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

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4 Physical activity coaching for adults with mobility limitations: protocol for the ComeBACK
5 pragmatic randomised controlled trial.
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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 common¹ 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* editorial⁶ 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

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

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

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39 Regular physical activity participation requires motivation, capability and opportunity.¹⁵
40 Simply advising people to be more active is unlikely to safely enhance activity levels.¹⁶
41 Rather, advice needs to be specific, individualised, supported by a behaviour change
42 framework and based on engagement with the person and their goals and priorities.¹⁷ Health
43 coaching interventions that involve behaviour change techniques including goal-setting and
44 are individually tailored are known to change behaviour in the general population.¹⁷⁻¹⁹ A
45 recent systematic review²⁰ found health coaching to improve physical activity levels in older
46 people (standardised mean difference = 0.29; 95% CI 0.18 to 0.39; $p < .001$) and others have
47 found motivational interviewing (a form of health coaching) to enhance physical activity in
48 people with chronic conditions²¹ and in hip fracture survivors.²² These trials focused on
49 health conditions so did not cater specifically for people with impaired mobility. The impact
50 of health coaching in this population is not known. Physical activity prescription in people
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3 with mobility limitations is complex so we hypothesise that tailored advice from
4 physiotherapists will enhance activity levels.
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7 In consultation with consumers, clinicians, and policy makers, our multidisciplinary team
8 developed two intervention packages based on behaviour change theories.^{15,23,24} Both
9 interventions involve the development of a goal-based tailored physical activity plan (made
10 in conjunction with a physiotherapist and sent to participant and their primary care physician
11 (referred as a General Practitioner (GP)), access to informational and motivational print and
12 on-line resources and encouragement of use of activity monitors and suitable smart phone
13 applications. We hypothesise that greater effects on measured physical activity levels will
14 be evident from an enhanced intervention package (that also includes a face-to-face
15 assessment and ongoing phone-based physical activity phone coaching both provided by a
16 physiotherapist) compared to a less intensive intervention package (that includes a single
17 phone call from a physiotherapist and text messages). We further hypothesise that both these
18 interventions will have greater impacts on physical activity levels than no intervention.
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29 **Methods and analysis**

30 Overview

31 This pragmatic 3-arm superiority trial with a waiting list control group (n=600) aims to
32 establish the effects on objectively measured physical activity among adults with self-
33 reported mobility limitations of:
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- 39 i). an enhanced intervention package (*Coaching to ComeBACK* group: one face-to-face
40 assessment from a physiotherapist, tailored physical activity plan sent to participant and GP,
41 physical activity phone coaching from a physiotherapist, activity monitors and/or apps,
42 booklet and access to on-line resources) compared with a less intensive intervention package
43 (*Texting to ComeBACK* group: single session of tailored advice by phone from a
44 physiotherapist with health coaching training, tailored physical activity plan sent to
45 participant and GP, unidirectional text messages, booklet and access to on-line resources);
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- 48 ii). an enhanced intervention package (*Coaching to ComeBACK* group) compared with no
49 intervention (*Texting to ComeBACK Later* waiting list control group);
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- 52 iii). a less intensive intervention package (*Texting to ComeBACK* group) compared with no
53 intervention (*Texting to ComeBACK Later* waiting list control group).
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3 A hybrid effectiveness-implementation design (Type 1)²⁵ will be used to collect
4 implementation outcomes at the same time as effectiveness outcomes. A nested process
5 evaluation will use both quantitative and qualitative methods to explore uptake and
6 acceptability of the intervention. The protocol for the process evaluation will be described
7 elsewhere. The PRACTIS guide²⁶ to implementation and scale-up of physical activity
8 interventions was used to ensure that the interventions (and study recruitment methods) were
9 as potentially scalable in future as possible. Future scale-up of the interventions, if found to
10 be effective, will be guided by the model developed by Milat et al,²⁷ along with the
11 implementation outcomes and other aspects of the process evaluation. An economic analysis,
12 which will be conducted alongside the trial, will aim to establish the cost- effectiveness and
13 cost-utility of the interventions compared to no intervention and to each other to assist
14 funders of preventive health interventions to assess the value of such an approach for future
15 investments. Figure 1 shows the overall logic for the trial and Table 1 shows the reasons for
16 choice of different components. The first participant was recruited on 13 February 2019 and
17 at the time of submission of this manuscript 50 participants had been randomised.
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30 31 Participants

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33 The trial will be conducted across four Australian states with recruitment through health
34 services in hospital departments and the general community through community organisations
35 as well as traditional and social media advertisements and stories. The trial will involve
36 consenting adults (18+ years) who are: living in the community (as opposed to residential care);
37 have a mobility limitation (self-reported difficulty or inability to walk 800m) but are able to
38 leave their home without physical assistance from another person (but may use a walking aid);
39 are judged by recruitment staff to have sufficient hearing and English language skills for a
40 phone-based intervention. Trial participants are likely to be affected by one or more common
41 and/or burdensome conditions such as, but not limited to, osteoarthritis, lower limb fractures,
42 lower limb amputations, stroke, brain injury and respiratory conditions and obesity. The trial
43 will exclude adults who are: permanent residents of residential aged care facilities; have the
44 following medical conditions: delirium, acute medical illnesses, severe psychiatric disorders,
45 rapidly progressive neurological diseases; have a major cognitive impairment (a diagnosis of
46 dementia or a Memory Impairment Screen score of less than 5); are currently undertaking 150
47 minutes or more of moderate to vigorous physical activity per week (based on self-report); full-
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3 time wheelchair user; unable to wear a *StepWatch Activity Monitor*; not a regular user of a
4 mobile phone (look at phone less than once per week); or have no internet access.
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9 Randomisation

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

26 Assessments will occur prior to randomisation and at 3, 6 and 12 months after randomisation.
27 The matchbox-sized *StepWatch Activity Monitors* used to objectively measure physical
28 activity (primary outcome 6-month measurement) will be mailed to participants with reply-
29 paid envelopes and clear instructions for use and will be worn at the ankle for periods of seven
30 consecutive days. Telephone calls will be made to participants who have not returned the
31 devices and to those who require assistance wearing the device. Questionnaires will be
32 administered online by participants or, if preferred mailed, or by phone by a research assistant
33 unaware of intervention group allocation. Monthly on-line or paper calendars, with phone
34 follow-up where necessary, will be used by participants to report falls and health and
35 community service usage over the 12-month trial period to enable cost collation for the
36 economic analyses. Where possible, data for all outcomes will be collected for those who
37 cease participation in the interventions. The primary outcome will be collected in a blinded
38 fashion. *StepWatch Activity Monitor* data will be processed and analysed by staff unaware of
39 intervention group allocation. All baseline measurements will be undertaken prior to group
40 allocation. Due to the nature of the intervention being tested, full blinding of participants to
41 intervention group allocation will not be possible. All the reassessments questionnaires will
42 however be undertaken by researchers blinded to group allocation
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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 authors²⁸ 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 Questionnaire²⁹, 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 Instrument³⁰), fear of falling and self-reported balance (5-point scales), individualised mobility goal attainment (Goal Attainment Scale³¹ at 6 and 12 months), mental wellbeing (Warwick-Edinburgh Mental Well-being Scale³²), quality of life (EuroQol 5D-5L³³), 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

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

42 Intervention design was undertaken by our multi-disciplinary author team guided by formal
43 (qualitative pilot work) and informal input from consumers in the target population as well as
44 consultations with clinicians, health service managers, population health service providers
45 and health policy makers. The COM-B (Capability Opportunity Motivation → Behaviour)
46 model of behaviour change¹⁵ was used to guide the intervention design, with self-
47 determination theory²³ and social cognitive theory²⁴ further underpinning the motivational
48 component. Table 1 overviews the aspects of the COM-B addressed by each aspect of the
49 intervention packages. Table 2 provides more detail on the interventions using the TIDieR
50 format.³⁶ The interventions are as follows.
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60 Group 1: Coaching to ComeBACK. Participants randomised to this group will be offered the

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3 following six intervention components.
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5 *i) a single face-to-face one-hour assessment* of mobility status, safety issues, medical, social
6 and environmental influences on mobility will be undertaken during a home visit by a
7 physiotherapist (employed locally). Where a home visit is not possible, a video conference
8 may be conducted as an alternative. At the end of the assessment, a phone or videoconference
9 call will be made to the health coach with both physiotherapist and the participant present to
10 introduce and handover to the health coach and discuss any particular issues.
11

12 *ii) phone-based health coaching* will be delivered by trained physiotherapists through a
13 centralised service. The initial session will include development of a tailored plan to improve
14 physical activity through participation in suitable activities in negotiation with the participant
15 and their carers (where appropriate). The choice of physical activity will be guided by
16 personal preference, logistics, physical abilities and evidence of effectiveness of different
17 intervention options. The coach will liaise with relevant treating health professionals to
18 identify contraindications or precautions to exercise and ensure other causes of mobility
19 limitation are optimally managed. Coaching sessions will be delivered at a tailored frequency
20 of approximately every 2 weeks over a 6-month period and will take an average of 20-30
21 min each session. The coaching will incorporate behaviour change strategies including
22 motivational interviewing (to explore and enhance reasons for being active (importance) and
23 confidence to make changes, as well as to explore social influences on activity) goal-setting,
24 problem-solving, building social support and experiential learning. The individually-
25 tailored, person-centred approach will determine each person's physical, cognitive, affective,
26 environmental and social barriers and facilitators to physical activity and develop physical
27 activity recommendations (including adaptations and/or assistance to overcome specific
28 barriers) for each individual. Coaching will link participants to existing community
29 programs, with a focus on identifying activities that participants will enjoy.³⁷ Suitable
30 options may include attendance at a group program, such as those indexed on the *Active and*
31 *Healthy* website (www.activeandhealthy.nsw.gov.au) and/or participation in sporting
32 opportunities that cater for people with impaired mobility. The coaching will also encourage
33 reduced sedentary and inactive time by spending more time standing and walking or
34 undertaking a home based exercise program, as well as increased use of active transport (i.e.
35 walking, using public transport). Staff have extensive experience in the management of
36 people with walking limitations, have undertaken courses in health coaching and received
37 two days of additional training in using behaviour change science and self-determination
38 theory to guide intervention from author Greaves.
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3 *iii) activity monitors and GPS-based tablet/smartphone applications.* Participants will be
4 offered an internet-connected activity monitor (such as the *Fitbit*) or a simple pedometer if
5 preferred, as pedometers are known to enhance physical activity through measurement and
6 behavioural reinforcement.³⁸
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10 *iv) physical activity plan developed jointly as outlined above will be shared with the*
11 *participant's GP with his/her consent.*
12

13 *v) paper-based booklet* on physical activity, safe mobility and behaviour change that is
14 study-specific, evidence-based and theoretically informed (by incorporating messaging and
15 images that are consistent with self-determination theory (promoting autonomy, competence
16 and relatedness for walking behaviour) and social cognitive theory (supporting self-
17 regulation and identifying /reinforcing the perceived benefits (social, physical,
18 emotional/affective)).
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20 *vi) closed study website* with 3 components: 1) why be active (incorporating motivational
21 components consistent with self-determination theory); 2) how to be active (links to
22 resources); 3) how others do it (video case studies using modelling of successful peer
23 behaviour as per Social Cognitive Theory).
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33 Group 2: Texting to ComeBACK. Participants randomised to this group will be offered the
34 following five intervention components. The first two intervention components are unique to
35 this group and the following three interventions are the same as Group 1.
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38 *i) single session of tailored advice provided by phone by a physiotherapist.* This will be
39 informed by the baseline assessment results and provide advice about appropriate physical
40 activity opportunities for the person's interests and level of mobility. A follow-up email will
41 be sent to summarise and reinforce key discussion points.
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45 *ii) text messages to encourage activity.* Pre-scheduled unidirectional text messages with
46 some tailoring and personalisation will commence at 5 times/week for the first month to
47 provide motivation support (again using messages designed to be consistent self-
48 determination theory (promoting autonomy, competence and relatedness for walking
49 behaviour) and social cognitive theory (supporting self-monitoring /self-regulation and
50 identifying /reinforcing the perceived benefits (social, physical, emotional/affective)),
51 planning support, problem-solving and maintenance support. Participants will then have the
52 option of increasing intensity (daily messages) or decreasing intensity (3 times/week) for the
53 next 4 months prior to a gradual reduction in the frequency of messages. There is also an
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3 opt-out feature available at all times.

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

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

10
11 v) closed study website with 3 components: 1) why be active; 2) how to be active (links to
12 resources including recommended activity monitors and physical activity Apps); 3) how
13 others do it (video case studies using modelling of successful peer behaviour as per Social
14 Cognitive Theory).

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

26 27 28 29 30 31 Patient and public involvement

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

37 38 39 40 41 42 43 Sample size

44 The trial's sample size (n=600) will provide 90% power to detect between-group differences of
45 1000 steps per day assuming a standard deviation of 3000 steps (estimated from our pilot data),
46 a dropout rate of 20%, alpha of 0.0167 (to adjust for multiplicity due to 3 trial arms), and
47 correlation between initial and final measures of 0.6 (from our pilot data). This calculation was
48 undertaken in Stata 13 using the *sampsi* command. On the basis of previous work by the
49 investigators and others, we consider between-group differences of this magnitude to be likely
50 to result in significant health benefits because 1000 steps/day, assuming a cadence of 80
51 steps/min, would equate to an additional 15 minutes of walking/day, a dose associated with
52 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 trial 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.

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

18 All authors contributed to the design of the study and preparation of the study protocol. This
19 manuscript was drafted by author Sherrington.
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37 **Competing interests statement**

38 The authors do not report any competing interests.
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43 **Word Count:** 4279 words (excluding references and tables)
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46 **References**

- 47 1. AIHW. *Australia's Welfare*. Canberra: Australian Institute of Health and Welfare.;2015.
- 48 2. Cummings SR, Studenski S, Ferrucci L. A diagnosis of disability--giving mobility clinical
49 visibility: a Mobility Working Group recommendation. *JAMA*. 2014;311(20):2061-2062.
- 50 3. Ma VY, Chan L, Carruthers KJ. Incidence, prevalence, costs, and impact on disability of
51 common conditions requiring rehabilitation in the United States: stroke, spinal cord injury,
52 traumatic brain injury, multiple sclerosis, osteoarthritis, rheumatoid arthritis, limb loss, and
53 back pain. *Arch Phys Med Rehabil*. 2014;95(5):986-995.e981.
- 54 4. Jones E, Pike J, Marshall T, Ye X. Quantifying the relationship between increased disability
55 and health care resource utilization, quality of life, work productivity, health care costs in
56 patients with multiple sclerosis in the US. *BMC Health Serv Res*. 2016;16:294.
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60

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.

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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, Gillaspay 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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 <u>capability</u> to suggest appropriate <u>opportunities</u> . Establishing /building <u>motivation</u> .
Patient-centred health coaching, incorporating behaviour change strategies including goal-setting and motivational interviewing	<ul style="list-style-type: none"> 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 <u>capability</u> to suggest appropriate <u>opportunities</u> . Encouragement of <u>capability</u> enhancement. Feedback to assist with ongoing <u>motivation</u>
Activity monitor or pedometer if desired	<ul style="list-style-type: none"> known to enhance physical activity in general population well accepted in pilot among people with mobility limitations 	Feedback to assist with ongoing <u>motivation</u> .
Tailored use of apps to encourage physical activity	<ul style="list-style-type: none"> 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 <u>motivation</u> .

