeks of the intervention only.

Intervention

The intervention is composed of app and non-app components, with non-app components referring to any content of the intervention that is delivered via participant handbook, text message or Email. App components consist of educational resources, self-monitoring, goal-setting and feedback. Participants will have continuous access to the app throughout the intervention period. For the first 3 months, which is the time between baseline and the primary endpoint, these components will be complemented by a messaging system providing personalised feedback on progress towards goals, prompting goal review and prompting practice of the target behaviours. The messaging component will cease at the 3-month assessment, but participants will have continued access to the app. Following completion of the study, participants will be able to continue to access and use the app for an indefinite period, however will not be required to complete any further assessments as part of this study. The app will be available on both Android and Apple based operating systems. Table 2 provides an overview of intervention strategies used to operationalise the social cognitive constructs in the intervention. In brief, the key constructs included relate to a person's confidence (self-efficacy) in their capacity to define and follow a specific plan, the purpose of which is to experience a desired result in the face of situational or environmental (socio-structural) factors that either impede or facilitate progress, whilst the motivation to pursue results is regulated by perceptions regarding the personal benefit of the result in question its importance (outcome expectations and expectancies).[29]

Educational resources

App resources will consist of educational information about the importance of the two behaviours, basic instructions on how to change each behaviour and guidance for app use (e.g., how to interpret traffic lights and progress graphs). This content will provide participants with knowledge on the health benefits of each behaviour, the current national

guidelines for physical activity and sleep and the importance of resistance training and incidental physical activity in addition to aerobic exercise, as well as the importance of all dimensions of sleep health (i.e., sleep duration, sleep quality, sleep timing). Resources will consist of a comprehensive range of stimulus control and sleep hygiene recommendations based on summaries of the evidence.[22] In addition to app content, participants will receive a total of three tool sheets (enclosed in the handbook), one tool sheet including goal-setting strategies,[41] for each behaviour, one that emphases action planning (again, one for each behaviour) and one tool sheet with information and instructions adapted from publicly available resources for the practice of stress management techniques (i.e., progressive muscle relaxation, deep breathing and mindfulness).[42-44] All tool sheets will be distributed at outset along with the participant handbook, which includes a brief study summary, a personalised timeline including assessment dates as well as a comprehensive troubleshooting guide covering the most common problems that may occur when installing and using the app. Participants in the intervention group will receive their materials following completion of their baseline assessment and waitlist controls will receive an identical package following their 6-month assessment. In addition, during each month of the intervention, one tool will be promoted via Email to encourage utilisation of these resources. Goal-setting tool sheets will be sent in week 3, followed by the action planning tool sheet in week 6 and the stress management tool sheet in week 9 for each participant. The examples given within the tool sheets are framed in a way that encourages participants to tailor any strategies to their own situation and priorities (for example: *Once I get fitter, I will finally be able to…*). Individuals are instructed to set goals that are personally relevant and meaningful to promote initial engagement, but the goal-setting information provided will provide reference to the recommended minimum of 150 minutes of moderate-intensity physical activity per week,[7] and a sleep duration of 7 to 9 hours per night[45] as overarching goals one should gradually

work towards. Weekly summary reports however, will focus on individual progress in relation to the individual goals set by the participant. Each report will detail progress in the form of totals and averages for both behaviours (i.e., active minutes, step count, resistance training sessions, bed and wake times, sleep hygiene, sleep quality), which will help participants understand how changes in the two behaviours are interrelated. Furthermore, participants will receive a weekly text message containing 1 of 12 educational and motivational facts relating to physical activity and sleep for better health (i.e., the consequences of poor sleep health). Each fact message will also refer to the resources section available in the app and encourage people to use it.

Self-monitoring

Participants will be asked to recall minutes of moderate to vigorous physical activity, and participation in resistance training, and manually enter this into the app every day. Daily steps will be objectively measured using the pedometer (Yamax SW200, Eagle Farm, QLD) provided and manually entered by participants into the app. Participants will not be asked to return their pedometer.

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Table 2.
Operationalisation of social cognitive factors and behaviour change strategies

SCT constructs	BCT[1]	Components	Description of intervention components
Self-efficacy	▪ Graded tasks ▪ Self-monitoring ▪ Goal review ▪ Feedback on performance ▪ Praise/rewards ▪ Relapse prevention/ coping ▪ Barrier identification/ problem solving ▪ Stress management	App log	Participants will be asked to recall and enter their activity and sleep behaviours. The daily log will allow entries for active minutes, daily steps, resistance training sessions, sleep and wake times, a sleep quality rating, as well a checklist of 10 sleep hygiene goals. Participants will be asked to tick off those sleep hygiene goals they implemented the previous day.
		App progress charts	Bar charts will provide a history for daily, weekly and 3-month progress in relation to goals per behaviour (for each of the items data are logged for).
		App dashboard traffic light	The activity dashboard produces a traffic light colour relating to total active minutes, while the colour of the sleep dashboard relates to total sleep duration. Goals can be adjusted at any time, which will determine the colours on the dashboard traffic light. This is dynamically updated as soon as a self-monitoring entry is made: 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.
		Tool sheets	A series of tool sheets delivered at weeks 3, 6, and 9 will promote goal-setting and action planning and give detailed guidance on how to set SMART goals and follow through with an action plan in the face of barriers (i.e., by being prepared).
		Weekly summary (Email)	This support feature will provide an overview of weekly totals and averages per behaviour (if sufficient data are available) and prompt participants to review goals, if needed.
		Prompts (SMS)	If participants fail to log any data on more than 4 days per week, they will receive a message prompting them to resume logging.
Perceived behavioural capacity	▪ Information on where and when to be active/engage in in sleep promoting behaviours ▪ Instructions on how to be active and engage in sleep promoting behaviours	App resources	The resources section will provide the current national guidelines on how much physical activity per week and how much sleep (hours) per night adults need. This section also includes brief content on the when, the where, who with and how of being active and sleeping well (e.g., sleep hygiene practices).
		Weekly facts (SMS)	Each week, participants will receive a short text message with educational content on activity and/or sleep and health to reinforce the importance of both behaviours.
		Tool sheets	Tool sheets provide more detailed information that enable a person to make positive changes to their physical activity and sleep levels and include action plan templates and examples of exercises. These materials will also include stress management techniques, such as PMR and controlled breathing.

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Outcome expectations/ expectancies	▪ Information about the behaviour in relation to health	Tool sheets	As part of the goal-setting tool sheet, participants will be asked to think about the reasons for wishing to improve their health behaviours and what they anticipate as personal benefits, following improved levels of activity and sleep (examples will be provided).
		App resources	This section will include information on why activity and sleep are important and how they contribute to health and wellbeing.
		App log personal goals	Participants will be asked to personalise their goals, but work towards recommended minima (150 MVPA/week; 7-9h sleep/night); goals are carried forward from previous entries unless adjusted
Goals	▪ Goal-setting ▪ Action Planning ▪ Self-monitoring ▪ Prompt practice ▪ Time Management ▪ Teach use of prompts ▪ Time management	App dashboard traffic light	Participants will be encouraged to put equal effort into improving both PA and sleep. This means 2 amber lights are better than one green and one red light.
		Tool sheets	Participants will receive goal-setting strategies and example action plans for guidance (per behaviour) as part of the tool sheets described above. One of 3 tools will be promoted specifically via Email at week 3, 6 and 9, respectively.
		Reminders	Participants are advised to set a daily bedtime reminder (optional) on their phone, which is intended to prompt a person's bedtime routine and will promote regular bed times.
		App resources	Environmental restructuring as part of good SH will be highlighted in the resource section and include details on *how to* manage the bedroom environment. Also includes information on activity & sleep in the social context and seeking support from those in the same household (housemates, partner, family members).
Sociostructural factors (social support & environment)	▪ Use of prompts ▪ Environmental restructuring ▪ Barrier identification ▪ Plan social support	Tool sheets	This will include short examples on how to identify and manage barriers around being active and getting good sleep and how to utilise one's social support and environment in favour of activity and sleep.

