BMJ Open

Physical activity coaching for adults with mobility limitations: protocol for the ComeBACK pragmatic randomised controlled trial.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-034696
Article Type:	Protocol
Date Submitted by the Author:	02-Oct-2019
Complete List of Authors:	Hassett, Leanne; University of Sydney, Sydney School of Public Health Tiedemann, Anne; University of Sydney, Australia, Hinman, Rana S.; University of Melbourne, Crotty, Maria; Flinders University, Rehabilitation, Aged and Extended Care Hoffmann, Tammy; Bond University, Harvey, Lisa; The University of Sydney, Kolling Institute; Taylor, Nicholas ; La Trobe University, Melbourne, Victoria, Australia Greaves, Colin; University of Birmingham School of Sport Exercise and Rehabilitation Sciences, School of Sport, Exercise and Rehabilitation Science Treacy, Daniel; The University of Sydney Jennings, Matthew; South Western Sydney Local Health District Milat, Andrew; New South Wales Ministry of Health, Centre for Epidemiology and Evidence Bennell, Kim; University of Melbourne, CHESM Howard, Kirsten; University of Sydney, School of Public Health van den Berg , Maayken; Flinders University Pinheiro , Marina; The University of Sydney Wong, Siobhan; The University of Sydney Kirkham, Catherine; The University of Sydney Ramsay, Elizabeth; The University of Sydney Sherrington, Catherine; University of Sydney, Sydney School of Public Health
Keywords:	Clinical trials < THERAPEUTICS, Rehabilitation medicine < INTERNAL MEDICINE, GERIATRIC MEDICINE

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Physical activity coaching for adults with mobility limitations: protocol for the ComeBACK pragmatic randomised controlled trial.

Hassett L,[1] Tiedemann A,[1] Hinman RS,[2] Crotty M,[3] Hoffmann T,[4] Harvey L,[5] Taylor NF,[6] Greaves CJ,[7] Treacy D,[1,8] Jennings M,[9] Milat A,[10,11] Bennell K,[2] Howard K,[11] van den Berg M,[3] Pinheiro M,[1] Wong S,[1] Kirkham C,[1] Ramsay E,[1] Sherrington C.[1]

[1]Institute for Musculoskeletal Health, University of Sydney

[2]Centre for Health, Exercise and Sports Medicine, Department of Physiotherapy, The University of Melbourne

[3]College of Medicine and Public Health, Flinders University

[4]Institute for Evidence-Based Healthcare, Bond University

[5]John Walsh Centre for Rehabilitation Research, Northern Clinical School, University of Sydney

[6]School of Allied Health, Human Services and Sport, La Trobe University

[7]School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham

[8]Sydney East Local Health District

[9]South Western Sydney Local Health District

[10]NSW Ministry of Health

[11]School of Public Health, University of Sydney

Corresponding author:

Prof Catherine Sherrington

cathie.sherrington@sydney.edu.au

Abstract

Introduction. Mobility limitation is a common and serious form of physical disability often resulting from neurological and musculoskeletal health conditions, ageing and/or physical inactivity. Participation in physical activity is likely to enhance physical and mental health in people with mobility limitations. In consultation with consumers, clinicians, and policy makers, we have developed two affordable and scalable intervention packages designed to enhance physical activity. Both are based on behaviour change theories and involve tailored physical activity advice from physiotherapists.

Methods and analysis. Among adults with self-reported mobility limitations, this pragmatic trial (n=600) aims to estimate the effects on physical activity of: i) an enhanced 6-month intervention package (one face-to-face physiotherapy assessment, tailored physical activity plan, physical activity phone coaching, informational/motivational resources and activity monitors) compared with a less intensive intervention package (single session of tailored phone advice, tailored physical activity plan, unidirectional text messages, informational/motivational resources); ii) the enhanced intervention package compared with no intervention (waiting list control group); iii) the less intensive intervention package compared with no intervention (waiting list control group). The primary outcome will be average steps per day, measured with the *StepWatch* activity monitor over a one-week period, 6 months after randomisation. Secondary outcomes will include other physical activity measures, difficulty walking, overall function and disability, individualised mobility goal attainment, mental wellbeing, quality of life and falls. A hybrid effectiveness-implementation design (Type 1) will be used to enable the collection of secondary implementation outcomes at the same time as the primary effectiveness outcome. An economic analysis will estimate the cost-effectiveness and cost-utility of the interventions compared to no intervention and to each other.

Ethics and dissemination. Ethical approval has been obtained. Dissemination will be via publications, conferences, newsletter articles, talks to clinicians and consumers and meetings with health department and health service managers.

Registration. ACTRN12618001983291

Strengths and limitations of this study

- Addressing an important and growing health problem
- Pragmatic evaluation (including cost effectiveness) of a scalable person-centred intervention with multiple recruitment sites and strategies
- Multi-disciplinary theory-based intervention design informed by consumers/clinicians and policy makers building on previous studies by the authors and others
- Six-month study timeframe will not enable questions about lasting intervention impacts to be answered.
- Staffing in the trial does not enable those who do not speak English to participate.

Introduction

Mobility limitation (i.e., difficulty or inability to walk) is a particularly common[1] and serious form of physical disability. It is primarily due to neurological and musculoskeletal health conditions, physiological ageing and inactivity-related deconditioning.[2] Walking impairment or 'dismobility' is predictive of adverse health outcomes, including death.[2] Widespread screening for walking problems has been suggested as an additional vital sign, and development and testing of interventions for people with walking difficulties has been highlighted as an urgent research priority.[2]

Walking is required for many daily activities, thus individuals with difficulty walking are often unable to perform daily activities and require care services. Mobility limitation is particularly common in older people and, as the population is ageing, the impact of mobility limitation is increasing. Interventions that are able to increase mobility and reduce service needs in people with mobility limitations is likely to yield benefits for individuals and financial benefits for societies. Mobility limitation also affects younger adults with chronic acquired or congenital musculoskeletal or neurological conditions, conditions which are becoming more common due to better survival from serious illnesses and injuries.[3] Mobility impairment with onset earlier in life also has an important impact on population health due to the lasting nature of the impairment and significant impacts on productivity.[4,5]

Physical activity participation has enormous untapped potential as a cost-effective approach to enhancing physical and mental health in people of most ages, health conditions and physical abilities.[6] A *Lancet* editorial[6] calls for physical activity to be taken more seriously as a population health intervention, given the strong evidence of physical and mental health benefits and poor participation rates. As well as enhancing the prevention and management of chronic conditions, physical activity is now known to have survival benefits.[7] For example, taking a greater number of steps per day was associated with lower all-cause mortality over a 10-year follow-up period.[8] In those who increased daily steps there was a substantial reduction in mortality risk after adjusting for baseline daily step count.[8]

People with health conditions affecting mobility can obtain additional benefits from physical activity including better mobility, fewer falls and less risk of hospitalisation.[9] Physical activity enhances mobility through improved aerobic capacity, muscle strength, balance and coordination.[10] More demanding mobility tasks such as stair-climbing and walking longer distances require greater levels of physical functioning. If a person's physical functioning is

lower than that required for independent performance of a particular activity i.e., below the "disability threshold", they will require assistance or aids. Greater physical functioning provides "reserve capacity" which acts as a buffer to ensure that functioning remains above the disability threshold even in the face of deterioration from factors such as physiological ageing, illness or injury. Much of the deterioration in physical fitness and mobility commonly thought to be due to ageing/health conditions is actually due to inactivity and thus at least partly treatable and preventable.[11] Trials have confirmed that physical activity can improve walking ability and prevent the onset of disability.[12] For example the onset of mobility disability was prevented by a structured physical activity program in people aged 70-89 who had some physical limitation at baseline.[12]

Unfortunately, people with mobility limitations are less active than the general population.[13] For example, 65% of Australians regularly participate in physical activities for recreation, exercise or sport, but only 24% of Australians with disabilities participate in such activities.[14] Although widespread provision of supervised structured exercise programs would be likely to significantly lessen mobility impairment at a population level, such an approach is unlikely to be broadly implemented by public health systems given the size of the target population. Self-funding of such interventions is out of reach for many individuals. More flexible intervention approaches that focus on physical activity more broadly, facilitate attendance at existing programs, include self-management approaches, and incorporate technology are likely to be more scalable. These approaches therefore warrant investigation.

Regular physical activity participation requires motivation, capability and opportunity.[15] Simply advising people to be more active is unlikely to safely enhance activity levels.[16] Rather, advice needs to be specific, individualised, supported by a behaviour change framework and based on engagement with the person and their goals and priorities.[17] Health coaching interventions that involve behaviour change techniques including goal-setting and are individually tailored are known to change behaviour in the general population.[17-19] A recent systematic review[20] found health coaching to improve physical activity levels in older people (standardised mean difference = 0.29; 95% CI 0.18 to 0.39; $p < .001$) and others have found motivational interviewing (a form of health coaching) to enhance physical activity in people with chronic conditions[21] and in hip fracture survivors.[22] These trials focused on health conditions so did not cater specifically for people with impaired mobility. The impact of health coaching in this population is not known. Physical activity prescription in people

with mobility limitations is complex so we hypothesise that tailored advice from physiotherapists will enhance activity levels.

In consultation with consumers, clinicians, and policy makers, our multidisciplinary team developed two intervention packages based on behaviour change theories.[15,23,24] Both interventions involve the development of a goal-based tailored physical activity plan (made in conjunction with a physiotherapist and sent to participant and their primary care physician (referred as a General Practitioner (GP)), access to informational and motivational print and on-line resources and encouragement of use of activity monitors and suitable smart phone applications. We hypothesise that greater effects on measured physical activity levels will be evident from an enhanced intervention package (that also includes a face-to-face assessment and ongoing phone-based physical activity phone coaching both provided by a physiotherapist) compared to a less intensive intervention package (that includes a single phone call from a physiotherapist and text messages). We further hypothesise that both these interventions will have greater impacts on physical activity levels than no intervention.

Methods and analysis

Overview

This pragmatic 3-arm superiority trial with a waiting list control group (n=600) aims to establish the effects on objectively measured physical activity among adults with self-reported mobility limitations of:

i). an enhanced intervention package (*Coaching to ComeBACK* group: one face-to-face assessment from a physiotherapist, tailored physical activity plan sent to participant and GP, physical activity phone coaching from a physiotherapist, activity monitors and/or apps, booklet and access to on-line resources) compared with a less intensive intervention package (*Texting to ComeBACK* group: single session of tailored advice by phone from a physiotherapist with health coaching training, tailored physical activity plan sent to participant and GP, unidirectional text messages, booklet and access to on-line resources);

ii). an enhanced intervention package (*Coaching to ComeBACK* group) compared with no intervention (*Texting to ComeBACK Later* waiting list control group);

iii). a less intensive intervention package (*Texting to ComeBACK* group) compared with no intervention (*Texting to ComeBACK Later* waiting list control group).

A hybrid effectiveness-implementation design (Type 1)[25] will be used to collect implementation outcomes at the same time as effectiveness outcomes. A nested process evaluation will use both quantitative and qualitative methods to explore uptake and acceptability of the intervention. The protocol for the process evaluation will be described elsewhere. The PRACTIS guide[26] to implementation and scale-up of physical activity interventions was used to ensure that the interventions (and study recruitment methods) were as potentially scalable in future as possible. Future scale-up of the interventions, if found to be effective, will be guided by the model developed by Milat et al,[27] along with the implementation outcomes and other aspects of the process evaluation. An economic analysis, which will be conducted alongside the trial, will aim to establish the cost- effectiveness and cost-utility of the interventions compared to no intervention and to each other to assist funders of preventive health interventions to assess the value of such an approach for future investments. Figure 1 shows the overall logic for the trial and Table 1 shows the reasons for choice of different components. The first participant was recruited on 13 February 2019 and at the time of submission of this manuscript 50 participants had been randomised.

Participants

The trial will be conducted across four Australian states with recruitment through health services in hospital departments and the general community through community organisations as well as traditional and social media advertisements and stories. The trial will involve consenting adults (18+ years) who are: living in the community (as opposed to residential care); have a mobility limitation (self-reported difficulty or inability to walk 800m) but are able to leave their home without physical assistance from another person (but may use a walking aid); are judged by recruitment staff to have sufficient hearing and English language skills for a phone-based intervention. Trial participants are likely to be affected by one or more common and/or burdensome conditions such as, but not limited to, osteoarthritis, lower limb fractures, lower limb amputations, stroke, brain injury and respiratory conditions and obesity. The trial will exclude adults who are: permanent residents of residential aged care facilities; have the following medical conditions: delirium, acute medical illnesses, severe psychiatric disorders, rapidly progressive neurological diseases; have a major cognitive impairment (a diagnosis of dementia or a Memory Impairment Screen score of less than 5); are currently undertaking 150 minutes or more of moderate to vigorous physical activity per week (based on self-report); full-

time wheelchair user; unable to wear a *StepWatch Activity Monitor*; not a regular user of a mobile phone (look at phone less than once per week); or have no internet access.

Randomisation

Each participant will be randomised to one of the three groups after completion of baseline assessments. The trial will use a centralised web-based randomisation system using REDCap (Research Electronic Data Capture). The randomisation schedule was developed by a researcher not involved in recruitment, outcome measurement or intervention delivery This process will ensure concealment of allocation to groups and an auditable process. Group allocation will use stratification to ensure balance by recruitment source (health service or community).

Assessments

Assessments will occur prior to randomisation and at 3, 6 and 12 months after randomisation. The matchbox-sized *StepWatch Activity Monitors* used to objectively measure physical activity (primary outcome 6-month measurement) will be mailed to participants with reply-paid envelopes and clear instructions for use and will be worn at the ankle for periods of seven consecutive days. Telephone calls will be made to participants who have not returned the devices and to those who require assistance wearing the device. Questionnaires will be administered online by participants or, if preferred mailed, or by phone by a research assistant unaware of intervention group allocation. Monthly on-line or paper calendars, with phone follow-up where necessary, will be used by participants to report falls and health and community service usage over the 12-month trial period to enable cost collation for the economic analyses. Where possible, data for all outcomes will be collected for those who cease participation in the interventions. The primary outcome will be collected in a blinded fashion. *StepWatch Activity Monitor* data will be processed and analysed by staff unaware of intervention group allocation. All baseline measurements will be undertaken prior to group allocation. Due to the nature of the intervention being tested, full blinding of participants to intervention group allocation will not be possible. All the reassessments questionnaires will however be undertaken by researchers blinded to group allocation

Outcomes

The primary outcome for the trial is physical activity, measured as average steps per day over a one-week period at 6 months post baseline with the *StepWatch Activity Monitor.* This device was chosen as prior research by the present authors[28] found it to be the most accurate device for step measurement in people with mobility impairment with average 98% (SD 12%) agreement with investigator-observed steps over a 6-minute period as opposed to 17% (SD 19%) for the more commonly-used *Actigraph* device. The *StepWatch Activity Monitor* is simple to use, can be mailed to participants and does not give feedback to the wearer.

Secondary outcomes will be measured at 3, 6 and 12 months post baseline. Measures undertaken at 12 months will compare the two intervention groups and assess physical activity maintenance in the intervention groups and uptake in the waiting list control group (*Texting to ComeBACK Later* Group). Secondary outcomes include other physical activity measures (self-reported physical activity using the Incidental and Planned Exercise Questionnaire[29], cadence and activity intensity from the *StepWatch Activity Monitor* (6 months only), attitudes to and experience of physical activity, pain (study specific questions), lower limb function and disability (Late Life Function and Disability Instrument[30]), fear of falling and self-reported balance (5-point scales), individualised mobility goal attainment (Goal Attainment Scale[31] at 6 and 12 months), mental wellbeing (Warwick-Edinburgh Mental Well-being Scale[32]), quality of life (EuroQol 5D-5L[33]), global perceived change scores for physical activity and walking, Body Mass Index, use of mobility aids and rate of falls (monitored using monthly calendars over 6 months). The EuroQol 5D-5L will also be used to enable calculation of quality-adjusted life years (QALYs) for the economic analyses.

Other measures Intervention costs and health and community service utilisation will be recorded for all participants and used as part of the economic evaluation. At the end of each intervention period (i.e., 6 months after randomisation for Groups 1 and 2 and 12 months after randomisation for Group 3), participant impressions of the program will be gathered through questionnaires designed specifically for the study intervention programs, enjoyment of the intervention will be measured using Physical Activity Enjoyment Scale (PACES)[34] and Working Alliance Inventory (WAI)[35] will assess the relationship between the participant and the health coach. The experiences and attitudes of stakeholders, including participants, health coaches, clinicians and health service managers will be explored via semi structured interviews

and focus groups in order to inform future development and implementation of the ComeBACK interventions.

Adverse events will be defined as an unwanted and usually harmful outcome (e.g. exercise-related falls, musculoskeletal injury or cardiovascular event). The event may or may not be related to the intervention, but it occurs while the person is participating in the intervention phase of the trial i.e. while they are doing mobility or physical activities. A minor adverse event is defined as an incident that results in no injury or minor injury. For example, a fall where the person sustains a small cut or bruise that requires none or minor medical intervention. A serious adverse event is defined as an incident that results in death, serious injury or hospitalisation. Adverse events will be monitored by records kept by participants and interviews at each follow-up period. Participants will also be asked to notify study staff immediately of any serious adverse events. Any adverse event occurring during the assessment and intervention process will be reported back to authors Hassett and Sherrington. It will then be decided if this is a recognised or unintended event relating to the study protocol. Unintended events will be reported to the independent Data Monitoring Committee that will be established for this trial and also be reported to the approving HREC. The research team will review the event and determine whether it is person specific or whether there is a potential for this to occur to other participants and therefore consideration would be given as to appropriateness of continuing the research.

Interventions

Intervention design was undertaken by our multi-disciplinary author team guided by formal (qualitative pilot work) and informal input from consumers in the target population as well as consultations with clinicians, health service managers, population health service providers and health policy makers. The COM-B (Capability Opportunity Motivation –> Behaviour) model of behaviour change[15] was used to guide the intervention design, with self-determination theory[23] and social cognitive theory[24] further underpinning the motivational component. Table 1 overviews the aspects of the COM-B addressed by each aspect of the intervention packages. Table 2 provides more detail on the interventions using the TIDieR format.[36] The interventions are as follows.

Group 1: Coaching to ComeBACK**.** Participants randomised to this group will be offered the

following six intervention components.

i) *a single face-to-face one-hour assessment* of mobility status, safety issues, medical, social and environmental influences on mobility will be undertaken during a home visit by a physiotherapist (employed locally). Where a home visit is not possible, a video conference may be conducted as an alternative. At the end of the assessment, a phone or videoconference call will be made to the health coach with both physiotherapist and the participant present to introduce and handover to the health coach and discuss any particular issues.

ii) *phone-based health coaching* will be delivered by trained physiotherapists through a centralised service. The initial session will include development of a tailored plan to improve physical activity through participation in suitable activities in negotiation with the participant and their carers (where appropriate). The choice of physical activity will be guided by personal preference, logistics, physical abilities and evidence of effectiveness of different intervention options. The coach will liaise with relevant treating health professionals to identify contraindications or precautions to exercise and ensure other causes of mobility limitation are optimally managed. Coaching sessions will be delivered at a tailored frequency of approximately every 2 weeks over a 6-month period and will take an average of 20-30 min each session. The coaching will incorporate behaviour change strategies including motivational interviewing (to explore and enhance reasons for being active (importance) and confidence to make changes, as well as to explore social influences on activity) goal-setting, problem-solving, building social support and experiential learning. The individually-tailored, person-centred approach will determine each person's physical, cognitive, affective, environmental and social barriers and facilitators to physical activity and develop physical activity recommendations (including adaptations and/or assistance to overcome specific barriers) for each individual. Coaching will link participants to existing community programs, with a focus on identifying activities that participants will enjoy.[37] Suitable options may include attendance at a group program, such as those indexed on the *Active and Healthy* website (www.activeandhealthy.nsw.gov.au) and/or participation in sporting opportunities that cater for people with impaired mobility. The coaching will also encourage reduced sedentary and inactive time by spending more time standing and walking or undertaking a home based exercise program, as well as increased use of active transport (i.e. walking, using public transport). Staff have extensive experience in the management of people with walking limitations, have undertaken courses in health coaching and received two days of additional training in using behaviour change science and self-determination theory to guide intervention from author Greaves.

iii) *activity monitors and GPS-based tablet/smartphone applications*. Participants will be offered an internet-connected activity monitor (such as the *Fitbit*) or a simple pedometer if preferred, as pedometers are known to enhance physical activity through measurement and behavioural reinforcement.[38]

iv) *physical activity plan developed jointly as outlined above will be shared with the* participant's GP with his/her consent.

v) *paper-based booklet* on physical activity, safe mobility and behaviour change that is study-specific, evidence-based and theoretically informed (by incorporating messaging and images that are consistent with self-determination theory (promoting autonomy, competence and relatedness for walking behaviour) and social cognitive theory (supporting self-regulation and identifying /reinforcing the perceived benefits (social, physical, emotional/affective).

vi) *closed study website* with 3 components: 1) why be active (incorporating motivational components consistent with self-determination theory); 2) how to be active (links to resources); 3) how others do it (video case studies using modelling of successful peer behaviour as per Social Cognitive Theory).

Group 2: Texting to ComeBACK**.** Participants randomised to this group will be offered the following five intervention components. The first two intervention components are unique to this group and the following three interventions are the same as Group 1.

i) *single session of tailored advice provided by phone by a physiotherapist.* This will be informed by the baseline assessment results and provide advice about appropriate physical activity opportunities for the person's interests and level of mobility. A follow-up email will be sent to summarise and reinforce key discussion points.

ii) *text messages to encourage activity.* Pre-scheduled unidirectional text messages with some tailoring and personalisation will commence at 5 times/week for the first month to provide motivation support (again using messages designed to be consistent self-determination theory (promoting autonomy, competence and relatedness for walking behaviour) and social cognitive theory (supporting self-monitoring /self-regulation and identifying /reinforcing the perceived benefits (social, physical, emotional/affective)), planning support, problem-solving and maintenance support. Participants will then have the option of increasing intensity (daily messages) or decreasing intensity (3 times/week) for the next 4 months prior to a gradual reduction in the frequency of messages. There is also an

opt-out feature available at all times.

iii) *physical activity plan* developed jointly as outlined above and will be shared with the participant's GP with their consent.

iv) *paper-based booklet* that has study-specific information on physical activity, safe mobility and behaviour change that is evidence-based and theoretically informed (as outlined above).

v) *closed study website* with 3 components: 1) why be active; 2) how to be active (links to resources including recommended activity monitors and physical activity Apps); 3) how others do it (video case studies using modelling of successful peer behaviour as per Social Cognitive Theory).