Paper-based and on-line resources to support behaviour change	<ul style="list-style-type: none"> • provision of evidence-based information in attractive format • including case studies to support behaviour change. 	Case studies and information to assist with <u>capability and motivation</u> .
Tailored physical activity plan developed and shared with GP	<ul style="list-style-type: none"> • credible and trusted source reinforcing behaviour changes suggested by health coach 	Increased <u>motivation</u> .
Group 2: Texting to ComeBACK		
Single session of tailored advice over the phone from a physiotherapist	<ul style="list-style-type: none"> • 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 <u>capability</u> to suggest appropriate <u>opportunities</u> .
Paper-based and on-line resources to support behaviour change	<ul style="list-style-type: none"> • provision of evidence-based information in attractive format • including case studies to support behaviour change. 	Case studies and information to assist with <u>capability and motivation</u> .
Text messages	<ul style="list-style-type: none"> • 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 <u>motivation and problem-solving (capability)</u>
Tailored physical activity plan developed and shared with GP	<ul style="list-style-type: none"> • credible and trusted source reinforcing behaviour changes suggested by health coach. 	Increased <u>motivation</u> .
Group 3: Texting to ComeBACK Later		
No intervention for 6 months	<ul style="list-style-type: none"> • pragmatic comparison • direct policy implications 	
Receipt of less intensive intervention after 6 months	<ul style="list-style-type: none"> • enhanced recruitment through provision of intervention for all participants. 	As above
Outcome		
Physical activity	<ul style="list-style-type: none"> • neglected costly population health problem. 	n/a

*Primarily using the COM-B system¹⁵ 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.

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

For peer review only

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	<ul style="list-style-type: none"> ➤ 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. 	<ul style="list-style-type: none"> ➤ 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	<ul style="list-style-type: none"> ➤ 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 	<ul style="list-style-type: none"> ➤ 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	<ul style="list-style-type: none"> ➤ 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 <i>Wellness Coaching Australia</i>; <i>Health Change Australia</i> and <i>Medicoach</i> as well as receiving training by study investigator (CG) in advanced motivational interviewing, a framework for “good (functional) motivation” and intervention techniques. 	<ul style="list-style-type: none"> ➤ 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 <i>Wellness Coaching Australia</i>; <i>Health Change Australia</i> and <i>Medicoach</i> as well as receiving training by study investigator (CG) in advanced motivational interviewing, a framework for “good (functional) motivation” and intervention techniques.
How	<ul style="list-style-type: none"> ➤ 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. 	<ul style="list-style-type: none"> ➤ 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	<ul style="list-style-type: none"> ➤ 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. 	<ul style="list-style-type: none"> ➤ 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	<ul style="list-style-type: none"> ➤ The face-to-face assessment will occur at the beginning of the intervention period and will last for ~ 1 hour. 	<ul style="list-style-type: none"> ➤ The one-off tailored advice session will occur at the beginning of the intervention period and will last for ~ 1 hour (this could

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- 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.

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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.

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* *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.

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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)

BMJ Open

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

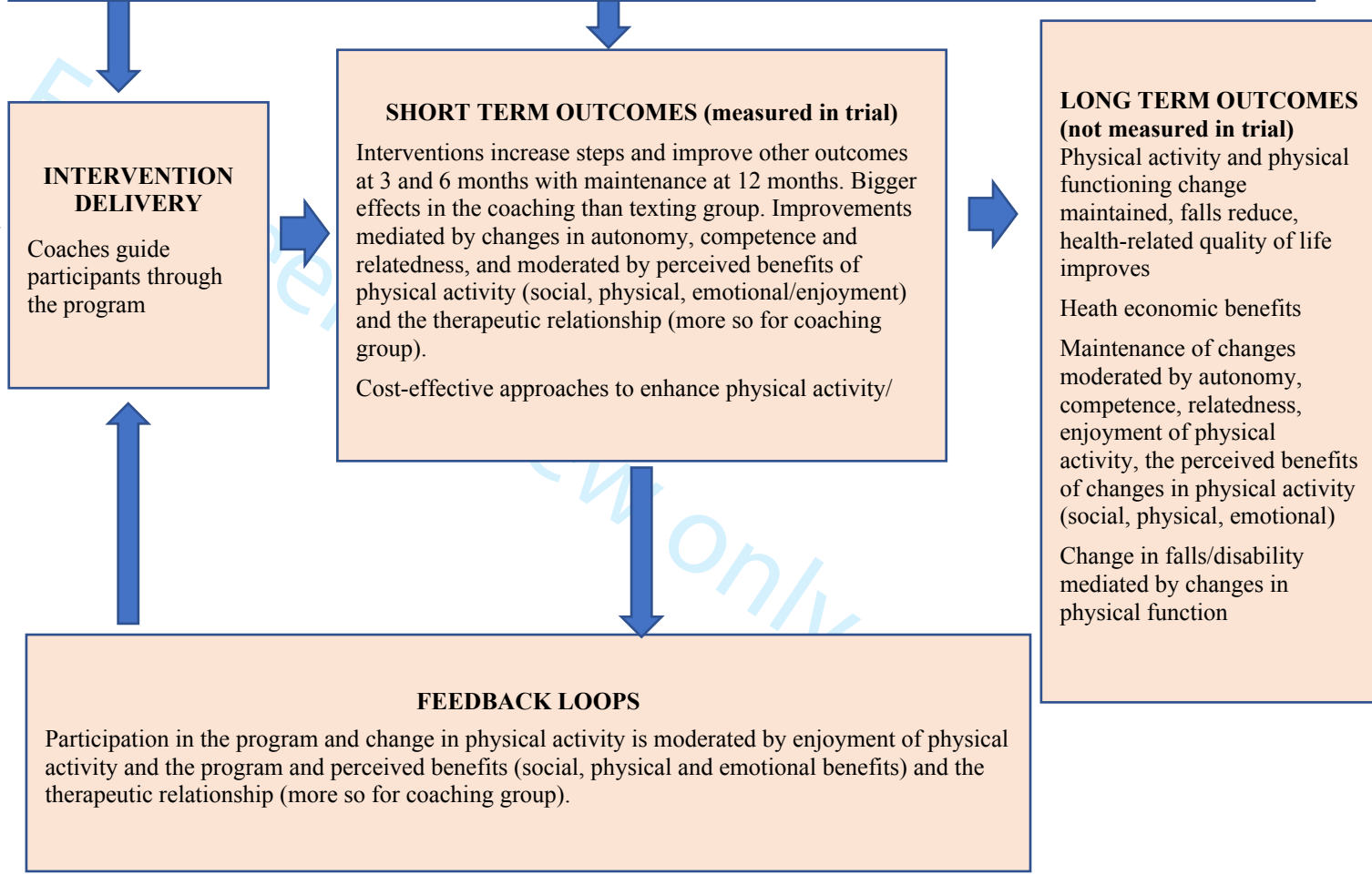


Figure 1: Logic model for the ComeBACK interventions



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)

1
2 Trial design 8 Description of trial design including type of trial (eg, parallel group,
3 crossover, factorial, single group), allocation ratio, and framework (eg,
4 superiority, equivalence, noninferiority, exploratory) (page 6)
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8 **Methods: Participants, interventions, and outcomes**
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10 Study setting 9 Description of study settings (eg, community clinic, academic hospital)
11 and list of countries where data will be collected. Reference to where
12 list of study sites can be obtained (page 7)
13

14 Eligibility criteria 10 Inclusion and exclusion criteria for participants. If applicable, eligibility
15 criteria for study centres and individuals who will perform the
16 interventions (eg, surgeons, psychotherapists) (page 7)
17
18

19 Interventions 11a Interventions for each group with sufficient detail to allow replication,
20 including how and when they will be administered (page 10, Table 1-
21 2)
22

23 11b Criteria for discontinuing or modifying allocated interventions for a
24 given trial participant (eg, drug dose change in response to harms,
25 participant request, or improving/worsening disease) n/a
26
27

28 11c Strategies to improve adherence to intervention protocols, and any
29 procedures for monitoring adherence (eg, drug tablet return,
30 laboratory tests) (page 10, Table 1-2)
31

32 11d Relevant concomitant care and interventions that are permitted or
33 prohibited during the trial (page 10, Table 1-2)
34

35 Outcomes 12 Primary, secondary, and other outcomes, including the specific
36 measurement variable (eg, systolic blood pressure), analysis metric
37 (eg, change from baseline, final value, time to event), method of
38 aggregation (eg, median, proportion), and time point for each
39 outcome. Explanation of the clinical relevance of chosen efficacy and
40 harm outcomes is strongly recommended (page 9)
41
42

43 Participant 13 Time schedule of enrolment, interventions (including any run-ins and
44 timeline washouts), assessments, and visits for participants. A schematic
45 diagram is highly recommended (see Figure) (page 9)
46
47

48 Sample size 14 Estimated number of participants needed to achieve study objectives
49 and how it was determined, including clinical and statistical
50 assumptions supporting any sample size calculations (page 13)
51

52 Recruitment 15 Strategies for achieving adequate participant enrolment to reach
53 target sample size (page 7)
54
55

56 **Methods: Assignment of interventions (for controlled trials)**
57

58 Allocation:
59
60

1			
2	Sequence	16a	Method of generating the allocation sequence (eg, computer-
3	generation		generated random numbers), and list of any factors for stratification.
4			To reduce predictability of a random sequence, details of any planned
5			restriction (eg, blocking) should be provided in a separate document
6			that is unavailable to those who enrol participants or assign
7			interventions (page 8)
8			
9			
10	Allocation	16b	Mechanism of implementing the allocation sequence (eg, central
11	concealment		telephone; sequentially numbered, opaque, sealed envelopes),
12	mechanism		describing any steps to conceal the sequence until interventions are
13			assigned (page 8)
14			
15	Implementation	16c	Who will generate the allocation sequence, who will enrol participants,
16			and who will assign participants to interventions (page 8)
17			
18			
19	Blinding	17a	Who will be blinded after assignment to interventions (eg, trial
20	(masking)		participants, care providers, outcome assessors, data analysts), and
21			how (page 8, page 13)
22			
23		17b	If blinded, circumstances under which unblinding is permissible, and
24			procedure for revealing a participant's allocated intervention during
25			the trial (n/a)
26			
27			

Methods: Data collection, management, and analysis

28			
29			
30	Data collection	18a	Plans for assessment and collection of outcome, baseline, and other
31	methods		trial data, including any related processes to promote data quality (eg,
32			duplicate measurements, training of assessors) and a description of
33			study instruments (eg, questionnaires, laboratory tests) along with
34			their reliability and validity, if known. Reference to where data
35			collection forms can be found, if not in the protocol (page 8-9)
36			
37			
38		18b	Plans to promote participant retention and complete follow-up,
39			including list of any outcome data to be collected for participants who
40			discontinue or deviate from intervention protocols (page 8)
41			
42	Data	19	Plans for data entry, coding, security, and storage, including any
43	management		related processes to promote data quality (eg, double data entry;
44			range checks for data values). Reference to where details of data
45			management procedures can be found, if not in the protocol (page 14)
46			
47			
48	Statistical	20a	Statistical methods for analysing primary and secondary outcomes.
49	methods		Reference to where other details of the statistical analysis plan can be
50			found, if not in the protocol (page 13)
51			
52		20b	Methods for any additional analyses (eg, subgroup and adjusted
53			analyses) (page 13)
54			
55		20c	Definition of analysis population relating to protocol non-adherence
56			(eg, as randomised analysis), and any statistical methods to handle
57			missing data (eg, multiple imputation) (page 13)
58			
59			
60			

Methods: Monitoring

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	Methods: Monitoring		
25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	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

25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	Ethics and dissemination		
25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	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)

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| 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) |

16 Appendices

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|-------------------------------|----|--|
| 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) |

25 *It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013
26 Explanation & Elaboration for important clarification on the items. Amendments to the
27 protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT
28 Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](#)"
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BMJ Open

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

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4 1 Physical activity coaching for adults with mobility limitations: protocol for the ComeBACK
5 2 pragmatic randomised controlled trial.
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1
2
3 **Abstract**
4

5
6 **Introduction.** Mobility limitation is common and often results from neurological and
7 musculoskeletal health conditions, ageing and/or physical inactivity. In consultation
8 with consumers, clinicians, and policy makers, we have developed two affordable and
9 scalable intervention packages designed to enhance physical activity for adults with
10 self-reported mobility limitations. Both are based on behaviour change theories and
11 involve tailored advice from physiotherapists.
12
13
14
15
16

17 **Methods and analysis.** This pragmatic randomised control trial (n=600) will be
18 undertaken among adults with self-reported mobility limitations. It aims to estimate the
19 effects on physical activity of: i) an enhanced 6-month intervention package (one face-
20 to-face physiotherapy assessment, tailored physical activity plan, physical activity
21 phone coaching from a physiotherapist, informational/motivational resources and activity
22 monitors) compared with a less intensive 6-month intervention package (single session
23 of tailored phone advice from a physiotherapist, tailored physical activity plan,
24 unidirectional text messages, informational/motivational resources); ii) the enhanced
25 intervention package compared with no intervention (6-month waiting list control
26 group); iii) the less intensive intervention package compared with no intervention
27 (waiting list control group). The primary outcome will be average steps per day,
28 measured with the *StepWatch* activity monitor over a one-week period, 6 months after
29 randomisation. Secondary outcomes include other physical activity measures,
30 measures of health and functioning, individualised mobility goal attainment, mental
31 wellbeing, quality of life, rate of falls, health utilisation and intervention evaluation. A
32 hybrid effectiveness-implementation design (Type 1) will be used to enable the
33 collection of secondary implementation outcomes at the same time as the primary
34 effectiveness outcome. An economic analysis will estimate the cost-effectiveness and
35 cost-utility of the interventions compared to no intervention and to each other.
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52 **Ethics and dissemination.** Ethical approval has been obtained by Sydney Local Health
53 District, Royal Prince Alfred Zone. Dissemination will be via publications,
54 conferences, newsletters, talks, and meetings with health department and health service
55 managers.
56

57
58 **Registration.** ACTRN12618001983291
59
60

1
2
3 57 **Strengths and limitations of this study**
4

- 5
6 58 • Pragmatic evaluation of a scalable person-centred intervention.
7
8 59 • Theory-based intervention informed by consumers, clinicians and policy
9 60 makers.
10
11
12 61 • Six-month study timeframe will not test long-term intervention impacts.
13
14
15 62 • Staffing in the trial does not enable those who do not speak English to
16 63 participate.
17
18
19 64 • Recruitment is based on self-reported mobility limitation rather than a
20 65 standardised measure.
21
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23
24 66

67 Introduction

68 Disability is an umbrella term for impairments, activity limitations and participation
69 restrictions.¹ Mobility limitation (i.e., difficulty or inability to walk) is a particularly
70 common² and serious form of physical disability. It is primarily due to neurological and
71 musculoskeletal health conditions, physiological ageing and inactivity-related
72 deconditioning.³ Walking impairment or ‘dismobility’ is predictive of adverse health
73 outcomes, including death.³ Widespread screening for walking problems has been suggested
74 as an additional vital sign, and development and testing of interventions for people with
75 walking difficulties has been highlighted as an urgent research priority.³

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

86 Physical activity participation has enormous untapped potential as a cost-effective approach
87 to enhancing physical and mental health in people of most ages, health conditions and
88 physical abilities.⁷ A *Lancet* editorial⁷ calls for physical activity to be taken more seriously
89 as a population health intervention, given the strong evidence of physical and mental health
90 benefits and poor participation rates. As well as enhancing the prevention and management
91 of chronic conditions, physical activity is now known to have survival benefits.⁸ For
92 example, taking a greater number of steps per day was associated with lower all-cause
93 mortality over a 10-year follow-up period (adjusted hazard ratio (AHR) for all-cause
94 mortality 0.94; 95% CI, 0.90 to 0.98 per 1 000 steps; $p = 0.004$).⁹ In those who increased
95 daily steps there was a substantial reduction in mortality risk after adjusting for baseline
96 daily step count (AHR, 0.39; 95% CI, 0.22 to 0.72; $p = 0.002$).⁹

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

1
2
3 99 activity enhances mobility through improved aerobic capacity, muscle strength, balance and
4
5 100 coordination.¹¹ More demanding mobility tasks such as stair-climbing and walking longer
6
7 101 distances require greater levels of physical functioning. If a person's physical functioning is
8
9 102 lower than that required for independent performance of a particular activity i.e., below the
10
11 103 "disability threshold", they will require assistance or aids. Greater physical functioning
12
13 104 provides "reserve capacity" which acts as a buffer to ensure that functioning remains above
14
15 105 the disability threshold even in the face of deterioration from factors such as physiological
16
17 106 ageing, illness or injury. Much of the deterioration in physical fitness and mobility
18
19 107 commonly thought to be due to ageing/health conditions is actually due to inactivity and thus
20
21 108 at least partly treatable and preventable.¹² Trials have confirmed that physical activity can
22
23 109 improve walking ability and prevent the onset of disability.¹³ For example the onset of
24
25 110 mobility disability was prevented by a structured physical activity program in people aged
26
27 111 70-89 who had some physical limitation at baseline.¹³

28 112 Unfortunately, people with mobility limitations are less active than the general population.¹⁴
29
30 113 For example, 65% of Australians regularly participate in physical activities for recreation,
31
32 114 exercise or sport, but only 24% of Australians with disabilities participate in such
33
34 115 activities.¹⁵ Although widespread provision of supervised structured exercise programs
35
36 116 would be likely to significantly lessen mobility impairment at a population level, such an
37
38 117 approach is unlikely to be broadly implemented by public health systems given the size of
39
40 118 the target population. Self-funding of such interventions is out of reach for many individuals.
41
42 119 More flexible intervention approaches that focus on physical activity more broadly, facilitate
43
44 120 attendance at existing programs, include self-management approaches, and incorporate
45
46 121 technology are likely to be more scalable. These approaches therefore warrant investigation.