Note. [1]Behaviour changes techniques were specified in accordance with the 40-item taxonomy of behaviour change techniques by Michie et al.[46]; MVPA = moderate-to-vigorous intensity physical activity; PA = physical activity; PMR = progressive muscle relaxation; SH = sleep hygiene;

Self-monitoring of sleep in the app will also be manually entered by participants. The sleep log consists of: *bedtime* (time of going to sleep), *wake time* (time of waking) and *sleep quality* (rating scale from 0 to 5 where 5 indicates high sleep quality). As an additional feature, this section of the app allows participants to log which sleep hygiene behaviours they practiced the previous day (Figure 2). These include consumption of caffeine, alcohol, nicotine, excessive intake of fluids or heavy meals before bedtime, regulation of the impact of light, noise and temperature in the bedroom, use of light-emitting devices, regular exercise, maintenance of consistent sleep and wake times, having and following a bedtime routine, creating comfort (e.g., proper pyjamas and bedding) and managing stress.[22] Participants can self-monitor these behaviours at any time of the day and update this information as many times per day as they prefer. The current study uses a manual data entry method based on self-monitoring. This method was selected for use in the current trial due to financial restrictions and because the Balanced study did not observe any between-group differences (i.e., manual entry vs. device-entered method (via Fitbit) in physical activity or sleep outcomes, or in time to non-usage attrition.[38]

Self-regulation

App feedback on behaviour will be provided using graphical displays of logged behaviour in relation to the goals set by the participant (Figure 3). Two types of graphical feedback are provided. There will be separate graphs for moderate-to-vigorous intensity physical activity, steps, resistance training, sleep duration, sleep quality, sleep timing and sleep hygiene. This information will provide a breakdown in the form of daily, 1-week and 3-month bar charts. The second graphical feedback to participants is via the dashboard which changes to one of three colours - green, orange and red in a traffic light system - to provide immediate feedback on participants' behaviour to in relation their goals on a daily basis (Figure 3). The

comparison of actual behaviour to goals based on a percentage of the goal achieved allows the use of consistent criteria across behaviours. This differs to the traffic light system originally used in Balanced, since process data from that study alluded to participants preferring to see this feedback based on goals rather than guidelines for each behaviour.[38]

As part of the goal review strategies, participants will be encouraged to evaluate their achievements in relation to goals and adjust their goals whenever needed. This will be facilitated by a personalised weekly summary of the previous week, delivered via Email, so that any reviews and adjustments of goals align with the most recent progress and foster self-efficacy. If a participant has logged data on less than 4 days per week (per behaviour), a text message will be sent to prompt practice. Likewise, once per week, if a participant only logs data for one behaviour, but not the other, a prompt will encourage him or her to engage in both behaviours equally.

Waitlist control group

Upon enrolment and allocation, the waitlist control group will not receive any intervention materials and only be required to complete their baseline, 3-month and 6-month assessments. After the 6-month assessment is completed, participants in this group will receive full access to the intervention.

Randomisation

Participants will be randomly allocated to 2 groups (intervention or control) after having completed their baseline assessment. Opaque sealed envelopes (n = 80 per group) will be prepared by BM using permuted block randomisation with block sizes of 4 and 8, following the procedures suggested by Doig et al.[47] Once a participant has completed their baseline

assessment, a researcher not associated with the study who is responsible for group allocation will open the envelope that is next in sequence and inform the project leader about the allocation outcome. Participants will be informed by the project leader and be sent a package containing study materials (i.e., handbook and pedometer), if they have been allocated to the intervention group (participants in the waitlist control group will receive their study materials after completing their 6-month assessment). The only exception for contravention with the allocation sequence will be made if family members or couples living in the same household enrol in the study, which would pose a high risk of contamination, especially between groups. For this reason, all individuals who are identified as members of the same household will be allocated to the same group. Neither the trial participants, nor the project lead (BM) will be blinded to group assignment.

Outcome measures

All measures will be assessed via online survey at baseline, 3 months, and 6 months, except for socio-demographics which will only be collected at baseline. The 3-month survey will further include process evaluation items that measure system usability and participant satisfaction (intervention group only). The two primary outcomes will be total minutes of moderate-to-vigorous physical activity and sleep quality. To increase adherence to scheduled assessments, participants who complete their survey will be entered into a draw for 1 of 5 $50 shopping vouchers. This information will not be provided prior to enrolment and is not intended to function as an incentive for individuals to sign up to participate, but merely to promote adherence to assessment requirements. Table 3 provides a summary of outcome measures and assessment time points. All online surveys will be pilot-tested and locked prior to study commencement to prevent any changes from being made once the study is underway. All survey forms will be hosted on Qualtrics®.

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Table 3.
Overview of outcome measures and assessment time points

Variables	Measure	Instrument	Time point of assessment		
			Baseline	3 months	6 months
Primary outcomes	Minutes of moderate- and vigorous intensity physical activity (last week)	The Active Australia Questionnaire (AAQ)	x	x	x
	Overall sleep quality (past 30 days)	The Pittsburgh Sleep Quality Index (PSQI)	x	x	x
Secondary outcomes	Health-related quality of life	The RAND-12 plus 3 items assessing energy/fatigue (RAND-36)	x	x	x
	Depression, Anxiety, Stress	The DASS-21	x	x	x
	Resistance training	Number of sessions per week and duration per session	x	x	x
	Sitting behaviour	The Workforce Sitting Questionnaire	x	x	x
	Sleep timing	The Sleep Timing Questionnaire	x	x	x
	Insomnia symptom severity	The Insomnia Severity Index (ISI)	x	x	x
	Daytime sleepiness	The Epworth Sleepiness Scale (ESS)	x	x	x
Process evaluation items (intervention group only)	Self-efficacy using a mobile app	The Internet Self-Efficacy Scale		x	
	User satisfaction	The Cognitive-Affective Model of Perceived User Satisfaction (CAMPUS)		x	
	App usage & engagement	The Balanced App database	Continuous recording		
	App usability	The System Usability Scale		x	
	Utility, advice acceptability & relevance	Semi-structured telephone interviews		x	
Sample characteristics	Demographics	Age, gender, height, weight, chronic disease status	x		
	Socioeconomic factors	Education, income, marital status, occupation, working hours	x		
	Morningness-Eveningness	The Morningness-Eveningness Questionnaire (MEQ)	x		
Moderators/ Mediators	Sleep hygiene behaviours	The Sleep Hygiene index (SHI)	x	x	x
	Environment	Perceived Neighbourhood Disorder	x	x	x
	Social cognitive factors	Social cognitive factors relating to physical activity Social cognitive factors relating to sleep hygiene behaviour	x	x	x
	Habit	The Automaticity Scale	x	x	x
	App usage & engagement	The Balanced App database	Continuous recording		

STUDY PROTOCOL: IMPROVING ADULTS PHYSICAL ACTIVITY AND SLEEP

Primary outcomes

Physical activity

The Active Australia Questionnaire (AAQ) has demonstrated acceptable reliability (rho = 0.64),[48 49] is sensitive to change in interventions,[50] and provides a measure of both the frequency and duration of moderate- and vigorous-intensity physical activity during the last week. This includes the total time spent in recreational walking and transport, moderate-intensity physical activity (e.g., swimming, golfing), aerobic activity (e.g., cycling, jogging) and vigorous gardening or yard work. Total minutes of moderate- and vigorous-intensity physical activity will be created by summing minutes of walking, moderate and vigorous (weighted by 2) intensity physical activity. Although objective assessment methods may be used to measure physical activity, it was not deemed feasible in the current study due to financial and pragmatic issues.