Group 3: Texting to ComeBACK Later (waiting list control)**.** This group will not receive any intervention for the first 6 months of the trial but will be advised to continue usual activity levels and health service use. After 6 months, this group will receive the Texting to ComeBACK intervention package as outlined above.

Patient and public involvement

The study protocol and choice of intervention and assessment tools used in this study was guided by feedback from consumers obtained as part of the endorsement of the trial by the Australia and Australia & New Zealand Musculoskeletal Clinical Trials Network (ANZMUSC) as well as information from interviews with participants in our previous studies.[39-41]

Sample size

The trial's sample size (n=600) will provide 90% power to detect between-group differences of 1000 steps per day assuming a standard deviation of 3000 steps (estimated from our pilot data), a dropout rate of 20%, alpha of 0.0167 (to adjust for multiplicity due to 3 trial arms), and correlation between initial and final measures of 0.6 (from our pilot data). This calculation was undertaken in Stata 13 using the *sampsi* command. On the basis of previous work by the investigators and others, we consider between-group differences of this magnitude to be likely to result in significant health benefits because 1000 steps/day, assuming a cadence of 80 steps/min, would equate to an additional 15 minutes of walking/day, a dose associated with health benefits and reduced mortality even in those with cardiovascular disease.[42]

Statistical analysis

Analysis of covariance, conducted using a linear regression approach, will be used to assess the effect of group allocation on the continuously-scored primary and secondary outcomes after adjusting for baseline scores and source of recruitment. Point estimates and their 95% confidence intervals will be used to interpret results. Given our interest in comparing the two interventions with each other and with the control condition, between-group differences with p-values < 0.0167 will be considered significant. Planned sub-group analyses will assess differential effects of the intervention based on the stratification variable of recruitment source, as well as for severity of mobility limitation and age. Secondary analyses using causal modelling will be conducted to establish intervention effects in people with greater adherence. Analyses will be pre-planned, by intention-to-treat, conducted while masked to group allocation and undertaken after range checks.

The economic evaluation will take the perspective of the health and community care funder. Health care costs, community service costs and intervention costs will be collected over the trail period. Using mean costs and mean health outcomes in each trial arm, the incremental costs per 1) additional person with increased physical activity of more than 1000 steps per day; and 2) QALY gained will be calculated; results will be plotted on a cost-effectiveness plane. Bootstrapping will be used to estimate a distribution around costs and health outcomes, and to calculate the confidence intervals around the incremental cost- effectiveness ratios. One-way sensitivity analysis will be conducted around key variables and a probabilistic sensitivity analysis will estimate uncertainty in all parameters. A cost-effectiveness acceptability curve will be plotted to provide information about the probability that the intervention is cost-effective, given willingness to pay for each benefit gained. Modelled analyses will explore the longer term cost-effectiveness of the intervention.

Ethics and dissemination

Ethical approval and local governance approvals have been obtained (Lead ethics committee: Sydney Local Health District, Royal Prince Alfred Zone, 2/08/2018 X18-0234). All amendment requests will be submitted to these committees. Written informed consent from all participants will be obtained by study staff prior to study enrolment. Participant confidentiality will be maintained at all times and all data will be stored securely.

Dissemination will be via publications, conferences, newsletter articles, talks to clinicians and consumers and meetings with health department and health service mangers. Intervention materials will be made freely available at the end of the trial. The International Committee of Medical Journal Editors recommended criteria for authorship on publications will be followed. Professional writers will not be used. The full protocol, de-identified data and statistical code will be made available upon reasonable request. All authors will have full access to study data.

Author contributions

All authors contributed to the design of the study and preparation of the study protocol. This manuscript was drafted by author Sherrington.

Funding statement

This work is supported by a project grant from the Australian National Health and Medical Research Council (APP 1145739). Authors LH, AT, RSH, CS receive salary funding from the Australian National Health and Medical Research Council Fellowship. The funders have no role in study design; collection, management, analysis, and interpretation of data; writing of the report; or the decision to submit the report for publication, and will not have ultimate authority over any of these activities.

Competing interests statement

The authors do not report any competing interests.

Word Count: 4279 words (excluding references and tables)

References

1. AIHW. *Australia's Welfare.* Canberra: Australian Institute of Health and Welfare.;2015.
2. Cummings SR, Studenski S, Ferrucci L. A diagnosis of dismobility--giving mobility clinical visibility: a Mobility Working Group recommendation. *JAMA.* 2014;311(20):2061-2062.
3. Ma VY, Chan L, Carruthers KJ. Incidence, prevalence, costs, and impact on disability of common conditions requiring rehabilitation in the United States: stroke, spinal cord injury, traumatic brain injury, multiple sclerosis, osteoarthritis, rheumatoid arthritis, limb loss, and back pain. *Arch Phys Med Rehabil.* 2014;95(5):986-995.e981.
4. Jones E, Pike J, Marshall T, Ye X. Quantifying the relationship between increased disability and health care resource utilization, quality of life, work productivity, health care costs in patients with multiple sclerosis in the US. *BMC Health Serv Res.* 2016;16:294.

5. Espahbodi S, Bassett P, Cavill C, Freeth M, Hole J, Sengupta R. Fatigue contributes to work productivity impairment in patients with axial spondyloarthritis: a cross-sectional UK study. *Clin Exper Rheumatol.* 2017;35(4):571-578.
6. Das P, Horton R. Physical activity-time to take it seriously and regularly. *Lancet.* 2016;388(10051):1254-1255.
7. Lee IM, Shiroma EJ, Kamada M, Bassett DR, Matthews CE, Buring JE. Association of Step Volume and Intensity With All-Cause Mortality in Older Women. *JAMA Intern Med.* 29 May 2019. Epub ahead of print.
8. Dwyer T, Pezic A, Sun C, et al. Objectively Measured Daily Steps and Subsequent Long Term All-Cause Mortality: The Tasped Prospective Cohort Study. *PLoS One.* 2015;10(11):e0141274.
9. Hoffmann TC, Maher CG, Briffa T, et al. Prescribing exercise interventions for patients with chronic conditions. *CMAJ.* 2016;188(7):510-518.
10. Garber CE, Blissmer B, Deschenes MR, et al. American College of Sports Medicine position stand. Quantity and quality of exercise for developing and maintaining cardiorespiratory, musculoskeletal, and neuromotor fitness in apparently healthy adults: guidance for prescribing exercise. *Med Sci Sports Exer.* 2011;43(7):1334-1359.
11. Pollock RD, Carter S, Velloso CP, et al. An investigation into the relationship between age and physiological function in highly active older adults. *J Physiol.* 2015;593(3):657-680.
12. Pahor M, Guralnik JM, Ambrosius WT, et al. Effect of structured physical activity on prevention of major mobility disability in older adults: the LIFE study randomized clinical trial. *JAMA.* 2014;311(23):2387-2396.
13. Carroll DD, Courtney-Long EA, Stevens AC, et al. Vital signs: disability and physical activity--United States, 2009-2012. *MMWR* 2014;63(18):407-413.
14. Sports and Physical Recreation: A Statistical Overview, Australia. Australian Bureau of Statistics; 2012.
15. Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implemen Sci.* 2011;6:42.
16. Hillsdon M, Thorogood M, White I, Foster C. Advising people to take more exercise is ineffective: a randomized controlled trial of physical activity promotion in primary care. *Internat J Epidemiol.* 2002;31(4):808-815.
17. Richards J, Hillsdon M, Thorogood M, Foster C. Face-to-face interventions for promoting physical activity. *Cochrane Database Syst Rev.* 2013;9:Cd010392.
18. Foster C, Richards J, Thorogood M, Hillsdon M. Remote and web 2.0 interventions for promoting physical activity. *Cochrane Database Syst Rev.* 2013;9:Cd010395.
19. Greaves CJ, Sheppard KE, Abraham C, et al. Systematic review of reviews of intervention components associated with increased effectiveness in dietary and physical activity interventions. *BMC Public Health.* 2011;11:119.
20. Oliveira J, Sherrington C, Amorim A, Dario A, Tiedemann A. What is the effect of health coaching on physical activity participation in people aged 60 years and over?: A systematic review of randomised controlled trials. *Brit J Sports Med.* 2017;51:1425-1432.
21. O'Halloran PD, Blackstock F, Shields N, et al. Motivational interviewing to increase physical activity in people with chronic health conditions: a systematic review and meta-analysis. *Clin Rehabil.* 2014;28(12):1159-1171.
22. O'Halloran PD, Shields N, Blackstock F, Wintle E, Taylor NF. Motivational interviewing increases physical activity and self-efficacy in people living in the community after hip fracture: a randomized controlled trial. *Clin Rehabil.* 2016;30(11):1108-1119.
23. Ryan RM, Deci EL. Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being. *Am Psychol.* 2000;55(1):68-78.
24. Bandura A. *Social foundations of thought and action: A social cognitive theory.* Englewood Cliffs, NJ: Prentice-Hall; 1986.
25. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Med Care.* 2012;50(3):217–226.

26. Koorts H, Eakin E, Estabrooks P, Timperio A, Salmon J, Bauman A. Implementation and scale up of population physical activity interventions for clinical and community settings: the PRACTIS guide. *Int J Behav Nutr Phys Act.* 2018;15(1):51.
27. Milat AJ, Newson R, King L. *Increasing the scale and adoption of public health interventions: A guide for developing a scaling up strategy.* North Sydney: NSW Ministry of Health;2014.
28. Treacy D, Hassett L, Schurr K, Chagpar S, Paul S, Sherrington C. Validity of different activity monitors to count steps in an inpatient rehabilitation setting. *Phys Ther*. 2017 97 (5) 581-588.
29. Delbaere K, Hauer K, Lord S. Evaluation of the Incidental and Planned Exercise Questionnaire (IPEQ) for older people. *Br J Sports Med* 2010;44:1029-1034.
30. Jette AM, Haley SM, Coster WJ, et al. Late life function and disability instrument: I. Development and evaluation of the disability component. *J Gerontol A Biol Sci Med Sci.* 2002;57(4):M209-216.
31. Tennant A. Goal attainment scaling: current methodological challenges. *Disabil Rehabil.* 2007;29(20-21):1583-1588.
32. Tennant R, Hiller L, Fishwick R, et al. The Warwick-Edinburgh Mental Well-being Scale (WEMWBS): development and UK validation. *Health Qual Life Outcomes.* 2007;5:63.
33. EuroQol--a new facility for the measurement of health-related quality of life. *Health policy (Amsterdam, Netherlands).* 1990;16(3):199-208.
34. Kendzierski D KD. Physical activity enjoyment scale: Two validation studies. *J Sport Exercise Psy.* 1991;13:50-64.
35. Hatcher RL, Gillaspy JA. Development and validation of a revised short version of the working alliance inventory. *Psychotherapy Research.* 2006;16:12-25.
36. Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ.* 2014;348:g1687.
37. Kiviniemi MT, Voss-Humke AM, Seifert AL. How do I feel about the behavior? The interplay of affective associations with behaviors and cognitive beliefs as influences on physical activity behavior. *Health psychol.* 2007;26(2):152-158.
38. Oliveira JS, Sherrington C, Zheng RY, Franco MR, Tiedemann A. Effect of interventions using physical activity trackers on physical activity in people aged 60 years and over: a systematic review and meta-analysis. *Br J Sports Med.* 2019.
39. Tiedemann A, Rissel C, Howard K, et al. Health coaching and pedometers to enhance physical activity and prevent falls in community-dwelling people aged 60 years and over: study protocol for the Coaching for Healthy AGEing (CHAnGE) cluster randomised controlled trial. *BMJ Open.* 2016;6(5):e012277.
40. Hassett L, van den Berg M, Lindley RI, et al. Effect of affordable technology on physical activity levels and mobility outcomes in rehabilitation: a protocol for the Activity and MObility UsiNg Technology (AMOUNT) rehabilitation trial. *BMJ Open.* 2016;6(6):e012074.
41. Oliveira JS, Sherrington C, Paul SS, et al. A combined physical activity and fall prevention intervention improved mobility-related goal attainment but not physical activity in older adults: a randomised trial. *J Physiother.* 2019;65(1):16-22.
42. Wen CP, Wai JP, Tsai MK, et al. Minimum amount of physical activity for reduced mortality and extended life expectancy: a prospective cohort study. *Lancet.* 2011;378(9798):1244-1253.

Table 1. Trial and intervention overview and reasoning by population, interventions, control and outcome

COMPONENT	RATIONALE	BEHAVIOURAL ASPECT ADDRESSED*
Population		
Adults with mobility limitation due to any reason, able to leave the house without assistance	• a group at risk of deterioration to dependence • inclusion of people with multiple reasons for mobility limitations because this provides a more scalable approach than a single disease focus • exclusion of more impaired people who probably require more supervised interventions	n/a
Recruited from clinical sites and the community across 4 states	• scalable approach with clear feasibility due to clinical links • enhanced generalisability of the sample to the Australian population	n/a
Group 1: Coaching to ComeBACK package		
One face-to-face assessment by physiotherapist	• likely to enhance intervention effectiveness, considered beneficial by participants and staff in pilot work • training of local staff for face to face assessments ensures the intervention is scalable	Expert assessment of capability to suggest appropriate opportunities. Establishing /building motivation.
Patient-centred health coaching, incorporating behaviour change strategies including goal-setting and motivational interviewing	• coaching is known to be effective for increased physical activity in general population, people with chronic disease and older people • use of a physiotherapist recognises the complexity of the population • individualised intervention caters for different conditions, needs and preferences • centralised coaching delivery is a scalable approach that facilitates quality control and economies of scale	Ongoing expert assessment of capability to suggest appropriate opportunities. Encouragement of capability enhancement. Feedback to assist with ongoing motivation
Activity monitor or pedometer if desired	• known to enhance physical activity in general population • well accepted in pilot among people with mobility limitations	Feedback to assist with ongoing motivation.
Tailored use of apps to encourage physical activity	• well accepted in previous studies • tailored choice of apps according to participant interest and type of physical activity considered safe and appropriate by physiotherapist	Feedback and rewards to assist with ongoing motivation.

Paper-based and on-line resources to support behaviour change	• provision of evidence-based information in attractive format • including case studies to support behaviour change.	Case studies and information to assist with capability and motivation.
Tailored physical activity plan developed and shared with GP	• credible and trusted source reinforcing behaviour changes suggested by health coach	Increased motivation.
Group 2: Texting to ComeBACK		
Single session of tailored advice over the phone from a physiotherapist	• use of physiotherapist recognises complexity of population • individualised intervention caters for different conditions, needs and preferences • centralised coaching delivery is a scalable approach that facilitates quality control and economies of scale	Expert assessment of capability to suggest appropriate opportunities.
Paper-based and on-line resources to support behaviour change	• provision of evidence-based information in attractive format • including case studies to support behaviour change.	Case studies and information to assist with capability and motivation.
Text messages	• text messages with some tailoring and personalisation able to be pre-scheduled. • pre-scheduled and uni-directional so highly scalable. • shown to be effective in previous studies.	Assist with motivation and problem-solving (capability)
Tailored physical activity plan developed and shared with GP	• credible and trusted source reinforcing behaviour changes suggested by health coach.	Increased motivation.
Group 3: Texting to ComeBACK Later		
No intervention for 6 months	• pragmatic comparison • direct policy implications	
Receipt of less intensive intervention after 6 months	• enhanced recruitment through provision of intervention for all participants.	As above
Outcome		
Physical activity	• neglected costly population health problem.	n/a

*Primarily using the COM-B system[15] for understanding behaviour change. Includes capability (an individual's psychological and physical capacity for physical activity including knowledge and skills), opportunity (factors outside the individual that enable or prompt behaviour) and motivation (brain processes that energise and direct behaviour, i.e., goals, decision-making, habits, emotional responding). This model acknowledges the role of individual action to change behaviours within a broader social context.

Table 2: Intervention description of the ComeBACK trial using the Template for Intervention Description and Replication (TIDieR) checklist

Intervention description using the Template for Intervention Description and Replication (TIDieR) checklist		
	Intervention Group 1	**Intervention Groups 2 and 3**
Brief name	**Coaching to ComeBACK**	**Texting to ComeBACK and Texting to ComeBACK later**
Why	Over 1 million Australians currently require assistance to, or are unable to, walk about their homes. The impact of mobility limitation is increasing due to population ageing. Physical activity participation has enormous untapped potential as a cost-effective approach to enhancing health in people of most ages, health conditions and physical abilities, however most people with mobility limitations are insufficiently active for health benefits. Remote interventions such as telephone health coaching and text-message support to encourage physical activity are scalable interventions which can be tailored to match the individual's capacity and preferences. Physical activity prescription for people with mobility limitations is complex as they face additional barriers to physical activity participation, thus interventions delivered by health professionals such as physiotherapists are needed. A theoretical basis combining COM-B (Capability Opportunity Motivation –> Behaviour) model of behaviour change, Self Determination Theory and Social Cognitive Theory informs the choice of intervention components and underpins all participant materials.	
What procedures	➢ Initial physiotherapy assessment to identify mobility status, safety issues, medical, social and environmental influences on mobility. Three-way (participant/health coach/physiotherapist) handover at end of session if possible. ➢ Fortnightly patient-centred health coaching incorporating behaviour change strategies including goal-setting, problem-solving, building social support, experiential learning and motivational interviewing. ➢ Development of tailored physical activity plan.	➢ One-off tailored advice to provide expert assessment of capability, identifying appropriate physical activity opportunities and to build motivation. Follow-up email to summarise and reinforce advice. ➢ Pre-scheduled text messages with some personalisation and tailoring commencing at 5 times/week to provide motivation support, planning support, problem-solving and maintenance support. ➢ Development of tailored physical activity plan.
What materials	➢ Study specific evidence-based and theoretically informed education booklet on physical activity, safe mobility and behaviour change. ➢ Access to closed study website with 3 components: 1) why be active 2) how to be active (links to resources); 3) how others do it (video case studies-modelling elements of Social Cognitive Theory). ➢ Physical activity plan shared with General Practitioner. ➢ Option to use activity monitor and/or physical activity	➢ Each participant must have his/her own mobile phone. ➢ Study specific evidence-based and theoretically informed education booklet on physical activity, safe mobility and behaviour change. ➢ Access to closed study website with 3 components: 1) why be active? 2) how to be active (links to resources); 3) how others do it (video case studies-modelling elements of Social Cognitive Theory). ➢ Physical activity plan shared with General Practitioner.

	apps for self-monitoring.	
Who provided	➢ Initial physiotherapy assessment conducted by tertiary trained local physiotherapists either employed by the study, paid casually or employed in the local health service. ➢ Health coaching provided by tertiary trained physiotherapists employed by the study with clinical experience working with the study population and research experience delivering telephone-based health coaching. Coaches attended courses through *Wellness Coaching Australia; Health Change Australia* and *Medicoach* as well as receiving training by study investigator (CG) in advanced motivational interviewing, a framework for "good (functional) motivation" and intervention techniques.	➢ Tailored advice and selection of text-messages provided by tertiary trained physiotherapists employed by the study with clinical experience working with the study population and research experience delivering telephone-based health coaching. Coaches attended courses through *Wellness Coaching Australia*; *Health Change Australia* and *Medicoach* as well as receiving training by study investigator (CG) in advanced motivational interviewing, a framework for "good (functional) motivation" and intervention techniques.
How	➢ The initial physiotherapy assessment will be conducted face-to-face in participants' homes or completed by a health service physiotherapist who has been delivering rehabilitation to the participants prior to the study. The handover will be via phone or videoconference. ➢ The health coaching will be delivered via telephone. ➢ Education booklet, physical activity plan, access details to website and activity monitor (optional) will be mailed to participants.	➢ The tailored advice will be delivered via telephone with follow-up email. ➢ Text messages will be pre-scheduled using a web-based short message service to be delivered to the participants mobile phone. ➢ Education booklet, physical activity plan and access details to website will be mailed to participants.
Where	➢ The intervention will be delivered remotely (apart from initial physiotherapy assessment) to community-dwelling people in Australia, initially commencing in the states of New South Wales, South Australia and Victoria.	➢ The intervention will be delivered remotely to community-dwelling people in Australia, initially commencing in the states of New South Wales, South Australia and Victoria.
When and how	➢ The face-to-face assessment will occur at the beginning of the intervention period and will last for ~ 1 hour.	➢ The one-off tailored advice session will occur at the beginning of the intervention period and will last for ~ 1 hour (this could

much	➢ The telephone-based health coaching will occur after the face-to-face assessment, at a tailored frequency and duration (approximately every 2 weeks for 20-30 min) for a total duration of 6 months. ➢ The education booklet and access details for website will be mailed prior to initial health coaching session. The physical activity plan and activity monitor (if requested) will be mailed (or emailed) after the initial health coaching session.	be broken into two calls if the participant fatigues or has limited time). An email/letter summary of the call will be sent in addition to the physical activity plan. ➢ The text messages will be pre-scheduled after the advice session to enable tailoring to the participants needs and preferences. They will be delivered 5 times/week for the first month. Participants will then have the option of increasing intensity (daily messages) or decreasing intensity (3 times/week) for the next 4 months prior to a gradual reduction in the frequency of messages. There is also an opt out feature available at all times. ➢ The education booklet and access details for website will be mailed prior to health coaching session. The physical activity plan will be mailed (or emailed) after the advice session.
Tailoring	The individually-tailored, person-centred approach will determine each person's physical, cognitive, affective, environmental and social barriers and develop physical activity recommendations (including adaptations and/or assistance to overcome specific barriers) for each individual. Both interventions will link or recommend participants to existing community programs, with a focus on identifying activities that participants will enjoy.[37] Suitable options may include attendance at a group program, such as those indexed on the *Active and Healthy* website (https://www.activeandhealthy.nsw.gov.au/) , and/or participation in sporting opportunities that cater for people with impaired mobility. Both interventions will also encourage reduced sedentary and inactive time by spending more time standing and walking and increased use of active transport (i.e. walking, using public transport) and/or undertaking a home based exercise programme.	

* *Texting to ComeBACK Later* group will receive the same intervention as the *Texting to ComeBACK* group with a 6-month delay.

Study resources (booklet, physical activity plan, website resources) will be made publicly available after the trial is completed.