47 122 Regular physical activity participation requires motivation, capability and opportunity.¹⁶
48
49 123 Simply advising people to be more active is unlikely to safely enhance activity levels.¹⁷
50
51 124 Rather, advice needs to be specific, individualised, supported by a behaviour change
52
53 125 framework and based on engagement with the person and their goals and priorities.¹⁸ Health
54
55 126 coaching interventions that involve behaviour change techniques including goal-setting and
56
57 127 are individually tailored are known to change behaviour in the general population.¹⁸⁻²⁰ A
58
59 128 recent systematic review²¹ found health coaching to improve physical activity levels in older
60
129 people (standardised mean difference = 0.29; 95% CI 0.18 to 0.39; $p < .001$) and others have
130
131 found motivational interviewing (a form of health coaching) to enhance physical activity in
people with chronic conditions²² and in hip fracture survivors.²³ These trials focused on

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3 132 health conditions so did not cater specifically for people with impaired mobility. The impact
4
5 133 of health coaching in this population is not known. Physical activity prescription in people
6
7 134 with mobility limitations is complex so we hypothesise that tailored advice from
8
9 135 physiotherapists will enhance activity levels.

10
11 136 In consultation with consumers, clinicians, and policy makers, our multidisciplinary
12
13 137 investigator team developed two intervention packages based on behaviour change theories
14
15 138 as outlined in the logic model (Fig. 1) and Table 1 and 2.^{16,24,25} Both interventions involve
16
17 139 the development of a goal-based tailored physical activity plan (made in conjunction with a
18
19 140 physiotherapist and sent to participants and their primary care physician (referred as a
20
21 141 General Practitioner (GP)) to reinforce physical activity participation), access to
22
23 142 informational and motivational print and on-line resources and encouragement of use of
24
25 143 activity monitors and suitable smart phone applications. We hypothesise that greater effects
26
27 144 on measured physical activity levels will be evident from an enhanced intervention package
28
29 145 (that also includes a face-to-face assessment and ongoing phone-based physical activity
30
31 146 phone coaching both provided by a physiotherapist) compared to a less intensive
32
33 147 intervention package (that includes a single phone call from a physiotherapist and text
34
35 148 messages). We further hypothesise that both these interventions will have greater impacts on
36
37 149 physical activity levels than no intervention.

38 150

39 151 **Methods and analysis**

40 152 Overview

41 153 This pragmatic superiority trial (n=600) will use 1:1 concealed on-line randomisation to
42
43 154 allocate adults with self-reported mobility limitations to a 6-month enhanced intervention, a
44
45 155 6-month less intensive intervention or a waiting list control group (who will receive the less
46
47 156 intensive intervention after 6 months). Between-group comparisons will be undertaken at 6
48
49 157 months (all groups) and at 12 months (comparing two intervention groups).

50 158 The study primarily aims to establish the effects of the interventions, compared to each other
51
52 159 and to control, on objectively-measured physical activity at 6-months (*Stepwatch*, steps per
53
54 160 day). Secondary outcomes include other physical activity measures, measures of health and
55
56 161 functioning, individualised mobility goal attainment, mental wellbeing, quality of life, rate of
57
58 162 falls, health utilisation and intervention evaluation. Secondary analyses will explore
59
60 163 differential effects on the basis of recruitment source (health professional referral versus

1
2
3 164 community advertising), assess implementation outcomes, and establish the cost-
4
5 165 effectiveness and cost-utility.
6

7 166 The trial is more pragmatic than explanatory in that it uses recruitment and intervention
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9 167 strategies relevant to the “real-world” and is intended to help support a decision on whether
10
11 168 such interventions should be delivered. A more explanatory trial would be undertaken in an
12
13 169 idealised setting, to give the intervention its best chance to demonstrate a beneficial effect.²⁶
14
15 170 A hybrid effectiveness-implementation design (Type 1)²⁷ will be used to collect
16
17 171 implementation outcomes at the same time as effectiveness outcomes. A nested process
18
19 172 evaluation will use both quantitative and qualitative methods to explore uptake by participants
20
21 173 and acceptability of the intervention (to participants, health coaches and other stakeholders).
22
23 174 The protocol for the process evaluation will be described elsewhere. The PRACTIS guide²⁸
24
25 175 to implementation and scale-up of physical activity interventions was used to ensure that the
26
27 176 interventions (and study recruitment methods) were as potentially scalable in future as
28
29 177 possible. Future scale-up of the interventions, if found to be effective, will be guided by the
30
31 178 model developed by Milat et al,²⁹ along with the implementation outcomes and other aspects
32
33 179 of the process evaluation. An economic analysis, which will be conducted alongside the trial,
34
35 180 will aim to establish the cost-effectiveness and cost-utility of the interventions compared to
36
37 181 no intervention and to each other to assist funders of preventive health interventions to assess
38
39 182 the value of such an approach for future investments. Table 1 shows the reasons for choice
40
41 183 of different components, Table 2 overviews the intervention in TIDieR format and Figure 1
42
43 184 shows the overall logic and broader context for the trial. The first participant was recruited
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45 185 on 13 February 2019 and at the time of submission of this manuscript 156 participants had
46
47 186 been randomised.

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49 187 The primary comparisons will assess the effect on objectively measured physical activity at
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51 188 6 months of the

- 52
53 189 i) enhanced intervention package (*Coaching to ComeBACK* group: one face-to-face
54
55 190 assessment from a physiotherapist, tailored physical activity plan sent to
56
57 191 participant and GP, physical activity phone coaching from a physiotherapist,
58
59 192 activity monitors and/or apps, booklet and access to on-line resources) compared
60
193 with a less intensive intervention package (*Texting to ComeBACK* group: single
194 session of tailored advice by phone from a physiotherapist with health coaching
195 training, tailored physical activity plan sent to participant and GP, unidirectional
196 text messages, booklet and access to on-line resources);

- 1
2
3 197 ii) the enhanced intervention package (*Coaching to ComeBACK* group) compared
4
5 198 with no intervention (*Texting to ComeBACK Later* waiting list control group);
6
7 199 iii) the less intensive intervention package (*Texting to ComeBACK* group) compared
8
9 200 with no intervention (*Texting to ComeBACK Later* waiting list control group).

10 201

11 202

12 203 Participants

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15
16 204 The trial will be conducted across four Australian states with recruitment through health
17
18 205 services in hospital departments and the general community through community organisations
19
20 206 as well as traditional and social media advertisements and stories. Participants with a range of
21
22 207 health conditions who report difficulty or inability to walk 800m will be recruited. The process
23
24 208 evaluation will explore differences in feasibility and efficiency of recruitment in each of the
25
26 209 settings to inform future implementation strategies.

27 210 The trial will involve consenting adults (18+ years) who are: living in the community (as
28
29 211 opposed to residential care); have a mobility limitation (self-reported difficulty or inability to
30
31 212 walk 800m) but are able to leave their home without physical assistance from another person
32
33 213 (but may use a walking aid); are judged by recruitment staff to have sufficient hearing and
34
35 214 English language skills for a phone-based intervention. Trial participants are likely to be
36
37 215 affected by one or more common and/or burdensome conditions such as, but not limited to,
38
39 216 osteoarthritis, lower limb fractures, lower limb amputations, stroke, brain injury, respiratory
40
41 217 conditions and obesity. The trial will exclude adults who are: permanent residents of residential
42
43 218 aged care facilities; have the following medical conditions: delirium, acute medical illnesses,
44
45 219 severe psychiatric disorders, rapidly progressive neurological diseases; have a major cognitive
46
47 220 impairment (a diagnosis of dementia or a Memory Impairment Screen score of less than 5); are
48
49 221 currently undertaking 150 minutes or more of moderate to vigorous physical activity per week
50
51 222 (based on self-report); full-time wheelchair user; unable to wear a *StepWatch Activity Monitor*;
52
53 223 not a regular user of a mobile phone (look at phone less than once per week); or have no internet
54
55 224 access.

56 225

57 226 Randomisation

58 227 Each participant will be randomised to one of the three groups after completion of baseline
59
60 228 assessments. The trial will use a centralised web-based randomisation system using REDCap

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

235 Assessments

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

256 Outcomes

257 The primary outcome for the trial is physical activity, measured as average steps per day over
258 a one-week period at 6 months post baseline with the *StepWatch Activity Monitor*. This device
259 was chosen as prior research by the present authors³⁰ found it to be the most accurate device
260 for step measurement in people with mobility impairment with average 98% (SD 12%)

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3 261 agreement with investigator-observed steps over a 6-minute period as opposed to 17% (SD
4 262 19%) for the more commonly-used *Actigraph* device. The *StepWatch Activity Monitor* is
5 263 simple to use, can be mailed to participants and does not give feedback to the wearer.

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8 264 Secondary outcomes will be measured at 3, 6 and 12 months post baseline. Measures
9 265 undertaken at 12 months will compare the two intervention groups and assess physical activity
10 266 maintenance in the intervention groups and uptake in the waiting list control group (*Texting*
11 267 *to ComeBACK Later* Group). Secondary outcomes include other physical activity measures
12 268 (self-reported physical activity using the Incidental and Planned Exercise Questionnaire³¹,
13 269 cadence, activity intensity (6 and 12 months only) and average steps per day (12 months only)
14 270 from the *StepWatch Activity Monitor*, global perceived change scores for physical activity and
15 271 walking, attitudes to and experience of physical activity), pain (study specific questions),
16 272 lower limb function and disability (Late Life Function and Disability Instrument³²), fear of
17 273 falling and self-reported balance (5-point scales), individualised mobility goal attainment
18 274 (Goal Attainment Scale³³ at 6 and 12 months), mental wellbeing (Warwick-Edinburgh Mental
19 275 Well-being Scale³⁴), quality of life (EuroQol 5D-5L³⁵), Body Mass Index, use of mobility
20 276 aids, rate of falls and health utilisation (monitored using monthly calendars over 12 months),
21 277 and measures evaluating impressions (study specific) and enjoyment (Physical Activity
22 278 Enjoyment Scale)³⁶ of the interventions and the therapeutic alliance between health coaches
23 279 and participants (Working Alliance Inventory)³⁷. The EuroQol 5D-5L will also be used to
24 280 enable calculation of quality-adjusted life years (QALYs) for the economic analyses.

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40 282 *Other measures* Intervention costs and health and community service utilisation, as collected
41 283 by monthly calendars, will be recorded for all participants and used as part of the economic
42 284 evaluation. The experiences and attitudes of stakeholders, including participants, health
43 285 coaches, clinicians and health service managers will be explored via semi structured interviews
44 286 and focus groups in order to inform future development and implementation of the
45 287 ComeBACK interventions.

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52 289 Adverse events will be defined as an unwanted and usually harmful outcome (e.g. exercise-
53 290 related falls, musculoskeletal injury, angina, shortness of breath or cardiovascular event). The
54 291 event may or may not be related to the intervention, but it occurs while the person is
55 292 participating in the intervention phase of the trial i.e. while they are doing mobility or physical
56 293 activities. A minor adverse event is defined as an incident that results in no injury or minor
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3 294 injury. For example, a fall where the person sustains a small cut or bruise that requires none
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5 295 or minor medical intervention. A serious adverse event is defined as an incident that results
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7 296 in death, serious injury or hospitalisation. Adverse events will be monitored by records kept
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9 297 by participants and interviews at each follow-up period. Participants will also be asked to
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11 298 notify study staff immediately of any serious adverse events. Any adverse event occurring
12
13 299 during the assessment and intervention process will be reported back to authors Hassett and
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15 300 Sherrington. It will then be decided if this is a recognised or unintended event relating to the
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17 301 study protocol. Unintended events will be reported to the independent Data Monitoring
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19 302 Committee that will be established for this trial and also be reported to the approving HREC.
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21 303 The research team will review the event and determine whether it is person specific or whether
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23 304 there is a potential for this to occur to other participants and therefore consideration would be
24
25 305 given as to appropriateness of continuing the research. Participants may experience muscle
26
27 306 soreness at the start of the physical activity program. This will be minimised by advice to
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29 307 increase activity levels gradually and to seek professional advice if soreness lasts for more
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31 308 than three days or interferes with daily activities.

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310 Interventions

311 Intervention design was undertaken by our multi-disciplinary author team guided by formal
312 (qualitative pilot work) and informal input from consumers in the target population as well as
313 consultations with clinicians, health service managers, population health service providers
314 and health policy makers. The COM-B (Capability Opportunity Motivation → Behaviour)
315 model of behaviour change¹⁶ was used to guide the intervention design, with self-
316 determination theory²⁴ and social cognitive theory²⁵ further underpinning the motivational
317 component. Table 1 overviews the aspects of the COM-B addressed by each aspect of the
318 intervention packages. Table 2 provides more detail on the interventions using the TIDieR
319 format.³⁸ The interventions are as follows.

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

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

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3 327 call will be made to the health coach with both physiotherapist and the participant present to
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5 328 introduce and handover to the health coach and discuss any particular issues.

6 329 *ii) phone-based health coaching* will be delivered by trained physiotherapists through a
7
8 330 centralised service. The initial session will include development of a tailored plan to improve
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10 331 physical activity through participation in suitable activities in negotiation with the participant
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12 332 and their carers (where appropriate). The choice of physical activity will be guided by
13
14 333 personal preference, logistics, physical abilities and evidence of effectiveness of different
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16 334 intervention options. The coach will liaise with relevant treating health professionals to
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18 335 identify contraindications or precautions to exercise and ensure other causes of mobility
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20 336 limitation are optimally managed. Coaching sessions will be delivered at a tailored frequency
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22 337 of approximately every 2 weeks over a 6-month period and will take an average of 20-30
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24 338 min each session. The coaching will incorporate behaviour change strategies including
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26 339 motivational interviewing (to explore and enhance reasons for being active (importance) and
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28 340 confidence to make changes, as well as to explore social influences on activity) goal-setting,
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30 341 problem-solving, building social support and experiential learning. The individually-
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32 342 tailored, person-centred approach will determine each person's physical, cognitive, affective,
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34 343 environmental and social barriers and facilitators to physical activity and develop physical
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36 344 activity recommendations (including adaptations and/or assistance to overcome specific
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38 345 barriers) for each individual. The health coach will link participants to existing community
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40 346 programs if desired, with a focus on identifying activities that participants will enjoy.³⁹
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42 347 Suitable options may include attendance at a group program, such as those indexed on the
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44 348 *Active and Healthy* website (www.activeandhealthy.nsw.gov.au) and/or participation in
45
46 349 sporting opportunities that cater for people with impaired mobility. The coaching will also
47
48 350 encourage reduced sedentary and inactive time by spending more time standing and walking
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50 351 or undertaking a home based exercise program, as well as increased use of active transport
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52 352 (i.e. walking, using public transport). Staff have extensive experience in the management of
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54 353 people with walking limitations, have undertaken courses in health coaching and received
55
56 354 two days of additional training in using behaviour change science and self-determination
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58 355 theory to guide intervention from author Greaves.

