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IMPLEMENTATION OF THE *StandingTall* PROGRAMME TO PREVENT FALLS IN OLDER PEOPLE: A PROCESS EVALUATION PROTOCOL

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ABSTRACT

Introduction: One in three people aged 65 years and over fall each year. The health, economic and personal impact of falls will grow substantially in the coming years due to population ageing. Developing and implementing cost-effective strategies to prevent falls and mobility problems among older people is therefore an urgent public health challenge. *StandingTall* is a low-cost, unsupervised, home-based balance exercise programme delivered through a computer or tablet. *StandingTall* has a simple user-interface that incorporates physical and behavioural elements designed to promote compliance. A large randomised controlled trial (RCT) in 503 community-dwelling older people has shown that *StandingTall* is safe, has high adherence rates (median: 90 minutes/week over 6-months) and is effective in improving balance and reducing falls in older people. The current project targets a major need for older people and will address the final steps needed to scale this innovative technology for widespread use by older people across Australia and internationally.

Methods and analysis: This project will endeavour to recruit 300 participants across three sites in Australia and 100 participants in the United Kingdom. The aim of the study is to evaluate the implementation of *StandingTall* into the community and health service settings in Australia and the United Kingdom. The nested process evaluation will use both quantitative and qualitative methods to explore uptake and acceptability of the *StandingTall* program and associated resources. The primary outcome is participant adherence to the *StandingTall* program over 6-months.

Ethics and dissemination: Ethical approval has been obtained. Dissemination will be via publications, conferences, newsletter articles, social media, talks to clinicians and consumers and meetings with health departments/managers.

Trial registration: Australian and New Zealand Clinical Trails Registry ACTRN12619001329156.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The *StandingTall* program is addressing an important and growing health problem – falls and fall-injury.
- *StandingTall* uses technology to deliver an unsupervised, progressive and individually-tailored exercise programme to improve balance and reduce fall risk in older people.
- This study aims to evaluate the implementation of *StandingTall* into real-world community and health service settings in Australia and the United Kingdom
- The study will evaluate facilitators and barriers to participant and health care worker uptake to expedite wide-spread dissemination.
- The COVID-19 crisis will provide new and relevant information regarding participant and health care worker uptake of Telehealth, as well as the facilitators and barriers to these procedures.

INTRODUCTION

Falls and fall-related injuries can lead to mobility-related disability and loss of independence in older people, causing both personal and community burden(1). Falls are reported as the leading cause of injury-related hospitalisation in older people and the 7th leading cause of all age disease burden in the western world(2). This will result in increased demand for health services unless effective and cost- effective fall prevention strategies can be implemented(3). By 2051, the projected total annual Australian health bill for fall-related injury will reach AUD$1.4 billion, which will create demands on the health system that will be difficult to meet(4).

There is clear evidence that falls in older people can be prevented with appropriately-designed exercise programmes. A Cochrane review concluded that exercise interventions are amongst the most effective strategies to reduce fall rates in community-dwelling older people(5). Therefore, widespread implementation of exercise as a single intervention is a fall prevention priority. Well-designed exercise programmes, including moderate to high-intensity balance exercise of sufficiently high dose (2 to 3 hours per week) over periods of 6-months or more, can reduce falls by up to 39%(6). Despite strong evidence that falls can be prevented, older people and many health professionals are often not aware that exercise is an effective strategy for preventing falls(1, 7-9). Further, achieving a sufficient dose for fall prevention effects in clinical practice can be difficult to achieve(10, 11). There is a clear gap between evidence and action(12).

Worldwide, national policies have developed fall prevention action plans (13-15). However, currently there is limited access to fall prevention programmes and therefore an unmet need for delivering accessible, evidence-based fall prevention interventions to older people (16-18).

Major shortcomings of many current programmes are that they are offered relatively short-term and lack long-term sustainability(17, 19, 20). Therefore, these programmes do not offer long-term protection from falls and/or functional decline. Novel methods for delivery of quality healthcare are required to ensure translation of effective, evidence-based fall prevention programmes while containing costs and using limited human resources to maximum effect(13). The ultimate success of a health promotion programme depends on its effectiveness and its reach and acceptability in the community(21).

StandingTall is an engaging balance training programme that is designed specifically for use by older people. It employs technology to deliver an evidence-based, individually-tailored exercise programme aimed at improving standing balance and reducing fall risk. The *StandingTall* programme includes behavioural change techniques to enhance exercise uptake and long-term adherence and is simple for older people to use independently at home(22, 23). *StandingTall* fills an important gap by giving older people the flexibility to exercise unsupervised at home and assists them to meet the required fall prevention exercise dose. While some people enjoy group exercise, some are unable (or unwilling(24)) to attend centre-based activities, and many will need to supplement group exercise with home-based exercise to reach their fall prevention target dose(24). *StandingTall* employs technology to provide an effective, long-term method for improving balance and reducing fall risk, using self-management and remote monitoring (adherence, exercise progression, exercise prescription). A large randomised controlled trial (RCT) in 503 community-dwelling older people has shown that *StandingTall* is safe, has high adherence rates (median: 90 minutes/week over 6-months) and is effective in improving balance and reducing falls in older people(25). By combining technology with evidence-based practice, *StandingTall* provides a novel solution to the fall

epidemic by providing older people with an effective, sustainable, low cost and enjoyable exercise programme thereby supporting older people to remain active and independent (26).

Understanding factors that may moderate real world uptake and adherence of *StandingTall* is key to its successful implementation on a broader scale. Process evaluation is a common tool used in pragmatic studies to assess the impact of intervention delivery and access within the study, as well as to gain understanding about how and why the intervention did or did not have its desired impact. The specific aims of this process evaluation are to investigate uptake and adherence to *StandingTall* by older people; examine how *StandingTall* is adopted by health professionals; and identify factors that will facilitate the embedding of *StandingTall* in usual care. Whilst this implementation study was conceived before the 2020 SARS-CoV-2 (COVID-19) pandemic, the delivery of falls prevention services in health and social care systems worldwide has been curtailed because of the need to reduce face-to-face contact. This has given rise to digital delivery of exercise programmes as they offer ways of delivering exercise regimens without, or with reduced, face-to-face contact(27, 28).