INTERVENTION COMPONENTS

- Initial assessment of health, social influences and mobility (coaching group face-to-face; texting group by phone).
- coach support to build and maintain intrinsic motivation (both groups).
- Person-centred delivery style to build autonomy /intrinsic motivation (both groups).
- Agreement of long-term goals and short-term SMART-ER action plans to make sustainable safe changes in physical activity (both groups).
- Physical activity plan sent to GP: credible source reinforcing behaviour (both groups)
- Access to a website and booklet with motivational and informational content (both groups).
- Text message support to build motivation, break down barriers, develop action plans and self-monitor emotional, physical and social benefits, to sustain motivation for physical activity. Some tailoring to individual goals and activities (texting group).
- Monitoring progress in activity levels using a choice of technologies and monitoring emotional, physical and social benefits, to sustain motivation for physical activity (coaching group) encouragement of self-monitoring progress in activity levels (texting group)
- Fortnightly health coach contact to review progress and revise plans, identify and assist with solving of barriers /problems, including safety issues (coaching group)

CONTEXT (TRIAL)

Participant engagement with ComeBACK (receipt/use of phone calls, text messages and support materials), physical activity and other outcomes at 3, 6 and 12 months may be influenced by:

- Participant characteristics age, gender, ethnicity, baseline and historical physical activity, mental health, socioeconomic status, education, disability severity and impact of co-morbidities (inc. BMI) and competing priorities)
- Environment characteristics: friendliness /safety of neighbourhood, social networks /influences
- Trial characteristics: recruitment strategy/pathway/intervention provider organisation, staff, training, co-interventions /usual care
- Trial staff training

INTERVENTION DELIVERY

Coaches guide participants through the program

SHORT TERM OUTCOMES (measured in trial)

Interventions increase steps and improve other outcomes at 3 and 6 months with maintenance at 12 months. Bigger effects in the coaching than texting group. Improvements mediated by changes in autonomy, competence and relatedness, and moderated by perceived benefits of physical activity (social, physical, emotional/enjoyment) and the therapeutic relationship (more so for coaching group).

Cost-effective approaches to enhance physical activity/

LONG TERM OUTCOMES (not measured in trial)

Physical activity and physical functioning change maintained, falls reduce, health-related quality of life improves

Heath economic benefits

Maintenance of changes moderated by autonomy, competence, relatedness, enjoyment of physical activity, the perceived benefits of changes in physical activity (social, physical, emotional)

Change in falls/disability mediated by changes in physical function

FEEDBACK LOOPS

Participation in the program and change in physical activity is moderated by enjoyment of physical activity and the program and perceived benefits (social, physical and emotional benefits) and the therapeutic relationship (more so for coaching group).

Figure 1: Logic model for the ComeBACK interventions

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym (Page 1)
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry (Page 1)
	2b	All items from the World Health Organization Trial Registration Data Set (Page 1)
Protocol version	3	Date and version identifier (n/a)
Funding	4	Sources and types of financial, material, and other support (Page 14)
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors (Page 1)
	5b	Name and contact information for the trial sponsor (Page 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 (Page 14)
	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) n/a
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 (page 4)
	6b	Explanation for choice of comparators (page 6, Table 1)
Objectives	7	Specific objectives or hypotheses (page 6)

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) (page 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 (page 7)
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) (page 7)
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered (page 10, Table 1-2)
	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) n/a
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) (page 10, Table 1-2)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial (page 10, Table 1-2)
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 (page 9)
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) (page 9)
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 (page 13)
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size (page 7)
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 (page 8)
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 (page 8)
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions (page 8)
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how (page 8, page 13)
	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 (page 8-9)
	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 (page 8)
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 (page 14)
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 (page 13)
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) (page 13)
	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) (page 13)

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 (page 10)
	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 (page 10)
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 (page 14)
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) (page 14)
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) (page 14)
	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 (page 14)
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site (page 15)
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 (page 14)
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 (n/a)

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 (page 14)
	31b	Authorship eligibility guidelines and any intended use of professional writers (page 14)
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code (page 14)
Appendices		
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates (Appendix 1)
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)

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Physical activity coaching for adults with mobility limitations: protocol for the ComeBACK pragmatic randomised controlled trial.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-034696.R1
Article Type:	Protocol
Date Submitted by the Author:	09-May-2020
Complete List of Authors:	Hassett, Leanne; University of Sydney, Sydney School of Public Health Tiedemann, Anne; University of Sydney, Australia, Hinman, Rana S.; University of Melbourne, Crotty, Maria; Flinders University, Rehabilitation, Aged and Extended Care Hoffmann, Tammy; Bond University, Harvey, Lisa; The University of Sydney, Kolling Institute; Taylor, Nicholas ; La Trobe University, Melbourne, Victoria, Australia Greaves, Colin; University of Birmingham School of Sport Exercise and Rehabilitation Sciences, School of Sport, Exercise and Rehabilitation Science Treacy, Daniel; The University of Sydney Jennings, Matthew; South Western Sydney Local Health District Milat, Andrew; New South Wales Ministry of Health, Centre for Epidemiology and Evidence Bennell, Kim; University of Melbourne, CHESM Howard, Kirsten; University of Sydney, School of Public Health van den Berg , Maayken; Flinders University Pinheiro , Marina; The University of Sydney Wong, Siobhan; The University of Sydney Kirkham, Catherine; The University of Sydney Ramsay, Elizabeth; The University of Sydney O'Rourke, Sandra; University of Sydney Sherrington, Catherine; University of Sydney, Sydney School of Public Health
Primary Subject Heading:	Public health
Secondary Subject Heading:	Rehabilitation medicine
Keywords:	Clinical trials < THERAPEUTICS, Rehabilitation medicine < INTERNAL MEDICINE, GERIATRIC MEDICINE

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Physical activity coaching for adults with mobility limitations: protocol for the ComeBACK pragmatic randomised controlled trial.

Hassett L,[1,2] Tiedemann A,[1] Hinman RS,[3] Crotty M,[4] Hoffmann T,[5] Harvey L,[6] Taylor NF,[7] Greaves CJ,[8] Treacy D,[1,9] Jennings M,[10] Milat A,[11,12] Bennell K,[3] Howard K,[12] van den Berg M,[13] Pinheiro M,[1,2] Wong S,[1] Kirkham C,[1] Ramsay E,[1] O'Rourke S,[1] Sherrington C.[1]

[1]Institute for Musculoskeletal Health, University of Sydney

[2]Sydney School of Health Sciences, University of Sydney

[3]Centre for Health, Exercise and Sports Medicine, Department of Physiotherapy, The University of Melbourne

[4]College of Medicine and Public Health, Flinders University

[5]Institute for Evidence-Based Healthcare, Bond University

[6]John Walsh Centre for Rehabilitation Research, Northern Clinical School, University of Sydney

[7]School of Allied Health, Human Services and Sport, La Trobe University

[8]School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham

[9]Sydney East Local Health District

[10]South Western Sydney Local Health District

[11]NSW Ministry of Health

[12]School of Public Health, University of Sydney

[13]College of Nursing and Health Sciences, Flinders University

Corresponding author: Prof Catherine Sherrington

Cathie.sherrington@sydney.edu.au

Abstract

Introduction. Mobility limitation is common and often results from neurological and musculoskeletal health conditions, ageing and/or physical inactivity. In consultation with consumers, clinicians, and policy makers, we have developed two affordable and scalable intervention packages designed to enhance physical activity for adults with self-reported mobility limitations. Both are based on behaviour change theories and involve tailored advice from physiotherapists.

Methods and analysis. This pragmatic randomised control trial (n=600) will be undertaken among adults with self-reported mobility limitations. It aims to estimate the effects on physical activity of: i) an enhanced 6-month intervention package (one face-to-face physiotherapy assessment, tailored physical activity plan, physical activity phone coaching from a physiotherapist, informational/motivational resources and activity monitors) compared with a less intensive 6-month intervention package (single session of tailored phone advice from a physiotherapist, tailored physical activity plan, unidirectional text messages, informational/motivational resources); ii) the enhanced intervention package compared with no intervention (6-month waiting list control group); iii) the less intensive intervention package compared with no intervention (waiting list control group). The primary outcome will be average steps per day, measured with the *StepWatch* activity monitor over a one-week period, 6 months after randomisation. Secondary outcomes include other physical activity measures, measures of health and functioning, individualised mobility goal attainment, mental wellbeing, quality of life, rate of falls, health utilisation and intervention evaluation. A hybrid effectiveness-implementation design (Type 1) will be used to enable the collection of secondary implementation outcomes at the same time as the primary effectiveness outcome. An economic analysis will estimate the cost-effectiveness and cost-utility of the interventions compared to no intervention and to each other.

Ethics and dissemination. Ethical approval has been obtained by Sydney Local Health District, Royal Prince Alfred Zone. Dissemination will be via publications, conferences, newsletters, talks, and meetings with health department and health service managers.

Registration. ACTRN12618001983291

Strengths and limitations of this study

- Pragmatic evaluation of a scalable person-centred intervention.
- Theory-based intervention informed by consumers, clinicians and policy makers.
- Six-month study timeframe will not test long-term intervention impacts.
- Staffing in the trial does not enable those who do not speak English to participate.
- Recruitment is based on self-reported mobility limitation rather than a standardised measure.

Introduction

Disability is an umbrella term for impairments, activity limitations and participation restrictions.[1] Mobility limitation (i.e., difficulty or inability to walk) is a particularly common[2] and serious form of physical disability. It is primarily due to neurological and musculoskeletal health conditions, physiological ageing and inactivity-related deconditioning.[3] Walking impairment or 'dismobility' is predictive of adverse health outcomes, including death.[3] Widespread screening for walking problems has been suggested as an additional vital sign, and development and testing of interventions for people with walking difficulties has been highlighted as an urgent research priority.[3]

Walking is required for many daily activities, thus individuals with difficulty walking are often unable to perform daily activities and require care services. Mobility limitation is particularly common in older people and, as the population is ageing, the impact of mobility limitation is increasing. Interventions that are able to increase mobility and reduce service needs in people with mobility limitations is likely to yield benefits for individuals and financial benefits for societies. Mobility limitation also affects younger adults with chronic acquired or congenital musculoskeletal or neurological conditions, conditions which are becoming more common due to better survival from serious illnesses and injuries.[4] Mobility impairment with onset earlier in life also has an important impact on population health due to the lasting nature of the impairment and significant impacts on productivity.[5,6]

Physical activity participation has enormous untapped potential as a cost-effective approach to enhancing physical and mental health in people of most ages, health conditions and physical abilities.[7] A *Lancet* editorial[7] calls for physical activity to be taken more seriously as a population health intervention, given the strong evidence of physical and mental health benefits and poor participation rates. As well as enhancing the prevention and management of chronic conditions, physical activity is now known to have survival benefits.[8] For example, taking a greater number of steps per day was associated with lower all-cause mortality over a 10-year follow-up period (adjusted hazard ratio (AHR) for all-cause mortality 0.94; 95% CI, 0.90 to 0.98 per 1 000 steps; $p = 0.004$).[9] In those who increased daily steps there was a substantial reduction in mortality risk after adjusting for baseline daily step count (AHR, 0.39; 95% CI, 0.22 to 0.72; p = 0.002).[9]

People with health conditions affecting mobility can obtain additional benefits from physical activity including better mobility, fewer falls and less risk of hospitalisation.[10] Physical

activity enhances mobility through improved aerobic capacity, muscle strength, balance and coordination.[11] More demanding mobility tasks such as stair-climbing and walking longer distances require greater levels of physical functioning. If a person's physical functioning is lower than that required for independent performance of a particular activity i.e., below the "disability threshold", they will require assistance or aids. Greater physical functioning provides "reserve capacity" which acts as a buffer to ensure that functioning remains above the disability threshold even in the face of deterioration from factors such as physiological ageing, illness or injury. Much of the deterioration in physical fitness and mobility commonly thought to be due to ageing/health conditions is actually due to inactivity and thus at least partly treatable and preventable.[12] Trials have confirmed that physical activity can improve walking ability and prevent the onset of disability.[13] For example the onset of mobility disability was prevented by a structured physical activity program in people aged 70-89 who had some physical limitation at baseline.[13]

Unfortunately, people with mobility limitations are less active than the general population.[14] For example, 65% of Australians regularly participate in physical activities for recreation, exercise or sport, but only 24% of Australians with disabilities participate in such activities.[15] Although widespread provision of supervised structured exercise programs would be likely to significantly lessen mobility impairment at a population level, such an approach is unlikely to be broadly implemented by public health systems given the size of the target population. Self-funding of such interventions is out of reach for many individuals. More flexible intervention approaches that focus on physical activity more broadly, facilitate attendance at existing programs, include self-management approaches, and incorporate technology are likely to be more scalable. These approaches therefore warrant investigation.

Regular physical activity participation requires motivation, capability and opportunity.[16] Simply advising people to be more active is unlikely to safely enhance activity levels.[17] Rather, advice needs to be specific, individualised, supported by a behaviour change framework and based on engagement with the person and their goals and priorities.[18] Health coaching interventions that involve behaviour change techniques including goal-setting and are individually tailored are known to change behaviour in the general population.[18-20] A recent systematic review[21] found health coaching to improve physical activity levels in older people (standardised mean difference = 0.29; 95% CI 0.18 to 0.39; $p < .001$) and others have found motivational interviewing (a form of health coaching) to enhance physical activity in people with chronic conditions[22] and in hip fracture survivors.[23] These trials focused on

health conditions so did not cater specifically for people with impaired mobility. The impact of health coaching in this population is not known. Physical activity prescription in people with mobility limitations is complex so we hypothesise that tailored advice from physiotherapists will enhance activity levels.

In consultation with consumers, clinicians, and policy makers, our multidisciplinary investigator team developed two intervention packages based on behaviour change theories as outlined in the logic model (Fig. 1) and Table 1 and 2.[16,24,25] Both interventions involve the development of a goal-based tailored physical activity plan (made in conjunction with a physiotherapist and sent to participants and their primary care physician (referred as a General Practitioner (GP)) to reinforce physical activity participation), access to informational and motivational print and on-line resources and encouragement of use of activity monitors and suitable smart phone applications. We hypothesise that greater effects on measured physical activity levels will be evident from an enhanced intervention package (that also includes a face-to-face assessment and ongoing phone-based physical activity phone coaching both provided by a physiotherapist) compared to a less intensive intervention package (that includes a single phone call from a physiotherapist and text messages). We further hypothesise that both these interventions will have greater impacts on physical activity levels than no intervention.

Methods and analysis

Overview

This pragmatic superiority trial (n=600) will use 1:1 concealed on-line randomisation to allocate adults with self-reported mobility limitations to a 6-month enhanced intervention, a 6-month less intensive intervention or a waiting list control group (who will receive the less intensive intervention after 6 months). Between-group comparisons will be undertaken at 6 months (all groups) and at 12 months (comparing two intervention groups).

The study primarily aims to establish the effects of the interventions, compared to each other and to control, on objectively-measured physical activity at 6-months (*Stepwatch*, steps per day). Secondary outcomes include other physical activity measures, measures of health and functioning, individualised mobility goal attainment, mental wellbeing, quality of life, rate of falls, health utilisation and intervention evaluation. Secondary analyses will explore differential effects on the basis of recruitment source (health professional referral versus

community advertising), assess implementation outcomes, and establish the cost-effectiveness and cost-utility.

The trial is more pragmatic than explanatory in that it uses recruitment and intervention strategies relevant to the "real-word" and is intended to help support a decision on whether such interventions should be delivered. A more explanatory trial would be undertaken in an idealised setting, to give the intervention its best chance to demonstrate a beneficial effect.[26] A hybrid effectiveness-implementation design (Type 1)[27] will be used to collect implementation outcomes at the same time as effectiveness outcomes. A nested process evaluation will use both quantitative and qualitative methods to explore uptake by participants and acceptability of the intervention (to participants, health coaches and other stakeholders). The protocol for the process evaluation will be described elsewhere. The PRACTIS guide[28] to implementation and scale-up of physical activity interventions was used to ensure that the interventions (and study recruitment methods) were as potentially scalable in future as possible. Future scale-up of the interventions, if found to be effective, will be guided by the model developed by Milat et al,[29] along with the implementation outcomes and other aspects of the process evaluation. An economic analysis, which will be conducted alongside the trial, will aim to establish the cost-effectiveness and cost-utility of the interventions compared to no intervention and to each other to assist funders of preventive health interventions to assess the value of such an approach for future investments. Table 1 shows the reasons for choice of different components, Table 2 overviews the intervention in TIDieR format and Figure 1 shows the overall logic and broader context for the trial. The first participant was recruited on 13 February 2019 and at the time of submission of this manuscript 156 participants had been randomised.

The primary comparisons will assess the effect on objectively measured physical activity at 6 months of the

i) enhanced intervention package (*Coaching to ComeBACK* group: one face-to-face assessment from a physiotherapist, tailored physical activity plan sent to participant and GP, physical activity phone coaching from a physiotherapist, activity monitors and/or apps, booklet and access to on-line resources) compared with a less intensive intervention package (*Texting to ComeBACK* group: single session of tailored advice by phone from a physiotherapist with health coaching training, tailored physical activity plan sent to participant and GP, unidirectional text messages, booklet and access to on-line resources);

ii) the enhanced intervention package (*Coaching to ComeBACK* group) compared with no intervention (*Texting to ComeBACK Later* waiting list control group);

iii) the less intensive intervention package (*Texting to ComeBACK* group) compared with no intervention (*Texting to ComeBACK Later* waiting list control group).

Participants

The trial will be conducted across four Australian states with recruitment through health services in hospital departments and the general community through community organisations as well as traditional and social media advertisements and stories. Participants with a range of health conditions who report difficulty or inability to walk 800m will be recruited. The process evaluation will explore differences in feasibility and efficiency of recruitment in each of the settings to inform future implementation strategies.

The trial will involve consenting adults (18+ years) who are: living in the community (as opposed to residential care); have a mobility limitation (self-reported difficulty or inability to walk 800m) but are able to leave their home without physical assistance from another person (but may use a walking aid); are judged by recruitment staff to have sufficient hearing and English language skills for a phone-based intervention. Trial participants are likely to be affected by one or more common and/or burdensome conditions such as, but not limited to, osteoarthritis, lower limb fractures, lower limb amputations, stroke, brain injury, respiratory conditions and obesity. The trial will exclude adults who are: permanent residents of residential aged care facilities; have the following medical conditions: delirium, acute medical illnesses, severe psychiatric disorders, rapidly progressive neurological diseases; have a major cognitive impairment (a diagnosis of dementia or a Memory Impairment Screen score of less than 5); are currently undertaking 150 minutes or more of moderate to vigorous physical activity per week (based on self-report); full-time wheelchair user; unable to wear a *StepWatch Activity Monitor*; not a regular user of a mobile phone (look at phone less than once per week); or have no internet access.

Randomisation

Each participant will be randomised to one of the three groups after completion of baseline assessments. The trial will use a centralised web-based randomisation system using REDCap

(Research Electronic Data Capture). The randomisation schedule was developed by a researcher not involved in recruitment, outcome measurement or intervention delivery. This process will ensure concealment of allocation to groups and an auditable process. Randomisation to groups will be stratified by whether participants were recruited from the general community (via advertising etc) or from health services.

Assessments

Assessments will occur prior to randomisation and at 3, 6 and 12 months after randomisation. The matchbox-sized *StepWatch Activity Monitors* used to objectively measure physical activity (primary outcome 6 month, secondary outcome 12 month) will be mailed to participants with reply-paid envelopes and clear instructions for use and will be worn at the ankle during waking hours for periods of seven consecutive days. Telephone calls will be made to participants who have not returned the devices and to those who require assistance wearing the device. Questionnaires will be administered online by participants or, if preferred mailed, or by phone by a research assistant unaware of intervention group allocation. Monthly on-line or paper calendars, with phone follow-up where necessary, will be used by participants to report falls and health and community service usage over the 12-month trial period to enable cost collation for the economic analyses. Where possible, data for all outcomes will be collected for all participants including those who cease participation in the interventions, unless the participant wishes to withdraw from the study. The primary outcome will be collected in a blinded fashion. *StepWatch Activity Monitor* data will be processed and analysed by staff unaware of intervention group allocation. All baseline measurements will be undertaken prior to group allocation. Due to the nature of the intervention being tested, full blinding of participants to intervention group allocation will not be possible. All the reassessment questionnaires will however be undertaken by researchers blinded to group allocation. Table 3 overviews the trial outcomes and measurement timepoints.

Outcomes

The primary outcome for the trial is physical activity, measured as average steps per day over a one-week period at 6 months post baseline with the *StepWatch Activity Monitor.* This device was chosen as prior research by the present authors[30] found it to be the most accurate device for step measurement in people with mobility impairment with average 98% (SD 12%)

agreement with investigator-observed steps over a 6-minute period as opposed to 17% (SD 19%) for the more commonly-used *Actigraph* device. The *StepWatch Activity Monitor* is simple to use, can be mailed to participants and does not give feedback to the wearer.

Secondary outcomes will be measured at 3, 6 and 12 months post baseline. Measures undertaken at 12 months will compare the two intervention groups and assess physical activity maintenance in the intervention groups and uptake in the waiting list control group (*Texting to ComeBACK Later* Group). Secondary outcomes include other physical activity measures (self-reported physical activity using the Incidental and Planned Exercise Questionnaire[31], cadence, activity intensity (6 and 12 months only) and average steps per day (12 months only) from the *StepWatch Activity Monitor*, global perceived change scores for physical activity and walking, attitudes to and experience of physical activity), pain (study specific questions), lower limb function and disability (Late Life Function and Disability Instrument[32]), fear of falling and self-reported balance (5-point scales), individualised mobility goal attainment (Goal Attainment Scale[33] at 6 and 12 months), mental wellbeing (Warwick-Edinburgh Mental Well-being Scale[34]), quality of life (EuroQol 5D-5L[35]), Body Mass Index, use of mobility aids, rate of falls and health utilisation (monitored using monthly calendars over 12 months), and measures evaluating impressions (study specific) and enjoyment (Physical Activity Enjoyment Scale)[36] of the interventions and the therapeutic alliance between health coaches and participants (Working Alliance Inventory)[37]. The EuroQol 5D-5L will also be used to enable calculation of quality-adjusted life years (QALYs) for the economic analyses.

Other measures Intervention costs and health and community service utilisation, as collected by monthly calendars, will be recorded for all participants and used as part of the economic evaluation. The experiences and attitudes of stakeholders, including participants, health coaches, clinicians and health service managers will be explored via semi structured interviews and focus groups in order to inform future development and implementation of the ComeBACK interventions.

Adverse events will be defined as an unwanted and usually harmful outcome (e.g. exercise-related falls, musculoskeletal injury, angina, shortness of breath or cardiovascular event). The event may or may not be related to the intervention, but it occurs while the person is participating in the intervention phase of the trial i.e. while they are doing mobility or physical activities. A minor adverse event is defined as an incident that results in no injury or minor

injury. For example, a fall where the person sustains a small cut or bruise that requires none or minor medical intervention. A serious adverse event is defined as an incident that results in death, serious injury or hospitalisation. Adverse events will be monitored by records kept by participants and interviews at each follow-up period. Participants will also be asked to notify study staff immediately of any serious adverse events. Any adverse event occurring during the assessment and intervention process will be reported back to authors Hassett and Sherrington. It will then be decided if this is a recognised or unintended event relating to the study protocol. Unintended events will be reported to the independent Data Monitoring Committee that will be established for this trial and also be reported to the approving HREC. The research team will review the event and determine whether it is person specific or whether there is a potential for this to occur to other participants and therefore consideration would be given as to appropriateness of continuing the research. Participants may experience muscle soreness at the start of the physical activity program. This will be minimised by advice to increase activity levels gradually and to seek professional advice if soreness lasts for more than three days or interferes with daily activities.

