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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

Anne Tiedemann,[1] Chris Rissel,[2] Kirsten Howard,[2] Allison Tong,[2] Dafna Merom,[3] Stuart Smith,[4] James Wickham,[5] Adrian Bauman,[2] Stephen R Lord,[6] Constance Vogler,[7,8] Richard I Lindley,[1] Judy M Simpson,[2] Margaret Allman-Farinelli,[9] Catherine Sherrington[1]

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For numbered affiliations see end of article.

Correspondence to
A/Prof Anne Tiedemann; atiedemann@georgeinstitute.org.au

ABSTRACT

Introduction: Prevention of falls and promotion of physical activity are essential for maximising well-being in older age. However, there is evidence that promoting physical activity among older people without providing fall prevention advice may increase fall rates. This trial aims to establish the impact of a physical activity and fall prevention programme compared with a healthy eating programme on physical activity and falls among people aged 60+ years.

Methods and analysis: This cluster randomised controlled trial will involve 60 groups of community-dwelling people aged 60+ years. Participating groups will be randomised to: (1) a physical activity and fall prevention intervention (30 groups), involving written information, fall risk assessment and prevention advice, a pedometer-based physical activity tracker and telephone-based health coaching; or (2) a healthy eating intervention (30 groups) involving written information and telephone-based dietary coaching. Primary outcomes will be objectively measured physical activity at 12 months post-randomisation and self-reported falls throughout the 12-month trial period. Secondary outcomes include: the proportion of fallers, the proportion of people meeting the Australian physical activity guidelines, body mass index, eating habits, mobility goal attainment, mobility-related confidence, quality of life, fear of falling, risk-taking behaviour, mood, well-being, self-reported physical activity, disability, and health and community service use. The between-group difference in the number of falls per person-year will be analysed using negative binomial regression models. For the continuously scored primary and secondary outcome measures, linear regression adjusted for corresponding baseline scores will assess the effect of group allocation. Analyses will be preplanned, conducted while masked to group allocation, will take into account cluster randomisation, and will use an intention-to-treat approach.

Ethics and dissemination: Protocol has been approved by the Human Research Ethics Committee at The University of Sydney, Australia (number 2015/517). Results will be disseminated via peer-reviewed journal articles, international conference presentations and participants' newsletters.

Trial registration number: ACTRN12615001190594.

Strengths and limitations of this study

- Addresses a key gap in the current evidence regarding physical activity and fall prevention among older people.
- Evaluation of a model for an integrated falls and physical activity assessment and intervention programme that could be directly implemented within existing health services.
- One limitation of this study is that the health coaching approach requires tailoring to the individual participant which complicates descriptions of this aspect of the intervention content used for both arms of the trial. Careful reporting of the number of delivered health coaching sessions, and inclusion of the topics covered in the health coaching will be required to accurately communicate the intervention details.

INTRODUCTION

Physical inactivity[1] and falls[2] are both important public health problems that can substantially impact health and independence in

older age. Health conditions that could be ameliorated with physical activity are particularly common in older people.[3 4] Approximately 30% of people aged 65 years and over fall at least once each year.[5] In Australia, this currently equates to 1 million people.[6] Both these problems need to be urgently addressed, as the proportion of older people in the population is rapidly rising—by 2050 up to 25% of the Australian population (10.5 million people) will be aged 65 years and over.[6]

Good nutrition is also an essential element for maximising health in older age.[7] Undernutrition plays a significant role in age-related functional decline, frailty and disability.[8] Despite this, there is a lack of well conducted research to investigate the effect of nutrition-based interventions on disability, quality of life and other markers of health in older people.[9] A large proportion of Australian adults are also not meeting the recommendations of the Australian Dietary Guidelines in relation to healthy eating.[10]

Exercise that challenges balance is most effective in preventing falls,[11] but exercise interventions found to be effective for fall prevention have not generally been of a high enough dose to ensure participants also meet physical activity recommendations and obtain broader health benefits.[12] Furthermore, two previous randomised controlled trials of physical activity interventions that successfully increased physical activity levels actually also increased falls.[13 14] These interventions included face-to-face physical activity counselling, a written exercise prescription and telephone-based follow-up among women aged 40–75 years,[13] and a nurse-prescribed brisk walking programme among postmenopausal women with a history of recent upper limb fracture.[14] Cohort studies provide conflicting information about the relationship between falls and physical activity with some finding protective effects[15] and others finding higher falls rates in more active people[16] particularly those with mobility limitations.[17] Taken together, these results suggest that physical activity programmes for older adults should include fall prevention components to maximise health benefits.