Sleep quality

The Pittsburgh Sleep Quality Index (PSQI) consists of 19 items and 7 component scores with scores ranging from 0 to 21.[51] Items assess problems with seven different components of sleep health in the last 30 days. Higher scores indicate poorer sleep quality and a score above 5 is commonly used to indicate poor sleep quality. The current study will use the PSQI as a continuous score. The PSQI is the most frequently used self-report instrument in sleep research.[52-54] The PSQI has demonstrated good reliability ($\alpha = 0.83$), is sensitive to change and has strong psychometric properties.[51 55] The 7 PSQI component scores consist of subjective sleep quality, sleep onset latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication and daytime dysfunction, all of which will be reported in addition to the total score. Although objective assessment methods (e.g., polysomnography, accelerometry) are known to provide accurate measures of sleep,[56] a

global measure of subjective sleep quality will be used in this study to observe the perceived restorative effect of sleep, which is difficult to measure using objective methods.[57]

Secondary outcomes

Health-related quality of life

Poor sleep quality and inadequate sleep duration are independently associated with low health-related quality of life.[58] The RAND-12 is a valid and reliable instrument[59] that is widely used to assesses multiple concepts of health such as physical functioning, role limitations due to physical and emotional problems, social functioning, emotional wellbeing, energy/fatigue, pain as well as general perceptions of health. In addition to the RAND-12 scale, 3 additional items that make up the energy/fatigue subscale in the 36-item version of the RAND will be asked (e.g., "How much of the time during the past 4 weeks did you feel tired?"), so that this domain can be evaluated separately. This will allow improvements in energy and fatigue during the course of the intervention to be assessed.

Depression, anxiety, and stress

The effect of changes in physical activity and sleep on participants' severity of depression, anxiety and stress symptoms will be assessed using the Depression-Anxiety-Stress Scale (DASS-21). The DASS-21 is reported to have satisfactory levels of internal consistency for its total scale (r = 0.93) as well as for its individual scales for depression (r = 0.88), anxiety (r = 0.82) and stress (r = 0.90).[60] In addition, DASS-21 scores will be examined as a potential moderator of intervention efficacy.

Resistance training

Since the AAQ does not capture resistance training and because the Synergy Study will promote regular resistance training, the number and duration of resistance training sessions per week will be assessed using two items adapted from previous studies that assessed resistance training.[61] One item will ask participants: "In the last week, on how many days have you participated in muscle strengthening activities (including weight/resistance training)?" and "What do you estimate was the total time (in hours/minutes) that you spent doing muscle strengthening activities (incl. weight/resistance training) in the last week?" The original items were adapted by changing the recall period from the previous month to the last week to align with the recall period used in the AAQ.

Sitting time

The Workforce Sitting Questionnaire (WFSQ) will provide a self-report measure of total domain-specific sitting time (over the last week), on workdays and non-workdays.[62] Domains include sitting time accumulated at work, watching TV, using a computer, using transport and doing other leisure activities. The WFSQ captures sitting time across several domains with acceptable validity (r = 0.45) and reliability (ICC = 0.63). Possible reductions in total sitting time may be a result of increased amounts of time allocated to light/incidental or moderate-to-vigorous physical activity.[63]

Sleep timing

A modified version of the validated Sleep Timing Questionnaire will be used to assess the variability in sleep and wake times on working days as well as non-working days.[64] To minimise participant burden, the instrument used will only include items on the stability of *usual* bed and wake times, and the *usual* bed and wake times per se. Response options are

categorical and scored on a scale from 1-11 with lower scores indicating less variability in bed or wake times (e.g., 1 = 0-15 min; 2 = 16-30 min; 11 = >4 hours).

Insomnia severity

The Insomnia Severity Index (ISI) is a valid and reliable instrument for measuring insomnia severity.[65] It can be used to classify individuals as having no insomnia (0-7), sub-threshold insomnia (8-14), moderate clinical insomnia (15-21) or severe clinical insomnia (22-28). This index will measure the proportion of the sample with potentially severe, yet undiagnosed insomnia symptoms. Whilst assessing the severity of sleep problems and the level of dissatisfaction with sleep a person can experience, the ISI also captures the extent to which the consequences of sleep problems manifest themselves in everyday life, for example "To what extent do you consider your sleep problem to interfere with your daily functioning (e.g. daytime fatigue, mood, ability to function at work/daily chores, concentration, memory, mood, etc.) currently?". Across a total of 7 items, responses are scored on a 5-point scale and summed to obtain a total score.

Daytime sleepiness

Daytime sleepiness is a further indicator of poor sleep health. It will be measured using the Epworth Sleepiness Scale (ESS), which assesses daytime sleepiness. This scale has demonstrated high internal consistency (Crohnbach's *alpha* = 0.88) and good reliability (*r* = 0.82) [66] and consists of 8 items that depicts various situations in which a person could experience dozing off (e.g., while sitting and reading or watching TV). Items are summed to calculate a total score from 0 to 24 with higher scores indicating higher levels of daytime sleepiness.

Process outcomes

Internet self-efficacy

Participants' confidence in using the smartphone app will be assessed using an adaptation of the Internet Self-Efficacy Scale to capture participants' overall understanding of app software, confidence in gathering information using the app and learning to use the app, as well as the ability to troubleshoot and resolve app problems.[67] Participants will rate their agreement using a total of eight statements (e.g., "I feel confident explaining why a task will not run on the smartphone/tablet") on a 7-point scale from *strongly disagree* to *strongly agree*.

Perceived user satisfaction

The Cognitive-Affective Model of Perceived User Satisfaction (CAMPUS) will be used to ask participants about thoughts and feelings associated with using the mobile app (Balanced). Using a 7-point scale ranging from *strongly disagree* to *strongly agree*, a total of 23 items enquire about participant opinion on the effects and aesthetics as part of the app design (15 items), its effectiveness and efficiency (5 items) and the level of satisfaction experienced when using the app (3 items) with the following anchors: *frustrated – contented*, *unhappy – gratified* and *sad – joyful*. Items will be adapted to refer specifically to the Balanced app, for example "I would consider my experience with using the Balanced app as innovative". This instrument has demonstrated adequate levels of reliability and validity.[68]

App usage

Overall interaction with the app will be measured continuously throughout the study period by the app database, which records the time and date a self-monitoring entry was made and the actual value or response entered into the app. Analysis of usage patterns will include the

number of self-monitoring entries made and the duration of self-monitoring throughout the intervention, similar to previous research.[69 70] These data will also be considered as a mediator of behaviour change in the intervention group.