METHODS AND ANALYSIS

This is an international, multisite, pragmatic clinical study with sites in Australia and United Kingdom. The project focuses on implementing the *StandingTall* programme across three partnering sites in Australia and one site in Northern England, United Kingdom (UK). In Australia, two health districts in New South Wales (NSW; Mid-North Coast Local Health District and Northern NSW Local Health District) and one site in Victoria (Austin Health) are involved. In Northern England (UK), participants are recruited from Greater Manchester, North West Coast, Yorkshire and the Humber and the North East. Inherent to the study, is the creation

of a website to guide the implementation (www.standingtall.org.au). The website wll provides information about the *StandingTall* programme, training modules and resources, with the overall aim to educate older persons and their families, as well as exercise therapists and other health professionals, on fall prevention and the *StandingTall* programme. Website resources include knowledge quizzes with tailored education recommendations, evidence-based fact sheets, safety checklists, *StandingTall* training modules, manuals, frequently asked questions, and blogs.

Participants

Participants are recruited through health services, community organisations and media advertisements. The study will involve consenting community-dwelling older people, aged 60+ years with sufficient English language skills to understand study documents. Key exclusion criteria are: residents of residential care facilities; acute medical illnesses, severe psychiatric disorders, progressive neurological diseases including dementia; unstable medical conditions that preclude exercise participation; considered not suitable for study participation by referring family doctor or healthcare worker; have mobility limitations (unable to walk 10m indoors without the use of a walking aid) and visual impairment that cannot be corrected with glasses. During the COVID-19 pandemic, Telehealth set-ups have been introduced which require additional inclusion criteria. Participants are requested to have a support person present who lives in the same house, or is maintaining regular face-to-face contact with the participant, is currently well and can provide supervision and assistance if necessary. Participants who feel that a support person is unnecessary need to be able to step up a street curb without assistance (i.e. without using their arms, walking aid or person) to proceed with the Telehealth set-up without a support person. Additionally, in the UK during COVID-19, potential participants who are familiar with strength and balance and known to services could elect to have a

telephone setup. Potential participants unfamiliar with strength and balance exercises and who cannot be seen by the exercise specialist/relevant professionals in person or via Telehealth will not be recruited until face-to-face becomes available.

StandingTall intervention programme

All participants will be asked to use the *StandingTall* exercise programme for 6 months. *StandingTall* comprises standing balance (e.g. standing on the floor and/or foam surface), walking (e.g. walking in circles or to targets in a grid), stepping (e.g. step and lift) and box (e.g. step up and over a box) exercises. Exercises are delivered through on-screen animated instructions with video demonstrations and tips. The *StandingTall* programme delivers unsupervised and progressive balance exercises using digital technology (computer/tablet and internet). The *StandingTall* programme progresses the weekly exercise dose from 40 minutes in the first two weeks to two hours from week nine onwards, through fortnightly 20-minute increases. Exercise intensity is individually tailored using a modified perceived exertion 5-point Likert scale (1=unstable, 5=very stable). Exercise intensity rating modifies the exercises to ensure they are of moderate-to-high challenge and increases/decreases exercise intensity according to the user's rating of ability. Participants can choose the timing and duration of their sessions.

Online *StandingTall* training (including safety) is provided for participants, support persons and exercise specialists through the *StandingTall* website. The training module includes a safety quiz, where an 80% pass mark is needed for participants and exercise specialists to receive access to the *StandingTall* programme and content management system (CMS), respectively. Before commencing the exercise programme, participants are recommended to have a set-up session with an exercise specialist (e.g. physiotherapist, exercise physiologist,

sports scientist, fitness leader or occupational therapist) with prior experience in delivering exercise to older people and who have completed the online training. This session can be done face-to-face (as intended originally) or via Telehealth (during the COVID-19 pandemic and beyond) and is meant to familiarise the participant with the programme and its features, cover exercise safety, and complete a balance assessment and a short exercise session. If at any point, the participant, support person or exercise specialist feel that the Telehealth set-up is unsafe, the session will be abandoned until such time that additional safety measures can be implemented, or face-to-face contact can resume.

The back-end (i.e. the content management system) of the *StandingTall* programme allows research staff and exercise specialists to remotely monitor exercise adherence and progression, as well as adjust exercise categories and intensity (if necessary, e.g. in the case of illness or holidays). Participants are contacted by phone if their adherence drops below 85% for two consecutive weeks to discuss any problems or issues and to encourage adherence.

Programme logic model

The study is conceptualised within a programme logic model, depicted in Figure 1, which represents the theory of action or how the intervention contributes to a set of specific outcomes through a series of intermediate results. It is underpinned by a theory of change: Implementation and Knowledge Utilisation Theory. The logic model illustrates how different elements work together to create the desired change in target groups and achieve desired outcomes. Like all models it provides simplifications; the key is for the logic model to show the components of the programme that are thought to be critical for generating outcomes of interest to programme stakeholders. The approach used here is an 'outcomes hierarchy' approach to programme logic. Using this approach, every element of the model is written as an

outcome and outcomes are connected. It shows the logical connections between inputs, outputs and outcomes using a type of 'if-then' logic.

There are three kinds of outcomes streams for *StandingTall* – (i) outcomes for participating organisations, which are expected to contribute to increased system capacity to support falls prevention; (ii) outcomes for study participants, which are expected to contribute to fewer falls among older people; and (iii) outcomes for health professionals, which are expected to contribute to more stakeholders recognising that exercise is key to falls prevention. Outcomes are categorised as short (3-6 months), medium (12 months) and longer term. The description below relates generic health service intervention outcomes (in bold) to specific outcomes for *StandingTall***.**

Model inputs include resourcing and coordinating the implementation of the programme at the local health service level, the development of the *StandingTall* programme, website, information and training modules, and a dedicated support system to assist and encourage participation. If these resources are sufficient then targeted health services and community groups will implement the intervention by committing to the study and agreeing on pathways and processes for older people to be referred (**Feasibility)**. The programme will function well across different digital platforms and be easy to use, and participants will be willing to pay a small amount to access the programme and subscribe to a helpline service **(Implementation Cost)**. Clinicians and other support persons will engage in the programme by accessing resources and training modules and these will meet their information needs and allow them to provide effective guidance to participants **(Appropriateness)**. If the programme activities are successfully implemented, then short-term outcomes are that at-risk older people will be referred to *StandingTall* via many pathways (**Adoption**), older people will understand potential

benefits, engage with the programme (**Acceptability)** and respond to feedback **(Coverage).** Clinicians and other support persons will make themselves available to provide sufficient support so that older people remain engaged **(Feasibility)**. If the short-term outcomes are achieved then in the medium term, *StandingTall* referral pathways are integrated into business-as-usual and clinicians and other support persons will approve of and continue to support the programme **(Sustainability).** At-risk older people will do prescribed exercise and maintain this overtime **(Fidelity)**. Long-term outcomes include fewer falls among older people and increased system capacity to support falls prevention.