Health coaching is an effective method to support behaviour change. There is sound evidence that structured telephone-based coaching services can lead to positive changes in health behaviours. This has included increased physical activity[18] as well as improved nutrition,[18] smoking cessation[19] and better management of chronic conditions.[20] Coaching services have a strong, evidence-based foundation in behaviour-change theories, such as Social Influence Theory, Social Cognitive Theory and the Transtheoretical Model,[21] and can be effectively delivered to large populations as part of preventive health services.[22]

Pedometer-based interventions can increase physical activity in older people. Pedometers are simple devices which record the number of steps an individual takes each day. Pedometers have demonstrated greater effects on physical activity than other intervention strategies including informational, behavioural and social approaches.[23] A key feature of pedometers is that they record incidental physical activity (eg, walking and stepping while completing household chores) in addition to more structured exercise participation (eg, going for a walk, undertaking a group exercise class). Several trials that have successfully increased physical activity in older people have used pedometers.[24] New technologies have enhanced pedometers with web and mobile phone feedback. New wearable activity monitors (such as the Fitbit) use sensor technology, are accurate[25] and provide accurate feedback on steps taken and distance travelled using personalised data tracking on websites, text messages and social media, yet are relatively affordable. These devices have the potential to be even more effective than traditional pedometers for increasing physical activity but have yet to be formally evaluated. Over 40% of older Australians are now regular internet users, so a web-linked approach is feasible in this population.[26]

We have developed a goal-based tailored physical activity and fall prevention intervention that uses health coaching, pedometer-based feedback and social interaction. We have pilot-tested this approach in people aged 60 years and older,[27] and preliminary results show that the intervention is well received and adhered to by older community dwellers.[28] Our intervention package is designed to increase physical activity and also prevent falls. We will implement this intervention with established groups of older people. This approach will encourage group members to support each other to become more active and use strategies to reduce their risk of falling as well as undertake physical activity together if they wish. This approach has been successfully used to promote participation in fall prevention exercise classes among seniors.[29]

The primary aim of this trial is to evaluate the effect of the combined physical activity promotion and fall prevention programme on objectively measured physical activity and self-reported falls compared with a healthy eating programme, among established groups of community-dwelling people aged 60 years and over. The secondary aims are to establish the impact of the interventions on the proportion of fallers, the proportion of people meeting the physical activity guidelines, body mass index, eating habits, mobility goal attainment, mobility-related confidence, quality of life, fear of falling, risk-taking behaviour, mood, well-being, self-reported physical activity and disability. We also aim to evaluate the cost-effectiveness and cost utility of these intervention approaches from the perspective of the health and community care funder.

METHODS AND ANALYSIS

Trial design

We will conduct a parallel group cluster randomised controlled trial. Each community-based group recruited will be considered as a cluster. The design of the trial is

illustrated in figure 1. This trial has been designed according to the CONsolidated Standards Of Reporting Trials (CONSORT) statement,[30] and is reported according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement,[31] and with reference to the Template for Intervention Description and Replication (TIDieR) checklist.[32]

Participants

Sixty groups (approximately 600 people) of consenting community-dwelling people aged 60 years and over will be randomised to either the physical activity and fall prevention intervention (30 groups), or a healthy eating intervention (30 groups). Groups will be eligible for inclusion in the trial if they include members who are predominantly aged 60 years and older, and if they hold meetings or other events for group members at least once every 2 months.

People will be eligible for inclusion in the trial if they: are aged 60+ years; are living in a private dwelling or retirement village; regularly attend (at least once every 2 months) meetings or other activities at the participating established community-based group.