Interventions

Intervention design was undertaken by our multi-disciplinary author team guided by formal (qualitative pilot work) and informal input from consumers in the target population as well as consultations with clinicians, health service managers, population health service providers and health policy makers. The COM-B (Capability Opportunity Motivation –> Behaviour) model of behaviour change[16] was used to guide the intervention design, with self-determination theory[24] and social cognitive theory[25] further underpinning the motivational component. Table 1 overviews the aspects of the COM-B addressed by each aspect of the intervention packages. Table 2 provides more detail on the interventions using the TIDieR format.[38] The interventions are as follows.

Group 1: Coaching to ComeBACK**.** Participants randomised to this group will be offered the following six intervention components.

i) *a single face-to-face one-hour assessment* of mobility status, safety issues, medical, social and environmental influences on mobility, will be undertaken during a home visit by a physiotherapist (employed locally). Where a home visit is not possible, a video conference may be conducted as an alternative. At the end of the assessment, a phone or videoconference

call will be made to the health coach with both physiotherapist and the participant present to introduce and handover to the health coach and discuss any particular issues.

ii) *phone-based health coaching* will be delivered by trained physiotherapists through a centralised service. The initial session will include development of a tailored plan to improve physical activity through participation in suitable activities in negotiation with the participant and their carers (where appropriate). The choice of physical activity will be guided by personal preference, logistics, physical abilities and evidence of effectiveness of different intervention options. The coach will liaise with relevant treating health professionals to identify contraindications or precautions to exercise and ensure other causes of mobility limitation are optimally managed. Coaching sessions will be delivered at a tailored frequency of approximately every 2 weeks over a 6-month period and will take an average of 20-30 min each session. The coaching will incorporate behaviour change strategies including motivational interviewing (to explore and enhance reasons for being active (importance) and confidence to make changes, as well as to explore social influences on activity) goal-setting, problem-solving, building social support and experiential learning. The individually-tailored, person-centred approach will determine each person's physical, cognitive, affective, environmental and social barriers and facilitators to physical activity and develop physical activity recommendations (including adaptations and/or assistance to overcome specific barriers) for each individual. The health coach will link participants to existing community programs if desired, with a focus on identifying activities that participants will enjoy.[39] Suitable options may include attendance at a group program, such as those indexed on the *Active and Healthy* website (www.activeandhealthy.nsw.gov.au) and/or participation in sporting opportunities that cater for people with impaired mobility. The coaching will also encourage reduced sedentary and inactive time by spending more time standing and walking or undertaking a home based exercise program, as well as increased use of active transport (i.e. walking, using public transport). Staff have extensive experience in the management of people with walking limitations, have undertaken courses in health coaching and received two days of additional training in using behaviour change science and self-determination theory to guide intervention from author Greaves.

iii) *activity monitors and GPS-based tablet/smartphone applications*. Participants will be offered an internet-connected activity monitor (such as the *Fitbit*) or a simple pedometer if preferred, as pedometers are known to enhance physical activity through measurement and behavioural reinforcement.[40]

iv) *physical activity plan* developed jointly as outlined above will be shared with the participant's GP with his/her consent soon after it is developed.

v) *paper-based booklet* on physical activity, safe mobility and behaviour change that is study-specific, evidence-based and theoretically informed (by incorporating messaging and images that are consistent with self-determination theory (promoting autonomy, competence and relatedness for walking behaviour) and social cognitive theory (supporting self-regulation and identifying /reinforcing the perceived benefits (social, physical, emotional/affective).

vi) *closed study website* with 3 components: 1) why be active (incorporating motivational components consistent with self-determination theory); 2) how to be active (links to resources); 3) how others do it (video case studies using modelling of successful peer behaviour as per Social Cognitive Theory).

Group 2: Texting to ComeBACK**.** Participants randomised to this group will be offered the following five intervention components. The first two intervention components are unique to this group and the following three interventions are the same as Group 1.

i) *single session of tailored advice provided by phone by a physiotherapist.* This call will last 50-60 minutes, will be informed by the baseline assessment results and provide advice about appropriate physical activity opportunities for the person's interests and level of mobility. A follow-up email will be sent to summarise and reinforce key discussion points.

ii) *text messages to encourage activity.* Pre-scheduled unidirectional text messages with some tailoring and personalisation will commence at 5 times/week for the first month to provide motivation support (again using messages designed to be consistent with self-determination theory (promoting autonomy, competence and relatedness for walking behaviour) and social cognitive theory (supporting self-monitoring /self-regulation and identifying /reinforcing the perceived benefits (social, physical, emotional/affective)), planning support, problem-solving and maintenance support. Participants will then have the option of increasing intensity (daily messages) or decreasing intensity (3 times/week) for the next 4 months prior to a gradual reduction in the frequency of messages. There is also an opt-out feature available at all times.

iii) *physical activity plan* developed jointly as outlined above and will be shared with the participant's GP with their consent soon after it is developed.

iv) *paper-based booklet* that has study-specific information on physical activity, safe mobility and behaviour change that is evidence-based and theoretically informed (as outlined above).

v) *closed study website* with 3 components: 1) why be active; 2) how to be active (links to resources including recommended activity monitors and physical activity Apps); 3) how others do it (video case studies using modelling of successful peer behaviour as per Social Cognitive Theory).

Group 3: Texting to ComeBACK Later (waiting list control)**.** This group will not receive any intervention for the first 6 months of the trial but will be advised to continue usual activity levels and health service use. After 6 months, this group will receive the Texting to ComeBACK intervention package as outlined above.

Patient and public involvement

The study protocol and choice of intervention and assessment tools used in this study was guided by feedback from consumers obtained as part of the endorsement of the trial by the Australia & New Zealand Musculoskeletal Clinical Trials Network (ANZMUSC) as well as information from interviews with participants in our previous studies.[41-43]

Sample size

The trial's sample size (n=600) will provide 90% power to detect between-group differences of 1000 steps per day assuming a standard deviation of 3000 steps (estimated from our pilot data), a dropout rate of 20%, alpha of 0.0167 (to adjust for multiplicity due to 3 trial arms), and correlation between initial and final measures of 0.6 (from our pilot data). This calculation was undertaken in Stata 13 using the *sampsi* command. On the basis of previous work by the investigators and others, we consider between-group differences of this magnitude to be likely to result in significant health benefits because 1000 steps/day, assuming a cadence of 80 steps/min, would equate to an additional 15 minutes of walking/day, a dose associated with health benefits and reduced mortality even in those with cardiovascular disease.[44]

Statistical analysis

Analysis of covariance, conducted using a linear regression approach, will be used to assess the effect of group allocation on the continuously-scored primary and secondary outcomes after

adjusting for baseline scores and source of recruitment. Point estimates and their 95% confidence intervals will be used to interpret results. Given our interest in comparing the two interventions with each other and with the control condition, between-group differences with p-values < 0.0167 will be considered significant. Planned sub-group analyses will assess differential effects of the intervention based on the stratification variable of recruitment source, as well as for severity of mobility limitation and age. Secondary analyses using causal modelling will be conducted to establish intervention effects in people with greater adherence. Analyses will be pre-planned, by intention-to-treat, conducted while masked to group allocation and undertaken after range checks. A detailed Statistical Analysis Plan will be developed and signed off by all investigators prior to analysis.

The economic evaluation will take the perspective of the health and community care funder. Health care costs, community service costs and intervention costs will be collected over the trail period. Using mean costs and mean health outcomes in each trial arm, the incremental costs per 1) additional person with increased physical activity of more than 1000 steps per day; and 2) QALY gained will be calculated; results will be plotted on a cost-effectiveness plane. Bootstrapping will be used to estimate a distribution around costs and health outcomes, and to calculate the confidence intervals around the incremental cost- effectiveness ratios. One-way sensitivity analysis will be conducted around key variables and a probabilistic sensitivity analysis will estimate uncertainty in all parameters. A cost-effectiveness acceptability curve will be plotted to provide information about the probability that the intervention is cost-effective, given willingness to pay for each benefit gained. Modelled analyses will explore the longer term cost-effectiveness of the intervention.

Ethics and dissemination

Ethical approval and local governance approvals have been obtained (Lead ethics committee: Sydney Local Health District, Royal Prince Alfred Zone (22/08/2018 X18-0234). All amendment requests will be submitted to these committees. Written informed consent from all participants will be obtained by study staff prior to study enrolment (see sample consent form in supplementary material). Participant confidentiality will be maintained at all times and all data will be stored securely. Dissemination will be via publications, conferences, newsletter articles, letters to participants, talks to healthcare professionals and consumers and meetings with health department and health service mangers. Intervention materials will be

made freely available at the end of the trial. The International Committee of Medical Journal Editors recommended criteria for authorship on publications will be followed. Professional writers will not be used. The full protocol, de-identified data and statistical code will be made available upon reasonable request. All authors will have full access to de-identified study data.

This study will address a key evidence gap regarding realistic scalable ways to enhance physical ability in people with impaired mobility. Trial results will provide direct information about the costs and benefits of the intervention approach compared with current practice to enable funders of preventive health interventions to decide whether such approaches are worth investing in as a population health intervention.

Author contributions

All authors contributed to the design of the study and preparation of the study protocol. This manuscript was drafted by author Sherrington.

Funding statement

This work is supported by a project grant from the Australian National Health and Medical Research Council (APP 1145739). Authors LH, AT, RSH, CS receive salary funding from the Australian National Health and Medical Research Council Fellowship. The funders have no role in study design; collection, management, analysis, and interpretation of data; writing of the report; or the decision to submit the report for publication, and will not have ultimate authority over any of these activities.

Competing interests statement

The authors do not report any competing interests.

Word Count: 4749 words (excluding references and tables)

References

1. WHO. Towards a common language for functioning, disability and health: ICF. . 2002.
2. AIHW. *Australia's Welfare.* Canberra: Australian Institute of Health and Welfare.;2015.
3. Cummings SR, Studenski S, Ferrucci L. A diagnosis of dismobility--giving mobility clinical visibility: a Mobility Working Group recommendation. *Jama.* 2014;311(20):2061-2062.
4. Ma VY, Chan L, Carruthers KJ. Incidence, prevalence, costs, and impact on disability of common conditions requiring rehabilitation in the United States: stroke, spinal cord injury, traumatic brain injury, multiple sclerosis, osteoarthritis, rheumatoid arthritis, limb loss, and back pain. *Archives of physical medicine and rehabilitation.* 2014;95(5):986-995.e981.

5. Jones E, Pike J, Marshall T, Ye X. Quantifying the relationship between increased disability and health care resource utilization, quality of life, work productivity, health care costs in patients with multiple sclerosis in the US. *BMC health services research.* 2016;16:294.
6. Espahbodi S, Bassett P, Cavill C, Freeth M, Hole J, Sengupta R. Fatigue contributes to work productivity impairment in patients with axial spondyloarthritis: a cross-sectional UK study. *Clinical and experimental rheumatology.* 2017;35(4):571-578.
7. Das P, Horton R. Physical activity-time to take it seriously and regularly. *Lancet (London, England).* 2016;388(10051):1254-1255.
8. Lee IM, Shiroma EJ, Kamada M, Bassett DR, Matthews CE, Buring JE. Association of Step Volume and Intensity With All-Cause Mortality in Older Women. *JAMA internal medicine.* 2019.
9. Dwyer T, Pezic A, Sun C, et al. Objectively Measured Daily Steps and Subsequent Long Term All-Cause Mortality: The Tasped Prospective Cohort Study. *PloS one.* 2015;10(11):e0141274.
10. Hoffmann TC, Maher CG, Briffa T, et al. Prescribing exercise interventions for patients with chronic conditions. *CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne.* 2016;188(7):510-518.
11. Garber CE, Blissmer B, Deschenes MR, et al. American College of Sports Medicine position stand. Quantity and quality of exercise for developing and maintaining cardiorespiratory, musculoskeletal, and neuromotor fitness in apparently healthy adults: guidance for prescribing exercise. *Medicine and Science in Sports and Exercise.* 2011;43(7):1334-1359.
12. Pollock RD, Carter S, Velloso CP, et al. An investigation into the relationship between age and physiological function in highly active older adults. *J Physiol.* 2015;593(3):657-680.
13. Pahor M, Guralnik JM, Ambrosius WT, et al. Effect of structured physical activity on prevention of major mobility disability in older adults: the LIFE study randomized clinical trial. *Jama.* 2014;311(23):2387-2396.
14. Carroll DD, Courtney-Long EA, Stevens AC, et al. Vital signs: disability and physical activity--United States, 2009-2012. *MMWR Morbidity and mortality weekly report.* 2014;63(18):407-413.
15. ABS. Sports and Physical Recreation: A Statistical Overview, Australia. In: Australian Bureau of Statistics; 2012.
16. Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implementation Science.* 2011;6:42.
17. Hillsdon M, Thorogood M, White I, Foster C. Advising people to take more exercise is ineffective: a randomized controlled trial of physical activity promotion in primary care. *International journal of epidemiology.* 2002;31(4):808-815.
18. Richards J, Hillsdon M, Thorogood M, Foster C. Face-to-face interventions for promoting physical activity. *The Cochrane database of systematic reviews.* 2013;9:Cd010392.
19. Foster C, Richards J, Thorogood M, Hillsdon M. Remote and web 2.0 interventions for promoting physical activity. *The Cochrane database of systematic reviews.* 2013;9:Cd010395.
20. Greaves CJ, Sheppard KE, Abraham C, et al. Systematic review of reviews of intervention components associated with increased effectiveness in dietary and physical activity interventions. *BMC public health.* 2011;11:119.
21. Oliveira J, Sherrington C, Amorim A, Dario A, Tiedemann A. What is the effect of health coaching on physical activity participation in people aged 60 years and over?: A systematic review of randomised controlled trials. . *British Journal of Sports Medicine.* 2017;51:1425-1432.
22. O'Halloran PD, Blackstock F, Shields N, et al. Motivational interviewing to increase physical activity in people with chronic health conditions: a systematic review and meta-analysis. *Clin Rehabil.* 2014;28(12):1159-1171.
23. O'Halloran PD, Shields N, Blackstock F, Wintle E, Taylor NF. Motivational interviewing increases physical activity and self-efficacy in people living in the community after hip fracture: a randomized controlled trial. *Clin Rehabil.* 2016;30(11):1108-1119.

24. Ryan RM, Deci EL. Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being. *The American psychologist.* 2000;55(1):68-78.
25. Bandura A. *Social foundations of thought and action: A social cognitive theory.* Englewood Cliffs, NJ: Prentice-Hall; 1986.
26. Loudon K, Treweek S, Sullivan F, Donnan P, Thorpe KE, Zwarenstein M. The PRECIS-2 tool: designing trials that are fit for purpose. *BMJ (Clinical research ed).* 2015;350:h2147.
27. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Medical Care.* 2012;50(3):217–226.
28. Koorts H, Eakin E, Estabrooks P, Timperio A, Salmon J, Bauman A. Implementation and scale up of population physical activity interventions for clinical and community settings: the PRACTIS guide. *The international journal of behavioral nutrition and physical activity.* 2018;15(1):51.
29. Milat AJ, Newson R, King L. *Increasing the scale and adoption of public health interventions: A guide for developing a scaling up strategy.* North Sydney: NSW Ministry of Health;2014.
30. Treacy D, Hassett L, Schurr K, Chagpar S, Paul S, Sherrington C. Physical Therapy. . *Validity of different activity monitors to count steps in an inpatient rehabilitation setting.* Accepted 12 Dec 2016.
31. Delbaere K, Hauer K, Lord S. Evaluation of the Incidental and Planned Exercise Questionnaire (IPEQ) for older people. *British Journal of Sports Medicine* 2010;44:1029-1034.
32. Jette AM, Haley SM, Coster WJ, et al. Late life function and disability instrument: I. Development and evaluation of the disability component. *J Gerontol A Biol Sci Med Sci.* 2002;57(4):M209-216.
33. Tennant A. Goal attainment scaling: current methodological challenges. *Disabil Rehabil.* 2007;29(20-21):1583-1588.
34. Tennant R, Hiller L, Fishwick R, et al. The Warwick-Edinburgh Mental Well-being Scale (WEMWBS): development and UK validation. *Health Qual Life Outcomes.* 2007;5:63.
35. EuroQol--a new facility for the measurement of health-related quality of life. *Health policy (Amsterdam, Netherlands).* 1990;16(3):199-208.
36. Kendzierski D, DeCarlo KJ. Physical Activity Enjoyment Scale: Two Validation Studies. 1991;13(1):50.
37. Hatcher RL, Gillaspy JA. Development and validation of a revised short version of the Working Alliance Inventory. *Psychotherapy Research.* 2006;16(1):12-25.
38. Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ (Clinical research ed).* 2014;348:g1687.
39. Kiviniemi MT, Voss-Humke AM, Seifert AL. How do I feel about the behavior? The interplay of affective associations with behaviors and cognitive beliefs as influences on physical activity behavior. *Health psychology : official journal of the Division of Health Psychology, American Psychological Association.* 2007;26(2):152-158.
40. J SO, Sherrington C, E RYZ, Franco MR, Tiedemann A. Effect of interventions using physical activity trackers on physical activity in people aged 60 years and over: a systematic review and meta-analysis. *Br J Sports Med.* 2019.
41. Tiedemann A, Rissel C, Howard K, et al. Health coaching and pedometers to enhance physical activity and prevent falls in community-dwelling people aged 60 years and over: study protocol for the Coaching for Healthy AGEing (CHAnGE) cluster randomised controlled trial. *BMJ open.* 2016;6(5):e012277.
42. Hassett L, van den Berg M, Lindley RI, et al. Effect of affordable technology on physical activity levels and mobility outcomes in rehabilitation: a protocol for the Activity and MObility UsiNg Technology (AMOUNT) rehabilitation trial. *BMJ open.* 2016;6(6):e012074.
43. Oliveira JS, Sherrington C, Paul SS, et al. A combined physical activity and fall prevention intervention improved mobility-related goal attainment but not physical activity in older adults: a randomised trial. *Journal of physiotherapy.* 2019;65(1):16-22.

44. Wen CP, Wai JP, Tsai MK, et al. Minimum amount of physical activity for reduced mortality and extended life expectancy: a prospective cohort study. *Lancet (London, England).* 2011;378(9798):1244-1253.
45. Farag I, Howard K, Ferreira ML, Sherrington C. Economic modelling of a public health programme for fall prevention. *Age Ageing.* 2015;44(3):409-414.

Table 1. Trial and intervention overview and reasoning by population, interventions, control and outcome

COMPONENT	RATIONALE	BEHAVIOURAL ASPECT ADDRESSED*
Population		
Adults with mobility limitation due to any reason, able to leave the house without assistance	• a group at risk of deterioration to dependence • inclusion of people with multiple reasons for mobility limitations because this provides a more scalable approach than a single disease focus • exclusion of more impaired people who probably require more supervised interventions	n/a
Recruited from clinical sites and the community across 4 states	• scalable approach with clear feasibility due to clinical links • enhanced generalisability of the sample to the Australian population	n/a
Group 1: Coaching to ComeBACK package		
One face-to-face assessment by physiotherapist	• likely to enhance intervention effectiveness, considered beneficial by participants and staff in pilot work • training of local staff for face to face assessments ensures the intervention is scalable	Expert assessment of capability to suggest appropriate opportunities. Establishing /building motivation.
Patient-centred health coaching, incorporating behaviour change strategies including goal-setting and motivational interviewing	• coaching is known to be effective for increased physical activity in general population, people with chronic disease and older people • use of a physiotherapist recognises the complexity of the population • individualised intervention caters for different conditions, needs and preferences • centralised coaching delivery is a scalable approach that facilitates quality control and economies of scale	Ongoing expert assessment of capability to suggest appropriate opportunities. Encouragement of capability enhancement. Feedback to assist with ongoing motivation.
Activity monitor or pedometer if desired	• known to enhance physical activity in general population • well accepted in pilot among people with mobility limitations	Feedback to assist with ongoing motivation.
Tailored use of apps to encourage physical activity	• well accepted in previous studies • tailored choice of apps according to participant interest and type of physical activity considered safe and appropriate by physiotherapist	Feedback and rewards to assist with ongoing motivation.
Paper-based and on-line resources to support behaviour change	• provision of evidence-based information in attractive format • including case studies to support behaviour change.	Case studies and information to assist with capability and motivation.
Tailored physical activity plan developed and shared with GP	• credible and trusted source reinforcing behaviour changes suggested by health coach	Increased motivation.

Group 2: Texting to ComeBACK		
Single session of tailored advice over the phone from a physiotherapist	• use of physiotherapist recognises complexity of population • individualised intervention caters for different conditions, needs and preferences • centralised coaching delivery is a scalable approach that facilitates quality control and economies of scale	Expert assessment of capability to suggest appropriate opportunities.
Paper-based and on-line resources to support behaviour change	• provision of evidence-based information in attractive format • including case studies to support behaviour change.	Case studies and information to assist with capability and motivation.
Text messages	• text messages with some tailoring and personalisation able to be pre-scheduled. • pre-scheduled and uni-directional so highly scalable. • shown to be effective in previous studies.	Assist with motivation and problem-solving (capability).
Tailored physical activity plan developed and shared with GP	• credible and trusted source reinforcing behaviour changes suggested by health coach.	Increased motivation.
Group 3: Texting to ComeBACK Later		
No intervention for 6 months	• pragmatic comparison • direct policy implications	
Receipt of less intensive intervention after 6 months	• enhanced recruitment through provision of intervention for all participants.	As above
Outcome		
Physical activity	• neglected costly population health problem.	n/a

*Primarily using the COM-B system[16] for understanding behaviour change. Includes capability (an individual's psychological and physical capacity for physical activity including knowledge and skills), opportunity (factors outside the individual that enable or prompt behaviour) and motivation (brain processes that energise and direct behaviour, i.e., goals, decision-making, habits, emotional responding). This model acknowledges the role of individual action to change behaviours within a broader social context.