Outcome measures

The nested process evaluation will use both quantitative and qualitative methods to explore uptake and acceptability of the *StandingTall* programme to provide direct guidance for programme scale up. Process evaluation data will be collected using *StandingTall* programme data, study logs and participant, support person, healthcare worker and health service manager surveys and/or interviews (Table 1). Process evaluation measures include programme adherence, acceptability, adoption, appropriateness, feasibility and sustainability (Table 1). The barriers/facilitators to Telehealth delivery (because of COVID-19) will be explored as part of the evaluation. Table 1 shows specific measures that will be undertaken as part of the process evaluation and how they relate to the programme logic model. The primary outcome for the study is adherence to the *StandingTall* programme over 6-months, measured as weekly training dose and total training dose recorded by the programme. The *StandingTall* programme records actual exercise minutes and does not include rests, watching instructional videos, set-up for each exercise or incomplete sessions. Therefore, a 10-minute session could take 20 minutes (or sometimes longer) depending on how many instructional videos the user watches and how many rests the user takes. Adherence data are automatically transferred to a secure server at

Neuroscience Research Australia. Weekly exercise minutes (adherence) can be monitored in the CMS. Secondary outcomes are described in Table 1 and evaluate acceptability, adoption, appropriateness, feasibility, implementation cost, coverage and sustainability. For consenting participants, we will seek ethical approval to link their health data. Using this linkage, we will calculate incidence and rate of fall-related hospital admissions from linked hospital records. In New South Wales, the linkage will be through the Centre for Health Record Linkage (CHeReL), in Victoria through The Centre for Victorian Data Linkage and in England through the National Health Service (NHS) Digital. Data linkage will be undertaken at 6 months after final data collection. An adverse event is defined as an unwanted and unusually harmful outcome (e.g. exercise-related fall, musculoskeletal injury or cardiovascular event). The event may or may not be related to the *StandingTall* programme but is recorded if it occurs while the person is participating in the programme (i.e. while they are doing *StandingTall* exercise activities).

Sample size calculation

The primary analysis will estimate mean adherence, measured as minutes of exercise per week. With a SD of 43.1 minutes (estimated from an earlier trial(25)), a sample size of 83 participants yield estimates of the mean with a confidence interval width less than or equal to +/- 10 minutes in 80% of studies. To allow for an approximately 20% loss to follow-up, we will recruit 100 participants per site (Australia) or per region (UK).

Statistical Analysis

Total exercise minutes and mean (95% CI) or median (interquartile range) weekly exercise minutes will be calculated from data recorded by the *StandingTall* programme and will be reported as adherence (primary outcome). Number and proportions of responses to survey

questions will be reported for the secondary outcome measures. Interviews will be audio-recorded, transcribed verbatim and thematic analysis will identify patterns within and across study sites. A combination of inductive and deductive coding will be used – commencing with examination of barriers and facilitators, but open to unexpected findings that may contribute to these or other themes. A discrete choice experiment survey will examine the user's preferences and acceptable trade-offs for aspects of *StandingTall*, including costs and other factors identified by qualitative interviews. A cost-benefit analysis will determine the return on investment of *StandingTall* from the perspective of the health care payer, taking into account health care and implementation costs, the overall benefit of *StandingTall* and potential number of users for widespread scale-up.

ETHICS AND DISSEMINATION

Ethical approval and local governance approvals have been obtained (Lead ethics committee in Australia: South Eastern Sydney Local Health District, (HREC 18/288 approved 28/02/2019) and in the UK: North West- Greater Manchester South Research Ethics Committee (IRAS: 268954 Approved 04/02/2020). All amendment requests will be submitted to these committees. Written informed consent, or during the COVID-19 pandemic informed online consent, from all participants will be obtained by study staff prior to study enrolment. Participant confidentiality and privacy will always be maintained, and all data will be stored securely. Health professionals, community referral agents and support persons will be emailed an invitation to complete an online survey. By completing the survey, consent will be implied to participate in the study when they click on the link. If health professionals, community referral agents and support persons are taking part in the interview or focus group sessions,

then written informed consent or online informed consent (during the COVID-19 pandemic) will be obtained.

Dissemination will be via publications, conferences, newsletter articles, talks to clinicians and consumers, and meetings with health department and health service mangers. The International Committee of Medical Journal Editors recommended criteria for authorship on publications will be followed. Professional writers will not be used. The full protocol and statistical code will be made available upon reasonable request.

TABLES AND FIGURES

Figure 1. *StandingTall* Programme logic. *(Note: The diagram is read from bottom to top and presents "if-then" relationships between inputs, effective delivery, and outcomes at different levels)*

Table 1. Study outcomes

Generic implementation outcome	Related *StandingTall* outcome/s	Variables or measures	Measurement tool
Fidelity	At risk older people use *StandingTall* as prescribed **(Primary outcome: Adherence)**	Adherence to the programme as weekly training dose and total training dose recorded by the programme	Adherence data transferred automatically from the programme
Acceptability	At risk older people understand the benefits, how to use the programme and about supports	% participants agree 'I like to use the *StandingTall* app'	Participant Survey at 3- and 6-months
		% participants that rate *StandingTall* as a good or excellent	Participant Survey at 6-months
		% hospital and community workers involved in study that rate *StandingTall* as a good or excellent falls prevention intervention	Hospital and Community Worker survey
		% support persons agree that *StandingTall* has had a positive or somewhat positive impact on their professional practice	Healthcare worker[a,]
Adoption	At risk older people are being referred by many pathways	Uptake by different referral agents: number of referral agents and number of referrals from each source	Study logs
		Number of referral agents referring 5 or more older people	Study logs
		Average hours per week provided by support persons to support participants' use of *StandingTall*[a]	Healthcare worker
		Average number of people supported by health care worker in 18-month period	Healthcare worker
		Uptake of participants: number older people referred who are accepted into study	Recruitment log
Appropriateness	Education modules meet stakeholders' information needs Support persons are actively	% respondents (participants and exercise specialists) agree the instruction modules on the *StandingTall* website are helpful	Website users module survey