Potential participants will be excluded from trial participation if they: already meet the Australian Physical Activity Guidelines for older adults[33] (operationalised as 150 min of moderate intensity physical activity per week, assessed using the Incidental and Planned Exercise Questionnaire (IPEQ)[34]), and have had a fall risk assessment and intervention programme in the past year; have a cognitive impairment (a diagnosis of dementia or a Memory Impairment Screen[35] score of less than 5); have

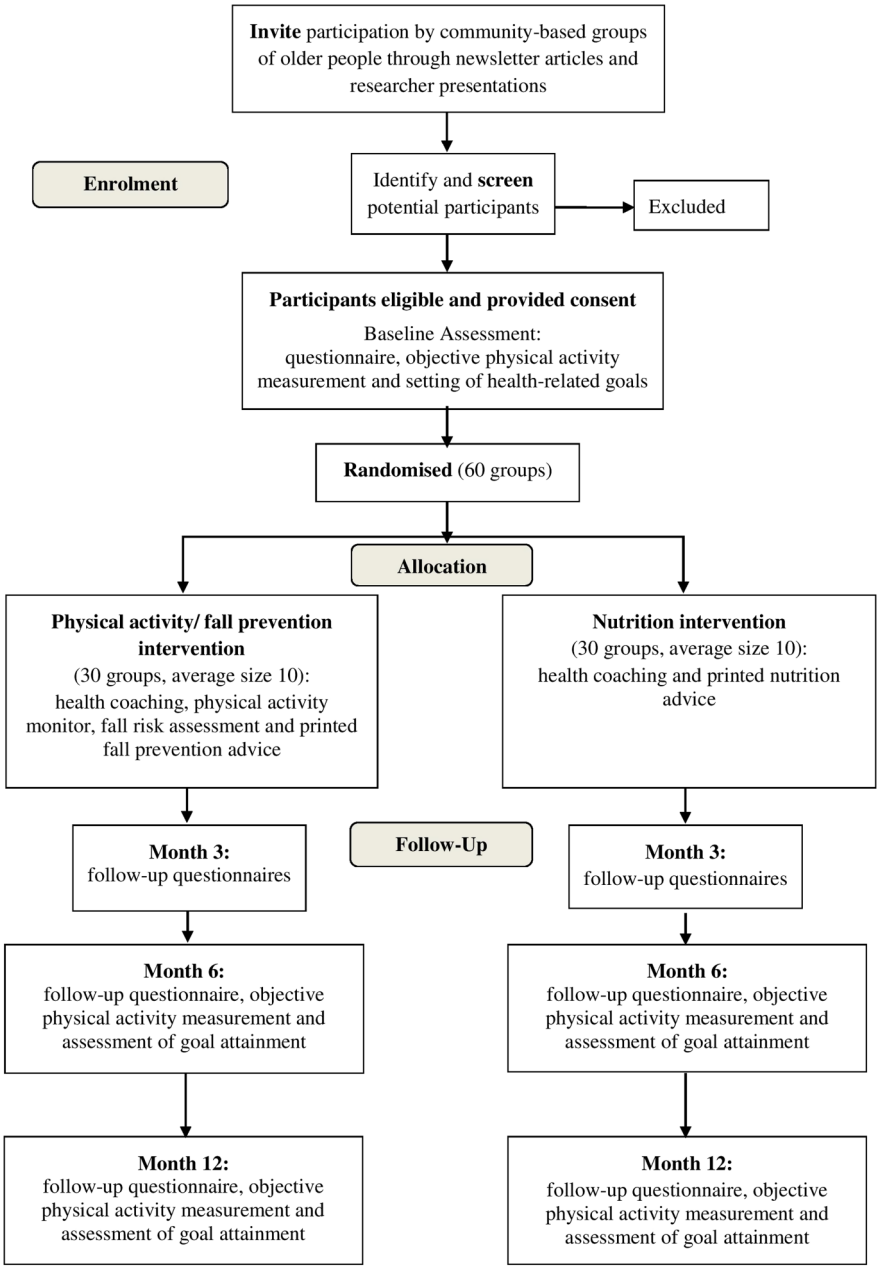

Figure 1 Trial design.

insufficient English language skills to fully participate in the programme; have a progressive neurological disease (eg, Parkinson's disease); have a medical condition precluding exercise (eg, unstable cardiac disease); or are unable to leave the house without physical assistance from another person. If it is unclear whether a potential participant meets the eligibility criteria, his/her permission will be sought to discuss this with a family member, other carer, or healthcare professional (eg, general practitioner).

