

BMJ Open 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 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 number 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 seventh-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 \$A1.4 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 among 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 (2–3 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 unwilling²⁴) 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 in 503 community-dwelling older people has shown that *StandingTall* is safe, has high adherence rates (median: 90 min/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. While 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 the UK. The project focuses on implementing the *StandingTall* programme across three partnering sites in Australia and one site in Northern England, 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 people 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,

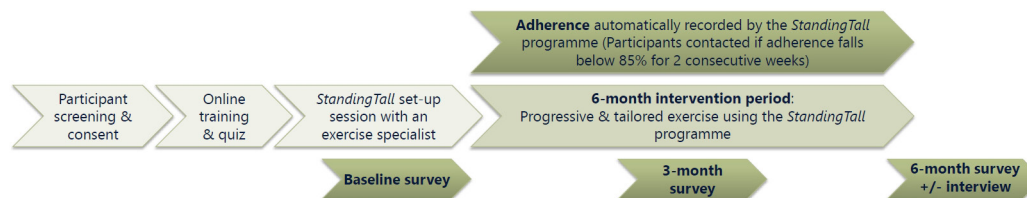


Figure 1 Participants flow through the study.

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 (ie, 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 (eg, standing on the floor and/or foam surface), walking (eg, walking in circles or to targets in a grid), stepping (eg, step and lift) and box (eg, 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 min in the first 2 weeks to 2 hours from week 9 onwards, through fortnightly 20 min 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/maintains/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 setup session with an exercise specialist (eg, 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 (ie, the CMS) 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, eg, 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