Usability of the App

App usability will be assessed using the 10-item System Usability Scale,[71] a valid and reliable tool that assesses participant satisfaction relating to the utility of the websites on a 5-point scale (items will be reworded for smartphone app usability). Higher total scores (range 1-100) relate to better usability. Example items include "I would imagine that most people would learn to use this system very quickly." or "I needed the support of a technical person to be able to use this system.".

Utility, Advice Acceptability and Relevance of the App

A participant sub-sample (10%) will be determined by random selection for semi-structured telephone interviews, which will take place once all participants have completed their 6-month assessments. These interviews will contribute valuable information for process evaluation and include general personal feedback, desirable improvements and preferences relating to future use. As part of these interviews, participants will be asked about their perception of the app's usefulness to improve changes in self-efficacy levels (confidence) toward physical activity and sleep health, coping with potential impediments (barriers) to being more active and sleeping better, maintaining new routines/action plans and keeping it a priority to be more active and sleeping better. Finally, advice acceptability and relevance in terms of the content will be examined based on a previously used questionnaire.[72]

Mediators and moderators

Social Cognitive Factors

Testing social cognitive factors as potential mediators of intervention efficacy may provide insights into some of the underlying mechanisms of behaviour change, as observed in previous health behaviour interventions.[73] Constructs from Social Cognitive Theory[29] will be assessed using partially modified items from previously developed scales, with distinct items per behaviour relating to the person's projections towards the occurrence of each behaviour *over the next three months.* The constructs of interest include self-efficacy, perceived behavioural capacity, outcome expectations and expectancies, goals, action planning and socio-structural factors including social support and the environment. Items are described in more detail below and Table 4 summarises the number of items per behaviour per construct and lists response options for each item.

Physical Activity Items

For physical activity, a total of 34 items will be used to assess the social cognitive factors and a sum score will be calculated for each construct. Prior to asking these questions, participants will be advised that in the context of these questions "regular physical activity is defined as doing at least 150 minutes of moderate intensity physical activity each week. Moderate intensity can be described as any type of aerobic activity performed at a level where a person begins to lightly sweat, but can still carry on a conversation. This may feel different from one person to another."

Self-efficacy

Self-efficacy levels in the context of barriers will be assessed using a modified version of validated measures[74] consisting of 10 items. Response choices for these items range from "not at all confident" (1) to "extremely confident" (5) and items share the same stem ("I am

confident that I can participate in regular physical activity […]"), followed by situations or circumstances that may impede regular engagement in physical activity (i.e., "when I am a little tired, I am in a bad mood or feeling depressed, I have to do it by myself, it becomes boring, I can't notice any improvements in my fitness, I have many other demands on my time, I feel a little stiff and sore, the weather is bad, I have to get up early, even on weekends, I am on vacation").

Behavioural capacity

Participants will be asked how confident they are about having the capacity to engage in specific amounts and intensities of physical activity, using 3 statements[75] and response options from "never" (1) to "always" (5). An example statement is: "I can run or jog for 10 minutes without stopping."

Outcome expectations and expectancies

Using 5 items per construct, a total of 10 items will assess participants' expectations and expectancies pertaining to perceived personal gains (outcome expectations) from engaging in regular physical activity, followed by the level of importance associated with these gains (outcome expectancies). On a 5-point Likert scale ("strongly disagree" to "strongly agree"), participants will be asked first to indicate their level of agreement with 1 of 5 statements (adapted from Dewar, et al. [76]) relating to perceived benefits of regular engagement in physical activity (e.g., "Being physically active can reduce my risk for some illnesses and diseases (e.g., heart disease, diabetes, some cancers, etc.)") and then rate the value this would have for themselves (e.g., "How important is [e.g., reducing your risk for illness and disease?]") on a 4-point Likert-type scale ("not at all important" to "extremely important").

One sum score will be calculated for outcome expectations and one for outcome expectancies.

Social support

The role a person's social network plays in influencing physical activity participation will be assessed by asking participants about their level of agreement (on a 7-point scale from "strongly disagree" to "strongly agree") with 2 items that were previously modified for use in the context of a physical activity intervention[77]: "People in my social network are likely to help me participate in regular physical activity." and "I feel that someone in my social network will provide me with the support I need to get regular physical activity.".

Environment

The impact a person's built and natural environment has on physical activity engagement will be measured using 3 items from the IPAQ environmental module[78] that are answered on a 5-point Likert scale. This scale has shown acceptable levels of reliability with intra-class correlations ranging from 0.36 - 0.98. The 3 items are "There are sidewalks on most of the streets in my local area.", "There are many interesting things to look at while walking my local area." and "My local area has several free or low-cost recreation facilities, such as parks, walking trails, biking paths, playgrounds, and recreation centres.". Higher total scores correspond with an environment that facilitates physical activity, whereas lower scores indicate environmental impediments that may have a negative influence on physical activity levels.

Goals

To further assess the motivational mechanisms that drive progress towards goal attainment[29], participants will be asked to indicate the extent to which they intend to be active on a regular basis using 2 adapted items: "Do you intend to do regular physical activity over the next 3 months?"[76] and "How motivated are you to do regular physical activity over the next 3 months?"[79] that are answered using 7-point Likert-type response choices ranging from "No, not really" (1) to "strongly intend" (7) and "Not at all motivated" (1) to "Extremely motivated" (7), respectively. For both items, higher scores indicate greater strength of goals and the 2 scores will be summed to obtain a total score for goals.

Planning

Plans concerning "when", "where", "how" and "what kind" of physical activity participants will engage in will be assessed using a previously modified scale[80] that consists of 4 respectively worded items, where higher scores are interpreted as more detailed planning ("no plans" (1) - "detailed plans" (7)).

Sleep Hygiene Items

To assess the same constructs as above in the context of sleep hygiene practice, a total of 72 items were developed using partially modified scales that were previously used to assess social cognitive factors in the context of other health behaviours (i.e., physical activity, diet).[74 76] Each scale will query each of the following nine sleep hygiene practices: (1) avoiding caffeinated beverages (coffee, tea, energy drinks, etc.) in the late afternoon or right before bedtime, (2) avoiding nicotine right before bedtime, (3) avoiding alcohol right before bedtime, (4) exercising regularly, (5) reducing stress levels, (6) reducing the impact of noise and nuisance in the bedroom, (7) keeping sleep and wake times consistent, (8) avoiding daytime naps and (9) avoiding the use of technological devices (e.g., phone, TV, laptop, etc.)

right before bedtime or in bed. To avoid overburdening participants, each construct will be assessed using a single item per sleep hygiene behaviour. Thus, each social cognitive construct will have nine items. Each construct will be scored as the sum of the nine sleep hygiene items, with a higher sum score indicating improvement. The environment construct however, will not be included for sleep hygiene behaviours, as this is already captured as part of the perceived neighbourhood disorder questionnaire described below.

Self-efficacy

Items assessing self-efficacy relating to sleep hygiene will be answered on a 5-point Likert-type scale ("not at all confident" to "extremely confident) using the commonly used stem "I can […]"[81] in connection with each of the 9 sleep hygiene behaviours (e.g., "[…] avoid alcohol right before bedtime.", "[…] reduce the impact of noise and nuisance in my bedroom.", etc.).