Recruitment and randomisation

Participant recruitment is from two cities in New South Wales, Australia: metropolitan Sydney, and regional Orange and surrounds, via direct contact with established community-based organisations for seniors, which started in November 2015. Randomisation and allocation of a participating group to intervention condition will take place after all participants within the group have provided individual consent, and completed the baseline questionnaires, the assessment of current physical activity participation, and the setting of mobility-related goals. To ensure allocation concealment, group allocation will be determined after baseline data collection using an automatic phone-based randomisation service (NHMRC Clinical Trials Centre). The randomisation sequence will be computer generated using a minimisation algorithm on the basis of the following stratification variables: rural/ urban group location and socioeconomic status of the groups, and whether the group gathering purpose involves physical activity or not. The research assistants in charge of collecting and entering all outcome data will be blinded to intervention allocation at both the cluster and individual level throughout the trial.

Physical activity and fall prevention intervention

Participants in the clusters allocated to the physical activity and fall prevention intervention (30 groups):

1. Will receive printed materials about increasing physical activity and preventing falls.
2. Will undergo an initial 2 h physiotherapy session (at home), in which:
   A. The QuickScreen fall risk assessment[36] will be conducted by a health coach with a professional background in physiotherapy or similar. This will take ~10 min to complete and will include assessment of key fall risk factors such as balance, mobility, vision, medication use and sensation;
   B. A fall prevention and physical activity plan will be jointly developed by the participant and the health coach using a motivational interviewing approach. This will involve goal setting and developing strategies to maximise motivation and maintenance of increased physical activity and strategies to prevent falls;
   C. A pedometer-based activity monitor will be provided by the health coach who will also demonstrate its use. Participants will be able to choose either a simple pedometer or a device which is able to connect to the internet (the Fitbit). Participants will be encouraged to wear the pedometer-based activity monitor during waking hours on a daily basis for the whole 12-month intervention period to record their daily steps, and provide feedback and motivation to increase their physical activity participation. The Fitbit enhanced pedometer is designed to synchronise wirelessly with computer software to download stored physical activity information. Participants will be encouraged to download and review their own data on a weekly basis or more often if desired. By agreeing to participate in this study and choosing to use the Fitbit, participants will also agree to be bound by the terms and conditions of use of the Fitbit device which will involve the downloading of their physical activity participation data to the Fitbit website.
3. Participants will receive access to telephone-based health coaching delivered by the same health coach who conducts the home visit and implements the intervention (as detailed above). The health coaching will focus on increasing physical activity and preventing falls. Participants will be encouraged to make contact with their health coach approximately once a fortnight for the first 6 months and then on a monthly basis for the remaining 6 months of the study. Health coaching will be used to identify barriers and facilitators to physical activity participation, and to provide education and support to assist participants to achieve their physical activity goals. During the fortnightly telephone contact, health coaches will also enquire about the circumstances of any falls that participants may have experienced, and they will discuss strategies for reducing the risk of future falls. Intervention participants will also be assisted to find suitable local exercise opportunities (eg, Tai Chi, balance and strength training) which will be identified using the NSW Ministry of Health's *Active and Healthy* online database (http://www.activeandhealthy.nsw.gov.au/). Access to the health coaching will cease at the conclusion of the study.

Healthy eating intervention

Participants in the clusters allocated to the nutrition programme (n=30 groups) will receive:

1. printed materials about healthy eating;
2. access to a health coaching service that focuses on healthy eating, through the NSW Ministry of Health *Get Healthy Information and Coaching Service (Get Healthy service)*. Participants will be contacted by the *Get Healthy service* approximately once a fortnight for the first 6 months, and then on a monthly basis for

the remaining 6 months of the study. During this time, the participants will be able to set healthy eating goals and discuss strategies for achieving those goals with the health coach who is a qualified dietitian. Participants will have the option of continuing to access the publicly available *Get Healthy service* at the conclusion of the study if they wish.

Despite the active control, the primary outcomes are not likely to be influenced by the active nature of the control intervention. Furthermore, some of the secondary outcomes are particularly focused on the active control intervention (eg, body mass index and eating habits), which will also allow us to evaluate the impact of this intervention among older people.

Table 1 summarises the contents of both interventions.