53 356 *iii) activity monitors and GPS-based tablet/smartphone applications.* Participants will be
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55 357 offered an internet-connected activity monitor (such as the *Fitbit*) or a simple pedometer if
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57 358 preferred, as pedometers are known to enhance physical activity through measurement and
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59 359 behavioural reinforcement.⁴⁰
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3 360 *iv) physical activity plan* developed jointly as outlined above will be shared with the
4 participant's GP with his/her consent soon after it is developed.

5 361
6 362 *v) paper-based booklet* on physical activity, safe mobility and behaviour change that is
7 study-specific, evidence-based and theoretically informed (by incorporating messaging and
8 images that are consistent with self-determination theory (promoting autonomy, competence
9 and relatedness for walking behaviour) and social cognitive theory (supporting self-
10 regulation and identifying /reinforcing the perceived benefits (social, physical,
11 emotional/affective)).
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15 368 *vi) closed study website* with 3 components: 1) why be active (incorporating motivational
16 components consistent with self-determination theory); 2) how to be active (links to
17 resources); 3) how others do it (video case studies using modelling of successful peer
18 behaviour as per Social Cognitive Theory).
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26 373 Group 2: Texting to ComeBACK. Participants randomised to this group will be offered the
27 following five intervention components. The first two intervention components are unique to
28 this group and the following three interventions are the same as Group 1.
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31 376 *i) single session of tailored advice provided by phone by a physiotherapist.* This call will last
32 50-60 minutes, will be informed by the baseline assessment results and provide advice about
33 appropriate physical activity opportunities for the person's interests and level of mobility. A
34 follow-up email will be sent to summarise and reinforce key discussion points.
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37 380 *ii) text messages to encourage activity.* Pre-scheduled unidirectional text messages with
38 some tailoring and personalisation will commence at 5 times/week for the first month to
39 provide motivation support (again using messages designed to be consistent with self-
40 determination theory (promoting autonomy, competence and relatedness for walking
41 behaviour) and social cognitive theory (supporting self-monitoring /self-regulation and
42 identifying /reinforcing the perceived benefits (social, physical, emotional/affective)),
43 planning support, problem-solving and maintenance support. Participants will then have the
44 option of increasing intensity (daily messages) or decreasing intensity (3 times/week) for the
45 next 4 months prior to a gradual reduction in the frequency of messages. There is also an
46 opt-out feature available at all times.
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52 390 *iii) physical activity plan* developed jointly as outlined above and will be shared with the
53 participant's GP with their consent soon after it is developed.
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3 392 *iv) paper-based booklet* that has study-specific information on physical activity, safe
4 mobility and behaviour change that is evidence-based and theoretically informed (as
5 393 outlined above).
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8 395 *v) closed study website* with 3 components: 1) why be active; 2) how to be active (links to
9 resources including recommended activity monitors and physical activity Apps); 3) how
10 396 others do it (video case studies using modelling of successful peer behaviour as per Social
11 397 Cognitive Theory).
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17 400 Group 3: Texting to ComeBACK Later (waiting list control). This group will not receive any
18 intervention for the first 6 months of the trial but will be advised to continue usual activity
19 401 levels and health service use. After 6 months, this group will receive the Texting to
20 402 ComeBACK intervention package as outlined above.
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25 405 Patient and public involvement

26 406 The study protocol and choice of intervention and assessment tools used in this study was
27 guided by feedback from consumers obtained as part of the endorsement of the trial by the
28 407 Australia & New Zealand Musculoskeletal Clinical Trials Network (ANZMUSC) as well as
29 information from interviews with participants in our previous studies.⁴¹⁻⁴³
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36 411 Sample size

37 412 The trial's sample size (n=600) will provide 90% power to detect between-group differences of
38 413 1000 steps per day assuming a standard deviation of 3000 steps (estimated from our pilot data),
39 a dropout rate of 20%, alpha of 0.0167 (to adjust for multiplicity due to 3 trial arms), and
40 414 correlation between initial and final measures of 0.6 (from our pilot data). This calculation was
41 undertaken in Stata 13 using the *sampsi* command. On the basis of previous work by the
42 415 investigators and others, we consider between-group differences of this magnitude to be likely
43 to result in significant health benefits because 1000 steps/day, assuming a cadence of 80
44 416 steps/min, would equate to an additional 15 minutes of walking/day, a dose associated with
45 417 health benefits and reduced mortality even in those with cardiovascular disease.⁴⁴
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55 422 Statistical analysis

56 423 Analysis of covariance, conducted using a linear regression approach, will be used to assess the
57 424 effect of group allocation on the continuously-scored primary and secondary outcomes after
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3 425 adjusting for baseline scores and source of recruitment. Point estimates and their 95%
4 426 confidence intervals will be used to interpret results. Given our interest in comparing the two
5 427 interventions with each other and with the control condition, between-group differences with
6 428 p-values < 0.0167 will be considered significant. Planned sub-group analyses will assess
7 429 differential effects of the intervention based on the stratification variable of recruitment source,
8 430 as well as for severity of mobility limitation and age. Secondary analyses using causal
9 431 modelling will be conducted to establish intervention effects in people with greater adherence.
10 432 Analyses will be pre-planned, by intention-to-treat, conducted while masked to group
11 433 allocation and undertaken after range checks. A detailed Statistical Analysis Plan will be
12 434 developed and signed off by all investigators prior to analysis.
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23 436 The economic evaluation will take the perspective of the health and community care funder.
24 437 Health care costs, community service costs and intervention costs will be collected over the
25 438 trial period. Using mean costs and mean health outcomes in each trial arm, the incremental
26 439 costs per 1) additional person with increased physical activity of more than 1000 steps per
27 440 day; and 2) QALY gained will be calculated; results will be plotted on a cost-effectiveness
28 441 plane. Bootstrapping will be used to estimate a distribution around costs and health outcomes,
29 442 and to calculate the confidence intervals around the incremental cost- effectiveness ratios.
30 443 One-way sensitivity analysis will be conducted around key variables and a probabilistic
31 444 sensitivity analysis will estimate uncertainty in all parameters. A cost-effectiveness
32 445 acceptability curve will be plotted to provide information about the probability that the
33 446 intervention is cost-effective, given willingness to pay for each benefit gained. Modelled
34 447 analyses will explore the longer term cost-effectiveness of the intervention.
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45 449 **Ethics and dissemination**

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47 450 Ethical approval and local governance approvals have been obtained (Lead ethics committee:
48 451 Sydney Local Health District, Royal Prince Alfred Zone (22/08/2018 X18-0234). All
49 452 amendment requests will be submitted to these committees. Written informed consent from
50 453 all participants will be obtained by study staff prior to study enrolment (see sample consent
51 454 form in supplementary material). Participant confidentiality will be maintained at all times
52 455 and all data will be stored securely. Dissemination will be via publications, conferences,
53 456 newsletter articles, letters to participants, talks to healthcare professionals and consumers and
54 457 meetings with health department and health service managers. Intervention materials will be
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3 458 made freely available at the end of the trial. The International Committee of Medical Journal
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5 459 Editors recommended criteria for authorship on publications will be followed. Professional
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7 460 writers will not be used. The full protocol, de-identified data and statistical code will be made
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9 461 available upon reasonable request. All authors will have full access to de-identified study data.

10 462

11 463 This study will address a key evidence gap regarding realistic scalable ways to enhance
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13 464 physical ability in people with impaired mobility. Trial results will provide direct information
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15 465 about the costs and benefits of the intervention approach compared with current practice to
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17 466 enable funders of preventive health interventions to decide whether such approaches are worth
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19 467 investing in as a population health intervention.

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21 469 **Author contributions**

22 470 All authors contributed to the design of the study and preparation of the study protocol. This
23
24 471 manuscript was drafted by author Sherrington.

25 472

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34
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36
37 479 authority over any of these activities.

38 480

39 481 **Competing interests statement**

40 482 The authors do not report any competing interests.

41 483

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43 485

44 486 **References**

- 45 487 1. WHO. Towards a common language for functioning, disability and health: ICF. . 2002.
46 488 2. AIHW. *Australia's Welfare*. Canberra: Australian Institute of Health and Welfare.;2015.
47 489 3. Cummings SR, Studenski S, Ferrucci L. A diagnosis of dismobility--giving mobility clinical
48 490 visibility: a Mobility Working Group recommendation. *Jama*. 2014;311(20):2061-2062.
49 491 4. Ma VY, Chan L, Carruthers KJ. Incidence, prevalence, costs, and impact on disability of
50 492 common conditions requiring rehabilitation in the United States: stroke, spinal cord injury,
51 493 traumatic brain injury, multiple sclerosis, osteoarthritis, rheumatoid arthritis, limb loss, and
52 494 back pain. *Archives of physical medicine and rehabilitation*. 2014;95(5):986-995.e981.

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2
3
4
5
6
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11
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41
42
43
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47
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50
51
52
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54
55
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58
59
60

- 495 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.
- 496
- 497
- 498 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.
- 499
- 500
- 501 7. Das P, Horton R. Physical activity-time to take it seriously and regularly. *Lancet (London, England)*. 2016;388(10051):1254-1255.
- 502
- 503 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.
- 504
- 505
- 506 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.
- 507
- 508
- 509 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.
- 510
- 511
- 512 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.
- 513
- 514
- 515 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.
- 516
- 517
- 518 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.
- 519
- 520
- 521 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.
- 522
- 523
- 524 15. ABS. Sports and Physical Recreation: A Statistical Overview, Australia. In: Australian Bureau of Statistics; 2012.
- 525
- 526 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.
- 527
- 528
- 529 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.
- 530
- 531
- 532 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.
- 533
- 534 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.
- 535
- 536
- 537 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.
- 538
- 539
- 540 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.
- 541
- 542
- 543
- 544 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.
- 545
- 546
- 547 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.
- 548
- 549

- 1
2
3 550 24. Ryan RM, Deci EL. Self-determination theory and the facilitation of intrinsic motivation,
4 551 social development, and well-being. *The American psychologist*. 2000;55(1):68-78.
5 552 25. Bandura A. *Social foundations of thought and action: A social cognitive theory*. Englewood
6 553 Cliffs, NJ: Prentice-Hall; 1986.
7 554 26. Loudon K, Treweek S, Sullivan F, Donnan P, Thorpe KE, Zwarenstein M. The PRECIS-2
8 555 tool: designing trials that are fit for purpose. *BMJ (Clinical research ed)*. 2015;350:h2147.
9 556 27. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid
10 557 designs: combining elements of clinical effectiveness and implementation research to enhance
11 558 public health impact. *Medical Care*. 2012;50(3):217–226.
12 559 28. Koorts H, Eakin E, Estabrooks P, Timperio A, Salmon J, Bauman A. Implementation and
13 560 scale up of population physical activity interventions for clinical and community settings: the
14 561 PRACTIS guide. *The international journal of behavioral nutrition and physical activity*.
15 562 2018;15(1):51.
16 563 29. Milat AJ, Newson R, King L. *Increasing the scale and adoption of public health
17 564 interventions: A guide for developing a scaling up strategy*. North Sydney: NSW Ministry of
18 565 Health;2014.
19 566 30. Treacy D, Hassett L, Schurr K, Chagpar S, Paul S, Sherrington C. Physical Therapy. .
20 567 *Validity of different activity monitors to count steps in an inpatient rehabilitation setting*.
21 568 Accepted 12 Dec 2016.
22 569 31. Delbaere K, Hauer K, Lord S. Evaluation of the Incidental and Planned Exercise
23 570 Questionnaire (IPEQ) for older people. *British Journal of Sports Medicine* 2010;44:1029-
24 571 1034.
25 572 32. Jette AM, Haley SM, Coster WJ, et al. Late life function and disability instrument: I.
26 573 Development and evaluation of the disability component. *J Gerontol A Biol Sci Med Sci*.
27 574 2002;57(4):M209-216.
28 575 33. Tennant A. Goal attainment scaling: current methodological challenges. *Disabil Rehabil*.
29 576 2007;29(20-21):1583-1588.
30 577 34. Tennant R, Hiller L, Fishwick R, et al. The Warwick-Edinburgh Mental Well-being Scale
31 578 (WEMWBS): development and UK validation. *Health Qual Life Outcomes*. 2007;5:63.
32 579 35. EuroQol--a new facility for the measurement of health-related quality of life. *Health policy
33 580 (Amsterdam, Netherlands)*. 1990;16(3):199-208.
34 581 36. Kendzierski D, DeCarlo KJ. Physical Activity Enjoyment Scale: Two Validation Studies.
35 582 1991;13(1):50.
36 583 37. Hatcher RL, Gillaspay JA. Development and validation of a revised short version of the
37 584 Working Alliance Inventory. *Psychotherapy Research*. 2006;16(1):12-25.
38 585 38. Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for
39 586 intervention description and replication (TIDieR) checklist and guide. *BMJ (Clinical research
40 587 ed)*. 2014;348:g1687.
41 588 39. Kiviniemi MT, Voss-Humke AM, Seifert AL. How do I feel about the behavior? The
42 589 interplay of affective associations with behaviors and cognitive beliefs as influences on
43 590 physical activity behavior. *Health psychology : official journal of the Division of Health
44 591 Psychology, American Psychological Association*. 2007;26(2):152-158.
45 592 40. J SO, Sherrington C, E RYZ, Franco MR, Tiedemann A. Effect of interventions using
46 593 physical activity trackers on physical activity in people aged 60 years and over: a systematic
47 594 review and meta-analysis. *Br J Sports Med*. 2019.
48 595 41. Tiedemann A, Rissel C, Howard K, et al. Health coaching and pedometers to enhance
49 596 physical activity and prevent falls in community-dwelling people aged 60 years and over:
50 597 study protocol for the Coaching for Healthy AGEing (CHANGE) cluster randomised
51 598 controlled trial. *BMJ open*. 2016;6(5):e012277.
52 599 42. Hassett L, van den Berg M, Lindley RI, et al. Effect of affordable technology on physical
53 600 activity levels and mobility outcomes in rehabilitation: a protocol for the Activity and
54 601 MObility UsiNg Technology (AMOUNT) rehabilitation trial. *BMJ open*. 2016;6(6):e012074.
55 602 43. Oliveira JS, Sherrington C, Paul SS, et al. A combined physical activity and fall prevention
56 603 intervention improved mobility-related goal attainment but not physical activity in older
57 604 adults: a randomised trial. *Journal of physiotherapy*. 2019;65(1):16-22.

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605 44. Wen CP, Wai JP, Tsai MK, et al. Minimum amount of physical activity for reduced mortality
606 and extended life expectancy: a prospective cohort study. *Lancet (London, England)*.
607 2011;378(9798):1244-1253.
608 45. Farag I, Howard K, Ferreira ML, Sherrington C. Economic modelling of a public health
609 programme for fall prevention. *Age Ageing*. 2015;44(3):409-414.

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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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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 <u>capability</u> to suggest appropriate <u>opportunities</u> . Establishing /building <u>motivation</u> .
Patient-centred health coaching, incorporating behaviour change strategies including goal-setting and motivational interviewing	<ul style="list-style-type: none"> 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 <u>capability</u> to suggest appropriate <u>opportunities</u> . Encouragement of <u>capability</u> enhancement. Feedback to assist with ongoing <u>motivation</u> .
Activity monitor or pedometer if desired	<ul style="list-style-type: none"> known to enhance physical activity in general population well accepted in pilot among people with mobility limitations 	Feedback to assist with ongoing <u>motivation</u> .
Tailored use of apps to encourage physical activity	<ul style="list-style-type: none"> 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 <u>motivation</u> .
Paper-based and on-line resources to support behaviour change	<ul style="list-style-type: none"> provision of evidence-based information in attractive format including case studies to support behaviour change. 	Case studies and information to assist with <u>capability</u> and <u>motivation</u> .
Tailored physical activity plan developed and shared with GP	<ul style="list-style-type: none"> credible and trusted source reinforcing behaviour changes suggested by health coach 	Increased <u>motivation</u> .