	engaged in *StandingTall*, understand role	% participants agree 'I find StandingTall is easy to use'	Participant 3- and 6-month surveys
		% support persons rate *StandingTall* as good or somewhat good fit with normal practice[a]	Healthcare worker
		% support persons agree the instruction modules on the *StandingTall* website are helpful[a]	Healthcare worker
Feasibility	Partner organisations/services commit to study Support persons give participants sufficient support At risk older people engage with *StandingTall*, respond to feedback	% hospital and community-based workers who regularly monitor patient's progress on *StandingTall* exercise programme	Study logs
		% hospital and community-based workers who regularly monitor patient's progress on *StandingTall* exercise programme	Hospital and community-based workers survey[a]
		Number of services/ partners agree to be involved and nature of involvement compared to numbers approached[a]	Study logs
		% participants agree 'I feel confident about doing the *StandingTall* exercises'[a]	Participant 3-month survey
Implementation cost		Implementation cost of each intervention component from a health sector perspective	Study and financial records
		% participants willing to pay a small one-off amount of $5 to access the *StandingTall* programme[a]	Participant survey at 6-months
		% participants interested in accessing the programme and advice from a helpline service as part of an annual subscription[a]	Participant survey at 6-months
Coverage[a]	At risk older people engage with *StandingTall*, respond to feedback	Number people enrolled in *StandingTall* by age and gender, at each study site and in total	REDCap
Sustainability	*StandingTall* referral pathways integrated into business as usual	% hospital and community-based workers who state they are definitely or probably going to keep using *StandingTall* as part of their patient care	Hospital and community based workers survey
		Number of health service managers' who state that the programme is being supported by relevant clinicians and partner organisations for continued use of *StandingTall* programme	Targeted health care services manager interview

	Number of health service managers who anticipate that *StandingTall* will become part of your district/region/hospitals business as usual	Targeted health care services manager interview
Adverse Events[a]	Adverse events while exercising using the *StandingTall* programme or thought to be directly related to the *StandingTall* programme	Participant, support person and exercise specialist report

[a]These outcomes are for descriptive purposes and are not listed as outcomes in the Australian and New Zealand Clinical Trial Registry

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AUTHOR CONTRIBUTIONS

All authors contributed to the design of the study and preparation of the study protocol. This manuscript was drafted by authors KD, MET, SO and WH. All authors revised the manuscript.

PATIENT AND PUBLIC INVOLVEMENT

Development of the *StandingTall* program involved consumer feedback and testing. The design and conduct of the implementation trial was informed by partner organisations including Local Health Districts.

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COMPETING INTERESTS STATEMENT

Wendy Hodge serves as an independent consultant and reports receiving personal fees from NeuRA, during the conduct of the study. The other authors do not report any competing interests.

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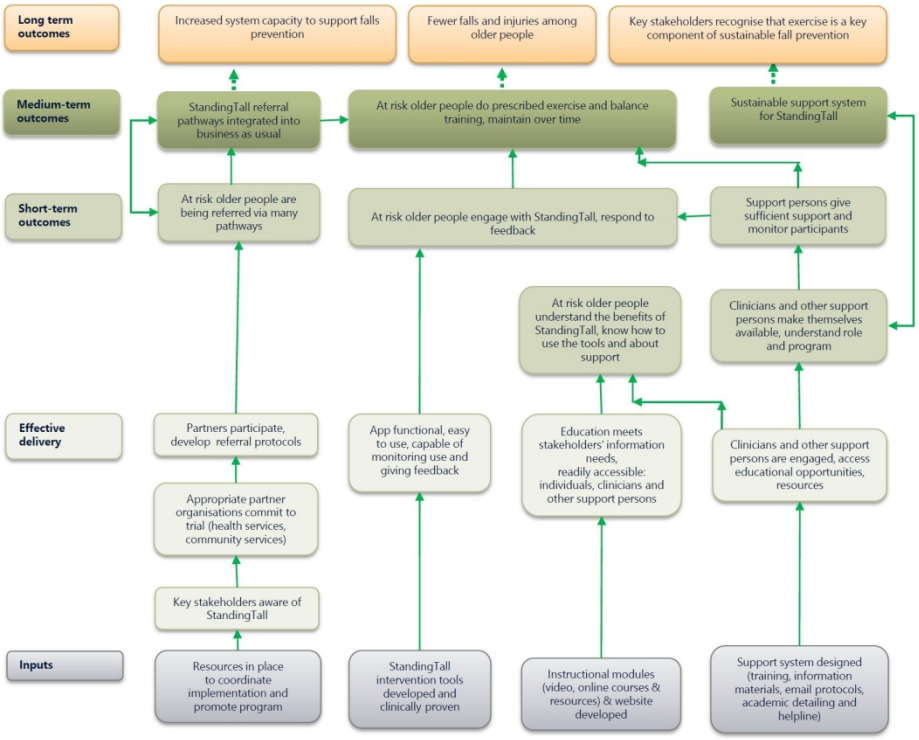

Figure 1. StandingTall Programme logic. (Note: The diagram is read from bottom to top and presents "if-then" relationships between inputs, effective delivery, and outcomes at different levels)

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IMPLEMENTATION OF THE *StandingTall* PROGRAMME TO PREVENT FALLS IN OLDER PEOPLE: A PROCESS EVALUATION PROTOCOL

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IMPLEMENTATION OF THE *StandingTall* PROGRAMME TO PREVENT FALLS IN OLDER PEOPLE: A PROCESS EVALUATION PROTOCOL

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ABSTRACT

Introduction: One in three people aged 65 years and over fall each year. The health, economic and personal impact of falls will grow substantially in the coming years due to population ageing. Developing and implementing cost-effective strategies to prevent falls and mobility problems among older people is therefore an urgent public health challenge. *StandingTall* is a low-cost, unsupervised, home-based balance exercise programme delivered through a computer or tablet. *StandingTall* has a simple user-interface that incorporates physical and behavioural elements designed to promote compliance. A large randomised controlled trial in 503 community-dwelling older people has shown that *StandingTall* is safe, has high adherence rates and is effective in improving balance and reducing falls. The current project targets a major need for older people and will address the final steps needed to scale this innovative technology for widespread use by older people across Australia and internationally.