Outcomes

Primary outcomes

The two primary outcomes will be: physical activity level, expressed as mean counts/min/day, assessed over a 7-day period using a matchbox-sized accelerometer (ActiGraph GT3X+), measured at 12 months post-randomisation; and fall rates, recorded with monthly postal calendars over a period of 12 months.

ActiGraph GT3X+ is an extensively researched accelerometer in the physical activity and public health field, and has been shown to be a valid instrument.[37] Participants will be instructed to wear the accelerometer on the right hip, attached via an adjustable elastic belt, for seven consecutive days during waking hours (except during water-based activities or bathing). Activity counts per second will be collected at a sampling frequency of

Table 1 Intervention description using the Template for Intervention Description and Replication (TIDieR) checklist

1. Brief name	The Coaching for Healthy Ageing (CHAnGE) trial
2. Why	Physical inactivity and falls in older people are important public health problems. Health conditions that could be ameliorated with physical activity are particularly common in older people. One in three people aged 65 years and over fall at least once annually, often resulting in significant injuries and ongoing disability. These problems need to be urgently addressed as the population's proportion of older people is rapidly rising. Good nutrition is also an essential element for maximising health in older age. A large proportion of Australian adults are not meeting the recommendations of the Australian Dietary Guidelines in relation to healthy eating.
3. What materials	Participants in the physical activity/fall prevention intervention will receive: ▶ A printed brochure containing information about fall prevention and increasing physical activity; ▶ An assessment of their fall risk factors using the QuickScreen fall risk assessment;[15] ▶ A wearable pedometer-based physical activity monitor to give feedback on the amount of daily physical activity achieved. Participants in the nutrition intervention will receive: ▶ A printed brochure containing information about healthy eating.
4. What procedures	For the physical activity/fall prevention intervention: ▶ Telephone-based health coaching will be used to identify barriers and facilitators to physical activity participation, and to provide education and support to assist participants to reduce their risk of falling, and to achieve their physical activity goals. For the nutrition intervention: ▶ Telephone-based health coaching will be used to identify barriers and facilitators to healthy eating, and to provide education and support to assist participants to improve their dietary habits.
5. Who provided	Health coaches with tertiary qualifications as physiotherapists or exercise physiologists will deliver the physical activity/fall prevention intervention. Health coaches with tertiary qualifications as dieticians will deliver the nutrition intervention.
6. How	The fall risk assessment and tailored fall prevention and physical activity plan will be delivered during one face-to-face interview for the physical activity/fall prevention intervention arm. Health coaching for both intervention arms will be delivered via telephone contact.
7. Where	The intervention will be delivered to community-dwelling people in Sydney and Orange, NSW, Australia.
8. When and how much	▶ For the physical activity/fall prevention intervention: the face-to-face assessment and interview will occur at the beginning of the intervention period, and will last for ~2 h. The telephone-based health coaching will occur after the face-to-face assessment and interview, once every 2 weeks for ~20 min for a total duration of 6 months, and then on a monthly basis for a further 6 months. ▶ For the nutrition intervention: The telephone-based health coaching will start at the beginning of the intervention period and will occur once every 2 weeks for ~20 min for a total duration of 6 months, and then on a monthly basis for a further 6 months.
9. Tailoring	▶ For the physical activity/fall prevention intervention: the fall prevention aspect of the intervention will be tailored to individual need with reference to the fall risk-assessment results. The physical activity plan will be tailored to participant goals, current physical ability and preferences. ▶ For the nutrition intervention: the healthy eating plan will be tailored to participant goals, current dietary habits and preferences.

30 Hz and reintegrated to 60 s epochs for data analysis. The mean counts/min/day ActiGraph (Axis 1) measure will be computed as the total counts accumulated in a valid day divided by the wear time of that day. To be considered as a valid day for analysis, ActiGraph wear time must include 10 h or more. Periods of 90 min or more of consecutive zeros (indicating non-use) will be considered as non-wear time. Accelerometer data will be manually checked against participant diaries/calendars to verify wear time, and erroneous data will be excluded prior to analysis. Physical activity participation will be assessed at 12 months after participant randomisation, and ActiGraph data will be extracted by a research assistant who is unaware of group assignment (ie, blinded outcome assessment).