Group 2: Texting to ComeBACK		
Single session of tailored advice over the phone from a physiotherapist	<ul style="list-style-type: none"> • 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 <u>capability</u> to suggest appropriate <u>opportunities</u> .
Paper-based and on-line resources to support behaviour change	<ul style="list-style-type: none"> • provision of evidence-based information in attractive format • including case studies to support behaviour change. 	Case studies and information to assist with <u>capability</u> and <u>motivation</u> .
Text messages	<ul style="list-style-type: none"> • 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 <u>motivation</u> and <u>problem-solving (capability)</u> .
Tailored physical activity plan developed and shared with GP	<ul style="list-style-type: none"> • credible and trusted source reinforcing behaviour changes suggested by health coach. 	Increased <u>motivation</u> .
Group 3: Texting to ComeBACK Later		
No intervention for 6 months	<ul style="list-style-type: none"> • pragmatic comparison • direct policy implications 	
Receipt of less intensive intervention after 6 months	<ul style="list-style-type: none"> • enhanced recruitment through provision of intervention for all participants. 	As above
Outcome		
Physical activity	<ul style="list-style-type: none"> • neglected costly population health problem. 	n/a

*Primarily using the COM-B system¹⁶ 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	<ul style="list-style-type: none"> ➤ 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. 	<ul style="list-style-type: none"> ➤ 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#	<ul style="list-style-type: none"> ➤ 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 	<ul style="list-style-type: none"> ➤ 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

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	<p>others do it (video case studies-modelling elements of Social Cognitive Theory).</p> <ul style="list-style-type: none"> ➤ Physical activity plan shared with General Practitioner. ➤ Option to use activity monitor and/or physical activity apps for self-monitoring. 	<p>case studies-modelling elements of Social Cognitive Theory).</p> <ul style="list-style-type: none"> ➤ Physical activity plan shared with General Practitioner.
Who provided	<ul style="list-style-type: none"> ➤ 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 <i>Wellness Coaching Australia; Health Change Australia</i> and <i>Medicoach</i> as well as receiving training by study investigator (CG) in advanced motivational interviewing, a framework for “good (functional) motivation” and intervention techniques. 	<ul style="list-style-type: none"> ➤ 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 <i>Wellness Coaching Australia; Health Change Australia</i> and <i>Medicoach</i> as well as receiving training by study investigator (CG) in advanced motivational interviewing, a framework for “good (functional) motivation” and intervention techniques.
How	<ul style="list-style-type: none"> ➤ 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. 	<ul style="list-style-type: none"> ➤ 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	<ul style="list-style-type: none"> ➤ 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. 	<ul style="list-style-type: none"> ➤ 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	<ul style="list-style-type: none"> ➤ 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 	<ul style="list-style-type: none"> ➤ 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.

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- 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.

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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

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Figure legend

Figure 1. Logic model for the ComeBACK intervention.

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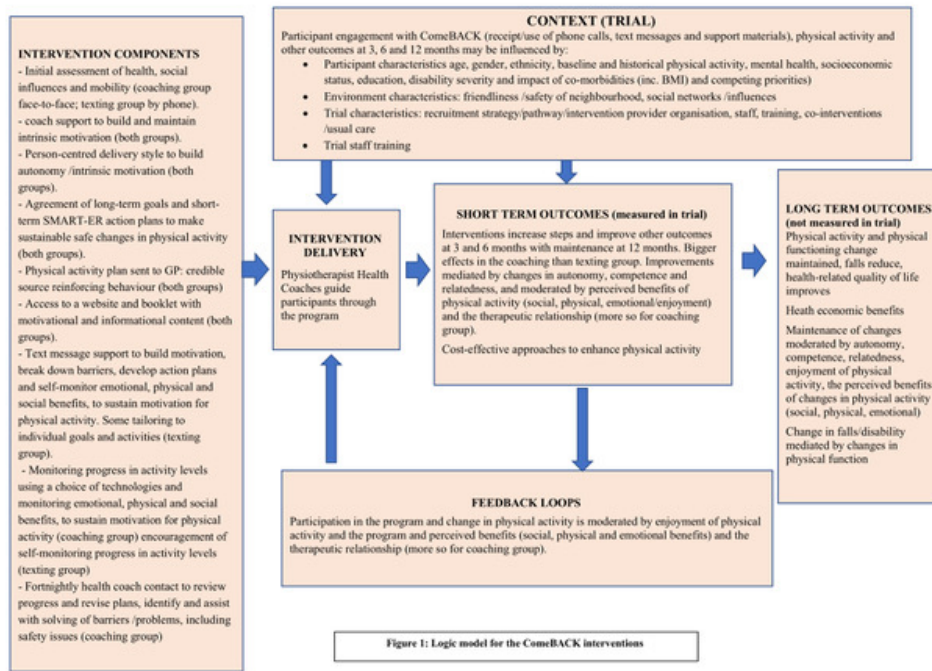


Figure 1. Logic model for the ComeBACK intervention.

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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

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2 recommendation made to incorporate physical activity into your daily routine will be negotiated
3 with you and this will be different for each person based on current activity levels and abilities.
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5 6 **Group 3 Texting to ComeBACK later group**

7 If you are allocated to the Texting to ComeBACK later group you will receive the usual care
8 provided by your health service providers for the first 6 months of the study. You will have no
9 contact with the study staff apart from the baseline, 3 and 6-month questionnaires. Following the
10 6-month reassessment you will receive the same intervention as Group 2 (Texting to ComeBACK)
11 as described above. This includes the single phone session of tailored advice from a
12 physiotherapist to improve physical activity (generally 30-45 minutes) as well as text message
13 follow up for 6 months and access to online resources to support you to be more active.
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15 The overall time commitment for the initial 6 months of the study period if allocated to the
16 Texting to ComeBACK later group is 0 minutes per month. This will then increase to 5 minutes per
17 month of reading phone text messages for the next 6-month period. The recommendation made
18 for you to incorporate physical activity into your daily routine will be negotiated with you and this
19 will be different for each person based on current activity levels and abilities.
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22 23 **Falls and health utilisation calendars**

24 All study participants will be asked to return monthly calendars (by reply-paid mail) containing
25 questions on any falls and subsequent injuries you may experience along with health utilisation. If
26 calendars are not returned, you will be telephoned to ask if you experienced any falls and physical
27 activity-related injuries during the past month. In order to reduce the risk of bias, the research
28 team member who collects the monthly calendars will not be aware of which group you have
29 been allocated to.
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32 The researchers would like to evaluate the benefits of the study beyond the 6-month intervention
33 period so we ask you to complete the calendars for a 12-month period.
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36 37 **Data Linkage Study**

38 We would like to track hospital and emergency department admissions, ambulance services and
39 any study participant deaths (birth, marriages and death registry records) for up to 2 years after
40 the completion of the study to evaluate if there are any long-term effects from the intervention.
41 Therefore, the researchers would like your permission to link the information you provide within
42 the ComeBACK study, with other sources of information that are routinely collected and managed
43 via the Population Health Research Network (PHRN) for Health data Record Linkage. A strict
44 process will be followed as per Data Linkage policies that ensures the confidentiality of your data.
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48 Data linkage has been used by health systems for many years to bring together information about
49 people, places and events in a way that protects individual privacy and allows researchers and
50 policy makers to gain information and insights about the health and well-being of our community.
51 Data linkage studies have helped to provide valuable information on the causes of and risk factors
52 for disease as well as the evaluation of new approaches to preventing and treating health
53 problems.
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56 If you want to opt out of the linking of your health information, there is an option to indicate this choice on
57 the consent form by ticking the box for opt out.
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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)

1
2 Trial design 8 Description of trial design including type of trial (eg, parallel group,
3 crossover, factorial, single group), allocation ratio, and framework (eg,
4 superiority, equivalence, noninferiority, exploratory) (page 6)
5
6
7

8 **Methods: Participants, interventions, and outcomes**
9

10 Study setting 9 Description of study settings (eg, community clinic, academic hospital)
11 and list of countries where data will be collected. Reference to where
12 list of study sites can be obtained (page 7)
13

14 Eligibility criteria 10 Inclusion and exclusion criteria for participants. If applicable, eligibility
15 criteria for study centres and individuals who will perform the
16 interventions (eg, surgeons, psychotherapists) (page 7)
17
18

19 Interventions 11a Interventions for each group with sufficient detail to allow replication,
20 including how and when they will be administered (page 10, Table 1-
21 2)
22

23 11b Criteria for discontinuing or modifying allocated interventions for a
24 given trial participant (eg, drug dose change in response to harms,
25 participant request, or improving/worsening disease) n/a
26
27

28 11c Strategies to improve adherence to intervention protocols, and any
29 procedures for monitoring adherence (eg, drug tablet return,
30 laboratory tests) (page 10, Table 1-2)
31

32 11d Relevant concomitant care and interventions that are permitted or
33 prohibited during the trial (page 10, Table 1-2)
34

35 Outcomes 12 Primary, secondary, and other outcomes, including the specific
36 measurement variable (eg, systolic blood pressure), analysis metric
37 (eg, change from baseline, final value, time to event), method of
38 aggregation (eg, median, proportion), and time point for each
39 outcome. Explanation of the clinical relevance of chosen efficacy and
40 harm outcomes is strongly recommended (page 9)
41
42

43 Participant 13 Time schedule of enrolment, interventions (including any run-ins and
44 timeline washouts), assessments, and visits for participants. A schematic
45 diagram is highly recommended (see Figure) (page 9)
46
47

48 Sample size 14 Estimated number of participants needed to achieve study objectives
49 and how it was determined, including clinical and statistical
50 assumptions supporting any sample size calculations (page 13)
51

52 Recruitment 15 Strategies for achieving adequate participant enrolment to reach
53 target sample size (page 7)
54
55

56 **Methods: Assignment of interventions (for controlled trials)**
57

58 Allocation:
59
60

1			
2	Sequence	16a	Method of generating the allocation sequence (eg, computer-
3	generation		generated random numbers), and list of any factors for stratification.
4			To reduce predictability of a random sequence, details of any planned
5			restriction (eg, blocking) should be provided in a separate document
6			that is unavailable to those who enrol participants or assign
7			interventions (page 8)
8			
9			
10	Allocation	16b	Mechanism of implementing the allocation sequence (eg, central
11	concealment		telephone; sequentially numbered, opaque, sealed envelopes),
12	mechanism		describing any steps to conceal the sequence until interventions are
13			assigned (page 8)
14			
15	Implementation	16c	Who will generate the allocation sequence, who will enrol participants,
16			and who will assign participants to interventions (page 8)
17			
18			
19	Blinding	17a	Who will be blinded after assignment to interventions (eg, trial
20	(masking)		participants, care providers, outcome assessors, data analysts), and
21			how (page 8, page 13)
22			
23		17b	If blinded, circumstances under which unblinding is permissible, and
24			procedure for revealing a participant's allocated intervention during
25			the trial (n/a)
26			
27			

Methods: Data collection, management, and analysis

28			
29			
30	Data collection	18a	Plans for assessment and collection of outcome, baseline, and other
31	methods		trial data, including any related processes to promote data quality (eg,
32			duplicate measurements, training of assessors) and a description of
33			study instruments (eg, questionnaires, laboratory tests) along with
34			their reliability and validity, if known. Reference to where data
35			collection forms can be found, if not in the protocol (page 8-9)
36			
37			
38		18b	Plans to promote participant retention and complete follow-up,
39			including list of any outcome data to be collected for participants who
40			discontinue or deviate from intervention protocols (page 8)
41			
42	Data	19	Plans for data entry, coding, security, and storage, including any
43	management		related processes to promote data quality (eg, double data entry;
44			range checks for data values). Reference to where details of data
45			management procedures can be found, if not in the protocol (page 14)
46			
47			
48	Statistical	20a	Statistical methods for analysing primary and secondary outcomes.
49	methods		Reference to where other details of the statistical analysis plan can be
50			found, if not in the protocol (page 13)
51			
52		20b	Methods for any additional analyses (eg, subgroup and adjusted
53			analyses) (page 13)
54			
55		20c	Definition of analysis population relating to protocol non-adherence
56			(eg, as randomised analysis), and any statistical methods to handle
57			missing data (eg, multiple imputation) (page 13)
58			
59			
60			

Methods: Monitoring

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	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)
25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	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

26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	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)

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| 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) |

16 Appendices

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|----------------------------|----|--|
| 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) |

25 *It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013
26 Explanation & Elaboration for important clarification on the items. Amendments to the
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BMJ Open

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

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4 1 Physical activity coaching for adults with mobility limitations: protocol for the ComeBACK
5 2 pragmatic hybrid effectiveness-implementation type 1 randomised controlled trial.
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26 **Abstract**

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

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

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

56 **Registration.** ACTRN12618001983291

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2
3 57 **Strengths and limitations of this study**
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- 6 58
- Pragmatic evaluation of a scalable person-centred intervention.
- 7
8 59
- Theory-based intervention informed by consumers, clinicians and policy
- 9 60 makers.
- 10
11
12 61
- Six-month study timeframe will not test long-term intervention impacts.
- 13
14
15 62
- Staffing in the trial does not enable those who do not speak English to
- 16 63 participate.
- 17
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19 64
- Recruitment is based on self-reported mobility limitation rather than a
- 20 65 standardised measure.
- 21
22
23
24 66

67 Introduction

68 Disability is an umbrella term for impairments, activity limitations and participation
69 restrictions.¹ Mobility limitation (i.e., difficulty or inability to walk) is a particularly
70 common² and serious form of physical disability. It is primarily due to neurological and
71 musculoskeletal health conditions, physiological ageing and inactivity-related
72 deconditioning.³ Walking impairment or ‘dismobility’ is predictive of adverse health
73 outcomes, including death.³ Widespread screening for walking problems has been suggested
74 as an additional vital sign, and development and testing of interventions for people with
75 walking difficulties has been highlighted as an urgent research priority.³

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

86 Physical activity participation has enormous untapped potential as a cost-effective approach
87 to enhancing physical and mental health in people of most ages, health conditions and
88 physical abilities.⁷ A *Lancet* editorial⁷ calls for physical activity to be taken more seriously
89 as a population health intervention, given the strong evidence of physical and mental health
90 benefits and poor participation rates. As well as enhancing the prevention and management
91 of chronic conditions, physical activity is now known to have survival benefits.⁸ For
92 example, taking a greater number of steps per day was associated with lower all-cause
93 mortality over a 10-year follow-up period (adjusted hazard ratio (AHR) for all-cause
94 mortality 0.94; 95% CI, 0.90 to 0.98 per 1 000 steps; $p = 0.004$).⁹ In those who increased
95 daily steps there was a substantial reduction in mortality risk after adjusting for baseline
96 daily step count (AHR, 0.39; 95% CI, 0.22 to 0.72; $p = 0.002$).⁹

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

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3 99 activity enhances mobility through improved aerobic capacity, muscle strength, balance and
4 coordination.¹¹ More demanding mobility tasks such as stair-climbing and walking longer
5 100 distances require greater levels of physical functioning. If a person's physical functioning is
6 101 lower than that required for independent performance of a particular activity i.e., below the
7 102 "disability threshold", they will require assistance or aids. Greater physical functioning
8 103 provides "reserve capacity" which acts as a buffer to ensure that functioning remains above
9 104 the disability threshold even in the face of deterioration from factors such as physiological
10 105 ageing, illness or injury. Much of the deterioration in physical fitness and mobility
11 106 commonly thought to be due to ageing/health conditions is actually due to inactivity and thus
12 107 at least partly treatable and preventable.¹² Trials have confirmed that physical activity can
13 108 improve walking ability and prevent the onset of disability.¹³ For example the onset of
14 109 mobility disability was prevented by a structured physical activity program in people aged
15 110 70-89 who had some physical limitation at baseline.¹³

16
17 112 Unfortunately, people with mobility limitations are less active than the general population.¹⁴
18 113 For example, 65% of Australians regularly participate in physical activities for recreation,
19 114 exercise or sport, but only 24% of Australians with disabilities participate in such
20 115 activities.¹⁵ Although widespread provision of supervised structured exercise programs
21 116 would be likely to significantly lessen mobility impairment at a population level, such an
22 117 approach is unlikely to be broadly implemented by public health systems given the size of
23 118 the target population. Self-funding of such interventions is out of reach for many individuals.
24 119 More flexible intervention approaches that focus on physical activity more broadly, facilitate
25 120 attendance at existing programs, include self-management approaches, and incorporate
26 121 technology are likely to be more scalable. These approaches therefore warrant investigation.