Behavioural capacity

Participants will be asked to rate ("never" (1) to "always" (5)) their perceived behavioural capacity of making various choices in favour of keeping good sleep health using "Whenever I have the opportunity to […]" as a stem. For example, "Whenever I have the opportunity to use technological devices right before bedtime or in bed, I know how to avoid or remove them." These items were adapted from previously used scales[76] with a focus on situations that challenge the reinforcement of making healthy dietary choices. In the context of avoiding behaviours that do not promote good sleep health, behavioural capacity can be thought of as a function of inhibitory control.[82]

Outcome expectations and expectancies

Similar to the scales described above for physical activity, those for sleep hygiene will be built on two single stems per sleep hygiene behaviour adapted from previous studies: "For me, [keeping consistent sleep and wake times] would help me sleep better."[74] and "How important is it to [e.g., keep sleep and wake times consistent] to sleep well?".[76] The outcome expectations items are answered on a 7-point Likert scale and the outcome expectancies items are answered on a 4-point scale ranging from "not at all important" (1) to "extremely important". Sum scores will be reported separately for each of the 2 constructs.

Social support

To assess social support as a socio-structural factor that may or may not have a facilitating effect on sleep hygiene practice, the commonly used stem "Most people who are important to me would encourage me to [e.g., reduce my stress levels.]"[79 82] will be used with response choices ranging from "strongly disagree" (1) to "strongly agree".

Goals

The extent to which people "intend to […]" practice sleep hygiene behaviours will be measured using a 7-point Likert-type scale (from "no, not really" to "strongly intend") with higher scores indicating stronger goals. This item was used previously in a sleep hygiene context.[82]

Planning

To test participants' plans with regards to practicing good sleep hygiene, each of the nine items assessing this construct will ask if a person has planned "where, when and how" to avoid caffeine, avoid nicotine, avoid alcohol, exercise regularly, reduce their stress levels, minimise the impact of noise and nuisance in their bedroom, keep their sleep and wake times

consistent, avoid daytime naps and avoid using technological devices right before bedtime or in bed. Whilst previous studies[80] have used 4 separate items to assess planning to engage in the behaviour ("when", "where", "how" and "what kind" of behaviour x), these were collapsed into one item per sleep hygiene behaviour to reduce response burden.

Table 4.
Social cognitive factors related to physical activity and sleep hygiene behaviours

Construct	Items	Response anchors
Physical Activity		
Self-efficacy	10	(1) not at all confident (5) extremely confident
Perceived behavioural capacity	3	(1) never (5) always
Outcome expectations	5	(1) strongly disagree (7) strongly agree
Outcome expectancies	5	(1) not at all important (4) extremely important
Environment	3	(1) strongly disagree (5) strongly agree
Social support	2	(1) strongly disagree (5) strongly agree
Goals	2	(1) no, not really (7) strongly intend; and (1) not at all motivated (7) extremely motivated
Action planning	4	(1) no detailed plans (7) detailed plans
Sleep Hygiene Behaviours (k = 9)		
Self-efficacy	9	(1) not at all confident (5) extremely confident
Perceived behavioural capacity	9	(1) never (5) always
Outcome expectations	9	(1) strongly disagree (7) strongly agree
Outcome expectancies	9	(1) not at all important (4) extremely important
Environment	9	(1) strongly disagree (5) strongly agree
Social support	9	(1) strongly disagree (5) strongly agree

Goals	9	(1) no, not really (7) strongly intend and
Action planning	9	(1) no detailed plans (7) detailed plans

Note. Each item per construct will refer to one of nine different sleep hygiene behaviours

Automaticity

Habits relating to lifestyle behaviours are non-conscious processes, which can act as determinants of behaviour and may even regulate behaviour independently of changes in conscious processes such as implementation intentions (goals).[83] The role that behavioural automaticity plays in the context of physical activity and sleep behaviours, respectively, will be taken into account using 1 item from the Automaticity Index per sleep hygiene behaviour (9 items),[84] and all 4 items of the index relating to physical activity (13 items in total), for example: "Reducing the impact of noise in my bedroom is something *I do automatically*.", "Exercise is something I do without thinking.".

Sleep hygiene

Sleep hygiene will be assessed to measure changes in in sleep hygiene behaviour using the 13-item Sleep Hygiene Index (SHI) developed by Mastin et al.[85] Higher global scores indicate poorer sleep hygiene behaviour, but there is no cut-off to label categories of sleep hygiene engagement. This instrument demonstrates acceptable internal consistency (α = 0.66) and test-retest reliability (r = 0.71, p <0.01).[85] Importantly, the SHI shows positive correlations (r = 0.48) with both the global scores (p <0.01) and the component scores (p <0.05 or less) of the Pittsburgh Sleep Quality Index.[85] Items are answered using a 5-point Likert scale from *never* (0) to *always* (4).

Environment

Perceptions about the order or disorder within a person's physical and/or social environment (i.e., neighbourhood peacefulness, safety, cleanliness) can have a significant influence on physical activity levels and the quality and duration of sleep.[86-88] A person's neighbourhood environment can also negatively affect mental health and participation in other health behaviours.[89] Based on an existing scale of neighbourhood disorder, which demonstrated good levels of construct validity and internal consistency/reliability,[90] 4 items will assess each of the following characteristics of neighbourhood disorder: *physical disorder* and *physical order, social disorder* and *social order*. These are assessed using the following items: (1) "My neighbourhood is noisy", (2) "My neighbourhood is clean", (3), "There is a lot of crime in my neighbourhood" and (4) "My neighbourhood is safe" These items will be answered on a 5-point scale from strongly disagree (1) to strongly agree (5) and the average responses across the four items will be calculated.

Sample characteristics

A range of demographic and socioeconomic factors such as age, gender, height and weight, education, income, marital status, occupation, working hours, etc. will be assessed. Participants will be asked to also indicate (allowing multiple selection) whether they have been told by a doctor that they have any of the following chronic diseases: arthritis, asthma, cancer, cerebrovascular disease (stroke), chronic obstructive pulmonary disease (emphysema), coronary heart disease (heart attack, angina), type-1 diabetes, type-2 diabetes, high blood pressure, kidney disease, mental illness (depression, anxiety, etc.), osteoporosis, irritable bowel syndrome, high cholesterol, or any other disease (to be specified by the participant). In addition, participants will be assessed for *morningness* or *eveningness* type,[91] as eveningness types are thought to be more prone to engage in activities that cause social jetlag, due to misalignments between times of sleep and times of social activity.[92]

Power and sample size

Meta-analyses of physical activity interventions typically report small to moderate increases in physical activity (Cohen's $d = 0.14 – 0.68$).[93 94] Moreover, poor sleep health, specifically the duration or quality of sleep, has small to moderate magnitude associations with lower physical activity levels.[95] Meta-analyses of non-pharmacological sleep interventions report small to medium effect sizes for changes in sleep quality (Hedge's $g = 0.35$ and Cohen's $d = 0.41$) in clinical populations,[96 97] and medium to large effect sizes ($d = 0.74$) in studies using exercise to improve sleep.[98] Therefore, based on these observations and feasibility data from a previous study,[38] it was assumed that a 3-month combined physical activity and sleep intervention that specifically targets both behaviours and leverages the bi-directional relationship between behaviours is likely to produce moderate increases in physical activity ($d = 0.45$) and moderate to large increases in sleep quality ($d = 0.65$). Pre-post correlations were based on preliminary data taken from a trial targeting and measuring changes in physical activity and sleep,[38] which showed correlations of $r = 0.57$ and $r = 0.60$ for physical activity and sleep quality, respectively; therefore a pre-post correlation of 0.60 was assumed in the current study. Assuming an alpha of 0.025 (due to measuring two primary outcomes; MVPA and sleep quality), power of 0.80, a moderate effect size ($d = 0.45$ for physical activity; $d = 0.65$ for sleep) and a pre-post correlation of 0.60, a total of 60 participants per group will be required for physical activity and 35 per group for sleep quality, the larger sample of which will be used.