Methods and analysis: This project will endeavour to recruit 300 participants across three sites in Australia and 100 participants in the United Kingdom (UK). The aim of the study is to evaluate the implementation of *StandingTall* into the community and health service settings in Australia and the UK. The nested process evaluation will use both quantitative and qualitative methods to explore uptake and acceptability of the *StandingTall* programme and associated resources. The primary outcome is participant adherence to the *StandingTall* programme over 6-months.

Ethics and dissemination: Ethical approval has been obtained from the South East Sydney Local Health District Human Research Ethics Committee (HREC reference 18/288) in Australia and the North West- Greater Manchester South Research Ethics Committee (IRAS ID: 268954) in the UK. Dissemination will be via publications, conferences, newsletter articles, social media, talks to clinicians and consumers and meetings with health departments/managers.

Trial registration: Australian and New Zealand Clinical Trails Registry ACTRN12619001329156.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- *StandingTall* uses technology to deliver unsupervised, progressive and tailored exercise to prevent falls in community-dwelling older people
- Implementation of *StandingTall* into community and health service settings will be evaluated
- The study will use quantitative and qualitative methods, including adherence to the intervention
- The study will explore facilitators and barriers to uptake and adherence
- COVID-19 caused a shift to telehealth delivery; facilitators and barriers to these procedures will be explored

INTRODUCTION

Falls and fall-related injuries can lead to mobility-related disability and loss of independence in older people, causing both personal and community burden(1). Falls are reported as the leading cause of injury-related hospitalisation in older people and the 7th leading cause of all age disease burden in the western world(2). This will result in increased demand for health services unless effective and cost- effective fall prevention strategies can be implemented(3). By 2051, the projected total annual Australian health bill for fall-related injury will reach AUD$1.4 billion, which will create demands on the health system that will be difficult to meet(4).

There is clear evidence that falls in older people can be prevented with appropriately-designed exercise programmes. A Cochrane review concluded that exercise interventions are amongst the most effective strategies to reduce fall rates in community-dwelling older people(5). Therefore, widespread implementation of exercise as a single intervention is a fall prevention priority. Well-designed exercise programmes, including moderate to high-intensity balance exercise of sufficiently high dose (2 to 3 hours per week) over periods of 6-months or more, can reduce falls by up to 39%(6). Despite strong evidence that falls can be prevented, older people and many health professionals are often not aware that exercise is an effective strategy for preventing falls(1, 7-9). Further, achieving a sufficient dose for fall prevention effects in clinical practice can be difficult to achieve(10, 11). There is a clear gap between evidence and action(12).

Worldwide, national policies have developed fall prevention action plans(13-15). However, currently there is limited access to fall prevention programmes and therefore an unmet need for delivering accessible, evidence-based fall prevention interventions to older people(16-18).

Major shortcomings of many current programmes are that they are offered relatively short-term and lack long-term sustainability(17, 19, 20). Therefore, these programmes do not offer long-term protection from falls and/or functional decline. Novel methods for delivery of quality healthcare are required to ensure translation of effective, evidence-based fall prevention programmes while containing costs and using limited human resources to maximum effect(13). The ultimate success of a health promotion programme depends on its effectiveness and its reach and acceptability in the community(21).

StandingTall is an engaging balance training programme that is designed specifically for use by older people. It employs technology to deliver an evidence-based, individually-tailored exercise programme aimed at improving standing balance and reducing fall risk. The *StandingTall* programme includes behavioural change techniques to enhance exercise uptake and long-term adherence and is simple for older people to use independently at home(22, 23). *StandingTall* fills an important gap by giving older people the flexibility to exercise unsupervised at home and assists them to meet the required fall prevention exercise dose. While some people enjoy group exercise, some are unable (or unwilling(24)) to attend centre-based activities, and many will need to supplement group exercise with home-based exercise to reach their fall prevention target dose(24). *StandingTall* employs technology to provide an effective, long-term method for improving balance and reducing fall risk, using self-management and remote monitoring (adherence, exercise progression, exercise prescription). A large randomised controlled trial (RCT) in 503 community-dwelling older people has shown that *StandingTall* is safe, has high adherence rates (median: 90 minutes/week over 6-months) and is effective in improving balance and reducing falls in older people(25). By combining technology with evidence-based practice, *StandingTall* will provide a novel solution to the fall

epidemic by providing older people with an effective, sustainable, low cost and enjoyable exercise programme thereby supporting older people to remain active and independent(26).

Understanding factors that may moderate real world uptake and adherence of *StandingTall* is key to its successful implementation on a broader scale. Process evaluation is a common tool used in pragmatic studies to assess the impact of intervention delivery and access within the study, as well as to gain understanding about how and why the intervention did or did not have its desired impact. The specific aims of this process evaluation are to investigate uptake and adherence to *StandingTall* by older people; examine how *StandingTall* is adopted by health professionals; and identify factors that will facilitate the embedding of *StandingTall* in usual care. Whilst this implementation study was conceived before the 2020 SARS-CoV-2 (COVID-19) pandemic, the delivery of falls prevention services in health and social care systems worldwide has been curtailed because of the need to reduce face-to-face contact. This has given rise to digital delivery of exercise programmes as they offer ways of delivering exercise regimens without, or with reduced, face-to-face contact(27, 28).

METHODS AND ANALYSIS

This is an international, multisite, pragmatic clinical study with sites in Australia and United Kingdom. The project focuses on implementing the *StandingTall* programme across three partnering sites in Australia and one site in Northern England, United Kingdom (UK). In Australia, two health districts in New South Wales (NSW; Mid-North Coast Local Health District and Northern NSW Local Health District) and one site in Victoria (Austin Health) are involved. In Northern England (UK), participants are recruited from Greater Manchester, North West Coast, Yorkshire and the Humber and the North East. Inherent to the study, is the creation

of a website to guide the implementation (www.standingtall.org.au). The website provides information about the *StandingTall* programme, training modules and resources, with the overall aim to educate older persons and their families, as well as exercise therapists and other health professionals, on fall prevention and the *StandingTall* programme. Website resources include knowledge quizzes with tailored education recommendations, evidence-based fact sheets, safety checklists, *StandingTall* training modules, manuals, frequently asked questions, and blogs.