27
28 122 Regular physical activity participation requires motivation, capability and opportunity.¹⁶
29 123 Simply advising people to be more active is unlikely to safely enhance activity levels.¹⁷
30 124 Rather, advice needs to be specific, individualised, supported by a behaviour change
31 125 framework and based on engagement with the person and their goals and priorities.¹⁸ Health
32 126 coaching interventions that involve behaviour change techniques including goal-setting and
33 127 are individually tailored are known to change behaviour in the general population.¹⁸⁻²⁰ A
34 128 recent systematic review²¹ found health coaching to improve physical activity levels in older
35 129 people (standardised mean difference = 0.29; 95% CI 0.18 to 0.39; $p < .001$) and others have
36 130 found motivational interviewing (a form of health coaching) to enhance physical activity in
37 131 people with chronic conditions²² and in hip fracture survivors.²³ These trials focused on

1
2
3 132 health conditions so did not cater specifically for people with impaired mobility. The impact
4
5 133 of health coaching in this population is not known. Physical activity prescription in people
6
7 134 with mobility limitations is complex so we hypothesise that tailored advice from
8
9 135 physiotherapists will enhance activity levels.

10
11 136 In consultation with consumers, clinicians, and policy makers, our multidisciplinary
12
13 137 investigator team developed two intervention packages based on behaviour change theories
14
15 138 as outlined in the logic model (Fig. 1) and Table 1 and 2.^{16,24,25} Both interventions involve
16
17 139 the development of a goal-based tailored physical activity plan (made in conjunction with a
18
19 140 physiotherapist and sent to participants and their primary care physician (referred as a
20
21 141 General Practitioner (GP)) to reinforce physical activity participation), access to
22
23 142 informational and motivational print and on-line resources and encouragement of use of
24
25 143 activity monitors and suitable smart phone applications. We hypothesise that greater effects
26
27 144 on measured physical activity levels will be evident from an enhanced intervention package
28
29 145 (that also includes a face-to-face assessment and ongoing phone-based physical activity
30
31 146 phone coaching both provided by a physiotherapist) compared to a less intensive
32
33 147 intervention package (that includes a single phone call from a physiotherapist and text
34
35 148 messages). We further hypothesise that both these interventions will have greater impacts on
36
37 149 physical activity levels than no intervention.

38 150

39 151 **Methods and analysis**

40 152 Overview

41 153 This pragmatic hybrid effectiveness-implementation design (Type 1) superiority trial (n=600)
42
43 154 will use 1:1 concealed on-line randomisation to allocate adults with self-reported mobility
44
45 155 limitations to a 6-month enhanced intervention, a 6-month less intensive intervention or a
46
47 156 waiting list control group (who will receive the less intensive intervention after 6 months).
48
49 157 Between-group comparisons will be undertaken at 6 months (all groups) and at 12 months
50
51 158 (comparing two intervention groups).

52
53 159 The study primarily aims to establish the effects of the interventions, compared to each other
54
55 160 and to control, on objectively-measured physical activity at 6-months (*Stepwatch*, steps per
56
57 161 day). Secondary outcomes include other physical activity measures, measures of health and
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59 162 functioning, individualised mobility goal attainment, mental wellbeing, quality of life, rate of
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163 falls, health utilisation and intervention evaluation. Secondary analyses will explore
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differential effects on the basis of recruitment source (health professional referral versus

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3 165 community advertising), assess implementation outcomes, and establish the cost-
4
5 166 effectiveness and cost-utility.

6
7 167 The trial is more pragmatic than explanatory in that it uses recruitment and intervention
8
9 168 strategies relevant to the “real-world” and is intended to help support a decision on whether
10
11 169 such interventions should be delivered. A more explanatory trial would be undertaken in an
12
13 170 idealised setting, to give the intervention its best chance to demonstrate a beneficial effect.²⁶
14
15 171 A hybrid effectiveness-implementation design (Type 1)²⁷ will be used to collect
16
17 172 implementation outcomes at the same time as effectiveness outcomes. A nested process
18
19 173 evaluation will use both quantitative and qualitative methods to explore uptake by participants
20
21 174 and acceptability of the intervention (to participants, health coaches and other stakeholders).
22
23 175 The protocol for the process evaluation will be described elsewhere. The PRACTIS guide²⁸
24
25 176 to implementation and scale-up of physical activity interventions was used to ensure that the
26
27 177 interventions (and study recruitment methods) were as potentially scalable in future as
28
29 178 possible. Future scale-up of the interventions, if found to be effective, will be guided by the
30
31 179 model developed by Milat et al,²⁹ along with the implementation outcomes and other aspects
32
33 180 of the process evaluation. An economic analysis, which will be conducted alongside the trial,
34
35 181 will aim to establish the cost-effectiveness and cost-utility of the interventions compared to
36
37 182 no intervention and to each other to assist funders of preventive health interventions to assess
38
39 183 the value of such an approach for future investments. Table 1 shows the reasons for choice
40
41 184 of different components, Table 2 overviews the intervention in TIDieR format and Figure 1
42
43 185 shows the overall logic and broader context for the trial. The first participant was recruited
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45 186 on 13 February 2019 and at the time of submission of this manuscript 156 participants had
46
47 187 been randomised.

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49 188 The primary comparisons will assess the effect on objectively measured physical activity at
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51 189 6 months of the

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53 190 i) enhanced intervention package (*Coaching to ComeBACK* group: one face-to-face
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55 191 assessment from a physiotherapist, tailored physical activity plan sent to
56
57 192 participant and GP, physical activity phone coaching from a physiotherapist,
58
59 193 activity monitors and/or apps, booklet and access to on-line resources) compared
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194 with a less intensive intervention package (*Texting to ComeBACK* group: single
195 session of tailored advice by phone from a physiotherapist with health coaching
196 training, tailored physical activity plan sent to participant and GP, unidirectional
197 text messages, booklet and access to on-line resources);

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3 198 ii) the enhanced intervention package (*Coaching to ComeBACK* group) compared
4
5 199 with no intervention (*Texting to ComeBACK Later* waiting list control group);
6
7 200 iii) the less intensive intervention package (*Texting to ComeBACK* group) compared
8
9 201 with no intervention (*Texting to ComeBACK Later* waiting list control group).
10
11 202
12 203

14 204 Participants

16 205 The trial will be conducted across four Australian states with recruitment through health
17 206 services in hospital departments and the general community through community organisations
18 207 as well as traditional and social media advertisements and stories. Participants with a range of
19 208 health conditions who report difficulty or inability to walk 800m³⁰ will be recruited. The
20 209 process evaluation will explore differences in feasibility and efficiency of recruitment in each
21 210 of the settings to inform future implementation strategies.

27 211 The trial will involve consenting adults (18+ years) who are: living in the community (as
28 212 opposed to residential care); have a mobility limitation (self-reported difficulty or inability to
29 213 walk 800m) but are able to leave their home without physical assistance from another person
30 214 (but may use a walking aid); are judged by recruitment staff to have sufficient hearing and
31 215 English language skills for a phone-based intervention. Trial participants are likely to be
32 216 affected by one or more common and/or burdensome conditions such as, but not limited to,
33 217 osteoarthritis, lower limb fractures, lower limb amputations, stroke, brain injury, respiratory
34 218 conditions and obesity. The trial will exclude adults who are: permanent residents of residential
35 219 aged care facilities; have the following medical conditions: delirium, acute medical illnesses,
36 220 severe psychiatric disorders, rapidly progressive neurological diseases; have a major cognitive
37 221 impairment (a diagnosis of dementia or a Memory Impairment Screen score of less than 5); are
38 222 currently undertaking 150 minutes or more of moderate to vigorous physical activity per week
39 223 (based on self-report); full-time wheelchair user; unable to wear a *StepWatch Activity Monitor*;
40 224 not a regular user of a mobile phone (look at phone less than once per week); or have no internet
41 225 access.
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55 227 Randomisation

57 228 Each participant will be randomised to one of the three groups after completion of baseline
58 229 assessments. The trial will use a centralised web-based randomisation system using REDCap
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3 230 (Research Electronic Data Capture). The randomisation schedule was developed by a
4
5 231 researcher not involved in recruitment, outcome measurement or intervention delivery. This
6
7 232 process will ensure concealment of allocation to groups and an auditable process.
8
9 233 Randomisation to groups will be stratified by whether participants were recruited from the
10
11 234 general community (via advertising etc) or from health services.

12 235

13 14 236 Assessments

15
16 237 Assessments will occur prior to randomisation and at 3, 6 and 12 months after randomisation.
17
18 238 The matchbox-sized *StepWatch Activity Monitors* used to objectively measure physical
19
20 239 activity (primary outcome 6 month, secondary outcome 12 month) will be mailed to
21
22 240 participants with reply-paid envelopes and clear instructions for use and will be worn at the
23
24 241 ankle during waking hours for periods of seven consecutive days. Telephone calls will be
25
26 242 made to participants who have not returned the devices and to those who require assistance
27
28 243 wearing the device. Questionnaires will be administered online by participants or, if preferred
29
30 244 mailed, or by phone by a research assistant unaware of intervention group allocation. Monthly
31
32 245 on-line or paper calendars, with phone follow-up where necessary, will be used by participants
33
34 246 to report falls and health and community service usage over the 12-month trial period to enable
35
36 247 cost collation for the economic analyses. Where possible, data for all outcomes will be
37
38 248 collected for all participants including those who cease participation in the interventions,
39
40 249 unless the participant wishes to withdraw from the study. The primary outcome will be
41
42 250 collected in a blinded fashion. *StepWatch Activity Monitor* data will be processed and analysed
43
44 251 by staff unaware of intervention group allocation. All baseline measurements will be
45
46 252 undertaken prior to group allocation. Due to the nature of the intervention being tested, full
47
48 253 blinding of participants to intervention group allocation will not be possible. All the
49
50 254 reassessment questionnaires will however be undertaken by researchers blinded to group
51
52 255 allocation. Table 3 overviews the trial outcomes and measurement timepoints.

53 256

54 257 Outcomes

55
56 258 The primary outcome for the trial is physical activity, measured as average steps per day over
57
58 259 a one-week period at 6 months post baseline with the *StepWatch Activity Monitor*. This device
59
60 260 was chosen as prior research by the present authors³¹ found it to be the most accurate device
261 for step measurement in people with mobility impairment with average 98% (SD 12%)

1
2
3 262 agreement with investigator-observed steps over a 6-minute period as opposed to 17% (SD
4 263 19%) for the more commonly-used *Actigraph* device. The *StepWatch Activity Monitor* is
5 264 simple to use, can be mailed to participants and does not give feedback to the wearer.

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7
8 265 Secondary outcomes will be measured at 3, 6 and 12 months post baseline. Measures
9 266 undertaken at 12 months will compare the two intervention groups and assess physical activity
10 267 maintenance in the intervention groups and uptake in the waiting list control group (*Texting*
11 268 *to ComeBACK Later* Group). Secondary outcomes include other physical activity measures
12 269 (self-reported physical activity using the Incidental and Planned Exercise Questionnaire³²,
13 270 cadence, activity intensity (6 and 12 months only) and average steps per day (12 months only)
14 271 from the *StepWatch Activity Monitor*, global perceived change scores for physical activity and
15 272 walking, attitudes to and experience of physical activity), pain (study specific questions),
16 273 lower limb function and disability (Late Life Function and Disability Instrument³³), fear of
17 274 falling and self-reported balance (5-point scales), individualised mobility goal attainment
18 275 (Goal Attainment Scale³⁴ at 6 and 12 months), mental wellbeing (Warwick-Edinburgh Mental
19 276 Well-being Scale³⁵), quality of life (EuroQol 5D-5L³⁶), Body Mass Index, use of mobility
20 277 aids, rate of falls and health utilisation (monitored using monthly calendars over 12 months),
21 278 and measures evaluating impressions (study specific) and enjoyment (Physical Activity
22 279 Enjoyment Scale)³⁷ of the interventions and the therapeutic alliance between health coaches
23 280 and participants (Working Alliance Inventory).³⁸ The EuroQol 5D-5L will also be used to
24 281 enable calculation of quality-adjusted life years (QALYs) for the economic analyses.

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40 283 *Other measures* Intervention costs and health and community service utilisation, as collected
41 284 by monthly calendars, will be recorded for all participants and used as part of the economic
42 285 evaluation. The experiences and attitudes of stakeholders, including participants, health
43 286 coaches, clinicians and health service managers will be explored via semi structured interviews
44 287 and focus groups in order to inform future development and implementation of the
45 288 ComeBACK interventions.

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51 289
52 290 Adverse events will be defined as an unwanted and usually harmful outcome (e.g. exercise-
53 291 related falls, musculoskeletal injury, angina, shortness of breath or cardiovascular event). The
54 292 event may or may not be related to the intervention, but it occurs while the person is
55 293 participating in the intervention phase of the trial i.e. while they are doing mobility or physical
56 294 activities. A minor adverse event is defined as an incident that results in no injury or minor
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3 295 injury. For example, a fall where the person sustains a small cut or bruise that requires none
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5 296 or minor medical intervention. A serious adverse event is defined as an incident that results
6
7 297 in death, serious injury or hospitalisation. Adverse events will be monitored by records kept
8
9 298 by participants and interviews at each follow-up period. Participants will also be asked to
10
11 299 notify study staff immediately of any serious adverse events. Any adverse event occurring
12
13 300 during the assessment and intervention process will be reported back to authors Hassett and
14
15 301 Sherrington. It will then be decided if this is a recognised or unintended event relating to the
16
17 302 study protocol. Unintended events will be reported to the 3-person independent Data
18
19 303 Monitoring Committee that has been established for this trial and comprises one medical
20
21 304 professional and two allied health professionals experienced in the care of people with
22
23 305 mobility limitations. Unintended events will also be reported to the approving HREC. The
24
25 306 research team will review the event and determine whether it is person specific or whether
26
27 307 there is a potential for this to occur to other participants and therefore consideration would be
28
29 308 given as to appropriateness of continuing the research. Participants may experience muscle
30
31 309 soreness at the start of the physical activity program. This will be minimised by advice to
32
33 310 increase activity levels gradually and to seek professional advice if soreness lasts for more
34
35 311 than three days or interferes with daily activities.

312

313 Interventions

314 Intervention design was undertaken by our multi-disciplinary author team guided by formal
315 (qualitative pilot work) and informal input from consumers in the target population as well as
316 consultations with clinicians, health service managers, population health service providers
317 and health policy makers. The COM-B (Capability Opportunity Motivation → Behaviour)
318 model of behaviour change¹⁶ was used to guide the intervention design, with self-
319 determination theory²⁴ and social cognitive theory²⁵ further underpinning the motivational
320 component. Table 1 overviews the aspects of the COM-B addressed by each aspect of the
321 intervention packages. Table 2 provides more detail on the interventions using the TIDieR
322 format.³⁹ The interventions are as follows.

323

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

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

1
2
3 328 physiotherapist (employed locally). Where a home visit is not possible, a video conference
4
5 329 will be conducted as an alternative. At the end of the assessment, a phone or videoconference
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7 330 call will be made to the health coach with both physiotherapist and the participant present to
8
9 331 introduce and handover to the health coach and discuss any particular issues.