Table 2: Intervention description of the ComeBACK randomised controlled trial using the Template for Intervention Description and Replication (TIDieR) checklist

Intervention description using the Template for Intervention Description and Replication (TIDieR) checklist		
	Intervention Group 1	**Intervention Groups 2 and 3**
Brief name	**Coaching to ComeBACK**	**Texting to ComeBACK and Texting to ComeBACK later***
Why	Over 1 million Australians currently require assistance to, or are unable to, walk about their homes. The impact of mobility limitation is increasing due to population ageing. Physical activity participation has enormous untapped potential as a cost-effective approach to enhancing health in people of most ages, health conditions and physical abilities, however most people with mobility limitations are insufficiently active for health benefits. Remote interventions such as telephone health coaching and text-message support to encourage physical activity are scalable interventions which can be tailored to match the individual's capacity and preferences. Physical activity prescription for people with mobility limitations is complex as they face additional barriers to physical activity participation, thus interventions delivered by health professionals such as physiotherapists are needed. A theoretical basis combining COM-B (Capability Opportunity Motivation –> Behaviour) model of behaviour change, Self Determination Theory and Social Cognitive Theory informs the choice of intervention components and underpins all participant materials.	
What procedures	➢ Initial physiotherapy assessment (by local or study physiotherapist) to identify mobility status, safety issues, medical, social and environmental influences on mobility. Three-way (participant/health coach physiotherapist/ assessment physiotherapist) handover at end of session if possible. ➢ Development of tailored physical activity plan. ➢ Fortnightly patient-centred health coaching from a physiotherapist trained in health coaching incorporating behaviour change strategies including goal-setting, problem-solving, building social support, experiential learning and motivational interviewing.	➢ One-off phone-based tailored advice from a physiotherapist trained in health coaching to provide expert assessment of capability, identifying appropriate physical activity opportunities and to build motivation. Follow-up email to summarise and reinforce advice. ➢ Development of tailored physical activity plan. ➢ Pre-scheduled text messages with some personalisation and tailoring (based on the physical activity plan) commencing at 5 times/week to provide motivation support, planning support, problem-solving and maintenance support.
What materials#	➢ Study specific evidence-based and theoretically informed education booklet on physical activity, safe mobility and behaviour change. ➢ Access to closed study website with 3 components: 1) why be active 2) how to be active (links to resources); 3) how	➢ Each participant must have his/her own mobile phone. ➢ Study specific evidence-based and theoretically informed education booklet on physical activity, safe mobility and behaviour change. ➢ Access to closed study website with 3 components: 1) why be active 2) how to be active (links to resources); 3) how others do it (video

	others do it (video case studies-modelling elements of Social Cognitive Theory). ➢ Physical activity plan shared with General Practitioner. ➢ Option to use activity monitor and/or physical activity apps for self-monitoring.	case studies-modelling elements of Social Cognitive Theory). ➢ Physical activity plan shared with General Practitioner.
Who provided	➢ Initial physiotherapy assessment conducted by tertiary trained local physiotherapists either employed by the study, paid casually or employed in the local health service. ➢ Health coaching provided by tertiary trained physiotherapists employed by the study with clinical experience working with the study population and research experience delivering telephone-based health coaching. Coaches attended courses through *Wellness Coaching Australia; Health Change Australia* and *Medicoach* as well as receiving training by study investigator (CG) in advanced motivational interviewing, a framework for "good (functional) motivation" and intervention techniques.	➢ Tailored advice and selection of text-messages provided by tertiary trained physiotherapists employed by the study with clinical experience working with the study population and research experience delivering telephone-based health coaching. Coaches attended courses through *Wellness Coaching Australia*; *Health Change Australia* and *Medicoach* as well as receiving training by study investigator (CG) in advanced motivational interviewing, a framework for "good (functional) motivation" and intervention techniques.
How	➢ The initial physiotherapy assessment will be conducted face-to-face in participants' homes or completed by a health service physiotherapist who has been delivering rehabilitation to the participants prior to the study. The handover will be via phone or videoconference. ➢ The health coaching will be delivered via telephone. ➢ Education booklet, physical activity plan, access details to website and activity monitor (optional) will be mailed to participants.	➢ The tailored advice will be delivered via telephone with follow-up email. ➢ Text messages will be pre-scheduled using a web-based short message service to be delivered to the participants mobile phone. ➢ Education booklet, physical activity plan and access details to website will be mailed to participants.
Where	➢ The intervention will be delivered remotely (apart from initial physiotherapy assessment) to community-dwelling people in Australia, initially commencing in the states of New South Wales, South Australia and Victoria.	➢ The intervention will be delivered remotely to community-dwelling people in Australia, initially commencing in the states of New South Wales, South Australia and Victoria.
When and how much	➢ The face-to-face assessment will occur at the beginning of the intervention period and will last for ~ 1 hour. ➢ The telephone-based health coaching will occur after the face-to-face assessment, at a tailored frequency and duration (approximately every 2 weeks for 20-30 min) for a total	➢ The one-off tailored advice session will occur at the beginning of the intervention period and will last for ~ 1 hour (this could be broken into two calls if the participant fatigues or has limited time). An email/letter summary of the call will be sent in addition to the physical activity plan.

	duration of 6 months. ➢ The education booklet and access details for website will be mailed prior to initial health coaching session. The physical activity plan and activity monitor (if requested) will be mailed (or emailed) after the initial health coaching session.	➢ The text messages will be pre-scheduled after the advice session to enable tailoring to the participants needs and preferences. They will be delivered 5 times/week for the first month. Participants will then have the option of increasing intensity (daily messages) or decreasing intensity (3 times/week) for the next 4 months prior to a gradual reduction in the frequency of messages. There is also an opt out feature available at all times. ➢ The education booklet and access details for website will be mailed prior to health coaching session. The physical activity plan will be mailed (or emailed) after the advice session.
Tailoring	The individually-tailored, person-centred approach will determine each person's physical, cognitive, affective, environmental and social barriers and develop physical activity recommendations (including adaptations and/or assistance to overcome specific barriers) for each individual. Both interventions will link or recommend participants to existing community programs, with a focus on identifying activities that participants will enjoy.[39] Suitable options may include attendance at a group program, such as those indexed on the *Active and Healthy* website (https://www.activeandhealthy.nsw.gov.au/) , and/or participation in sporting opportunities that cater for people with impaired mobility. Both interventions will also encourage reduced sedentary and inactive time by spending more time standing and walking and increased use of active transport (i.e. walking, using public transport) and/or undertaking a home based exercise programme.	

* *Texting to ComeBACK Later* group will receive the same intervention as the *Texting to ComeBACK* group with a 6-month delay.

Study resources (booklet, physical activity plan, website resources) will be made publicly available after the trial is completed.

Table 3. List of measures collected at baseline assessment (BA), 3 months (3A), 6 months (6A), and at 12-month reassessment (12A) for all study participants.

Information collected for all participants	BA	3A	6A	12A	O
Socio-demographics. Age, gender, education, occupation, country of birth, language, living arrangements, health condition, agency support	Y	N	N	N	N
General health and function					
Functional Co-morbidity Index	Y	N	N	N	N
Technology exposure	Y	N	N	N	N
Mobility aids	Y	Y	Y	Y	S
BMI	Y	Y	Y	Y	S
Pain related questions	Y	Y	Y	Y	S
Self-reported Fear of Falling and Balance level	Y	Y	Y	Y	S
Late Life lower limb extremity Function and Disability Instrument[32]	Y	Y	Y	Y	S
Individualised mobility Goal Attainment Scale[33]	Y	N	Y	Y	S
Quality of life					
The EQ5D-5L[35]	Y	Y	Y	Y	S
Mental well being					
Warwick-Edinburgh Mental Well-being Scale[34]	Y	Y	Y	Y	S
Physical Activity					
Average steps per days measured over a one-week period using a StepWatch Activity Monitor	Y	N	Y	Y	P
Cadence and activity intensity levels using a StepWatch Activity Monitor	Y	N	Y	Y	S
The Incidental and Planned Exercise Questionnaire (IPEQ)	Y	Y	Y	Y	S
Global Perceived Change scales on physical activity and walking	N	Y	Y	Y	S

Attitudes to Physical Activity	Y	Y	Y	Y	S
Experiences of Physical Activity	N	Y	Y	Y	S
Falls and Health Utilisation					
Falls and fall related injuries (monthly diaries for 12 months)[45]					S
Use of health services (monthly diaries for 12 months)[45]					S
Medication use	Y		Y	Y	N
Intervention Evaluations					
Impressions of program			Y#	Y%	S
Physical Activity Enjoyment Scale (PACES)			Y#	Y%	S
Work Alliance Inventory-Short Revised Participant (WAI-SR)			Y#	Y%	S
Work Alliance Inventory-Short Revised Therapist (WAI-SRT)			Y#	Y%	S

Note: Y=YES, N=NO, BA=Baseline Assessment, 3A= 3 months assessment 6A= 6 months assessment 12A=12 month assessment, O=Outcome measure, S=Secondary, P=Primary, #=Group 1&2, %=Group 3

Figure legend

Figure 1. Logic model for the ComeBACK intervention.

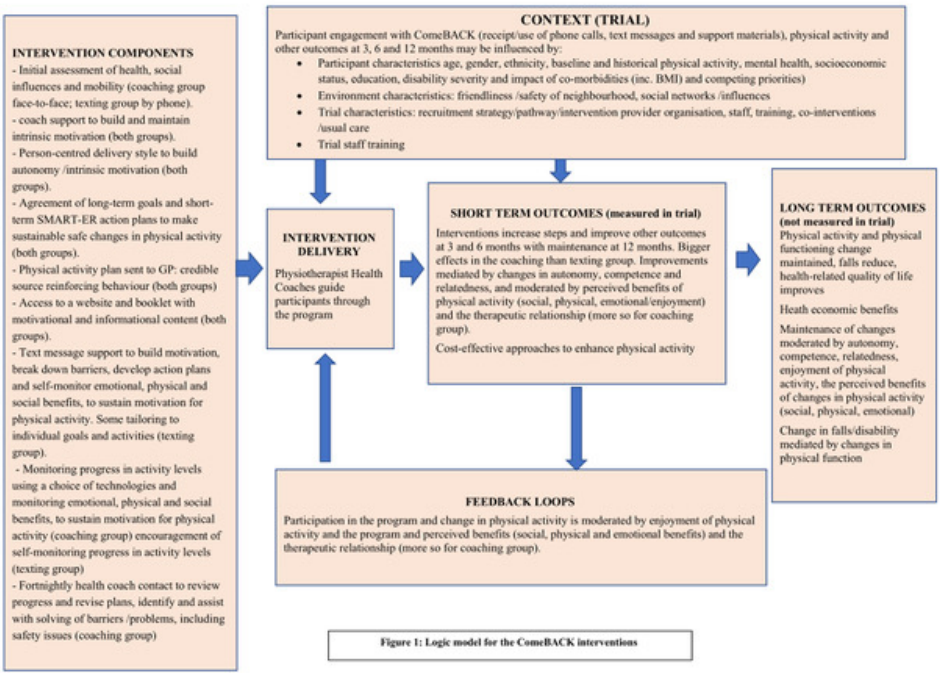

Figure 1. Logic model for the ComeBACK intervention.

54x38mm (300 x 300 DPI)

Physical Activity Coaching for Adults with Mobility Limitations: A Pragmatic Randomised Controlled Trial

INFORMATION FOR PARTICIPANTS

Invitation

You are invited to participate in a research study, looking at the benefits of two physical activity intervention programs aimed at improving physical activity levels among adults with self-reported difficulty walking.

The principal investigators for the study are:

Professor Catherine Sherrington - University of Sydney
Professor Rana Hinman - University of Melbourne
Professor Maria Crotty - The Flinders University of South Australia
Professor Tammy Hoffmann - Bond University Limited
Professor Lisa Harvey – University of Sydney
Professor Nicholas Taylor - La Trobe University
Doctor Leanne Hassett - University of Sydney
Associate Professor Anne Tiedemann - University of Sydney

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

What is the purpose of this study?

This study is a randomised controlled trial. The purpose of this study is to investigate the impact of two physical activity intervention packages on the physical activity levels of adults who report that they have walking difficulties compared to no intervention. The information in this sheet can help you decide if you would like to take part in this study and describes what you can expect.

Study procedures and what is involved

The study will be conducted over 12 months. If you agree to participate in this study, you will be required to sign the Participant Consent Form prior to the commencement of any study procedures.

Once it is confirmed that you are eligible to take part in the study, you will be asked to complete a series of questionnaires about your general health, medical, fall history and current physical activity habits. These questionnaires will also be repeated at 3, 6 and 12 months after study commencement. The questionnaires will take about 20 minutes to complete each time.

In addition to the questionnaires, the amount of physical activity you do will be measured at the start of the study and again at 6 and 12 months after study commencement over a 7-day period using a *StepWatch* activity monitor. This small device is worn around your ankle during the day and is able to accurately estimate how physically active a person has been throughout the day. The *StepWatch* will be posted to you with clear instructions for use and telephone support will be available. You will also be provided with pre-paid envelopes to return the device and questionnaires to the research centre.

Group Allocation

To determine the benefits of the two intervention programs there will be three groups. The first group of people (Coaching to ComeBACK) will receive the intervention program for 6 months which involves an in-person physical activity assessment, telephone health coaching, , choice to use technology to monitor your activity levels and access to online resources. The second group of people (Texting to ComeBACK) will take part in an intervention program for 6 months, which involves a telephone-based physical activity assessment, and text messaging and access to online resources. The third group of people (Texting to ComeBACK later) will not have any intervention for the first 6 months but will then receive the same intervention as the second group (Texting to ComeBACK). If you decide to participate in this research study, you will be randomly allocated to one of the three groups. All groups will receive any usual care provided by your health service providers.

Group 1 Coaching to ComeBACK ***Group***

If you are allocated to the Coaching to ComeBACK group you will receive

i) *a single face-to-face one-hour assessment* of mobility and physical activities undertaken at a home visit from a physiotherapist from which a tailored plan to improve physical activity through participation in suitable activities will be developed in negotiation with you. The choice of physical activity will be guided by personal preference, logistics, physical abilities and evidence of effectiveness.

ii) *6 month phone-based coaching* will be delivered by trained physiotherapists through a centralised service and will support you in getting started and then to keep on going with your physical activity plan. You will be encouraged to access the service approximately once a fortnight for 6 months during the study. Phone coaching appointments vary according to your needs but you could expect that they generally last around 20-30 minutes/session. Access to this service will stop at the conclusion of the study intervention period.

iii) in addition you will be offered technology to use where appropriate to help you being active e.g. (the Fitbit) or a simple pedometer that does not connect to the internet.

iv) have access to online resources to help you be more physically active.

The overall time commitment for the Coaching to ComeBACK group following the initial 1-hour face-to-face assessment is 60 minutes per month of phone based coaching during the 6-month intervention period. The recommendation made to incorporate physical activity into your daily routine will be negotiated with you and this will be different for each person based on current activity levels and abilities.

Group 2 Texting to ComeBACK ***Group***

If you are allocated to Texting to ComeBACK group you will receive

i) *a single phone* session of tailored advice from a physiotherapist to develop a plan to improve physical activity through participation in suitable activities which will be developed in negotiation with you. The choice of physical activity will be guided by personal preference, logistics, physical abilities and evidence of effectiveness. The length of this phone session does vary according to your needs but you could expect that it will generally last around 30 -45 minutes.

ii) *text message follow up* for 6 months intervention duration of the study. You will be able to opt out of receiving these messages at any time.

iii) have access to online resources.

The overall time commitment for the Texting to ComeBACK group following the initial 45-minute phone based session is 5 minutes per month of reading phone text messages. The

recommendation made to incorporate physical activity into your daily routine will be negotiated with you and this will be different for each person based on current activity levels and abilities.

Group 3 Texting to ComeBACK ***later group***

If you are allocated to the Texting to ComeBACK later group you will receive the usual care provided by your health service providers for the first 6 months of the study. You will have no contact with the study staff apart from the baseline, 3 and 6-month questionnaires. Following the 6-month reassessment you will receive the same intervention as Group 2 (Texting to ComeBACK) as described above. This includes the single phone session of tailored advice from a physiotherapist to improve physical activity (generally 30-45 minutes) as well as text message follow up for 6 months and access to online resources to support you to be more active.

The overall time commitment for the initial 6 months of the study period if allocated to the Texting to ComeBACK later group is 0 minutes per month. This will then increase to 5 minutes per month of reading phone text messages for the next 6-month period. The recommendation made for you to incorporate physical activity into your daily routine will be negotiated with you and this will be different for each person based on current activity levels and abilities.

Falls and health utilisation calendars

All study participants will be asked to return monthly calendars (by reply-paid mail) containing questions on any falls and subsequent injuries you may experience along with health utilisation. If calendars are not returned, you will be telephoned to ask if you experienced any falls and physical activity-related injuries during the past month. In order to reduce the risk of bias, the research team member who collects the monthly calendars will not be aware of which group you have been allocated to.

The researchers would like to evaluate the benefits of the study beyond the 6-month intervention period so we ask you to complete the calendars for a 12-month period.

Data Linkage Study

We would like to track hospital and emergency department admissions, ambulance services and any study participant deaths (birth, marriages and death registry records) for up to 2 years after the completion of the study to evaluate if there are any long-term effects from the intervention. Therefore, the researchers would like your permission to link the information you provide within the ComeBACK study, with other sources of information that are routinely collected and managed via the Population Health Research Network (PHRN) for Health data Record Linkage. A strict process will be followed as per Data Linkage policies that ensures the confidentiality of your data.

Data linkage has been used by health systems for many years to bring together information about people, places and events in a way that protects individual privacy and allows researchers and policy makers to gain information and insights about the health and well-being of our community. Data linkage studies have helped to provide valuable information on the causes of and risk factors for disease as well as the evaluation of new approaches to preventing and treating health problems.

If you want to opt out of the linking of your health information, there is an option to indicate this choice on the consent form by ticking the box for opt out.

Qualitative Study

To evaluate the enjoyment and efficiency of the intervention programs a small subset of participants (30-40) will be invited to participate in a semi-structured interview at 3 time points across the study (3 months, 6 months and 12 months). These telephone interviews will be conducted by a researcher who is not involved in delivering the intervention and they will generally last 30 to 40 minutes. We will ask for your consent to audio record each interview prior to the commencement of the interview. Interviews will cover advantages and disadvantages of the intervention, motivation, self-efficacy, confidence, beliefs about physical activity and facilitators and barriers to participation in each component of the intervention.

How is this study being paid for?

The study is funded through a competitive research project grant from the National Health and Medical Research Council. The investigators of this research study declare no duality or conflict of interest.

Are there risks?

While the risks involved with participation in this research are low, there is a slight chance that you may experience muscle soreness at the start of the physical activity program. There is also a chance of more general risk such as falls. This risk is taken into consideration by the researchers involved who are experienced with assessing older people and people with walking difficulties and safety precautions are used and are consistent with current clinical practice.

In addition, your GP will be notified that you are participating in this study and be encouraged to contact us if they think participation will cause you harm. You will be asked to provide contact details for your GP during the Baseline Questionnaire to allow this to occur.

As part of this study you will be asked to answer questions about physical activity, activities of daily living and other aspects of health. If you experience any distress when answering questions, you have the right not to answer the question and leave the response blank.

The interventions may also include health coaching, tailored advice and goal setting approaches. Health coaching employs a motivational interviewing approach that acknowledges the individual's difficulty in becoming more active and explores the confidence they have about engaging in physical activity and develops individualized strategies that can be implemented. If you happen to experience distress during health coaching, the health professional providing the coaching will be able to discuss and explore relevant issues, providing emotional support and advice and refer you back to your GP if required.

Benefits

While we intend that this research study furthers our knowledge and may improve physical activity levels of adults with walking problems in the future, we cannot guarantee that you will receive direct benefits from the study. Access to this intervention service will cease at the conclusion of the study.

Costs

Participation in this study will not cost you anything, nor will you be reimbursed for your time.

Voluntary Participation

Participation in this study is entirely voluntary. If you do take part, you can withdraw at any time without having to give a reason. Whatever your decision, please be assured that it will not affect your medical treatment or your relationship with the research staff or institutions who may be caring for you.

Sometimes during the course of a study, new information becomes available about the treatment that is being studied. While you are participating in this study, you will be kept informed of any significant new findings, which may affect your willingness to continue in the study.

Confidentiality

Under Australian privacy law all information collected about you must be kept confidential, unless you agree to it being released. Only the researchers in the study, your family doctor and you will know whether you are participating in this study. At the time of entry to the study, you will be assigned a study identification number that will be used on all data collection sheets. Identifiable data (e.g. name, date of birth) will be removed from other data and stored separately in a locked filing cabinet and password protected computer database at The University of Sydney with access only by study staff. All data collected within this study will be stored for 15 years as required by national ethics legislature. You have a right to request access to your data during this time. After this time, paper copies will be securely shredded and electronic copies will be securely deleted. The study results will be published in peer reviewed journals, presented at conferences or other professional forums, but individual participants will not be identifiable in such a presentation.

Future use of data for research purposes

Data such as age, sex and study outcomes may be combined with data from other studies or provided to other researchers to answer new research questions at the completion of this study. At no time will identifiable data be shared or used without your additional consent.

Further Information

When you have read this information, Researchers at the University of Sydney will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact them on 02 8627 6235.

Ethics Approval and Complaints

This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District. Any person with concerns or complaints about the conduct of this study should contact the Executive Officer on 02 9515 6766 and quote protocol number X18-0234 .

The conduct of this study at the [name of hospital] has been authorised by the [name of Local Health District]. Any person with concerns or complaints about the conduct of this study may also contact the Research Governance Officer [or other officer] on [telephone number] and quote protocol number [insert local protocol number].

Thank you for taking the time to consider this study.

This information sheet is for you to keep.