Participants

Participants are recruited through health services, community organisations and media advertisements. The study will involve consenting community-dwelling older people, aged 60 years or older with sufficient English language skills to understand study documents. Key exclusion criteria are: residents of aged care facilities; acute medical illnesses, severe psychiatric disorders, progressive neurological diseases including dementia; unstable medical conditions that preclude exercise participation; considered not suitable for study participation by referring family doctor or healthcare worker; have mobility limitations (unable to walk 10m indoors without the use of a walking aid) and visual impairment that cannot be corrected with glasses. During the COVID-19 pandemic, telehealth set-ups have been introduced which require additional inclusion criteria. Participants are requested to have a support person present who lives in the same house, or is maintaining regular face-to-face contact with the participant, is currently well and can provide supervision and assistance if necessary. Participants who feel that a support person is unnecessary need to be able to step up a street curb without assistance (i.e. without using their arms, walking aid or another person) to proceed with the telehealth set-up without a support person. Additionally, in the UK during COVID-19, potential participants who are familiar with strength and balance and known to services could elect to have a

telephone setup. Potential participants unfamiliar with strength and balance exercises and who cannot be seen by the exercise specialist/relevant professionals in person or via telehealth will not be recruited until face-to-face becomes available. Participants are not restricted regarding concomitant care, interventions or activity.

StandingTall intervention programme

Figure 1 demonstrates participants flow through the study. All participants will be asked to use the *StandingTall* exercise programme for 6 months. *StandingTall* comprises standing balance (e.g. standing on the floor and/or foam surface), walking (e.g. walking in circles or to targets in a grid), stepping (e.g. step and lift) and box (e.g. step up and over a box) exercises. Exercises are delivered through on-screen animated instructions with video demonstrations and tips. The *StandingTall* programme delivers unsupervised and progressive balance exercises using digital technology (computer/tablet and internet). The *StandingTall* programme progresses the weekly exercise dose from 40 minutes in the first two weeks to two hours from week nine onwards, through fortnightly 20-minute increases. Exercise intensity is individually tailored using a modified perceived exertion 5-point Likert scale (1=unstable, 5=very stable). Exercise intensity rating modifies the exercises to ensure they are of moderate-to-high challenge and increases/decreases exercise intensity according to the user's rating of ability. Participants can choose the timing and duration of their sessions.

Online *StandingTall* training (including safety) is provided for participants, support persons and exercise specialists through the *StandingTall* website. The training module includes a safety quiz, where an 80% pass mark is needed for participants and exercise specialists to receive access to the *StandingTall* programme and content management system (CMS), respectively. Before commencing the exercise programme, participants are recommended to

have a set-up session with an exercise specialist (e.g. physiotherapist, exercise physiologist, sports scientist, fitness leader or occupational therapist) with prior experience in delivering exercise to older people and who have completed the online training (Figure 1). This session can be face-to-face (as intended originally) or via telehealth/video conferencing (during the COVID-19 pandemic and beyond) and is meant to familiarise the participant with the programme and its features, cover exercise safety, and complete a balance assessment and a short exercise session. If at any point, the participant, support person or exercise specialist feel that the telehealth/video conferencing set-up is unsafe, the session will be abandoned until such time that additional safety measures can be implemented, or face-to-face contact can resume.

The back-end (i.e. the content management system) of the *StandingTall* programme allows research staff and exercise specialists at the local health service level to remotely monitor exercise adherence and progression, as well as adjust exercise categories and intensity (if necessary, e.g. in the case of illness or holidays). Participants are contacted by phone if their adherence drops below 85% for two consecutive weeks to discuss any problems or issues and to encourage adherence (Figure 1). If participants need programme support during their 6-month intervention period, they can contact a central study helpline and/or their exercise specialist.

Programme logic model

The study is conceptualised within a programme logic model, depicted in Figure 2, which represents the theory of action or how the intervention contributes to a set of specific outcomes through a series of intermediate results. It is underpinned by a theory of change: Implementation and Knowledge Utilisation Theory. The logic model illustrates how different elements work together to create the desired change in target groups and achieve desired

outcomes. Like all models it provides simplifications; the key is for the logic model to show the components of the programme that are thought to be critical for generating outcomes of interest to programme stakeholders. The approach used here is an 'outcomes hierarchy' approach to programme logic. Using this approach, every element of the model is written as an outcome and outcomes are connected. It shows the logical connections between inputs, outputs and outcomes using a type of 'if-then' logic. Figure 2 illustrates the model inputs and how effective programme delivery will be achieved if these inputs are sufficient.

There are three kinds of outcomes streams for *StandingTall* – (i) outcomes for participating organisations, which are expected to contribute to increased system capacity to support falls prevention; (ii) outcomes for study participants, which are expected to contribute to fewer falls among older people; and (iii) outcomes for health professionals, which are expected to contribute to more stakeholders recognising that exercise is key to falls prevention (Figure 2). Outcomes are categorised as short (3-6 months), medium (12 months) and longer term.

Short-term outcomes relate to adoption, appropriateness, acceptability, fidelity and coverage (Table 1)**.** Medium and long-term outcomes include fewer falls among older people and increased system capacity to support falls prevention, and relate to feasibility, sustainability and implementation cost (Table 1**).**

Outcome measures

The nested process evaluation will use both quantitative and qualitative methods to explore uptake and acceptability of the *StandingTall* programme to provide direct guidance for programme scale up. Process evaluation data will be collected using *StandingTall* programme data, study logs and participant, support person, healthcare worker and health service manager

surveys and/or interviews (Table 1). The data collection time-points for participants are presented in Figure 1.

The primary outcome for the study is adherence to the *StandingTall* programme over 6-months (fidelity; Table 1), measured as weekly training dose and total training dose recorded by the programme. The *StandingTall* programme records actual exercise minutes and does not include rests, watching instructional videos, set-up for each exercise or incomplete sessions. Therefore, a 10-minute session could take 20 minutes (or sometimes longer) depending on how many instructional videos the user watches and how many rests the user takes. Adherence data are automatically transferred to a secure server at Neuroscience Research Australia. Weekly exercise minutes (adherence) can be monitored in the CMS.

Secondary process evaluation outcomes examine adoption, appropriateness, acceptability, feasibility, sustainability and implementation cost (Table 1). The barriers/facilitators to telehealth/video conferencing delivery (because of COVID-19) will be explored as part of the evaluation.

An adverse event is defined as an unwanted and unusually harmful outcome (e.g. exercise-related fall, musculoskeletal injury or cardiovascular event). The event may or may not be related to the *StandingTall* programme but is recorded if it occurs while the person is participating in the programme (i.e. while they are doing *StandingTall* exercise activities). Adverse events are reported to the data monitoring committee and unexpected and serious adverse events are reported to the governing site and/or Research Ethics Committee (REC), as appropriate and in accordance with the local mandatory reporting policies. Annual reports are provided to the REC and governing sites.