10 332 *ii) phone-based health coaching* will be delivered by trained physiotherapists through a
11
12 333 centralised service. The initial session will include development of a tailored plan to improve
13
14 334 physical activity through participation in suitable activities in negotiation with the participant
15
16 335 and their carers (where appropriate). The choice of physical activity will be guided by
17
18 336 personal preference, logistics, physical abilities and evidence of effectiveness of different
19
20 337 intervention options. The coach will liaise with relevant treating health professionals to
21
22 338 identify contraindications or precautions to exercise and ensure other causes of mobility
23
24 339 limitation are optimally managed. Coaching sessions will be delivered at a tailored frequency
25
26 340 of approximately every 2 weeks over a 6-month period and will take an average of 20-30
27
28 341 min each session. The coaching will incorporate behaviour change strategies including
29
30 342 motivational interviewing (to explore and enhance reasons for being active (importance) and
31
32 343 confidence to make changes, as well as to explore social influences on activity) goal-setting,
33
34 344 problem-solving, building social support and experiential learning. The individually-
35
36 345 tailored, person-centred approach will determine each person's physical, cognitive, affective,
37
38 346 environmental and social barriers and facilitators to physical activity and develop physical
39
40 347 activity recommendations (including adaptations and/or assistance to overcome specific
41
42 348 barriers) for each individual. The health coach will link participants to existing community
43
44 349 programs if desired, with a focus on identifying activities that participants will enjoy.⁴⁰
45
46 350 Suitable options may include attendance at a group program, such as those indexed on the
47
48 351 *Active and Healthy* website (www.activeandhealthy.nsw.gov.au) and/or participation in
49
50 352 sporting opportunities that cater for people with impaired mobility. The coaching will also
51
52 353 encourage reduced sedentary and inactive time by spending more time standing and walking
53
54 354 or undertaking a home based exercise program, as well as increased use of active transport
55
56 355 (i.e. walking, using public transport). Staff have extensive experience in the management of
57
58 356 people with walking limitations, have undertaken courses in health coaching and received
59
60 357 two days of additional training in using behaviour change science and self-determination
358 theory to guide intervention from author Greaves.

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

1
2
3 362 behavioural reinforcement.⁴¹

4
5 363 *iv) physical activity plan* developed jointly as outlined above will be shared with the
6
7 364 participant's GP with his/her consent soon after it is developed.

8
9 365 *v) paper-based booklet* on physical activity, safe mobility and behaviour change that is
10
11 366 study-specific, evidence-based and theoretically informed (by incorporating messaging and
12
13 367 images that are consistent with self-determination theory (promoting autonomy, competence
14
15 368 and relatedness for walking behaviour) and social cognitive theory (supporting self-
16
17 369 regulation and identifying /reinforcing the perceived benefits (social, physical,
18
19 370 emotional/affective).

20
21 371 *vi) closed study website* with 3 components: 1) why be active (incorporating motivational
22
23 372 components consistent with self-determination theory); 2) how to be active (links to
24
25 373 resources); 3) how others do it (video case studies using modelling of successful peer
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27 374 behaviour as per Social Cognitive Theory).

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

379 *i) single session of tailored advice provided by phone by a physiotherapist.* This call will last
380 50-60 minutes, will be informed by the baseline assessment results and provide advice about
381 appropriate physical activity opportunities for the person's interests and level of mobility. A
382 follow-up email will be sent to summarise and reinforce key discussion points.

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

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

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3 395 *iv) paper-based booklet* that has study-specific information on physical activity, safe
4 396 mobility and behaviour change that is evidence-based and theoretically informed (as
5 397 outlined above).

8 398 *v) closed study website* with 3 components: 1) why be active; 2) how to be active (links to
9 399 resources including recommended activity monitors and physical activity Apps); 3) how
10 400 others do it (video case studies using modelling of successful peer behaviour as per Social
11 401 Cognitive Theory).

12 402

13 403 Group 3: Texting to ComeBACK Later (waiting list control). This group will not receive any
14 404 intervention for the first 6 months of the trial but will be advised to continue usual activity
15 405 levels and health service use. After 6 months, this group will receive the Texting to
16 406 ComeBACK intervention package as outlined above.

17 407

18 408 Patient and public involvement

19 409 Consultations with consumers, clinicians, and policy makers assisted in the design of
20 410 intervention and study methods. This input was gained from a) input from our multidisciplinary
21 411 study team that includes health service managers and clinicians; b) from informal discussions
22 412 with health service managers, health professionals, health service users, community members
23 413 and those delivering interventions in our previous trials,⁴²⁻⁴⁴ c) formal qualitative work
24 414 involving participants in our previous trials^{45,46} and our systematic reviews of qualitative
25 415 studies.^{47,48}

26 416

27 417 The study protocol and choice of intervention and assessment tools (including the burden on
28 418 participants) was further guided by feedback from consumers obtained as part of the
29 419 endorsement of the trial by the Australia & New Zealand Musculoskeletal Clinical Trials
30 420 Network (ANZMUSC). Study results will be disseminated to participants via email or paper
31 421 letters.

32 422

33 423 Sample size

34 424 The trial's sample size (n=600) will provide 90% power to detect between-group differences of
35 425 1000 steps per day assuming a standard deviation of 3000 steps (estimated from our pilot data),
36 426 a dropout rate of 20%, alpha of 0.0167 (to adjust for multiplicity due to 3 trial arms), and
37 427 correlation between initial and final measures of 0.6 (from our pilot data). This calculation was
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3 428 undertaken in Stata 13 using the *sampsi* command. On the basis of previous work by the
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5 429 investigators and others, we consider between-group differences of this magnitude to be likely
6
7 430 to result in significant health benefits because 1000 steps/day, assuming a cadence of 80
8
9 431 steps/min, would equate to an additional 15 minutes of walking/day, a dose associated with
10
11 432 health benefits and reduced mortality even in those with cardiovascular disease.⁴⁹

12 433

13 434 Statistical analysis

15 435 Analysis of covariance, conducted using a linear regression approach, will be used to assess the
16
17 436 effect of group allocation on the continuously-scored primary and secondary outcomes after
18
19 437 adjusting for baseline scores and source of recruitment. Point estimates and their 95%
20
21 438 confidence intervals will be used to interpret results. Given our interest in comparing the two
22
23 439 interventions with each other and with the control condition, between-group differences with
24
25 440 p-values < 0.0167 will be considered significant. Planned sub-group analyses will assess
26
27 441 differential effects of the intervention based on the stratification variable of recruitment source,
28
29 442 as well as for severity of mobility limitation and age. Secondary analyses using causal
30
31 443 modelling will be conducted to establish intervention effects in people with greater adherence.
32
33 444 Analyses will be pre-planned, by intention-to-treat, conducted while masked to group
34
35 445 allocation and undertaken after range checks. A detailed Statistical Analysis Plan will be
36
37 446 developed and signed off by all investigators prior to analysis.

36 447

38 448 The economic evaluation will take the perspective of the health and community care funder.

40 449 Health care costs, community service costs and intervention costs will be collected over the
41
42 450 trial period. Using mean costs and mean health outcomes in each trial arm, the incremental
43
44 451 costs per 1) additional person with increased physical activity of more than 1000 steps per
45
46 452 day; and 2) QALY gained will be calculated; results will be plotted on a cost-effectiveness
47
48 453 plane. Bootstrapping will be used to estimate a distribution around costs and health outcomes,
49
50 454 and to calculate the confidence intervals around the incremental cost- effectiveness ratios.
51
52 455 One-way sensitivity analysis will be conducted around key variables and a probabilistic
53
54 456 sensitivity analysis will estimate uncertainty in all parameters. A cost-effectiveness
55
56 457 acceptability curve will be plotted to provide information about the probability that the
57
58 458 intervention is cost-effective, given willingness to pay for each benefit gained. Modelled
59
60 459 analyses will explore the longer term cost-effectiveness of the intervention.

59 460

461 **Ethics and dissemination**

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

474

475 **Discussion**

476

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

485

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

489

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

493

494 **Author contributions**

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

513

514

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521 authority over any of these activities.

522

523 **Competing interests statement**

524 The authors do not report any competing interests.

525

526 **Word Count:** 5154 words (excluding references and tables)

527

528 **References**

- 529 1. WHO. Towards a common language for functioning, disability and health: ICF. . 2002.
- 530 2. AIHW. *Australia's Welfare*. Canberra: Australian Institute of Health and Welfare.;2015.
- 531 3. Cummings SR, Studenski S, Ferrucci L. A diagnosis of disability--giving mobility clinical
532 visibility: a Mobility Working Group recommendation. *Jama*. 2014;311(20):2061-2062.
- 533 4. Ma VY, Chan L, Carruthers KJ. Incidence, prevalence, costs, and impact on disability of
534 common conditions requiring rehabilitation in the United States: stroke, spinal cord injury,
535 traumatic brain injury, multiple sclerosis, osteoarthritis, rheumatoid arthritis, limb loss, and
536 back pain. *Archives of physical medicine and rehabilitation*. 2014;95(5):986-995.e981.
- 537 5. Jones E, Pike J, Marshall T, Ye X. Quantifying the relationship between increased disability
538 and health care resource utilization, quality of life, work productivity, health care costs in
539 patients with multiple sclerosis in the US. *BMC health services research*. 2016;16:294.
- 540 6. Espahbodi S, Bassett P, Cavill C, Freeth M, Hole J, Sengupta R. Fatigue contributes to work
541 productivity impairment in patients with axial spondyloarthritis: a cross-sectional UK study.
542 *Clinical and experimental rheumatology*. 2017;35(4):571-578.
- 543 7. Das P, Horton R. Physical activity-time to take it seriously and regularly. *Lancet (London,*
544 *England)*. 2016;388(10051):1254-1255.
- 545 8. Lee IM, Shiroma EJ, Kamada M, Bassett DR, Matthews CE, Buring JE. Association of Step
546 Volume and Intensity With All-Cause Mortality in Older Women. *JAMA internal medicine*.
547 2019.
- 548 9. Dwyer T, Pezic A, Sun C, et al. Objectively Measured Daily Steps and Subsequent Long
549 Term All-Cause Mortality: The Tasped Prospective Cohort Study. *PLoS one*.
550 2015;10(11):e0141274.
- 551 10. Hoffmann TC, Maher CG, Briffa T, et al. Prescribing exercise interventions for patients with
552 chronic conditions. *CMAJ : Canadian Medical Association journal = journal de l'Association
553 medicale canadienne*. 2016;188(7):510-518.
- 554 11. Garber CE, Blissmer B, Deschenes MR, et al. American College of Sports Medicine position
555 stand. Quantity and quality of exercise for developing and maintaining cardiorespiratory,
556 musculoskeletal, and neuromotor fitness in apparently healthy adults: guidance for
557 prescribing exercise. *Medicine and Science in Sports and Exercise*. 2011;43(7):1334-1359.
- 558 12. Pollock RD, Carter S, Velloso CP, et al. An investigation into the relationship between age
559 and physiological function in highly active older adults. *J Physiol*. 2015;593(3):657-680.
- 560 13. Pahor M, Guralnik JM, Ambrosius WT, et al. Effect of structured physical activity on
561 prevention of major mobility disability in older adults: the LIFE study randomized clinical
562 trial. *Jama*. 2014;311(23):2387-2396.
- 563 14. Carroll DD, Courtney-Long EA, Stevens AC, et al. Vital signs: disability and physical
564 activity--United States, 2009-2012. *MMWR Morbidity and mortality weekly report*.
565 2014;63(18):407-413.
- 566 15. ABS. Sports and Physical Recreation: A Statistical Overview, Australia. In: Australian
567 Bureau of Statistics; 2012.
- 568 16. Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for
569 characterising and designing behaviour change interventions. *Implementation Science*.
570 2011;6:42.
- 571 17. Hillsdon M, Thorogood M, White I, Foster C. Advising people to take more exercise is
572 ineffective: a randomized controlled trial of physical activity promotion in primary care.
573 *International journal of epidemiology*. 2002;31(4):808-815.
- 574 18. Richards J, Hillsdon M, Thorogood M, Foster C. Face-to-face interventions for promoting
575 physical activity. *The Cochrane database of systematic reviews*. 2013;9:Cd010392.
- 576 19. Foster C, Richards J, Thorogood M, Hillsdon M. Remote and web 2.0 interventions for
577 promoting physical activity. *The Cochrane database of systematic reviews*.
578 2013;9:Cd010395.
- 579 20. Greaves CJ, Sheppard KE, Abraham C, et al. Systematic review of reviews of intervention
580 components associated with increased effectiveness in dietary and physical activity
581 interventions. *BMC public health*. 2011;11:119.

- 1
2
3 582 21. Oliveira J, Sherrington C, Amorim A, Dario A, Tiedemann A. What is the effect of health
4 583 coaching on physical activity participation in people aged 60 years and over?: A systematic
5 584 review of randomised controlled trials. . *British Journal of Sports Medicine*. 2017;51:1425-
6 585 1432.
- 7 586 22. O'Halloran PD, Blackstock F, Shields N, et al. Motivational interviewing to increase physical
8 587 activity in people with chronic health conditions: a systematic review and meta-analysis. *Clin*
9 588 *Rehabil*. 2014;28(12):1159-1171.
- 10 589 23. O'Halloran PD, Shields N, Blackstock F, Wintle E, Taylor NF. Motivational interviewing
11 590 increases physical activity and self-efficacy in people living in the community after hip
12 591 fracture: a randomized controlled trial. *Clin Rehabil*. 2016;30(11):1108-1119.
- 13 592 24. Ryan RM, Deci EL. Self-determination theory and the facilitation of intrinsic motivation,
14 593 social development, and well-being. *The American psychologist*. 2000;55(1):68-78.
- 15 594 25. Bandura A. *Social foundations of thought and action: A social cognitive theory*. Englewood
16 595 Cliffs, NJ: Prentice-Hall; 1986.
- 17 596 26. Loudon K, Treweek S, Sullivan F, Donnan P, Thorpe KE, Zwarenstein M. The PRECIS-2
18 597 tool: designing trials that are fit for purpose. *BMJ (Clinical research ed)*. 2015;350:h2147.
- 19 598 27. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid
20 599 designs: combining elements of clinical effectiveness and implementation research to enhance
21 600 public health impact. *Medical Care*. 2012;50(3):217-226.
- 22 601 28. Koorts H, Eakin E, Estabrooks P, Timperio A, Salmon J, Bauman A. Implementation and
23 602 scale up of population physical activity interventions for clinical and community settings: the
24 603 PRACTIS guide. *The international journal of behavioral nutrition and physical activity*.
25 604 2018;15(1):51.
- 26 605 29. Milat AJ, Newson R, King L. *Increasing the scale and adoption of public health*
27 606 *interventions: A guide for developing a scaling up strategy*. North Sydney: NSW Ministry of
28 607 Health;2014.
- 29 608 30. Weiss CO, Fried LP, Bandeen-Roche K. Exploring the hierarchy of mobility performance in
30 609 high-functioning older women. *J Gerontol A Biol Sci Med Sci*. 2007;62(2):167-173.
- 31 610 31. Treacy D, Hassett L, Schurr K, Chagpar S, Paul S, Sherrington C. Physical Therapy. .
32 611 *Validity of different activity monitors to count steps in an inpatient rehabilitation setting*.
33 612 Accepted 12 Dec 2016.
- 34 613 32. Delbaere K, Hauer K, Lord S. Evaluation of the Incidental and Planned Exercise
35 614 Questionnaire (IPEQ) for older people. *British Journal of Sports Medicine* 2010;44:1029-
36 615 1034.
- 37 616 33. Jette AM, Haley SM, Coster WJ, et al. Late life function and disability instrument: I.
38 617 Development and evaluation of the disability component. *J Gerontol A Biol Sci Med Sci*.
39 618 2002;57(4):M209-216.
- 40 619 34. Tennant A. Goal attainment scaling: current methodological challenges. *Disabil Rehabil*.
41 620 2007;29(20-21):1583-1588.
- 42 621 35. Tennant R, Hiller L, Fishwick R, et al. The Warwick-Edinburgh Mental Well-being Scale
43 622 (WEMWBS): development and UK validation. *Health Qual Life Outcomes*. 2007;5:63.
- 44 623 36. EuroQol--a new facility for the measurement of health-related quality of life. *Health policy*
45 624 *(Amsterdam, Netherlands)*. 1990;16(3):199-208.
- 46 625 37. Kendzierski D, DeCarlo KJ. Physical Activity Enjoyment Scale: Two Validation Studies.
47 626 1991;13(1):50.
- 48 627 38. Hatcher RL, Gillaspay JA. Development and validation of a revised short version of the
49 628 Working Alliance Inventory. *Psychotherapy Research*. 2006;16(1):12-25.
- 50 629 39. Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for
51 630 intervention description and replication (TIDieR) checklist and guide. *BMJ (Clinical research*
52 631 *ed)*. 2014;348:g1687.
- 53 632 40. Kiviniemi MT, Voss-Humke AM, Seifert AL. How do I feel about the behavior? The
54 633 interplay of affective associations with behaviors and cognitive beliefs as influences on
55 634 physical activity behavior. *Health psychology : official journal of the Division of Health*
56 635 *Psychology, American Psychological Association*. 2007;26(2):152-158.