Meta-analyses of physical activity and sleep interventions report average drop-out rates of 20%,[94 96] however, the majority of web-based trials report drop-out rates that are higher than that.[93] As there is insufficient information available on attrition in m-health interventions, the

sample size for this study will be inflated to account for a 25% drop-out. Therefore, the total sample size is 80 participants per group or 160 in total. A sample of this size will also be adequately powered to detect mediated effect sizes of small ($\beta = 0.14$) magnitude.[99] The participant recruitment phase will conclude once 160 complete baseline responses have been obtained.

Analyses

Analyses will apply the *intention-to-treat* principle. Analysis of primary outcomes will be blinded to group allocation and overseen by an independent statistician. The primary aim of this study will be to examine differences in physical activity and sleep quality between the intervention group and the control group at the 3-month primary time point. Between-group differences in physical activity (AAQ minutes) and sleep quality (PSQI) will be estimated using Generalised Linear Mixed Models (GLMM) adjusting for baseline measures of the outcome, including all available data in the analysis. The model will include fixed effects for group, time and their interaction. A random intercept will be used to account for repeated measures on individuals. Separate GLMM will be used to examine changes in physical activity and sleep.

Sensitivity analyses using Pattern Mixture Modelling will be conducted to examine the impact of missing data on outcomes. Where the GLMM assumes data are missing at random, Pattern Mixture Modelling is robust to the assumed pattern of missing data. Group differences in secondary outcome measures will be estimated using the same linear mixed modelling approach, setting an alpha of 0.025 for each outcome. Potential mediators and moderators of intervention efficacy will be examined using established approaches.[100]

Generalised linear mixed models and survival analysis will be used to examine differences in usage patterns.

Ethics and dissemination

Any type of adverse events reported by study participants that occurred in relation to their participation in the study will be recorded and reported to the HREC. This may include events reported by participants, including musculoskeletal injuries associated with the uptake or increase in physical activity or emotional distress due to any survey items of sensitive nature. Great care will be taken to avoid and prevent adverse events and the research team will provide every possible assistance to remediate those events, should they occur. The participant information statement interested individuals will have access to prior to consenting to participate details any potential risks of discomfort associated with participation in the study and provides contact details and information of national support services (e.g., Black Dog Institute, Lifeline, etc.).

Survey data will be exported directly from Qualtrics® as a text file and imported in electronic form for scoring and analysis using statistics software. A detailed database will track participants' progress through the trial including the scheduling of assessments and reminders to complete assessments. Intervention usage will be monitored throughout the trial by BM and MJD by way of the password-protected app database. Given the purpose of the trial, the data to be collected as well as the nature of the intervention, no *Data Monitoring Committee* will be established. Detailed strategies, including Email/text message reminders will be used to remind participants about upcoming assessments. All Newcastle-based members of the research team (BM, MJD, ATR, RCP) and other associated personnel will have access to the information in both identified and re-identifiable forms. Should statistical analysis advice be

sought, access to the data will be granted in re-identifiable form using unique numerical identifiers and access approved by the relevant Ethics Committee.

Print data will be stored in locked filing cabinets accessible only to the research team. Electronic data will be stored on password-protected computers or servers only accessible to the research team. Data will be retained for 15 years in accordance with section 3.1.1 of the *Australian Code for the Responsible Conduct of Research* and all (paper and electronic) records will be disposed of in accordance with the requirements of the *Australian Code for the Responsible Conduct of Research*.

Results from the outcome measures will not be presented in a way that adversely affects the confidentiality of participants. The description of participants will not allow identification of individual participants, and individual results and individual names will not be revealed. Final reports and publications will only consist of aggregated results. At the completion of the study, participants will receive a plain English summary of study results. Scientific reports of the main outcomes, secondary outcomes and process evaluation will be submitted to peer-reviewed journals. Results will also be incorporated into student theses and presented at national and international conferences.

DISCUSSION

It is advised that adults accumulate a weekly minimum of 150 minutes of moderate intensity physical activity, combined with muscle strengthening activities on two days per week,[7] and also achieve 7-9 hours of good quality sleep each night.[101] Engaging in the recommended levels of physical activity and maintaining good sleep health contributes to overall health and wellbeing through risk reductions associated with chronic diseases such as heart disease and

type-2-diabetes.[3-6] Engaging in optimal levels of physical activity and sleep health can also positively contribute to long-term weight management, mental health and overall quality of life.[102-104] Notwithstanding this wide spectrum of benefits, a large proportion of the population does not accumulate sufficient physical activity and/or achieve optimal sleep.

Wide reaching behavioural programmes, such as those offered through m-health interventions, have the potential to elicit the much needed shift of relatively large groups of the population toward levels of physical activity and sleep that meet recommendations.[105] Multiple behaviour interventions are effective at changing health behaviours[19] and whilst m-health interventions as such have been shown to effectively improve physical activity and sleep health as individual behaviours,[106 107] there is additional evidence from website-based interventions supporting the efficacy of remotely delivered interventions targeting multiple behaviours in combination.[108 109] To yield positive changes in health behaviour, such interventions need to include educational information, incorporate behaviour change techniques and deliver a level of guidance that endorse the initiation and maintenance of health behaviour change.[29 110] Systematic reviews of the effectiveness of multiple health behaviour interventions suggested that those targeting related behaviours (e.g., diet and physical activity) produced greater behaviour change than those targeting unrelated behaviours (e.g., smoking and physical activity),[111] and that specific intervention techniques are necessary for each behaviour.[26] Physical activity and sleep are suggested to have a bi-directional relationship,[16] yet no previous RCTs have combined physical activity and sleep in one intervention and therefore have not utilised the synergistic relationship between physical activity and sleep. The Synergy Study addresses this by targeting both physical activity and sleep, simultaneously, using specific intervention techniques to enhance participants' self-regulatory skills in relation to the two health behaviours and thus, leverages the potential for

synergistic improvements in both behaviours. An advantage of this study lies in its mode of delivery, which involves mobile technology and therefore blends into day-to-day life. A key intervention strategy is the use of goal-setting and feedback to promote behaviour change. It seeks to achieve this through the promotion of dynamic goals and action plans, the implementation of a personalised support system further addresses potential barriers (i.e., low levels of self-efficacy) that can increase the gap between participant intentions (goals and plans) and behavioural outcomes,[112] and contribute to long-term behaviour maintenance. This includes knowledge on how to set attainable goals and having strategies in place that facilitate the occurrence of healthy behaviours, despite challenging situations or unfavourable environmental factors.[29] The structured promotion of goal-setting strategies, combined with action plans that define in detail how an individual will implement the intended behaviour, is known to be effective in changing health behaviours.[110]

Additional strengths of this study include its randomised waitlist controlled study design, which will allow making inferences about the causal links between the intervention and changes in behaviour. The use of remote delivery through a m-health format makes it possible to recruit nationwide and has the potential to be scaled up further including an international version of the programme. Delivering the Synergy study in multiple countries however, would require further refinement of the contents and adaptation to cross-cultural factors as well as geographical differences. While it is the first aim of this study to test the intervention's efficacy to produce changes in two primary outcomes, the pre-specified secondary outcomes (mental health, quality of life) will give insight into changes in parameters of health and wellbeing that may be very meaningful to the participant. And finally, this study will generate knowledge on social cognitive determinants of behaviour change relating to sleep health and explore how these factors differ between physical activity

and sleep. This will enhance the understanding of underlying mechanisms associated with successful behaviour change in both behaviours and also further the application of social cognitive theories in the multi health behaviour context. The limitations of this study include the study duration, which, although at 6 months is longer than many studies,[93] does not provide insight into longer term changes and behaviour maintenance; and the lack of a comparator condition receiving only the sleep or the physical activity programme to determine the magnitude each intervention component has on its own. It is beyond the scope of this study to test long-term efficacy exceeding 6 months, but future trials may be encouraged to do this, provided the Synergy Study proves efficacious in the short term with indications of effect retention at the 6-month time point.