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym (Page 1)
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry (Page 1)
	2b	All items from the World Health Organization Trial Registration Data Set (Page 1)
Protocol version	3	Date and version identifier (n/a)
Funding	4	Sources and types of financial, material, and other support (Page 14)
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors (Page 1)
	5b	Name and contact information for the trial sponsor (Page 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 (Page 14)
	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) n/a
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 (page 4)
	6b	Explanation for choice of comparators (page 6, Table 1)
Objectives	7	Specific objectives or hypotheses (page 6)

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) (page 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 (page 7)
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) (page 7)
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered (page 10, Table 1-2)
	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) n/a
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) (page 10, Table 1-2)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial (page 10, Table 1-2)
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 (page 9)
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) (page 9)
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 (page 13)
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size (page 7)
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 (page 8)
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 (page 8)
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions (page 8)
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how (page 8, page 13)
	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 (page 8-9)
	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 (page 8)
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 (page 14)
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 (page 13)
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) (page 13)
	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) (page 13)

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 (page 10)
	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 (page 10)
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 (page 14)
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) (page 14)
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) (page 14)
	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 (page 14)
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site (page 15)
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 (page 14)
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 (n/a)

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 (page 14)
	31b	Authorship eligibility guidelines and any intended use of professional writers (page 14)
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code (page 14)
Appendices		
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates (Appendix 1)
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)

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Physical activity coaching for adults with mobility limitations: protocol for the ComeBACK pragmatic hybrid effectiveness-implementation type 1 randomised controlled trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-034696.R2
Article Type:	Protocol
Date Submitted by the Author:	21-Aug-2020
Complete List of Authors:	Hassett, Leanne; University of Sydney, Sydney School of Public Health Tiedemann, Anne; University of Sydney, Australia, Hinman, Rana S.; University of Melbourne, Crotty, Maria; Flinders University, Rehabilitation, Aged and Extended Care Hoffmann, Tammy; Bond University, Harvey, Lisa; The University of Sydney, Kolling Institute; Taylor, Nicholas ; La Trobe University, Melbourne, Victoria, Australia Greaves, Colin; University of Birmingham School of Sport Exercise and Rehabilitation Sciences, School of Sport, Exercise and Rehabilitation Science Treacy, Daniel; The University of Sydney Jennings, Matthew; South Western Sydney Local Health District Milat, Andrew; New South Wales Ministry of Health, Centre for Epidemiology and Evidence Bennell, Kim; University of Melbourne, CHESM Howard, Kirsten; University of Sydney, School of Public Health van den Berg , Maayken; Flinders University Pinheiro , Marina; The University of Sydney Wong, Siobhan; The University of Sydney Kirkham, Catherine; The University of Sydney Ramsay, Elizabeth; The University of Sydney O'Rourke, Sandra; University of Sydney Sherrington, Catherine; University of Sydney, Sydney School of Public Health
Primary Subject Heading:	Public health
Secondary Subject Heading:	Rehabilitation medicine
Keywords:	Clinical trials < THERAPEUTICS, Rehabilitation medicine < INTERNAL MEDICINE, GERIATRIC MEDICINE

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Physical activity coaching for adults with mobility limitations: protocol for the ComeBACK pragmatic hybrid effectiveness-implementation type 1 randomised controlled trial.

Hassett L,[1,2] Tiedemann A,[1] Hinman RS,[3] Crotty M,[4] Hoffmann T,[5] Harvey L,[6] Taylor NF,[7] Greaves CJ,[8] Treacy D,[1,9] Jennings M,[10] Milat A,[11,12] Bennell K,[3] Howard K,[12] van den Berg M,[13] Pinheiro M,[1,2] Wong S,[1] Kirkham C,[1] Ramsay E,[1] O'Rourke S,[1] Sherrington C.[1]

[1]Institute for Musculoskeletal Health, University of Sydney/ Sydney Local Health District

[2]Sydney School of Health Sciences, University of Sydney

[3]Centre for Health, Exercise and Sports Medicine, Department of Physiotherapy, The University of Melbourne

[4]College of Medicine and Public Health, Flinders University

[5]Institute for Evidence-Based Healthcare, Bond University

[6]John Walsh Centre for Rehabilitation Research, Northern Clinical School, University of Sydney

[7]School of Allied Health, Human Services and Sport, La Trobe University

[8]School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham

[9]Sydney East Local Health District

[10]South Western Sydney Local Health District

[11]NSW Ministry of Health

[12]School of Public Health, University of Sydney

[13]College of Nursing and Health Sciences, Flinders University

Corresponding author: Prof Catherine Sherrington

Cathie.sherrington@sydney.edu.au

Abstract

Introduction. Mobility limitation is common and often results from neurological and musculoskeletal health conditions, ageing and/or physical inactivity. In consultation with consumers, clinicians, and policy makers, we have developed two affordable and scalable intervention packages designed to enhance physical activity for adults with self-reported mobility limitations. Both are based on behaviour change theories and involve tailored advice from physiotherapists.

Methods and analysis. This pragmatic hybrid effectiveness-implementation type 1 randomised control trial (n=600) will be undertaken among adults with self-reported mobility limitations. It aims to estimate the effects on physical activity of: i) an enhanced 6-month intervention package (one face-to-face physiotherapy assessment, tailored physical activity plan, physical activity phone coaching from a physiotherapist, informational/motivational resources and activity monitors) compared with a less intensive 6-month intervention package (single session of tailored phone advice from a physiotherapist, tailored physical activity plan, unidirectional text messages, informational/motivational resources); ii) the enhanced intervention package compared with no intervention (6-month waiting list control group); iii) the less intensive intervention package compared with no intervention (waiting list control group). The primary outcome will be average steps per day, measured with the *StepWatch* activity monitor over a one-week period, 6 months after randomisation. Secondary outcomes include other physical activity measures, measures of health and functioning, individualised mobility goal attainment, mental wellbeing, quality of life, rate of falls, health utilisation and intervention evaluation. The hybrid effectiveness-implementation design (Type 1) will be used to enable the collection of secondary implementation outcomes at the same time as the primary effectiveness outcome. An economic analysis will estimate the cost-effectiveness and cost-utility of the interventions compared to no intervention and to each other.

Ethics and dissemination. Ethical approval has been obtained by Sydney Local Health District, Royal Prince Alfred Zone. Dissemination will be via publications, conferences, newsletters, talks, and meetings with health managers.

Registration. ACTRN12618001983291

Strengths and limitations of this study

- Pragmatic evaluation of a scalable person-centred intervention.
- Theory-based intervention informed by consumers, clinicians and policy makers.
- Six-month study timeframe will not test long-term intervention impacts.
- Staffing in the trial does not enable those who do not speak English to participate.
- Recruitment is based on self-reported mobility limitation rather than a standardised measure.

Introduction

Disability is an umbrella term for impairments, activity limitations and participation restrictions.[1] Mobility limitation (i.e., difficulty or inability to walk) is a particularly common[2] and serious form of physical disability. It is primarily due to neurological and musculoskeletal health conditions, physiological ageing and inactivity-related deconditioning.[3] Walking impairment or 'dismobility' is predictive of adverse health outcomes, including death.[3] Widespread screening for walking problems has been suggested as an additional vital sign, and development and testing of interventions for people with walking difficulties has been highlighted as an urgent research priority.[3]

Walking is required for many daily activities, thus individuals with difficulty walking are often unable to perform daily activities and require care services. Mobility limitation is particularly common in older people and, as the population is ageing, the impact of mobility limitation is increasing. Interventions that are able to increase mobility and reduce service needs in people with mobility limitations is likely to yield benefits for individuals and financial benefits for societies. Mobility limitation also affects younger adults with chronic acquired or congenital musculoskeletal or neurological conditions, conditions which are becoming more common due to better survival from serious illnesses and injuries.[4] Mobility impairment with onset earlier in life also has an important impact on population health due to the lasting nature of the impairment and significant impacts on productivity.[5,6]

Physical activity participation has enormous untapped potential as a cost-effective approach to enhancing physical and mental health in people of most ages, health conditions and physical abilities.[7] A *Lancet* editorial[7] calls for physical activity to be taken more seriously as a population health intervention, given the strong evidence of physical and mental health benefits and poor participation rates. As well as enhancing the prevention and management of chronic conditions, physical activity is now known to have survival benefits.[8] For example, taking a greater number of steps per day was associated with lower all-cause mortality over a 10-year follow-up period (adjusted hazard ratio (AHR) for all-cause mortality 0.94; 95% CI, 0.90 to 0.98 per 1 000 steps; $p = 0.004$).[9] In those who increased daily steps there was a substantial reduction in mortality risk after adjusting for baseline daily step count (AHR, 0.39; 95% CI, 0.22 to 0.72; p = 0.002).[9]

People with health conditions affecting mobility can obtain additional benefits from physical activity including better mobility, fewer falls and less risk of hospitalisation.[10] Physical

activity enhances mobility through improved aerobic capacity, muscle strength, balance and coordination.[11] More demanding mobility tasks such as stair-climbing and walking longer distances require greater levels of physical functioning. If a person's physical functioning is lower than that required for independent performance of a particular activity i.e., below the "disability threshold", they will require assistance or aids. Greater physical functioning provides "reserve capacity" which acts as a buffer to ensure that functioning remains above the disability threshold even in the face of deterioration from factors such as physiological ageing, illness or injury. Much of the deterioration in physical fitness and mobility commonly thought to be due to ageing/health conditions is actually due to inactivity and thus at least partly treatable and preventable.[12] Trials have confirmed that physical activity can improve walking ability and prevent the onset of disability.[13] For example the onset of mobility disability was prevented by a structured physical activity program in people aged 70-89 who had some physical limitation at baseline.[13]

Unfortunately, people with mobility limitations are less active than the general population.[14] For example, 65% of Australians regularly participate in physical activities for recreation, exercise or sport, but only 24% of Australians with disabilities participate in such activities.[15] Although widespread provision of supervised structured exercise programs would be likely to significantly lessen mobility impairment at a population level, such an approach is unlikely to be broadly implemented by public health systems given the size of the target population. Self-funding of such interventions is out of reach for many individuals. More flexible intervention approaches that focus on physical activity more broadly, facilitate attendance at existing programs, include self-management approaches, and incorporate technology are likely to be more scalable. These approaches therefore warrant investigation.

Regular physical activity participation requires motivation, capability and opportunity.[16] Simply advising people to be more active is unlikely to safely enhance activity levels.[17] Rather, advice needs to be specific, individualised, supported by a behaviour change framework and based on engagement with the person and their goals and priorities.[18] Health coaching interventions that involve behaviour change techniques including goal-setting and are individually tailored are known to change behaviour in the general population.[18-20] A recent systematic review[21] found health coaching to improve physical activity levels in older people (standardised mean difference = 0.29; 95% CI 0.18 to 0.39; $p < .001$) and others have found motivational interviewing (a form of health coaching) to enhance physical activity in people with chronic conditions[22] and in hip fracture survivors.[23] These trials focused on

health conditions so did not cater specifically for people with impaired mobility. The impact of health coaching in this population is not known. Physical activity prescription in people with mobility limitations is complex so we hypothesise that tailored advice from physiotherapists will enhance activity levels.

In consultation with consumers, clinicians, and policy makers, our multidisciplinary investigator team developed two intervention packages based on behaviour change theories as outlined in the logic model (Fig. 1) and Table 1 and 2.[16,24,25] Both interventions involve the development of a goal-based tailored physical activity plan (made in conjunction with a physiotherapist and sent to participants and their primary care physician (referred as a General Practitioner (GP)) to reinforce physical activity participation), access to informational and motivational print and on-line resources and encouragement of use of activity monitors and suitable smart phone applications. We hypothesise that greater effects on measured physical activity levels will be evident from an enhanced intervention package (that also includes a face-to-face assessment and ongoing phone-based physical activity phone coaching both provided by a physiotherapist) compared to a less intensive intervention package (that includes a single phone call from a physiotherapist and text messages). We further hypothesise that both these interventions will have greater impacts on physical activity levels than no intervention.

Methods and analysis

Overview

This pragmatic hybrid effectiveness-implementation design (Type 1) superiority trial (n=600) will use 1:1 concealed on-line randomisation to allocate adults with self-reported mobility limitations to a 6-month enhanced intervention, a 6-month less intensive intervention or a waiting list control group (who will receive the less intensive intervention after 6 months). Between-group comparisons will be undertaken at 6 months (all groups) and at 12 months (comparing two intervention groups).

The study primarily aims to establish the effects of the interventions, compared to each other and to control, on objectively-measured physical activity at 6-months (*Stepwatch*, steps per day). Secondary outcomes include other physical activity measures, measures of health and functioning, individualised mobility goal attainment, mental wellbeing, quality of life, rate of falls, health utilisation and intervention evaluation. Secondary analyses will explore differential effects on the basis of recruitment source (health professional referral versus

community advertising), assess implementation outcomes, and establish the cost-effectiveness and cost-utility.

The trial is more pragmatic than explanatory in that it uses recruitment and intervention strategies relevant to the "real-word" and is intended to help support a decision on whether such interventions should be delivered. A more explanatory trial would be undertaken in an idealised setting, to give the intervention its best chance to demonstrate a beneficial effect.[26] A hybrid effectiveness-implementation design (Type 1)[27] will be used to collect implementation outcomes at the same time as effectiveness outcomes. A nested process evaluation will use both quantitative and qualitative methods to explore uptake by participants and acceptability of the intervention (to participants, health coaches and other stakeholders). The protocol for the process evaluation will be described elsewhere. The PRACTIS guide[28] to implementation and scale-up of physical activity interventions was used to ensure that the interventions (and study recruitment methods) were as potentially scalable in future as possible. Future scale-up of the interventions, if found to be effective, will be guided by the model developed by Milat et al,[29] along with the implementation outcomes and other aspects of the process evaluation. An economic analysis, which will be conducted alongside the trial, will aim to establish the cost-effectiveness and cost-utility of the interventions compared to no intervention and to each other to assist funders of preventive health interventions to assess the value of such an approach for future investments. Table 1 shows the reasons for choice of different components, Table 2 overviews the intervention in TIDieR format and Figure 1 shows the overall logic and broader context for the trial. The first participant was recruited on 13 February 2019 and at the time of submission of this manuscript 156 participants had been randomised.

The primary comparisons will assess the effect on objectively measured physical activity at 6 months of the

i) enhanced intervention package (*Coaching to ComeBACK* group: one face-to-face assessment from a physiotherapist, tailored physical activity plan sent to participant and GP, physical activity phone coaching from a physiotherapist, activity monitors and/or apps, booklet and access to on-line resources) compared with a less intensive intervention package (*Texting to ComeBACK* group: single session of tailored advice by phone from a physiotherapist with health coaching training, tailored physical activity plan sent to participant and GP, unidirectional text messages, booklet and access to on-line resources);

ii) the enhanced intervention package (*Coaching to ComeBACK* group) compared with no intervention (*Texting to ComeBACK Later* waiting list control group);

iii) the less intensive intervention package (*Texting to ComeBACK* group) compared with no intervention (*Texting to ComeBACK Later* waiting list control group).

Participants

The trial will be conducted across four Australian states with recruitment through health services in hospital departments and the general community through community organisations as well as traditional and social media advertisements and stories. Participants with a range of health conditions who report difficulty or inability to walk 800m[30] will be recruited. The process evaluation will explore differences in feasibility and efficiency of recruitment in each of the settings to inform future implementation strategies.

The trial will involve consenting adults (18+ years) who are: living in the community (as opposed to residential care); have a mobility limitation (self-reported difficulty or inability to walk 800m) but are able to leave their home without physical assistance from another person (but may use a walking aid); are judged by recruitment staff to have sufficient hearing and English language skills for a phone-based intervention. Trial participants are likely to be affected by one or more common and/or burdensome conditions such as, but not limited to, osteoarthritis, lower limb fractures, lower limb amputations, stroke, brain injury, respiratory conditions and obesity. The trial will exclude adults who are: permanent residents of residential aged care facilities; have the following medical conditions: delirium, acute medical illnesses, severe psychiatric disorders, rapidly progressive neurological diseases; have a major cognitive impairment (a diagnosis of dementia or a Memory Impairment Screen score of less than 5); are currently undertaking 150 minutes or more of moderate to vigorous physical activity per week (based on self-report); full-time wheelchair user; unable to wear a *StepWatch Activity Monitor*; not a regular user of a mobile phone (look at phone less than once per week); or have no internet access.

Randomisation

Each participant will be randomised to one of the three groups after completion of baseline assessments. The trial will use a centralised web-based randomisation system using REDCap

(Research Electronic Data Capture). The randomisation schedule was developed by a researcher not involved in recruitment, outcome measurement or intervention delivery. This process will ensure concealment of allocation to groups and an auditable process. Randomisation to groups will be stratified by whether participants were recruited from the general community (via advertising etc) or from health services.

Assessments

Assessments will occur prior to randomisation and at 3, 6 and 12 months after randomisation. The matchbox-sized *StepWatch Activity Monitors* used to objectively measure physical activity (primary outcome 6 month, secondary outcome 12 month) will be mailed to participants with reply-paid envelopes and clear instructions for use and will be worn at the ankle during waking hours for periods of seven consecutive days. Telephone calls will be made to participants who have not returned the devices and to those who require assistance wearing the device. Questionnaires will be administered online by participants or, if preferred mailed, or by phone by a research assistant unaware of intervention group allocation. Monthly on-line or paper calendars, with phone follow-up where necessary, will be used by participants to report falls and health and community service usage over the 12-month trial period to enable cost collation for the economic analyses. Where possible, data for all outcomes will be collected for all participants including those who cease participation in the interventions, unless the participant wishes to withdraw from the study. The primary outcome will be collected in a blinded fashion. *StepWatch Activity Monitor* data will be processed and analysed by staff unaware of intervention group allocation. All baseline measurements will be undertaken prior to group allocation. Due to the nature of the intervention being tested, full blinding of participants to intervention group allocation will not be possible. All the reassessment questionnaires will however be undertaken by researchers blinded to group allocation. Table 3 overviews the trial outcomes and measurement timepoints.

Outcomes

The primary outcome for the trial is physical activity, measured as average steps per day over a one-week period at 6 months post baseline with the *StepWatch Activity Monitor.* This device was chosen as prior research by the present authors[31] found it to be the most accurate device for step measurement in people with mobility impairment with average 98% (SD 12%)

agreement with investigator-observed steps over a 6-minute period as opposed to 17% (SD 19%) for the more commonly-used *Actigraph* device. The *StepWatch Activity Monitor* is simple to use, can be mailed to participants and does not give feedback to the wearer.

Secondary outcomes will be measured at 3, 6 and 12 months post baseline. Measures undertaken at 12 months will compare the two intervention groups and assess physical activity maintenance in the intervention groups and uptake in the waiting list control group (*Texting to ComeBACK Later* Group). Secondary outcomes include other physical activity measures (self-reported physical activity using the Incidental and Planned Exercise Questionnaire[32], cadence, activity intensity (6 and 12 months only) and average steps per day (12 months only) from the *StepWatch Activity Monitor*, global perceived change scores for physical activity and walking, attitudes to and experience of physical activity), pain (study specific questions), lower limb function and disability (Late Life Function and Disability Instrument[33]), fear of falling and self-reported balance (5-point scales), individualised mobility goal attainment (Goal Attainment Scale[34] at 6 and 12 months), mental wellbeing (Warwick-Edinburgh Mental Well-being Scale[35]), quality of life (EuroQol 5D-5L[36]), Body Mass Index, use of mobility aids, rate of falls and health utilisation (monitored using monthly calendars over 12 months), and measures evaluating impressions (study specific) and enjoyment (Physical Activity Enjoyment Scale)[37] of the interventions and the therapeutic alliance between health coaches and participants (Working Alliance Inventory).[38] The EuroQol 5D-5L will also be used to enable calculation of quality-adjusted life years (QALYs) for the economic analyses.

Other measures Intervention costs and health and community service utilisation, as collected by monthly calendars, will be recorded for all participants and used as part of the economic evaluation. The experiences and attitudes of stakeholders, including participants, health coaches, clinicians and health service managers will be explored via semi structured interviews and focus groups in order to inform future development and implementation of the ComeBACK interventions.

Adverse events will be defined as an unwanted and usually harmful outcome (e.g. exercise-related falls, musculoskeletal injury, angina, shortness of breath or cardiovascular event). The event may or may not be related to the intervention, but it occurs while the person is participating in the intervention phase of the trial i.e. while they are doing mobility or physical activities. A minor adverse event is defined as an incident that results in no injury or minor

injury. For example, a fall where the person sustains a small cut or bruise that requires none or minor medical intervention. A serious adverse event is defined as an incident that results in death, serious injury or hospitalisation. Adverse events will be monitored by records kept by participants and interviews at each follow-up period. Participants will also be asked to notify study staff immediately of any serious adverse events. Any adverse event occurring during the assessment and intervention process will be reported back to authors Hassett and Sherrington. It will then be decided if this is a recognised or unintended event relating to the study protocol. Unintended events will be reported to the 3-person independent Data Monitoring Committee that has been established for this trial and comprises one medical professional and two allied health professionals experienced in the care of people with mobility limitations. Unintended events will also be reported to the approving HREC. The research team will review the event and determine whether it is person specific or whether there is a potential for this to occur to other participants and therefore consideration would be given as to appropriateness of continuing the research. Participants may experience muscle soreness at the start of the physical activity program. This will be minimised by advice to increase activity levels gradually and to seek professional advice if soreness lasts for more than three days or interferes with daily activities.

Interventions

Intervention design was undertaken by our multi-disciplinary author team guided by formal (qualitative pilot work) and informal input from consumers in the target population as well as consultations with clinicians, health service managers, population health service providers and health policy makers. The COM-B (Capability Opportunity Motivation –> Behaviour) model of behaviour change[16] was used to guide the intervention design, with self-determination theory[24] and social cognitive theory[25] further underpinning the motivational component. Table 1 overviews the aspects of the COM-B addressed by each aspect of the intervention packages. Table 2 provides more detail on the interventions using the TIDieR format.[39] The interventions are as follows.

Group 1: Coaching to ComeBACK**.** Participants randomised to this group will be offered the following six intervention components.

i) *a single face-to-face one-hour assessment* of mobility status, safety issues, medical, social and environmental influences on mobility, will be undertaken during a home visit by a

physiotherapist (employed locally). Where a home visit is not possible, a video conference will be conducted as an alternative. At the end of the assessment, a phone or videoconference call will be made to the health coach with both physiotherapist and the participant present to introduce and handover to the health coach and discuss any particular issues.

ii) *phone-based health coaching* will be delivered by trained physiotherapists through a centralised service. The initial session will include development of a tailored plan to improve physical activity through participation in suitable activities in negotiation with the participant and their carers (where appropriate). The choice of physical activity will be guided by personal preference, logistics, physical abilities and evidence of effectiveness of different intervention options. The coach will liaise with relevant treating health professionals to identify contraindications or precautions to exercise and ensure other causes of mobility limitation are optimally managed. Coaching sessions will be delivered at a tailored frequency of approximately every 2 weeks over a 6-month period and will take an average of 20-30 min each session. The coaching will incorporate behaviour change strategies including motivational interviewing (to explore and enhance reasons for being active (importance) and confidence to make changes, as well as to explore social influences on activity) goal-setting, problem-solving, building social support and experiential learning. The individually-tailored, person-centred approach will determine each person's physical, cognitive, affective, environmental and social barriers and facilitators to physical activity and develop physical activity recommendations (including adaptations and/or assistance to overcome specific barriers) for each individual. The health coach will link participants to existing community programs if desired, with a focus on identifying activities that participants will enjoy.[40] Suitable options may include attendance at a group program, such as those indexed on the *Active and Healthy* website (www.activeandhealthy.nsw.gov.au) and/or participation in sporting opportunities that cater for people with impaired mobility. The coaching will also encourage reduced sedentary and inactive time by spending more time standing and walking or undertaking a home based exercise program, as well as increased use of active transport (i.e. walking, using public transport). Staff have extensive experience in the management of people with walking limitations, have undertaken courses in health coaching and received two days of additional training in using behaviour change science and self-determination theory to guide intervention from author Greaves.

iii) *activity monitors and GPS-based tablet/smartphone applications*. Participants will be offered an internet-connected activity monitor (such as the *Fitbit*) or a simple pedometer if preferred, as pedometers are known to enhance physical activity through measurement and

behavioural reinforcement.[41]

iv) *physical activity plan* developed jointly as outlined above will be shared with the participant's GP with his/her consent soon after it is developed.

v) *paper-based booklet* on physical activity, safe mobility and behaviour change that is study-specific, evidence-based and theoretically informed (by incorporating messaging and images that are consistent with self-determination theory (promoting autonomy, competence and relatedness for walking behaviour) and social cognitive theory (supporting self-regulation and identifying /reinforcing the perceived benefits (social, physical, emotional/affective).

vi) *closed study website* with 3 components: 1) why be active (incorporating motivational components consistent with self-determination theory); 2) how to be active (links to resources); 3) how others do it (video case studies using modelling of successful peer behaviour as per Social Cognitive Theory).