Sample size calculation

The primary analysis will estimate mean adherence, measured as minutes of exercise per week. With a SD of 43.1 minutes (estimated from an earlier trial(25)), a sample size of 83 participants yield estimates of the mean with a confidence interval width less than or equal to +/- 10 minutes in 80% of studies. To allow for an approximately 20% loss to follow-up, we will recruit 100 participants per site (Australia) or per region (UK).

Statistical Analysis

The nested process evaluation will use both quantitative and qualitative methods to explore uptake and acceptability of the *StandingTall* programme. Total exercise minutes and mean (95% CI) or median (interquartile range) weekly exercise minutes will be calculated from data recorded by the *StandingTall* programme and will be reported as adherence (primary outcome). Number and proportions of responses to survey questions will be reported for the secondary outcome measures. Missing data will be left missing; no imputation methods will be used. Interviews will be audio-recorded, transcribed verbatim and thematic analysis will identify patterns within and across study sites. A combination of inductive and deductive coding will be used – commencing with examination of barriers and facilitators, but open to unexpected findings that may contribute to these or other themes. A discrete choice experiment survey will examine the user's preferences and acceptable trade-offs for aspects of *StandingTall*, including costs and other factors identified by qualitative interviews.

ETHICS AND DISSEMINATION

Ethical approval and local governance approvals have been obtained (Lead ethics committee in Australia: South Eastern Sydney Local Health District, (HREC 18/288 approved 28/02/2019) and in the UK: North West- Greater Manchester South Research Ethics Committee (IRAS: 268954 Approved 04/02/2020). All amendment requests will be submitted to these committees. Potential participants will provide verbal consent to be screened for eligibility (Figure 1). Written informed consent, or during the COVID-19 pandemic informed online consent, will be obtained from all eligible participants by study staff prior to study enrolment (Figure 1). Participant confidentiality and privacy will always be maintained, and all data will be stored securely. Data access will only be provided to study staff and investigators. Health professionals, community referral agents and support persons will be emailed an invitation to complete an online survey. By completing the survey, consent will be implied to participate in the study when they click on the link. If health professionals, community referral agents and support persons are taking part in the interview or focus group sessions, then written informed consent or online informed consent (during the COVID-19 pandemic) will be obtained.

Dissemination will be via publications, conferences, newsletter articles, talks to clinicians and consumers, and meetings with health department and health service mangers. The International Committee of Medical Journal Editors recommended criteria for authorship on publications will be followed. Professional writers will not be used. The full protocol and statistical code will be made available upon reasonable request.

TABLES AND FIGURES

Figure 1. Participants flow through the study

Figure 2. *StandingTall* Programme logic. *(Note: The diagram is read from bottom to top and presents "if-then" relationships between inputs, effective delivery, and outcomes at different levels)*

Table 1. Study outcomes

Generic implementation outcome	Related *StandingTall* outcome/s	Variables or measures	Measurement tool
Adoption	At risk older people are being referred by many pathways	Uptake by different referral agents: number of referral agents and number of referrals from each source	Study logs
		Number of referral agents referring 5 or more older people	Study logs
		Average hours per week provided by support persons to support participants' use of *StandingTall*[a]	Support person survey[b]
		Average number of people supported by health care worker in 18-month period[a]	Support person survey[b]
		Uptake of participants: number older people referred who are accepted into study	Recruitment log
Appropriateness	Education modules meet stakeholders' information needs Support persons are actively engaged in *StandingTall*, understand role	% respondents (participants and exercise specialists) agree the instruction modules on the *StandingTall* website are helpful	Website users module survey
		% participants agree 'I find *StandingTall* is easy to use'[a]	Participant 3- and 6-month surveys
		% support persons rate *StandingTall* as good or somewhat good fit with normal practise[a]	Support person survey[b]
		% support persons agree the instruction modules on the *StandingTall* website are helpful[a]	Support person survey[b]
Acceptability	At risk older people understand the benefits, how to use the programme and about supports	% participants agree 'I like to use the *StandingTall* app'	Participant Survey at 3- and 6-months
		% participants that rate *StandingTall* as a good or excellent	Participant Survey at 6-months
		% hospital and community workers involved in study that rate *StandingTall* as a good or excellent falls prevention intervention	Hospital and Community Worker survey

		% support persons agree that *StandingTall* has had a positive or somewhat positive impact on their professional practice	Support person survey[b]
Fidelity	At risk older people use *StandingTall* as prescribed	Adherence to the programme as weekly training dose and total training dose recorded by the programme **(Primary outcome)**	Adherence data transferred automatically from the programme
Coverage[a]	At risk older people engage with *StandingTall*, respond to feedback	Number people enrolled in *StandingTall* by age and gender, at each study site and in total	REDCap
Feasibility	Partner organisations/services commit to study Support persons give participants sufficient support At risk older people engage with *StandingTall*, respond to feedback	% hospital and community-based workers who regularly monitor patient's progress on *StandingTall* exercise programme	Study logs
		% hospital and community-based workers who regularly monitor patient's progress on *StandingTall* exercise programme[a]	Hospital and community-based workers survey
		Number of services/ partners agree to be involved and nature of involvement compared to numbers approached[a]	Study logs
		% participants agree 'I feel confident about doing the *StandingTall* exercises'[a]	Participant 3-month survey
Sustainability	*StandingTall* referral pathways integrated into business as usual	% hospital and community-based workers who state they are definitely or probably going to keep using *StandingTall* as part of their patient care	Hospital and community based workers survey
		Number of health service managers' who state that the programme is being supported by relevant clinicians and partner organisations for continued use of *StandingTall* programme	Targeted health care services manager interview
		Number of health service managers who anticipate that *StandingTall* will become part of your district/region/hospitals business as usual	Targeted health care services manager interview
Implementation cost		Implementation cost of each intervention component from a health sector perspective	Study and financial records

	% participants willing to pay a small one-off amount of $5 to access the *StandingTall* programme[a]	Participant survey at 6-months
	% participants interested in accessing the programme and advice from a helpline service as part of an annual subscription[a]	Participant survey at 6-months
Adverse Events[a]	Adverse events while exercising using the *StandingTall* programme or thought to be directly related to the *StandingTall* programme	Participant, support person and exercise specialist report