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3 636 41. J SO, Sherrington C, E RYZ, Franco MR, Tiedemann A. Effect of interventions using
4 637 physical activity trackers on physical activity in people aged 60 years and over: a systematic
5 638 review and meta-analysis. *Br J Sports Med*. 2019.
- 6 639 42. Tiedemann A, Rissel C, Howard K, et al. Health coaching and pedometers to enhance
7 640 physical activity and prevent falls in community-dwelling people aged 60 years and over:
8 641 study protocol for the Coaching for Healthy AGEing (CHAnGE) cluster randomised
9 642 controlled trial. *BMJ open*. 2016;6(5):e012277.
- 10 643 43. Hassett L, van den Berg M, Lindley RI, et al. Effect of affordable technology on physical
11 644 activity levels and mobility outcomes in rehabilitation: a protocol for the Activity and
12 645 MObility UsiNg Technology (AMOUNT) rehabilitation trial. *BMJ open*. 2016;6(6):e012074.
- 13 646 44. Oliveira JS, Sherrington C, Paul SS, et al. A combined physical activity and fall prevention
14 647 intervention improved mobility-related goal attainment but not physical activity in older
15 648 adults: a randomised trial. *Journal of physiotherapy*. 2019;65(1):16-22.
- 16 649 45. Hamilton C, McCluskey A, Hassett L, Killington M, Lovarini M. Patient and therapist
17 650 experiences of using affordable feedback-based technology in rehabilitation: a qualitative
18 651 study nested in a randomized controlled trial. *Clin Rehabil*. 2018;32(9):1258-1270.
- 19 652 46. Haynes ASCWGTAMDRCLDTA. "Someone's got my back": Older people's experience of
20 653 the Coaching for Healthy Ageing program for promoting physical activity and preventing
21 654 falls. *Journal of Aging and Physical Activity*. Accepted 9 July 2019.
- 22 655 47. Franco MR, Tong A, Howard K, et al. Older people's perspectives on participation in physical
23 656 activity: a systematic review and thematic synthesis of qualitative literature. *Br J Sports Med*.
24 657 2015;49(19):1268-1276.
- 25 658 48. Jang H, Clemson L, Lovarini M, Willis K, Lord SR, Sherrington C. Cultural influences on
26 659 exercise participation and fall prevention: a systematic review and narrative synthesis. *Disabil*
27 660 *Rehabil*. 2016;38(8):724-732.
- 28 661 49. Wen CP, Wai JP, Tsai MK, et al. Minimum amount of physical activity for reduced mortality
29 662 and extended life expectancy: a prospective cohort study. *Lancet (London, England)*.
30 663 2011;378(9798):1244-1253.
- 31 664 50. Farag I, Howard K, Ferreira ML, Sherrington C. Economic modelling of a public health
32 665 programme for fall prevention. *Age Ageing*. 2015;44(3):409-414.
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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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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 <u>capability</u> to suggest appropriate <u>opportunities</u> . Establishing /building <u>motivation</u> .
Patient-centred health coaching, incorporating behaviour change strategies including goal-setting and motivational interviewing	<ul style="list-style-type: none"> 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 <u>capability</u> to suggest appropriate <u>opportunities</u> . Encouragement of <u>capability</u> enhancement. Feedback to assist with ongoing <u>motivation</u> .
Activity monitor or pedometer if desired	<ul style="list-style-type: none"> known to enhance physical activity in general population well accepted in pilot among people with mobility limitations 	Feedback to assist with ongoing <u>motivation</u> .
Tailored use of apps to encourage physical activity	<ul style="list-style-type: none"> 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 <u>motivation</u> .
Paper-based and on-line resources to support behaviour change	<ul style="list-style-type: none"> provision of evidence-based information in attractive format including case studies to support behaviour change. 	Case studies and information to assist with <u>capability</u> and <u>motivation</u> .
Tailored physical activity plan developed and shared with GP	<ul style="list-style-type: none"> credible and trusted source reinforcing behaviour changes suggested by health coach 	Increased <u>motivation</u> .

Group 2: Texting to ComeBACK		
Single session of tailored advice over the phone from a physiotherapist	<ul style="list-style-type: none"> • 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 <u>capability</u> to suggest appropriate <u>opportunities</u> .
Paper-based and on-line resources to support behaviour change	<ul style="list-style-type: none"> • provision of evidence-based information in attractive format • including case studies to support behaviour change. 	Case studies and information to assist with <u>capability</u> and <u>motivation</u> .
Text messages	<ul style="list-style-type: none"> • 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 <u>motivation</u> and <u>problem-solving (capability)</u> .
Tailored physical activity plan developed and shared with GP	<ul style="list-style-type: none"> • credible and trusted source reinforcing behaviour changes suggested by health coach. 	Increased <u>motivation</u> .
Group 3: Texting to ComeBACK Later		
No intervention for 6 months	<ul style="list-style-type: none"> • pragmatic comparison • direct policy implications 	
Receipt of less intensive intervention after 6 months	<ul style="list-style-type: none"> • enhanced recruitment through provision of intervention for all participants. 	As above
Outcome		
Physical activity	<ul style="list-style-type: none"> • neglected costly population health problem. 	n/a

*Primarily using the COM-B system¹⁶ 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.

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

For peer review only

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	<ul style="list-style-type: none"> ➤ 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. 	<ul style="list-style-type: none"> ➤ 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#	<ul style="list-style-type: none"> ➤ 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. 	<ul style="list-style-type: none"> ➤ 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

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provided	<p>trained local physiotherapists either employed by the study, paid casually or employed in the local health service.</p> <ul style="list-style-type: none"> ➤ 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 <i>Wellness Coaching Australia; Health Change Australia</i> and <i>Medicoach</i> as well as receiving training by study investigator (CG) in advanced motivational interviewing, a framework for “good (functional) motivation” and intervention techniques. 	<p>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 <i>Wellness Coaching Australia; Health Change Australia</i> and <i>Medicoach</i> as well as receiving training by study investigator (CG) in advanced motivational interviewing, a framework for “good (functional) motivation” and intervention techniques.</p>
How	<ul style="list-style-type: none"> ➤ 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. 	<ul style="list-style-type: none"> ➤ 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	<ul style="list-style-type: none"> ➤ 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. 	<ul style="list-style-type: none"> ➤ 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	<ul style="list-style-type: none"> ➤ 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. 	<ul style="list-style-type: none"> ➤ 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

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Figure legend

Figure 1. Logic model for the ComeBACK intervention.

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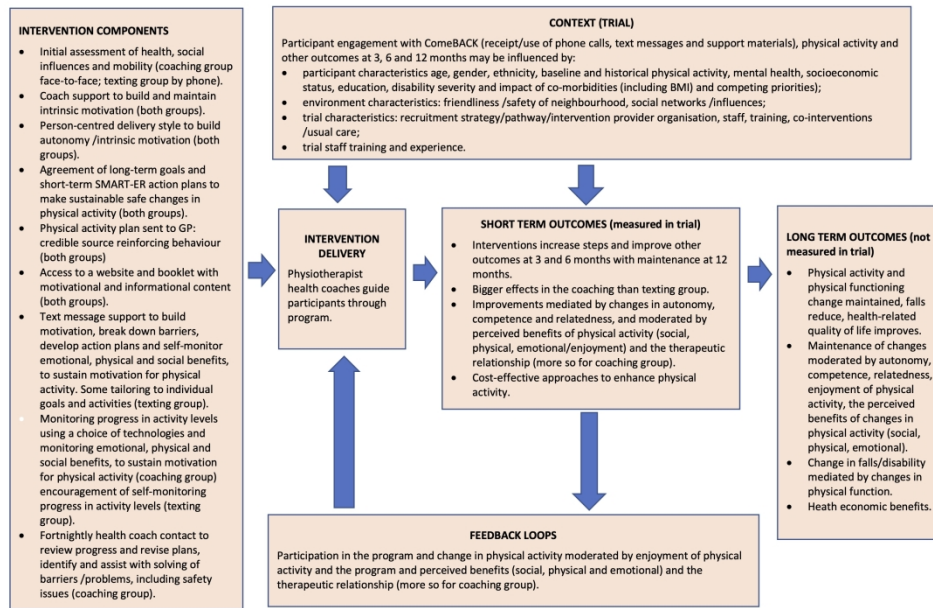


Figure 1. Logic model for the ComeBACK intervention.

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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

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2 recommendation made to incorporate physical activity into your daily routine will be negotiated
3 with you and this will be different for each person based on current activity levels and abilities.
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5 6 **Group 3 Texting to ComeBACK later group**

7 If you are allocated to the Texting to ComeBACK later group you will receive the usual care
8 provided by your health service providers for the first 6 months of the study. You will have no
9 contact with the study staff apart from the baseline, 3 and 6-month questionnaires. Following the
10 6-month reassessment you will receive the same intervention as Group 2 (Texting to ComeBACK)
11 as described above. This includes the single phone session of tailored advice from a
12 physiotherapist to improve physical activity (generally 30-45 minutes) as well as text message
13 follow up for 6 months and access to online resources to support you to be more active.
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15 The overall time commitment for the initial 6 months of the study period if allocated to the
16 Texting to ComeBACK later group is 0 minutes per month. This will then increase to 5 minutes per
17 month of reading phone text messages for the next 6-month period. The recommendation made
18 for you to incorporate physical activity into your daily routine will be negotiated with you and this
19 will be different for each person based on current activity levels and abilities.
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22 23 **Falls and health utilisation calendars**

24 All study participants will be asked to return monthly calendars (by reply-paid mail) containing
25 questions on any falls and subsequent injuries you may experience along with health utilisation. If
26 calendars are not returned, you will be telephoned to ask if you experienced any falls and physical
27 activity-related injuries during the past month. In order to reduce the risk of bias, the research
28 team member who collects the monthly calendars will not be aware of which group you have
29 been allocated to.
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32 The researchers would like to evaluate the benefits of the study beyond the 6-month intervention
33 period so we ask you to complete the calendars for a 12-month period.
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36 37 **Data Linkage Study**

38 We would like to track hospital and emergency department admissions, ambulance services and
39 any study participant deaths (birth, marriages and death registry records) for up to 2 years after
40 the completion of the study to evaluate if there are any long-term effects from the intervention.
41 Therefore, the researchers would like your permission to link the information you provide within
42 the ComeBACK study, with other sources of information that are routinely collected and managed
43 via the Population Health Research Network (PHRN) for Health data Record Linkage. A strict
44 process will be followed as per Data Linkage policies that ensures the confidentiality of your data.
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48 Data linkage has been used by health systems for many years to bring together information about
49 people, places and events in a way that protects individual privacy and allows researchers and
50 policy makers to gain information and insights about the health and well-being of our community.
51 Data linkage studies have helped to provide valuable information on the causes of and risk factors
52 for disease as well as the evaluation of new approaches to preventing and treating health
53 problems.
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56 If you want to opt out of the linking of your health information, there is an option to indicate this choice on
57 the consent form by ticking the box for opt out.
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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)

1
2 Trial design 8 Description of trial design including type of trial (eg, parallel group,
3 crossover, factorial, single group), allocation ratio, and framework (eg,
4 superiority, equivalence, noninferiority, exploratory) (page 6)
5
6
7

8 **Methods: Participants, interventions, and outcomes**
9

10 Study setting 9 Description of study settings (eg, community clinic, academic hospital)
11 and list of countries where data will be collected. Reference to where
12 list of study sites can be obtained (page 7)
13

14 Eligibility criteria 10 Inclusion and exclusion criteria for participants. If applicable, eligibility
15 criteria for study centres and individuals who will perform the
16 interventions (eg, surgeons, psychotherapists) (page 7)
17
18

19 Interventions 11a Interventions for each group with sufficient detail to allow replication,
20 including how and when they will be administered (page 10, Table 1-
21 2)
22

23 11b Criteria for discontinuing or modifying allocated interventions for a
24 given trial participant (eg, drug dose change in response to harms,
25 participant request, or improving/worsening disease) n/a
26
27

28 11c Strategies to improve adherence to intervention protocols, and any
29 procedures for monitoring adherence (eg, drug tablet return,
30 laboratory tests) (page 10, Table 1-2)
31

32 11d Relevant concomitant care and interventions that are permitted or
33 prohibited during the trial (page 10, Table 1-2)
34

35 Outcomes 12 Primary, secondary, and other outcomes, including the specific
36 measurement variable (eg, systolic blood pressure), analysis metric
37 (eg, change from baseline, final value, time to event), method of
38 aggregation (eg, median, proportion), and time point for each
39 outcome. Explanation of the clinical relevance of chosen efficacy and
40 harm outcomes is strongly recommended (page 9)
41
42

43 Participant 13 Time schedule of enrolment, interventions (including any run-ins and
44 timeline washouts), assessments, and visits for participants. A schematic
45 diagram is highly recommended (see Figure) (page 9)
46
47

48 Sample size 14 Estimated number of participants needed to achieve study objectives
49 and how it was determined, including clinical and statistical
50 assumptions supporting any sample size calculations (page 13)
51
52

53 Recruitment 15 Strategies for achieving adequate participant enrolment to reach
54 target sample size (page 7)
55

56 **Methods: Assignment of interventions (for controlled trials)**
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58 Allocation:
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1			
2	Sequence	16a	Method of generating the allocation sequence (eg, computer-
3	generation		generated random numbers), and list of any factors for stratification.
4			To reduce predictability of a random sequence, details of any planned
5			restriction (eg, blocking) should be provided in a separate document
6			that is unavailable to those who enrol participants or assign
7			interventions (page 8)
8			
9			
10	Allocation	16b	Mechanism of implementing the allocation sequence (eg, central
11	concealment		telephone; sequentially numbered, opaque, sealed envelopes),
12	mechanism		describing any steps to conceal the sequence until interventions are
13			assigned (page 8)
14			
15	Implementation	16c	Who will generate the allocation sequence, who will enrol participants,
16			and who will assign participants to interventions (page 8)
17			
18			
19	Blinding	17a	Who will be blinded after assignment to interventions (eg, trial
20	(masking)		participants, care providers, outcome assessors, data analysts), and
21			how (page 8, page 13)
22			
23		17b	If blinded, circumstances under which unblinding is permissible, and
24			procedure for revealing a participant's allocated intervention during
25			the trial (n/a)
26			
27			

Methods: Data collection, management, and analysis

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29			
30	Data collection	18a	Plans for assessment and collection of outcome, baseline, and other
31	methods		trial data, including any related processes to promote data quality (eg,
32			duplicate measurements, training of assessors) and a description of
33			study instruments (eg, questionnaires, laboratory tests) along with
34			their reliability and validity, if known. Reference to where data
35			collection forms can be found, if not in the protocol (page 8-9)
36			
37			
38		18b	Plans to promote participant retention and complete follow-up,
39			including list of any outcome data to be collected for participants who
40			discontinue or deviate from intervention protocols (page 8)
41			
42	Data	19	Plans for data entry, coding, security, and storage, including any
43	management		related processes to promote data quality (eg, double data entry;
44			range checks for data values). Reference to where details of data
45			management procedures can be found, if not in the protocol (page 14)
46			
47			
48	Statistical	20a	Statistical methods for analysing primary and secondary outcomes.
49	methods		Reference to where other details of the statistical analysis plan can be
50			found, if not in the protocol (page 13)
51			
52		20b	Methods for any additional analyses (eg, subgroup and adjusted
53			analyses) (page 13)
54			
55		20c	Definition of analysis population relating to protocol non-adherence
56			(eg, as randomised analysis), and any statistical methods to handle
57			missing data (eg, multiple imputation) (page 13)
58			
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60			

Methods: Monitoring

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	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)
24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	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

26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	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)

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| 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) |

16 Appendices

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| 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) |

25 *It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013
26 Explanation & Elaboration for important clarification on the items. Amendments to the
27 protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT
28 Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)"
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