Group 2: Texting to ComeBACK**.** Participants randomised to this group will be offered the following five intervention components. The first two intervention components are unique to this group and the following three interventions are the same as Group 1.

i) *single session of tailored advice provided by phone by a physiotherapist.* This call will last 50-60 minutes, will be informed by the baseline assessment results and provide advice about appropriate physical activity opportunities for the person's interests and level of mobility. A follow-up email will be sent to summarise and reinforce key discussion points.

ii) *text messages to encourage activity.* Pre-scheduled unidirectional text messages with some tailoring and personalisation will commence at 5 times/week for the first month to provide motivation support (again using messages designed to be consistent with self-determination theory (promoting autonomy, competence and relatedness for walking behaviour) and social cognitive theory (supporting self-monitoring /self-regulation and identifying /reinforcing the perceived benefits (social, physical, emotional/affective)), planning support, problem-solving and maintenance support. Participants will then have the option of increasing intensity (daily messages) or decreasing intensity (3 times/week) for the next 4 months prior to a gradual reduction in the frequency of messages. There is also an opt-out feature available at all times.

iii) *physical activity plan* developed jointly as outlined above and will be shared with the participant's GP with their consent soon after it is developed.

iv) *paper-based booklet* that has study-specific information on physical activity, safe mobility and behaviour change that is evidence-based and theoretically informed (as outlined above).

v) *closed study website* with 3 components: 1) why be active; 2) how to be active (links to resources including recommended activity monitors and physical activity Apps); 3) how others do it (video case studies using modelling of successful peer behaviour as per Social Cognitive Theory).

Group 3: Texting to ComeBACK Later (waiting list control)**.** This group will not receive any intervention for the first 6 months of the trial but will be advised to continue usual activity levels and health service use. After 6 months, this group will receive the Texting to ComeBACK intervention package as outlined above.

Patient and public involvement

Consultations with consumers, clinicians, and policy makers assisted in the design of intervention and study methods. This input was gained from a) input from our multidisciplinary study team that includes health service managers and clinicians; b) from informal discussions with health service managers, health professionals, health service users, community members and those delivering interventions in our previous trials,[42-44] c) formal qualitative work involving participants in our previous trials[45,46] and our systematic reviews of qualitative studies.[47,48]

The study protocol and choice of intervention and assessment tools (including the burden on participants) was further guided by feedback from consumers obtained as part of the endorsement of the trial by the Australia & New Zealand Musculoskeletal Clinical Trials Network (ANZMUSC). Study results will be disseminated to participants via email or paper letters.

Sample size

The trial's sample size (n=600) will provide 90% power to detect between-group differences of 1000 steps per day assuming a standard deviation of 3000 steps (estimated from our pilot data), a dropout rate of 20%, alpha of 0.0167 (to adjust for multiplicity due to 3 trial arms), and correlation between initial and final measures of 0.6 (from our pilot data). This calculation was

undertaken in Stata 13 using the *sampsi* command. On the basis of previous work by the investigators and others, we consider between-group differences of this magnitude to be likely to result in significant health benefits because 1000 steps/day, assuming a cadence of 80 steps/min, would equate to an additional 15 minutes of walking/day, a dose associated with health benefits and reduced mortality even in those with cardiovascular disease.[49]

Statistical analysis

Analysis of covariance, conducted using a linear regression approach, will be used to assess the effect of group allocation on the continuously-scored primary and secondary outcomes after adjusting for baseline scores and source of recruitment. Point estimates and their 95% confidence intervals will be used to interpret results. Given our interest in comparing the two interventions with each other and with the control condition, between-group differences with p-values < 0.0167 will be considered significant. Planned sub-group analyses will assess differential effects of the intervention based on the stratification variable of recruitment source, as well as for severity of mobility limitation and age. Secondary analyses using causal modelling will be conducted to establish intervention effects in people with greater adherence. Analyses will be pre-planned, by intention-to-treat, conducted while masked to group allocation and undertaken after range checks. A detailed Statistical Analysis Plan will be developed and signed off by all investigators prior to analysis.

The economic evaluation will take the perspective of the health and community care funder. Health care costs, community service costs and intervention costs will be collected over the trail period. Using mean costs and mean health outcomes in each trial arm, the incremental costs per 1) additional person with increased physical activity of more than 1000 steps per day; and 2) QALY gained will be calculated; results will be plotted on a cost-effectiveness plane. Bootstrapping will be used to estimate a distribution around costs and health outcomes, and to calculate the confidence intervals around the incremental cost- effectiveness ratios. One-way sensitivity analysis will be conducted around key variables and a probabilistic sensitivity analysis will estimate uncertainty in all parameters. A cost-effectiveness acceptability curve will be plotted to provide information about the probability that the intervention is cost-effective, given willingness to pay for each benefit gained. Modelled analyses will explore the longer term cost-effectiveness of the intervention.

Ethics and dissemination

Ethical approval and local governance approvals have been obtained (Lead ethics committee: Sydney Local Health District, Royal Prince Alfred Zone (22/08/2018 X18-0234). All amendment requests will be submitted to these committees. Written informed consent from all participants will be obtained by study staff prior to study enrolment (see sample consent form in supplementary material). Participant confidentiality will be maintained at all times and all data will be stored securely. Dissemination will be via publications, conferences, newsletter articles, letters to participants, talks to healthcare professionals and consumers and meetings with health department and health service mangers. Intervention materials will be made freely available at the end of the trial. The International Committee of Medical Journal Editors recommended criteria for authorship on publications will be followed. Professional writers will not be used. The full protocol, de-identified data and statistical code will be made available upon reasonable request. All authors will have full access to de-identified study data.

Discussion

This study will address a key evidence gap regarding realistic scalable ways to enhance physical ability in people with impaired mobility. The trial interventions are designed to be tailored yet scalable. The interventions are designed by health professionals and involve individualised health professional input, but have minimal face to face contact in an effort to minimise travel time, increase availability and enable greater efficiency. The use of a central centre to deliver the interventions is a model designed to be implemented if found to be effective. The inclusion of the lower intensity (text message) group aims to ascertain whether there is sufficient benefits from this less resource intensive model.

It would have been useful and interesting to measure performance outcomes such as mobility, balance and strength at 6 and 12 months, but the size of the trial, geographic spread of participants and budget constraints preclude this.

Trial results will provide direct information about the costs and benefits of the intervention approach compared with current practice to enable funders of preventive health interventions to decide whether such approaches are worth investing in as a population health intervention.

Author contributions

All authors contributed to the design of the study and preparation of the study protocol. This manuscript was drafted by author Sherrington who oversees all aspects of the study. Author Hassett oversees the intervention aspects of the study and the Sydney sites. Author O'Rourke oversees data collection and integrity and privacy. Author van den Berg oversees the South Australian sites. Authors Hinman, and Taylor oversee the Victorian sites. Author Hoffman overs the Queensland sites. Authors Sherrington, Hinman, Crotty, Hoffman, Harvey, Taylor, Hassett and Tiedemann were Chief Investigators on the Grant application. Authors Milat. Treacy, Bennell, Howard and Jennings were Associate Investigators on the Grant application. Associate Investigator Herbert is not an author on this paper but will guide statistical analysis. Authors Treacy, Jennings and Milat are senior clinicians and/or policy leaders. Author Pinheiro will undertake the economic evaluation under guidance from author Howard. Author Greaves guided the use of behaviour change theory in intervention design. Author Milat will guide the use of the scale-up tool he developed. Authors ORourke, Kirkham and Ramsay are employed to work on the study. Authors Kirkham and Ramsay are the physiotherapists who deliver the health coaching interventions and assisted with the design of the interventions. Author Wong is a PhD student who will lead the implementation/process evaluation (to be reported separately). We are grateful to study participants and to the patient advisors who helped shape the intervention.

Funding statement

This work is supported by a project grant from the Australian National Health and Medical Research Council (APP 1145739). Authors LH, AT, RSH, CS receive salary funding from the Australian National Health and Medical Research Council Fellowship. The funders have no role in study design; collection, management, analysis, and interpretation of data; writing of the report; or the decision to submit the report for publication, and will not have ultimate authority over any of these activities.

Competing interests statement

The authors do not report any competing interests.

Word Count: 5154 words (excluding references and tables)

References

1. WHO. Towards a common language for functioning, disability and health: ICF. . 2002.
2. AIHW. *Australia's Welfare.* Canberra: Australian Institute of Health and Welfare.;2015.
3. Cummings SR, Studenski S, Ferrucci L. A diagnosis of dismobility--giving mobility clinical visibility: a Mobility Working Group recommendation. *Jama.* 2014;311(20):2061-2062.
4. Ma VY, Chan L, Carruthers KJ. Incidence, prevalence, costs, and impact on disability of common conditions requiring rehabilitation in the United States: stroke, spinal cord injury, traumatic brain injury, multiple sclerosis, osteoarthritis, rheumatoid arthritis, limb loss, and back pain. *Archives of physical medicine and rehabilitation.* 2014;95(5):986-995.e981.
5. Jones E, Pike J, Marshall T, Ye X. Quantifying the relationship between increased disability and health care resource utilization, quality of life, work productivity, health care costs in patients with multiple sclerosis in the US. *BMC health services research.* 2016;16:294.
6. Espahbodi S, Bassett P, Cavill C, Freeth M, Hole J, Sengupta R. Fatigue contributes to work productivity impairment in patients with axial spondyloarthritis: a cross-sectional UK study. *Clinical and experimental rheumatology.* 2017;35(4):571-578.
7. Das P, Horton R. Physical activity-time to take it seriously and regularly. *Lancet (London, England).* 2016;388(10051):1254-1255.
8. Lee IM, Shiroma EJ, Kamada M, Bassett DR, Matthews CE, Buring JE. Association of Step Volume and Intensity With All-Cause Mortality in Older Women. *JAMA internal medicine.* 2019.
9. Dwyer T, Pezic A, Sun C, et al. Objectively Measured Daily Steps and Subsequent Long Term All-Cause Mortality: The Tasped Prospective Cohort Study. *PloS one.* 2015;10(11):e0141274.
10. Hoffmann TC, Maher CG, Briffa T, et al. Prescribing exercise interventions for patients with chronic conditions. *CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne.* 2016;188(7):510-518.
11. Garber CE, Blissmer B, Deschenes MR, et al. American College of Sports Medicine position stand. Quantity and quality of exercise for developing and maintaining cardiorespiratory, musculoskeletal, and neuromotor fitness in apparently healthy adults: guidance for prescribing exercise. *Medicine and Science in Sports and Exercise.* 2011;43(7):1334-1359.
12. Pollock RD, Carter S, Velloso CP, et al. An investigation into the relationship between age and physiological function in highly active older adults. *J Physiol.* 2015;593(3):657-680.
13. Pahor M, Guralnik JM, Ambrosius WT, et al. Effect of structured physical activity on prevention of major mobility disability in older adults: the LIFE study randomized clinical trial. *Jama.* 2014;311(23):2387-2396.
14. Carroll DD, Courtney-Long EA, Stevens AC, et al. Vital signs: disability and physical activity--United States, 2009-2012. *MMWR Morbidity and mortality weekly report.* 2014;63(18):407-413.
15. ABS. Sports and Physical Recreation: A Statistical Overview, Australia. In: Australian Bureau of Statistics; 2012.
16. Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implementation Science.* 2011;6:42.
17. Hillsdon M, Thorogood M, White I, Foster C. Advising people to take more exercise is ineffective: a randomized controlled trial of physical activity promotion in primary care. *International journal of epidemiology.* 2002;31(4):808-815.
18. Richards J, Hillsdon M, Thorogood M, Foster C. Face-to-face interventions for promoting physical activity. *The Cochrane database of systematic reviews.* 2013;9:Cd010392.
19. Foster C, Richards J, Thorogood M, Hillsdon M. Remote and web 2.0 interventions for promoting physical activity. *The Cochrane database of systematic reviews.* 2013;9:Cd010395.
20. Greaves CJ, Sheppard KE, Abraham C, et al. Systematic review of reviews of intervention components associated with increased effectiveness in dietary and physical activity interventions. *BMC public health.* 2011;11:119.

21. Oliveira J, Sherrington C, Amorim A, Dario A, Tiedemann A. What is the effect of health coaching on physical activity participation in people aged 60 years and over?: A systematic review of randomised controlled trials. . *British Journal of Sports Medicine.* 2017;51:1425-1432.
22. O'Halloran PD, Blackstock F, Shields N, et al. Motivational interviewing to increase physical activity in people with chronic health conditions: a systematic review and meta-analysis. *Clin Rehabil.* 2014;28(12):1159-1171.
23. O'Halloran PD, Shields N, Blackstock F, Wintle E, Taylor NF. Motivational interviewing increases physical activity and self-efficacy in people living in the community after hip fracture: a randomized controlled trial. *Clin Rehabil.* 2016;30(11):1108-1119.
24. Ryan RM, Deci EL. Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being. *The American psychologist.* 2000;55(1):68-78.
25. Bandura A. *Social foundations of thought and action: A social cognitive theory.* Englewood Cliffs, NJ: Prentice-Hall; 1986.
26. Loudon K, Treweek S, Sullivan F, Donnan P, Thorpe KE, Zwarenstein M. The PRECIS-2 tool: designing trials that are fit for purpose. *BMJ (Clinical research ed).* 2015;350:h2147.
27. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Medical Care.* 2012;50(3):217–226.
28. Koorts H, Eakin E, Estabrooks P, Timperio A, Salmon J, Bauman A. Implementation and scale up of population physical activity interventions for clinical and community settings: the PRACTIS guide. *The international journal of behavioral nutrition and physical activity.* 2018;15(1):51.
29. Milat AJ, Newson R, King L. *Increasing the scale and adoption of public health interventions: A guide for developing a scaling up strategy.* North Sydney: NSW Ministry of Health;2014.
30. Weiss CO, Fried LP, Bandeen-Roche K. Exploring the hierarchy of mobility performance in high-functioning older women. *J Gerontol A Biol Sci Med Sci.* 2007;62(2):167-173.
31. Treacy D, Hassett L, Schurr K, Chagpar S, Paul S, Sherrington C. Physical Therapy. . *Validity of different activity monitors to count steps in an inpatient rehabilitation setting.* Accepted 12 Dec 2016.
32. Delbaere K, Hauer K, Lord S. Evaluation of the Incidental and Planned Exercise Questionnaire (IPEQ) for older people. *British Journal of Sports Medicine* 2010;44:1029-1034.
33. Jette AM, Haley SM, Coster WJ, et al. Late life function and disability instrument: I. Development and evaluation of the disability component. *J Gerontol A Biol Sci Med Sci.* 2002;57(4):M209-216.
34. Tennant A. Goal attainment scaling: current methodological challenges. *Disabil Rehabil.* 2007;29(20-21):1583-1588.
35. Tennant R, Hiller L, Fishwick R, et al. The Warwick-Edinburgh Mental Well-being Scale (WEMWBS): development and UK validation. *Health Qual Life Outcomes.* 2007;5:63.
36. EuroQol--a new facility for the measurement of health-related quality of life. *Health policy (Amsterdam, Netherlands).* 1990;16(3):199-208.
37. Kendzierski D, DeCarlo KJ. Physical Activity Enjoyment Scale: Two Validation Studies. 1991;13(1):50.
38. Hatcher RL, Gillaspy JA. Development and validation of a revised short version of the Working Alliance Inventory. *Psychotherapy Research.* 2006;16(1):12-25.
39. Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ (Clinical research ed).* 2014;348:g1687.
40. Kiviniemi MT, Voss-Humke AM, Seifert AL. How do I feel about the behavior? The interplay of affective associations with behaviors and cognitive beliefs as influences on physical activity behavior. *Health psychology : official journal of the Division of Health Psychology, American Psychological Association.* 2007;26(2):152-158.

41. J SO, Sherrington C, E RYZ, Franco MR, Tiedemann A. Effect of interventions using physical activity trackers on physical activity in people aged 60 years and over: a systematic review and meta-analysis. *Br J Sports Med.* 2019.
42. Tiedemann A, Rissel C, Howard K, et al. Health coaching and pedometers to enhance physical activity and prevent falls in community-dwelling people aged 60 years and over: study protocol for the Coaching for Healthy AGEing (CHAnGE) cluster randomised controlled trial. *BMJ open.* 2016;6(5):e012277.
43. Hassett L, van den Berg M, Lindley RI, et al. Effect of affordable technology on physical activity levels and mobility outcomes in rehabilitation: a protocol for the Activity and MObility UsiNg Technology (AMOUNT) rehabilitation trial. *BMJ open.* 2016;6(6):e012074.
44. Oliveira JS, Sherrington C, Paul SS, et al. A combined physical activity and fall prevention intervention improved mobility-related goal attainment but not physical activity in older adults: a randomised trial. *Journal of physiotherapy.* 2019;65(1):16-22.
45. Hamilton C, McCluskey A, Hassett L, Killington M, Lovarini M. Patient and therapist experiences of using affordable feedback-based technology in rehabilitation: a qualitative study nested in a randomized controlled trial. *Clin Rehabil.* 2018;32(9):1258-1270.
46. Haynes ASCWGTAMDRCLDTA. "Someone's got my back": Older people's experience of the Coaching for Healthy Ageing program for promoting physical activity and preventing falls. *Journal of Aging and Physical Activity.* Accepted 9 July 2019.
47. Franco MR, Tong A, Howard K, et al. Older people's perspectives on participation in physical activity: a systematic review and thematic synthesis of qualitative literature. *Br J Sports Med.* 2015;49(19):1268-1276.
48. Jang H, Clemson L, Lovarini M, Willis K, Lord SR, Sherrington C. Cultural influences on exercise participation and fall prevention: a systematic review and narrative synthesis. *Disabil Rehabil.* 2016;38(8):724-732.
49. Wen CP, Wai JP, Tsai MK, et al. Minimum amount of physical activity for reduced mortality and extended life expectancy: a prospective cohort study. *Lancet (London, England).* 2011;378(9798):1244-1253.
50. Farag I, Howard K, Ferreira ML, Sherrington C. Economic modelling of a public health programme for fall prevention. *Age Ageing.* 2015;44(3):409-414.

Table 1. Trial and intervention overview and reasoning by population, interventions, control and outcome

COMPONENT	RATIONALE	BEHAVIOURAL ASPECT ADDRESSED*
Population		
Adults with mobility limitation due to any reason, able to leave the house without assistance	• a group at risk of deterioration to dependence • inclusion of people with multiple reasons for mobility limitations because this provides a more scalable approach than a single disease focus • exclusion of more impaired people who probably require more supervised interventions	n/a
Recruited from clinical sites and the community across 4 states	• scalable approach with clear feasibility due to clinical links • enhanced generalisability of the sample to the Australian population	n/a
Group 1: Coaching to ComeBACK package		
One face-to-face assessment by physiotherapist	• likely to enhance intervention effectiveness, considered beneficial by participants and staff in pilot work • training of local staff for face to face assessments ensures the intervention is scalable	Expert assessment of capability to suggest appropriate opportunities. Establishing /building motivation.
Patient-centred health coaching, incorporating behaviour change strategies including goal-setting and motivational interviewing	• coaching is known to be effective for increased physical activity in general population, people with chronic disease and older people • use of a physiotherapist recognises the complexity of the population • individualised intervention caters for different conditions, needs and preferences • centralised coaching delivery is a scalable approach that facilitates quality control and economies of scale	Ongoing expert assessment of capability to suggest appropriate opportunities. Encouragement of capability enhancement. Feedback to assist with ongoing motivation.
Activity monitor or pedometer if desired	• known to enhance physical activity in general population • well accepted in pilot among people with mobility limitations	Feedback to assist with ongoing motivation.
Tailored use of apps to encourage physical activity	• well accepted in previous studies • tailored choice of apps according to participant interest and type of physical activity considered safe and appropriate by physiotherapist	Feedback and rewards to assist with ongoing motivation.
Paper-based and on-line resources to support behaviour change	• provision of evidence-based information in attractive format • including case studies to support behaviour change.	Case studies and information to assist with capability and motivation.
Tailored physical activity plan developed and shared with GP	• credible and trusted source reinforcing behaviour changes suggested by health coach	Increased motivation.

Group 2: Texting to ComeBACK		
Single session of tailored advice over the phone from a physiotherapist	• use of physiotherapist recognises complexity of population • individualised intervention caters for different conditions, needs and preferences • centralised coaching delivery is a scalable approach that facilitates quality control and economies of scale	Expert assessment of capability to suggest appropriate opportunities.
Paper-based and on-line resources to support behaviour change	• provision of evidence-based information in attractive format • including case studies to support behaviour change.	Case studies and information to assist with capability and motivation.
Text messages	• text messages with some tailoring and personalisation able to be pre-scheduled. • pre-scheduled and uni-directional so highly scalable. • shown to be effective in previous studies.	Assist with motivation and problem-solving (capability).
Tailored physical activity plan developed and shared with GP	• credible and trusted source reinforcing behaviour changes suggested by health coach.	Increased motivation.
Group 3: Texting to ComeBACK Later		
No intervention for 6 months	• pragmatic comparison • direct policy implications	
Receipt of less intensive intervention after 6 months	• enhanced recruitment through provision of intervention for all participants.	As above
Outcome		
Physical activity	• neglected costly population health problem.	n/a

*Primarily using the COM-B system[16] for understanding behaviour change. Includes capability (an individual's psychological and physical capacity for physical activity including knowledge and skills), opportunity (factors outside the individual that enable or prompt behaviour) and motivation (brain processes that energise and direct behaviour, i.e., goals, decision-making, habits, emotional responding). This model acknowledges the role of individual action to change behaviours within a broader social context.