[a]These outcomes are for descriptive and/or process evaluation purposes and are not listed as outcomes in the Australian and New Zealand Clinical Trial Registry

[b]For the purposes of qualitative follow-up, support person refers to exercise specialists, caregivers, family and friends

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AUTHOR CONTRIBUTIONS

MET, CT, SO, LC, JCTC, SRL, TL, DB, JB, JC, JD, HHH, WH, KH, PJ, LR, GM, MM, LM, CMS, LW, NW, AZ and KD contributed to the design of the study and preparation of the study protocol. KD is Chief Investigator for the project, SRL, LC, JCTC, KH and CT are co-investigators, MET is Project Manager in Australia, HHH is Project Manager in the UK and SO is the Australian Project Officer. DB, AZ, NW, CMS, JD are associate investigators from partner organisations. JB, JC, PJ, RL, LM and LW are study staff involved in recruiting, data collection and management, follow-up, technological support and/or app development. KD, WH, MM and MET were involved in planning the evaluation of the study. This manuscript was drafted by authors KD, MET, SO and WH. MET, CT, SO, LC, JCTC, SRL, TL, DB, JB, JC, JD, HHH, WH, KH, PJ, LR, GM, MM, LM, CMS, LW, NW, AZ and KD revised the manuscript and all authors approved the submitted manuscript.

PATIENT AND PUBLIC INVOLVEMENT

Development of the *StandingTall* programme involved consumer feedback and testing. The design and conduct of the implementation trial was informed by partner organisations including Local Health Districts.

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COMPETING INTERESTS STATEMENT

Wendy Hodge and Marita Merlene work for ARTD Consultants who are a consultancy firm paid to evaluate the study. The other authors do not report any competing interests.

Word count

2682

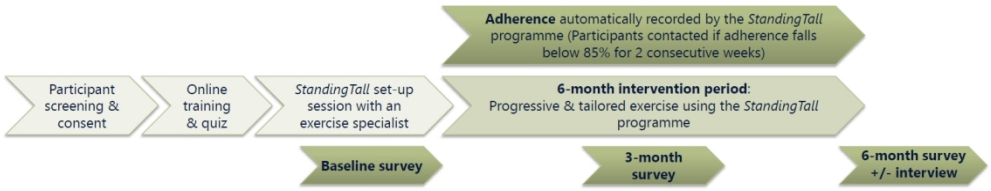

Figure 1. Participants flow through the study

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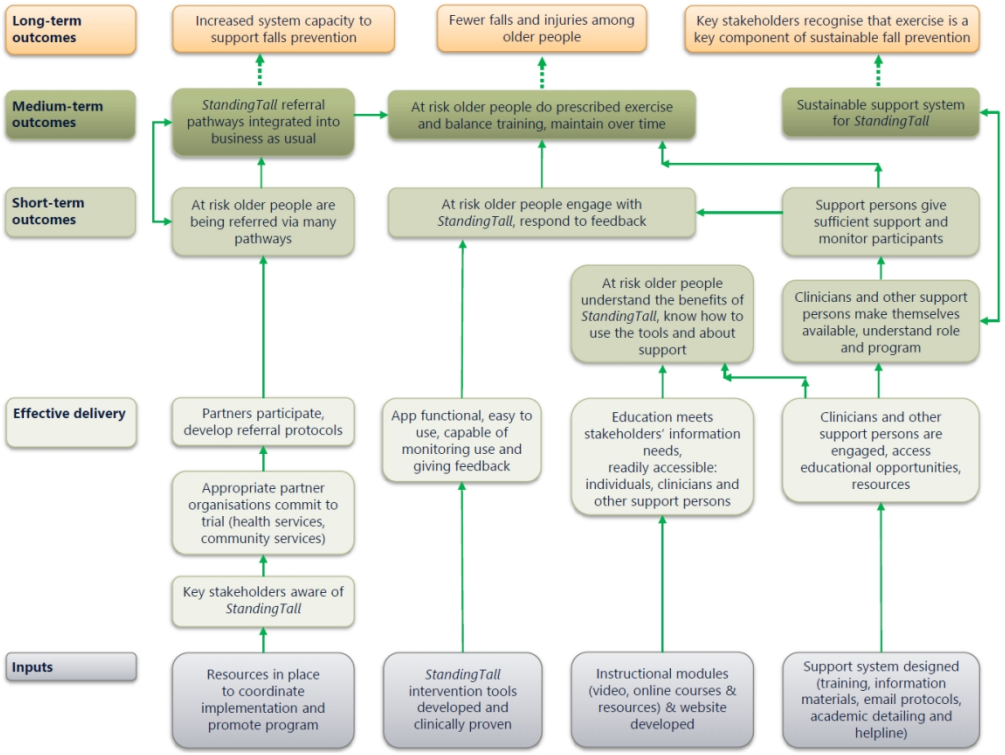

Figure 2. StandingTall Programme logic. (Note: The diagram is read from bottom to top and presents "if-then" relationships between inputs, effective delivery, and outcomes at different levels)

916x686mm (38 x 38 DPI)

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

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

Section/item	ItemNo	Description	Page no from track changes (TC) document
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	P1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Abstract
	2b	All items from the World Health Organization Trial Registration Data Set	available at ANZCTR
Protocol version	3	Date and version identifier	n/a
Funding	4	Sources and types of financial, material, and other support	P26
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	P1, P26
	5b	Name and contact information for the trial sponsor	On trial registry
	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	P26
	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)	ANZCTR, p15, n/a for manuscript
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	P6-8
	6b	Explanation for choice of comparators	n/a, no comparison group

Objectives	7	Specific objectives or hypotheses	P8
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	P8
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	P8-9
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	P9-11
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	P10-11
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	P10
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	P11
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	P10
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	P14, P16, Table 1
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	P15
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	P9
Methods: Assignment of interventions (for controlled trials)			
Allocation:			

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	n/a
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	n/a
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	n/a
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n/a
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Figure 1, Open Science Framework
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	P11
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Survey data entry is electronic
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	P16
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	n/a
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	n/a for non-adherence, p16
Methods: Monitoring			

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	P15
	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	P15
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	P15
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	P16-17
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)	P16
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	P16-17
	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	P17
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	P27
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	P17
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Abstract, P17

	31b	Authorship eligibility guidelines and any intended use of professional writers	P17
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	P17
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	n/a for manuscript
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

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