Falls will be measured on a monthly basis for a 12-month period after randomisation. The internationally recognised fall definition will be used: 'an unexpected event in which the participant comes to rest on the ground, floor, or lower level, as a result of a loss of balance'.[38] Participants will complete 13 monthly fall calendars (to account for study starting part-way through the month), which will be mailed to the research centre in reply-paid, preaddressed envelopes. If calendars are not returned, participants will be telephoned to ask about their fall history for that month. Any fall reported on the calendars will be followed up with a phone call to obtain further information about the details and consequences of the fall. This method for collection of fall data is recommended as best practice by the Prevention of Falls Network Europe.[38]

Secondary outcome measures

The secondary outcomes will be: the proportion of fallers; the proportion of ActiGraph wear time in sedentary, light, moderate and vigorous physical activity; body mass index, measured with self-reported height and weight; eating habits, assessed with questions from the Australian Health Survey;[39] mobility-related goal attainment, assessed using the Goal Attainment Scale;[40] quality of life, assessed with the EQ-5D-5L;[41] fear of falling, assessed using the short-form Falls Efficacy Scale International;[42] mood, assessed with the Positive and Negative Affect Schedule;[43] risk-taking behaviour, assessed with a 5-item self-report tool;[44] well-being, assessed with a 26-item composite scale of well-being (the COMPAS-W scale);[45] mobility-related confidence, assessed with the Modified Gait Efficacy Scale;[46] self-reported physical activity, assessed with the IPEQ;[34] disability, assessed with the WHO Disability Assessment Schedule II;[47] and health and community service use, assessed using monthly calendars as described above. All secondary outcomes will be measured at baseline, 3, 6 and 12 months after randomisation, except for the proportion of fallers (ascertained with monthly fall diaries), goal attainment and body mass index (measured at 6 and 12 months only) and ActiGraph wear time in sedentary, light, moderate and vigorous physical activity (measured at baseline, 6 and 12 months only).

Analysis of outcomes

Accelerometer data will be analysed using ActiLife 6 software. Acceptable wear time will be defined as 4 days or more of 10 h or more per day. To account for correlation among individuals within clusters, all statistical models will use a generalised estimating equations approach with an exchangeable correlation structure. The number of falls per person-year will be analysed using negative binomial regression models to estimate the difference in rates between intervention conditions after 1 year (primary outcome). For the continuously scored primary and secondary outcome measures, linear regression will be used to assess the effect of group allocation, with their corresponding baseline scores as a covariate. Log-binomial regression, or a robust Poisson regression in case of convergence issues will be used to compare groups on dichotomous outcome measures (proportion of fallers, proportion meeting physical activity cut points). Planned subgroup analyses will assess differential effects of the intervention by baseline physical activity levels and history of falls. Secondary analyses using causal modelling will be conducted to establish intervention effects in people with greater adherence.

The economic evaluation will take the perspective of the health and community care funder, and will include benefits measured in terms of falls prevented, extra people with increased physical activity and Quality Adjusted Life Years (QALY) gained. As well as the healthcare costs outlined above, data will be collected on the cost to deliver the interventions (staff, training, capital costs and consumables). Using the mean costs and the mean health outcomes in each trial arm, the incremental cost per (1) fall prevented, (2) additional person with increased activity, (3) additional person with improved eating habits and (4) QALY gain calculated from the SF-6D will be compared between intervention conditions; 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 CIs around the incremental cost-effectiveness ratios. One-way sensitivity analysis will be conducted around key variables and a probabilistic sensitivity analysis to estimate the joint 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 additional QALY gained.

Analyses will be conducted using the Stata V.13 software package. All analyses will be preplanned, conducted while masked to group allocation and will use an intention-to-treat approach.