Table 2: Intervention description of the ComeBACK randomised controlled trial using the Template for Intervention Description and Replication (TIDieR) checklist

Intervention description using the Template for Intervention Description and Replication (TIDieR) checklist		
	Intervention Group 1	**Intervention Groups 2 and 3**
Brief name	**Coaching to ComeBACK**	**Texting to ComeBACK and Texting to ComeBACK later***
Why	Over 1 million Australians currently require assistance to, or are unable to, walk about their homes. The impact of mobility limitation is increasing due to population ageing. Physical activity participation has enormous untapped potential as a cost-effective approach to enhancing health in people of most ages, health conditions and physical abilities, however most people with mobility limitations are insufficiently active for health benefits. Remote interventions such as telephone health coaching and text-message support to encourage physical activity are scalable interventions which can be tailored to match the individual's capacity and preferences. Physical activity prescription for people with mobility limitations is complex as they face additional barriers to physical activity participation, thus interventions delivered by health professionals such as physiotherapists are needed. A theoretical basis combining COM-B (Capability Opportunity Motivation –> Behaviour) model of behaviour change, Self Determination Theory and Social Cognitive Theory informs the choice of intervention components and underpins all participant materials.	
What procedures	➢ Initial physiotherapy assessment (by local or study physiotherapist) to identify mobility status, safety issues, medical, social and environmental influences on mobility. Three-way (participant/health coach physiotherapist/ assessment physiotherapist) handover at end of session if possible. ➢ Development of tailored physical activity plan. ➢ Fortnightly patient-centred health coaching from a physiotherapist trained in health coaching incorporating behaviour change strategies including goal-setting, problem-solving, building social support, experiential learning and motivational interviewing.	➢ One-off phone-based tailored advice from a physiotherapist trained in health coaching to provide expert assessment of capability, identifying appropriate physical activity opportunities and to build motivation. Follow-up email to summarise and reinforce advice. ➢ Development of tailored physical activity plan. ➢ Pre-scheduled text messages with some personalisation and tailoring (based on the physical activity plan) commencing at 5 times/week to provide motivation support, planning support, problem-solving and maintenance support.
What materials#	➢ Study specific evidence-based and theoretically informed education booklet on physical activity, safe mobility and behaviour change. ➢ Access to closed study website with 3 components: 1) why be active 2) how to be active (links to resources); 3) how others do it (video case studies-modelling elements of Social Cognitive Theory). ➢ Physical activity plan shared with General Practitioner. ➢ Option to use activity monitor and/or physical activity apps for self-monitoring.	➢ Each participant must have his/her own mobile phone. ➢ Study specific evidence-based and theoretically informed education booklet on physical activity, safe mobility and behaviour change. ➢ Access to closed study website with 3 components: 1) why be active 2) how to be active (links to resources); 3) how others do it (video case studies-modelling elements of Social Cognitive Theory). ➢ Physical activity plan shared with General Practitioner.
Who	➢ Initial physiotherapy assessment conducted by tertiary	➢ Tailored advice and selection of text-messages provided by tertiary

provided	trained local physiotherapists either employed by the study, paid casually or employed in the local health service. ➢ Health coaching provided by tertiary trained physiotherapists employed by the study with clinical experience working with the study population and research experience delivering telephone-based health coaching. Coaches attended courses through *Wellness Coaching Australia; Health Change Australia* and *Medicoach* as well as receiving training by study investigator (CG) in advanced motivational interviewing, a framework for "good (functional) motivation" and intervention techniques.	trained physiotherapists employed by the study with clinical experience working with the study population and research experience delivering telephone-based health coaching. Coaches attended courses through *Wellness Coaching Australia*; *Health Change Australia* and *Medicoach* as well as receiving training by study investigator (CG) in advanced motivational interviewing, a framework for "good (functional) motivation" and intervention techniques.
How	➢ The initial physiotherapy assessment will be conducted face-to-face in participants' homes or completed by a health service physiotherapist who has been delivering rehabilitation to the participants prior to the study. The handover will be via phone or videoconference. ➢ The health coaching will be delivered via telephone. ➢ Education booklet, physical activity plan, access details to website and activity monitor (optional) will be mailed to participants.	➢ The tailored advice will be delivered via telephone with follow-up email. ➢ Text messages will be pre-scheduled using a web-based short message service to be delivered to the participants mobile phone. ➢ Education booklet, physical activity plan and access details to website will be mailed to participants.
Where	➢ The intervention will be delivered remotely (apart from initial physiotherapy assessment) to community-dwelling people in Australia, initially commencing in the states of New South Wales, South Australia and Victoria.	➢ The intervention will be delivered remotely to community-dwelling people in Australia, initially commencing in the states of New South Wales, South Australia and Victoria.
When and how much	➢ The face-to-face assessment will occur at the beginning of the intervention period and will last for ~ 1 hour. ➢ The telephone-based health coaching will occur after the face-to-face assessment, at a tailored frequency and duration (approximately every 2 weeks for 20-30 min) for a total duration of 6 months. ➢ The education booklet and access details for website will be mailed prior to initial health coaching session. The physical activity plan and activity monitor (if requested) will be mailed (or emailed) after the initial health coaching session.	➢ The one-off tailored advice session will occur at the beginning of the intervention period and will last for ~ 1 hour (this could be broken into two calls if the participant fatigues or has limited time). An email/letter summary of the call will be sent in addition to the physical activity plan. ➢ The text messages will be pre-scheduled after the advice session to enable tailoring to the participants needs and preferences. They will be delivered 5 times/week for the first month. Participants will then have the option of increasing intensity (daily messages) or decreasing intensity (3 times/week) for the next 4 months prior to a gradual reduction in the frequency of messages. There is also an opt out

	feature available at all times. ➢ The education booklet and access details for website will be mailed prior to health coaching session. The physical activity plan will be mailed (or emailed) after the advice session.
Tailoring	The individually-tailored, person-centred approach will determine each person's physical, cognitive, affective, environmental and social barriers and develop physical activity recommendations (including adaptations and/or assistance to overcome specific barriers) for each individual. Both interventions will link or recommend participants to existing community programs, with a focus on identifying activities that participants will enjoy.[40] Suitable options may include attendance at a group program, such as those indexed on the *Active and Healthy* website (https://www.activeandhealthy.nsw.gov.au/) , and/or participation in sporting opportunities that cater for people with impaired mobility. Both interventions will also encourage reduced sedentary and inactive time by spending more time standing and walking and increased use of active transport (i.e. walking, using public transport) and/or undertaking a home based exercise programme.

* *Texting to ComeBACK Later* group will receive the same intervention as the *Texting to ComeBACK* group with a 6-month delay.

Study resources (booklet, physical activity plan, website resources) will be made publicly available after the trial is completed.

Table 3. List of measures collected at baseline assessment (BA), 3 months (3A), 6 months (6A), and at 12-month reassessment (12A) for all study participants.

Information collected for all participants	BA	3A	6A	12A	O
Socio-demographics. Age, gender, education, occupation, country of birth, language, living arrangements, health condition, agency support	Y	N	N	N	N
General health and function					
Functional Co-morbidity Index	Y	N	N	N	N
Technology exposure	Y	N	N	N	N
Mobility aids	Y	Y	Y	Y	S
BMI	Y	Y	Y	Y	S
Pain related questions	Y	Y	Y	Y	S
Self-reported Fear of Falling and Balance level	Y	Y	Y	Y	S
Late Life lower limb extremity Function and Disability Instrument[33]	Y	Y	Y	Y	S
Individualised mobility Goal Attainment Scale[34]	Y	N	Y	Y	S
Quality of life					
The EQ5D-5L[36]	Y	Y	Y	Y	S
Mental well being					
Warwick-Edinburgh Mental Well-being Scale[35]	Y	Y	Y	Y	S
Physical Activity					
Average steps per days measured over a one-week period using a StepWatch Activity Monitor	Y	N	Y	Y	P
Cadence and activity intensity levels using a StepWatch Activity Monitor	Y	N	Y	Y	S
The Incidental and Planned Exercise Questionnaire (IPEQ)	Y	Y	Y	Y	S
Global Perceived Change scales on physical activity and walking	N	Y	Y	Y	S

Attitudes to Physical Activity	Y	Y	Y	Y	S
Experiences of Physical Activity	N	Y	Y	Y	S
Falls and Health Utilisation					
Falls and fall related injuries (monthly diaries for 12 months)[50]					S
Use of health services (monthly diaries for 12 months)[50]					S
Medication use	Y		Y	Y	N
Intervention Evaluations					
Impressions of program			Y#	Y%	S
Physical Activity Enjoyment Scale (PACES)			Y#	Y%	S
Work Alliance Inventory-Short Revised Participant (WAI-SR)			Y#	Y%	S
Work Alliance Inventory-Short Revised Therapist (WAI-SRT)			Y#	Y%	S

Note: Y=YES, N=NO, BA=Baseline Assessment, 3A= 3 months assessment 6A= 6 months assessment 12A=12 month assessment, O=Outcome measure, S=Secondary, P=Primary, #=Group 1&2, %=Group 3

Figure legend

Figure 1. Logic model for the ComeBACK intervention.

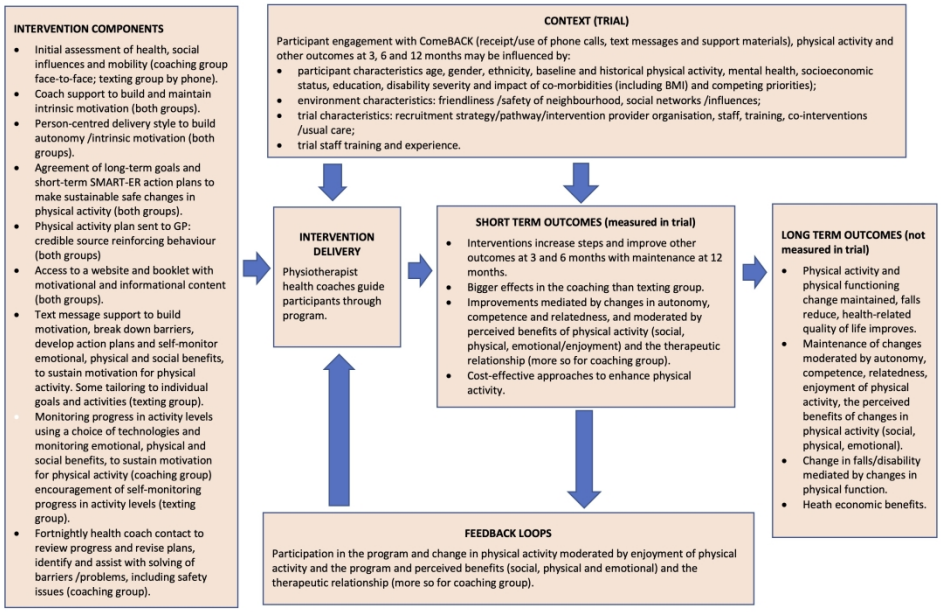

Figure 1. Logic model for the ComeBACK intervention.

297x209mm (300 x 300 DPI)

Physical Activity Coaching for Adults with Mobility Limitations: A Pragmatic Randomised Controlled Trial

INFORMATION FOR PARTICIPANTS

Invitation

You are invited to participate in a research study, looking at the benefits of two physical activity intervention programs aimed at improving physical activity levels among adults with self-reported difficulty walking.

The principal investigators for the study are:

Professor Catherine Sherrington - University of Sydney
Professor Rana Hinman - University of Melbourne
Professor Maria Crotty - The Flinders University of South Australia
Professor Tammy Hoffmann - Bond University Limited
Professor Lisa Harvey – University of Sydney
Professor Nicholas Taylor - La Trobe University
Doctor Leanne Hassett - University of Sydney
Associate Professor Anne Tiedemann - University of Sydney

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

What is the purpose of this study?

This study is a randomised controlled trial. The purpose of this study is to investigate the impact of two physical activity intervention packages on the physical activity levels of adults who report that they have walking difficulties compared to no intervention. The information in this sheet can help you decide if you would like to take part in this study and describes what you can expect.

Study procedures and what is involved

The study will be conducted over 12 months. If you agree to participate in this study, you will be required to sign the Participant Consent Form prior to the commencement of any study procedures.

Once it is confirmed that you are eligible to take part in the study, you will be asked to complete a series of questionnaires about your general health, medical, fall history and current physical activity habits. These questionnaires will also be repeated at 3, 6 and 12 months after study commencement. The questionnaires will take about 20 minutes to complete each time.

In addition to the questionnaires, the amount of physical activity you do will be measured at the start of the study and again at 6 and 12 months after study commencement over a 7-day period using a *StepWatch* activity monitor. This small device is worn around your ankle during the day and is able to accurately estimate how physically active a person has been throughout the day. The *StepWatch* will be posted to you with clear instructions for use and telephone support will be available. You will also be provided with pre-paid envelopes to return the device and questionnaires to the research centre.

Group Allocation

To determine the benefits of the two intervention programs there will be three groups. The first group of people (Coaching to ComeBACK) will receive the intervention program for 6 months which involves an in-person physical activity assessment, telephone health coaching, , choice to use technology to monitor your activity levels and access to online resources. The second group of people (Texting to ComeBACK) will take part in an intervention program for 6 months, which involves a telephone-based physical activity assessment, and text messaging and access to online resources. The third group of people (Texting to ComeBACK later) will not have any intervention for the first 6 months but will then receive the same intervention as the second group (Texting to ComeBACK). If you decide to participate in this research study, you will be randomly allocated to one of the three groups. All groups will receive any usual care provided by your health service providers.

Group 1 Coaching to ComeBACK ***Group***

If you are allocated to the Coaching to ComeBACK group you will receive

i) *a single face-to-face one-hour assessment* of mobility and physical activities undertaken at a home visit from a physiotherapist from which a tailored plan to improve physical activity through participation in suitable activities will be developed in negotiation with you. The choice of physical activity will be guided by personal preference, logistics, physical abilities and evidence of effectiveness.

ii) *6 month phone-based coaching* will be delivered by trained physiotherapists through a centralised service and will support you in getting started and then to keep on going with your physical activity plan. You will be encouraged to access the service approximately once a fortnight for 6 months during the study. Phone coaching appointments vary according to your needs but you could expect that they generally last around 20-30 minutes/session. Access to this service will stop at the conclusion of the study intervention period.

iii) in addition you will be offered technology to use where appropriate to help you being active e.g. (the Fitbit) or a simple pedometer that does not connect to the internet.

iv) have access to online resources to help you be more physically active.

The overall time commitment for the Coaching to ComeBACK group following the initial 1-hour face-to-face assessment is 60 minutes per month of phone based coaching during the 6-month intervention period. The recommendation made to incorporate physical activity into your daily routine will be negotiated with you and this will be different for each person based on current activity levels and abilities.

Group 2 Texting to ComeBACK ***Group***

If you are allocated to Texting to ComeBACK group you will receive

i) *a single phone* session of tailored advice from a physiotherapist to develop a plan to improve physical activity through participation in suitable activities which will be developed in negotiation with you. The choice of physical activity will be guided by personal preference, logistics, physical abilities and evidence of effectiveness. The length of this phone session does vary according to your needs but you could expect that it will generally last around 30 -45 minutes.

ii) *text message follow up* for 6 months intervention duration of the study. You will be able to opt out of receiving these messages at any time.

iii) have access to online resources.

The overall time commitment for the Texting to ComeBACK group following the initial 45-minute phone based session is 5 minutes per month of reading phone text messages. The

recommendation made to incorporate physical activity into your daily routine will be negotiated with you and this will be different for each person based on current activity levels and abilities.

Group 3 Texting to ComeBACK ***later group***

If you are allocated to the Texting to ComeBACK later group you will receive the usual care provided by your health service providers for the first 6 months of the study. You will have no contact with the study staff apart from the baseline, 3 and 6-month questionnaires. Following the 6-month reassessment you will receive the same intervention as Group 2 (Texting to ComeBACK) as described above. This includes the single phone session of tailored advice from a physiotherapist to improve physical activity (generally 30-45 minutes) as well as text message follow up for 6 months and access to online resources to support you to be more active.

The overall time commitment for the initial 6 months of the study period if allocated to the Texting to ComeBACK later group is 0 minutes per month. This will then increase to 5 minutes per month of reading phone text messages for the next 6-month period. The recommendation made for you to incorporate physical activity into your daily routine will be negotiated with you and this will be different for each person based on current activity levels and abilities.

Falls and health utilisation calendars

All study participants will be asked to return monthly calendars (by reply-paid mail) containing questions on any falls and subsequent injuries you may experience along with health utilisation. If calendars are not returned, you will be telephoned to ask if you experienced any falls and physical activity-related injuries during the past month. In order to reduce the risk of bias, the research team member who collects the monthly calendars will not be aware of which group you have been allocated to.

The researchers would like to evaluate the benefits of the study beyond the 6-month intervention period so we ask you to complete the calendars for a 12-month period.

Data Linkage Study

We would like to track hospital and emergency department admissions, ambulance services and any study participant deaths (birth, marriages and death registry records) for up to 2 years after the completion of the study to evaluate if there are any long-term effects from the intervention. Therefore, the researchers would like your permission to link the information you provide within the ComeBACK study, with other sources of information that are routinely collected and managed via the Population Health Research Network (PHRN) for Health data Record Linkage. A strict process will be followed as per Data Linkage policies that ensures the confidentiality of your data.

Data linkage has been used by health systems for many years to bring together information about people, places and events in a way that protects individual privacy and allows researchers and policy makers to gain information and insights about the health and well-being of our community. Data linkage studies have helped to provide valuable information on the causes of and risk factors for disease as well as the evaluation of new approaches to preventing and treating health problems.

If you want to opt out of the linking of your health information, there is an option to indicate this choice on the consent form by ticking the box for opt out.

Qualitative Study

To evaluate the enjoyment and efficiency of the intervention programs a small subset of participants (30-40) will be invited to participate in a semi-structured interview at 3 time points across the study (3 months, 6 months and 12 months). These telephone interviews will be conducted by a researcher who is not involved in delivering the intervention and they will generally last 30 to 40 minutes. We will ask for your consent to audio record each interview prior to the commencement of the interview. Interviews will cover advantages and disadvantages of the intervention, motivation, self-efficacy, confidence, beliefs about physical activity and facilitators and barriers to participation in each component of the intervention.

How is this study being paid for?

The study is funded through a competitive research project grant from the National Health and Medical Research Council. The investigators of this research study declare no duality or conflict of interest.

Are there risks?

While the risks involved with participation in this research are low, there is a slight chance that you may experience muscle soreness at the start of the physical activity program. There is also a chance of more general risk such as falls. This risk is taken into consideration by the researchers involved who are experienced with assessing older people and people with walking difficulties and safety precautions are used and are consistent with current clinical practice.

In addition, your GP will be notified that you are participating in this study and be encouraged to contact us if they think participation will cause you harm. You will be asked to provide contact details for your GP during the Baseline Questionnaire to allow this to occur.

As part of this study you will be asked to answer questions about physical activity, activities of daily living and other aspects of health. If you experience any distress when answering questions, you have the right not to answer the question and leave the response blank.

The interventions may also include health coaching, tailored advice and goal setting approaches. Health coaching employs a motivational interviewing approach that acknowledges the individual's difficulty in becoming more active and explores the confidence they have about engaging in physical activity and develops individualized strategies that can be implemented. If you happen to experience distress during health coaching, the health professional providing the coaching will be able to discuss and explore relevant issues, providing emotional support and advice and refer you back to your GP if required.

Benefits

While we intend that this research study furthers our knowledge and may improve physical activity levels of adults with walking problems in the future, we cannot guarantee that you will receive direct benefits from the study. Access to this intervention service will cease at the conclusion of the study.

Costs

Participation in this study will not cost you anything, nor will you be reimbursed for your time.

Voluntary Participation

Participation in this study is entirely voluntary. If you do take part, you can withdraw at any time without having to give a reason. Whatever your decision, please be assured that it will not affect your medical treatment or your relationship with the research staff or institutions who may be caring for you.

Sometimes during the course of a study, new information becomes available about the treatment that is being studied. While you are participating in this study, you will be kept informed of any significant new findings, which may affect your willingness to continue in the study.

Confidentiality

Under Australian privacy law all information collected about you must be kept confidential, unless you agree to it being released. Only the researchers in the study, your family doctor and you will know whether you are participating in this study. At the time of entry to the study, you will be assigned a study identification number that will be used on all data collection sheets. Identifiable data (e.g. name, date of birth) will be removed from other data and stored separately in a locked filing cabinet and password protected computer database at The University of Sydney with access only by study staff. All data collected within this study will be stored for 15 years as required by national ethics legislature. You have a right to request access to your data during this time. After this time, paper copies will be securely shredded and electronic copies will be securely deleted. The study results will be published in peer reviewed journals, presented at conferences or other professional forums, but individual participants will not be identifiable in such a presentation.

Future use of data for research purposes

Data such as age, sex and study outcomes may be combined with data from other studies or provided to other researchers to answer new research questions at the completion of this study. At no time will identifiable data be shared or used without your additional consent.

Further Information

When you have read this information, Researchers at the University of Sydney will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact them on 02 8627 6235.

Ethics Approval and Complaints

This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District. Any person with concerns or complaints about the conduct of this study should contact the Executive Officer on 02 9515 6766 and quote protocol number X18-0234 .

The conduct of this study at the [name of hospital] has been authorised by the [name of Local Health District]. Any person with concerns or complaints about the conduct of this study may also contact the Research Governance Officer [or other officer] on [telephone number] and quote protocol number [insert local protocol number].

Thank you for taking the time to consider this study.

This information sheet is for you to keep.

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym (Page 1)
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry (Page 1)
	2b	All items from the World Health Organization Trial Registration Data Set (Page 1)
Protocol version	3	Date and version identifier (n/a)
Funding	4	Sources and types of financial, material, and other support (Page 14)
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors (Page 1)
	5b	Name and contact information for the trial sponsor (Page 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 (Page 14)
	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) n/a
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 (page 4)
	6b	Explanation for choice of comparators (page 6, Table 1)
Objectives	7	Specific objectives or hypotheses (page 6)

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) (page 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 (page 7)
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) (page 7)
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered (page 10, Table 1-2)
	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) n/a
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) (page 10, Table 1-2)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial (page 10, Table 1-2)
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 (page 9)
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) (page 9)
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 (page 13)
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size (page 7)
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 (page 8)
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 (page 8)
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions (page 8)
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how (page 8, page 13)
	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 (page 8-9)
	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 (page 8)
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 (page 14)
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 (page 13)
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) (page 13)
	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) (page 13)

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 (page 10)
	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 (page 10)
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 (page 14)
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) (page 14)
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) (page 14)
	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 (page 14)
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site (page 15)
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 (page 14)
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 (n/a)

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 (page 14)
	31b	Authorship eligibility guidelines and any intended use of professional writers (page 14)
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code (page 14)
Appendices		
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates (Appendix 1)
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)

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.