CONCLUSION

This study protocol provides the rationale and methods associated with the implementation and evaluation of the Synergy Study, a theory-based m-health intervention including personalised support, with the aim to improve physical activity and sleep health in Australian adults. To the authors' knowledge, this study will be the first to simultaneously target changes in these two behaviours, using a sophisticated combination of technologies and evidence-based strategies and test the efficacy of this approach in a randomised controlled trial. Findings from this trial will provide valuable knowledge pertaining to the design of m-health interventions that combine behaviours in a format with wide reach.

Study sponsorship, funding and organisation

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The trial is sponsored by the University of Newcastle and will be coordinated independently of the study sponsor and funder by the Priority Research Centre for Physical Activity and Nutrition, University of Newcastle, Australia and managed by project lead BM and overseen by chief investigator MJD. The study funder and sponsor will have no role in the conducting or evaluation of the trial, nor did the study funder and sponsor have any authority over the study design, collection, management, analysis and interpretation of data, the preparation of manuscripts or the submission of reports.

Declaration of interests

The authors and principal investigators of this study protocol declare no conflict of interest.

Roles and responsibilities

Any amendments to the study protocol will be submitted to the Human Research Ethics Committee (HREC) and updated on the trial register (ANZCTR) once full ethical approval has been obtained. All authors meet ICMJE criteria for authorship in that they have contributed substantially to the conceptual design; or the processes of data collection, analysis or interpretation; the drafts and revisions of the study protocol and manuscript; granted approval of the final version of the study protocol; and acknowledged their accountability with regards to the integrity and accuracy of this study protocol.[113] In detail, the first author of this protocol (BM) will be responsible for administrative and managerial procedures related to all phases of the trial, which will be supervised by MJD and RCP. ATR will fulfil this role, in the case of BM's temporary illness or absence. BM, MJD, ATR and RCP contributed to the development of study materials, all authors (BM, RCP, ATR, CV, WJB and MJD) have contributed to the conceptual design of the trial and the writing of the

protocol and will be involved in the interpretation of results, the evaluation of the trial and dissemination of study findings.

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Table 1. *Overview and content of message-based support service*

Table 2. *Operationalisation of social cognitive factors and behaviour change strategies*

Table 3. *Overview of outcome measures and assessment time points*

Table 4. *Social cognitive factors related to physical activity and sleep hygiene behaviours*

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Figure 1. *Flow of participants in the Synergy Study*

Figure 2. *Sleep hygiene log items*

Figure 3. *Screenshots of app screens for self-monitoring and feedback relative to goals*

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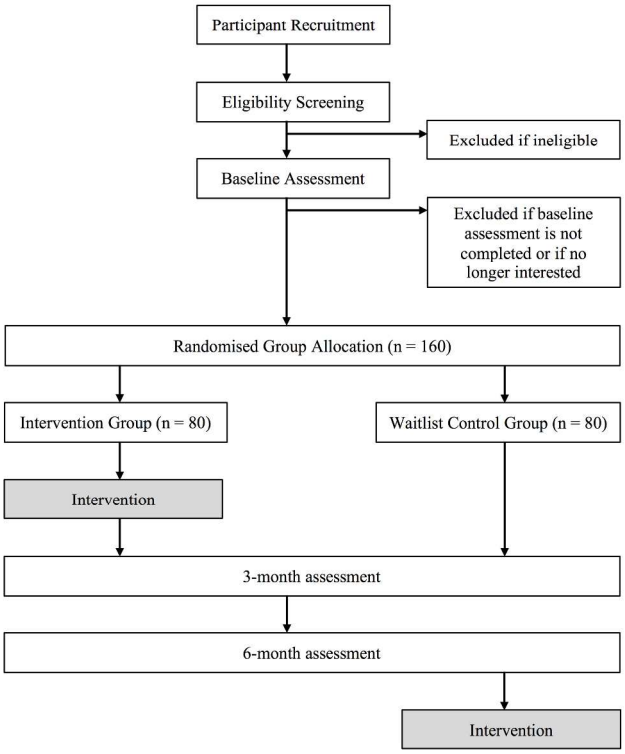

Figure 1. Flow of participants in the Synergy Study

296x420mm (300 x 300 DPI)

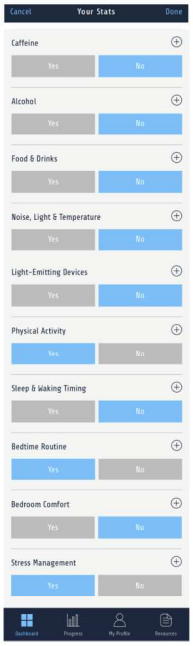

Figure 2. Sleep hygiene log items.

Figure 2. Sleep hygiene log items

296x420mm (300 x 300 DPI)

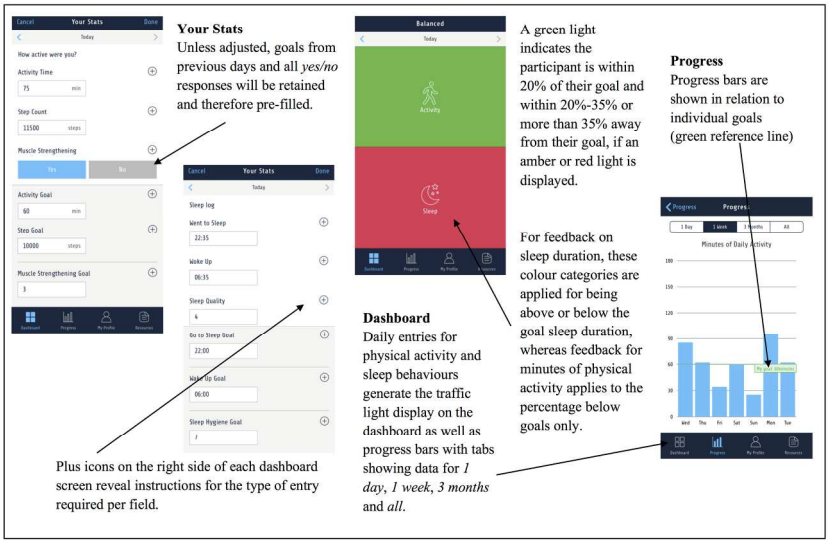

Figure 3. Screenshots of app screens for self-monitoring and feedback relative to goals

209x148mm (300 x 300 DPI)

STUDY PROTOCOL: IMPROVING ADULTS PHYSICAL ACTIVITY AND SLEEP

Appendix 1.
WHO Trial Registration Data Set (Version 1.2.1)

1. **Primary Registry and Trial Identifying Number**
   Australia New Zealand Clinical Trial Registry (ANZCTR): ACTRN12617000376347

2. **Date of Registration in Primary Registry**
   13/03/2017

3. **Secondary Identifying Numbers**
   Universal Trial Number (UTN): U1111-1186-6588 (obtained on 19/08/2016)

4. **Source(s) of Monetary or Material Support**
   National Heart Foundation of Australia – This project is supported by Vanguard Grant (ID 100629) and also by a Future Leader Fellowship (ID 100029) from the National Heart Foundation of Australia.