Sample size justification

A total of 30 clusters per intervention condition with an average of 10 individuals in each cluster (ie, 600 participants) will provide 90% power to detect a 10% between-group difference in the primary physical activity outcome at the 5% two-sided significance level. This

calculation was undertaken in Stata V.13 using the cluster sampsi command, and assumed a between-group difference of 23 mean counts/min during wear time, SD of 120, dropout rate of 20%, 0.6 correlation between baseline and final measures and an intracluster correlation (ICC) of 0.01. The estimates of mean accelerometer counts per minute were taken from a large sample of accelerometer data.[48] The 60 clusters will provide 80% power to detect as significant, at the 5% two-sided significance level, a 30% lower rate of falls in intervention group participants than control participants (IRR=0.67), that is, the primary falls outcome. For this calculation, we used PASS V.14 (Power Analysis and Sample Size) Software (2015, NCSS, LLC, Kaysville, Utah, USA) and coefficients from previous studies: overdispersion in the negative binomial regression model was assumed to be 0.65 based on a previous trial. We assumed: a control group rate of falls of 0.06 per person-month over the follow-up period, as this was the rate in a study of a similar population; a design effect of 1.09 with an ICC of 0.01; and withdrawal of six clusters. An average follow-up period of 11 months was used to account for loss to follow-up. This sample size is also expected to be sufficient to detect between-condition differences in the order of 10–15% for the secondary outcome measures.

Data management

Participant data will be collected by written survey questionnaires posted to participants, and by face-to-face physical assessments for those participants allocated to the physical activity/fall prevention intervention. To ensure confidentiality, the final dataset will contain reidentifiable information only. Demographic information linking the participant to the data will be stored on a separate file. All data will be entered onto a password protected database and maintained on a firewall protected local network server at The George Institute for Global Health. Paper files will be stored in a locked filing cabinet in the Chief Investigators office. Access to all data will be limited to authorised study staff. All publications associated with the results of the study will involve deidentified data, so participant confidentiality will be maintained.

Data monitoring

The Research Manager will be notified within 12 h of any research staff member witnessing or becoming aware of a participant reporting an adverse event. Participants will also be asked about the occurrence of adverse events in the questionnaires completed at 3, 6 and 12 months postrandomisation. A Data and Safety Monitoring Board (DSMB), independent from the study sponsor and competing interests, will be convened to monitor serious adverse events (SAE), in order to ensure the safety of participants. If an SAE occurs, the Research Manager will notify the DSMB Chair within 48 h.

ETHICS AND DISSEMINATION

The trial protocol has been approved by the Human Research Ethics Committee at The University of Sydney, Sydney, Australia (approval number 2015/517). The results of this trial will be disseminated via peer-reviewed journal articles, presentations at international conferences and participant newsletters.

DISCUSSION

This trial is highly significant given the dual importance of falls and inactivity for older individuals and healthcare systems. It will provide rigorous direct evidence about the effectiveness and cost-effectiveness of a healthy ageing programme targeting falls and inactivity among older people. It will also provide evidence of the effectiveness and cost-effectiveness of a programme involving nutrition information and health coaching for improving eating habits among older people. This trial addresses key knowledge gaps and will enable healthcare funders to decide whether the benefits of these preventive programmes outweigh their costs.

The results of this trial are likely to translate into tangible benefits for the community in terms of reduced fall-related injuries and the multitude of health problems associated with physical inactivity and poor nutrition, and thus, reduced demand for health and community services. If proven effective, this trial will provide a model for two healthy ageing strategies which could be directly implemented within health services.

Author affiliations
[1]The George Institute for Global Health, Sydney Medical School, The University of Sydney, Sydney, New South Wales, Australia
[2]Sydney School of Public Health, Sydney Medical School, The University of Sydney, Sydney, New South Wales, Australia
[3]School of Science and Health, Western Sydney University, Sydney, New South Wales, Australia
[4]Faculty of Arts and Business, University of the Sunshine Coast, Sippy Downs, Queensland, Australia
[5]School of Biomedical Sciences, Charles Sturt University, Orange, New South Wales, Australia
[6]Neuroscience Research Australia, University of New South Wales, Randwick, New South Wales, Australia
[7]Northern Clinical School, Sydney Medical School, The University of Sydney, Sydney, New South Wales, Australia
[8]Department of Aged Care, Royal North Shore Hospital, Sydney, New South Wales, Australia
[9]Charles Perkins Centre, The University of Sydney, Sydney, New South Wales, Australia

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Contributors AT and CS conceived of the study. All authors contributed to the study design and implementation methods. AT is the study manager at the Sydney site and JW is the study manager at the Orange site. AT, CS and JMS will conduct the primary statistical analyses. All authors contributed to refinement of the study protocol and approved the final manuscript.

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