5. **Primary Sponsor**
   The University of Newcastle

6. **Secondary Sponsor(s)**
   None

7. **Contact for Public Queries**
   Associate Prof Mitch Duncan, ATC Building Level 3, The University of Newcastle, University Drive, Callaghan NSW 2308, Australia *Email:* Mitch.Duncan@newcastle.edu.au Phone: +61 2 4921 7805

8. **Contact for Scientific Queries**
   Associate Prof Mitch Duncan, ATC Building Level 3, The University of Newcastle, University Drive, Callaghan NSW 2308, Australia *Email:* Mitch.Duncan@newcastle.edu.au Phone: +61 2 4921 7805

9. **Public Title**
   Testing the effectiveness of a mobile device delivered program to improve physical activity and sleep among inactive Australian adults with poor sleep.

10. **Scientific Title**
    A randomised controlled trial using a theory-based m-health intervention to improve physical activity and sleep health in adults: The Synergy Study protocol.

11. **Countries of Recruitment**
    Australia

12. **Health Condition(s) or Problem(s) Studied**
    Physical inactivity and poor sleep health will be targeted to promote the prevention of chronic diseases such as type-2 diabetes, heart disease and obesity through greater levels of physical activity and better sleep health (characterised by optimal sleep duration, good sleep quality and consistent bed and wake times).

    If the study is conducted in healthy human volunteers belonging to the target population

of the intervention (e.g. preventive or screening interventions), enter the particular health condition(s) or problem(s) being prevented.

13. **Intervention(s)**

Intervention Group: The intervention group will receive a combined physical activity and sleep intervention using a mobile app and personalised support for 3 months

Intervention Description: The mobile app will operationalise goal-setting, self-monitoring and feedback strategies in relation to physical activity and sleep health. The message-based support service (Email and text messaging) will provide feedback on progress towards goals, prompts to practice the two behaviours and review/adjust goals, daily reminders (optional) and tool sheets on goal-setting, action planning and stress management. Participants will be asked to self-monitor their daily physical activity and sleep behaviours and set personal goals for both behaviours within the app. We will advise participants to log both behaviours on a daily basis, whereas goals can be reset at any time (if need be) or otherwise will remain unchanged. A summary report, which is sent to participants once weekly will assist with the process of goal review. Goal achievement is considered successful, if participants are within 20% of their goal. For example, if a participant aimed for 30 min of activity, their feedback dashboard (traffic light) will display a green light and their goal is reached, if the participant logged at least 24 min of activity or more for that day. Multiple entries per day are possible. A pedometer will be shipped to participants to facilitate the logging of a daily step count. Participants will be asked to set relevant and achievable goals (guidance provided); however, we will encourage individuals to gradually work towards the recommended minimum of physical activity (PA) and sleep as per national guidelines, which is 150 min/week (plus 2 days of resistance training) for PA and 7-9 hours of sleep per night. The app and all other components are informed by social cognitive theories and follow behaviour change taxonomies to ensure consistency with implementation standards and reporting. Participants will be given continuous access to the app.

Waitlist Control Group:
Following the 6-month follow-up assessment, thee waitlist control group will receive full access to the intervention

14. **Key Inclusion and Exclusion Criteria**

Interested individuals meeting any of the following criteria are not eligible to participate:

- not residing in Australia;
- not between 18 and 55 years old;
- reporting a height and weight that is not consistent with a BMI between 18.5 and 35;
- accumulating more than 90 minutes of moderate/vigorous physical activity per week;
- rating their sleep-quality (over the past month) as *fairly good* or *very good*;
- currently pregnant or having given birth in the past 12 months;
- having a condition that would make it unsafe or limits their ability to increase activity levels or change sleep behaviours;
- having a diagnosed sleep disorder (chronic insomnia, sleep apnoea, sleepwalking, narcolepsy, restless legs syndrome, etc.);
- currently consuming hypnotics (sleep inducing medication);

- being employed in any night shift work;
- planning frequent travel (once a month or more often) to a destination with a shift in
- time zone by more than three hours during the intervention period;
- currently using a self-monitoring system or device to track or log physical activity or
- sleep (this includes non-device assisted applications); and
- not having access to an internet-enabled iOS (Apple) or Android smartphone or tablet.

14. **Study Type**
Study type consists of:
- Type of study: interventional
- Study design: 2-arm RCT with a waitlist control group
  - Method of allocation: randomized
  - Masking: unmasked
  - Assignment: intervention group vs. waitlist control group
  - Purpose: to determine causal effect of the intervention
- Phase: n/a
- Allocation concealment and sequence: Opaque envelopes (k = 80 per group) using permuted block randomization with block sizes of 4 and 8. A researcher not associated with the study who is responsible for group allocation will open the envelope that is next in sequence and inform the project leader about the allocation outcome.

15. **Date of First Enrolment**
01/06/2017

16. **Target Sample Size**
n = 160 (80 per group)

17. **Recruitment Status**
Recruiting (participants are currently being recruited and enrolled)

18. **Primary Outcome(s)**
Two primary outcomes have been specified for this study

- **Physical Activity**
- The Active Australia Questionnaire
- 0, 3 and 6 months

- **Sleep Quality**
- The Pittsburgh Sleep Quality Index
- 0, 3 and 6 months

19. **Key Secondary Outcomes**
- **Health-related quality of life**
- RAND-12 plus 3 items from the RAND-36 assessing energy/fatigue
- 0, 3 and 6 months

- **Mental Health (depression, anxiety, stress)**
- Depression-Anxiety-Stress Scale (DASS-21)
- 0, 3 and 6 months

- **Resistance training**
- Number of sessions per week and duration per session
- 0, 3 and 6 months

- **Sitting time**
- Workforce Sitting Questionnaire
- 0, 3 and 6 months

- **Sleep timing**
- Sleep Timing Questionnaire
- 0, 3 and 6 months

- **Insomnia symptom severity**
- Insomnia Severity Index
- 0, 3 and 6 months

- **Daytime sleepiness**
- Epworth Sleepiness Scale
- 0, 3 and 6 months

STUDY PROTOCOL: IMPROVING ADULTS PHYSICAL ACTIVITY AND SLEEP

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	5
	2b	All items from the World Health Organization Trial Registration Data Set	Appendix 1
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	32
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1;32
	5b	Name and contact information for the trial sponsor	1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	32
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	32
Introduction			

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3ff
	6b	Explanation for choice of comparators	n/a
Objectives	7	Specific objectives or hypotheses	5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6f
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9ff
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	17
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	16; 18
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	19ff
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	8

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	28f
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	6
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	17
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	17
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	17
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	17
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	18ff
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	18

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	30
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	30
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	30
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	30
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	31
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	33
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	n/a
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	32

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	6
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	31
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	32
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	31
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	10
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	31
	31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Appendix 2
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a