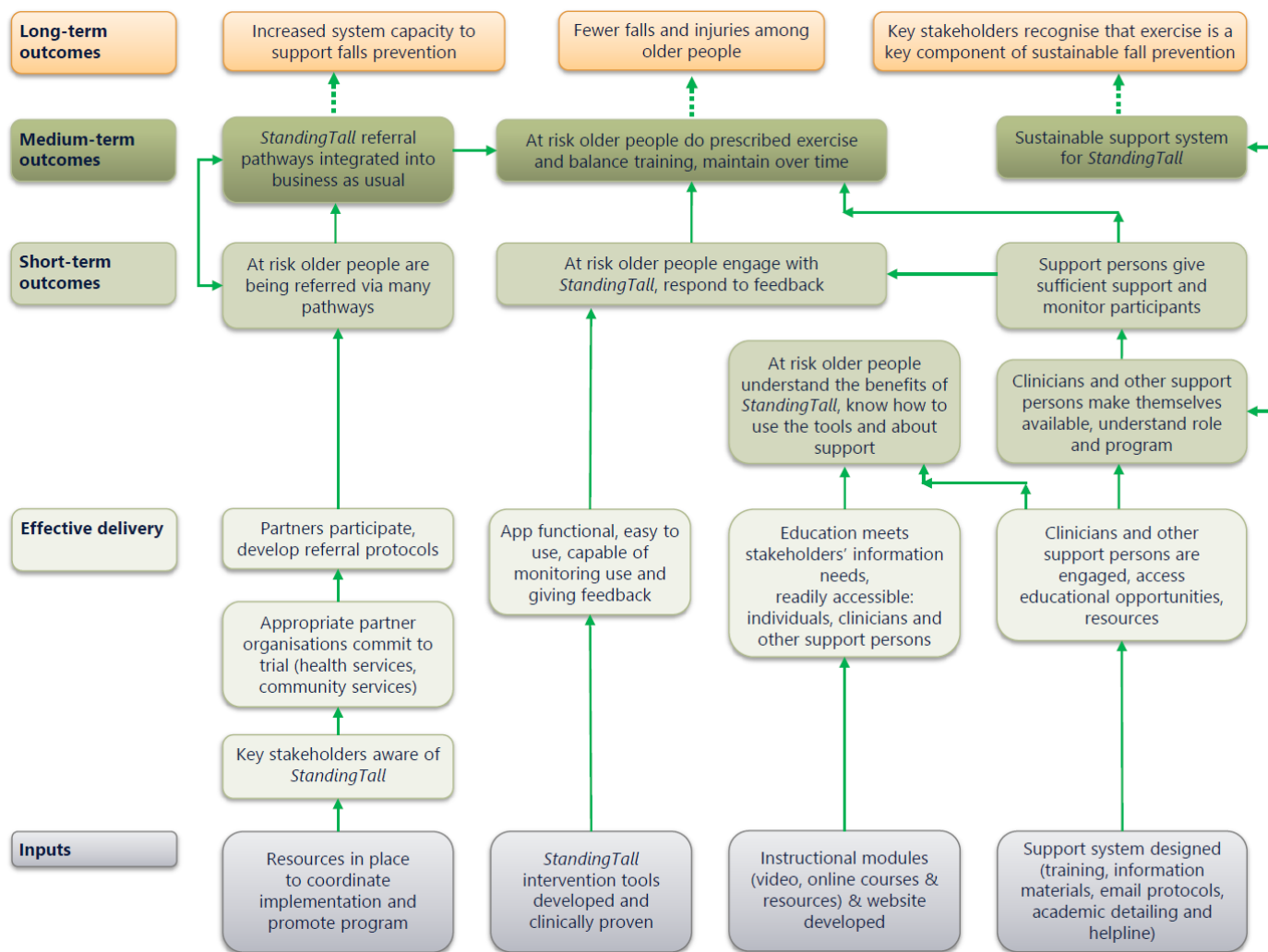


Figure 2 *StandingTall* Programme logic. (The diagram is read from bottom to top and presents 'if-then' relationships between inputs, effective delivery, and outcomes at different levels).

effective programme delivery will be achieved if these inputs are sufficient.

There are three kinds of outcomes streams for *StandingTall*—(1) outcomes for participating organisations, which are expected to contribute to increased system capacity to support falls prevention; (2) outcomes for study participants, which are expected to contribute to fewer falls among older people and (3) 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, coverage and feasibility (table 1). Medium and long-term outcomes include fewer falls among older people and increased system capacity to support falls prevention, and relate to 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, health-care 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 or setup for each exercise. Therefore, a 10 min session could take 20 min (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.

Table 1 Study outcomes

Generic implementation outcome	Related <i>StandingTail</i> outcome/s	Variables or measures	Measurement tool
Adoption	At risk older people are being referred by many pathways	Uptake by different referral agents: no of referral agents and no of referrals from each source No of referral agents referring five or more older people Average hours per week provided by support persons to support participants' use of <i>StandingTail</i> * Average no of people supported by healthcare worker in 18-month period* Uptake of participants: no older people referred who are accepted into study	Study logs Study logs Support person survey† Support person survey† Recruitment log
Appropriateness	Education modules meet stakeholders' information needs Support persons are actively engaged in <i>StandingTail</i> , understand role	% respondents (participants and exercise specialists) agree the instruction modules on the <i>StandingTail</i> website are helpful % participants agree 'I find <i>StandingTail</i> is easy to use** % support persons rate <i>StandingTail</i> as good or somewhat good fit with normal practise* % support persons agree the instruction modules on the <i>StandingTail</i> website are helpful*	Website users module survey Participant 3-month and 6-month surveys Support person survey† Support person survey†
Acceptability	At risk older people understand the benefits, how to use the programme and about supports	% participants agree 'I like to use the <i>StandingTail</i> app' % participants that rate <i>StandingTail</i> as a good or excellent % hospital and community workers involved in study that rate <i>StandingTail</i> as a good or excellent falls prevention intervention % support persons agree that <i>StandingTail</i> has had a positive or somewhat positive impact on their professional practice	Participant Survey at 3 and 6 months Participant Survey at 6 months Hospital and Community Worker survey Support person survey†
Fidelity	At risk older people use <i>StandingTail</i> 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*	At risk older people engage with <i>StandingTail</i> , respond to feedback	No people enrolled in <i>StandingTail</i> by age and gender, at each study site and in total	REDCap

Continued

Table 1 Continued

Generic implementation outcome	Related <i>Standing Tall</i> outcome/s	Variables or measures	Measurement tool
Feasibility	Partner organisations/services commit to study Support persons give participants sufficient support At risk older people engage with <i>Standing Tall</i> , respond to feedback	% hospital and community-based workers who regularly monitor patient's progress on <i>Standing Tall</i> exercise programme % hospital and community-based workers who regularly monitor patient's progress on <i>Standing Tall</i> exercise programme* No of services/ partners agree to be involved and nature of involvement compared with numbers approached* % participants agree 'I feel confident about doing the <i>Standing Tall</i> exercises'	Study logs Hospital and community-based workers survey Study logs Participant 3-month survey
Sustainability	<i>Standing Tall</i> referral pathways integrated into business as usual	% hospital and community-based workers who state they are definitely or probably going to keep using <i>Standing Tall</i> as part of their patient care No of health service managers' who state that the programme is being supported by relevant clinicians and partner organisations for continued use of <i>Standing Tall</i> programme No of health service managers who anticipate that <i>Standing Tall</i> will become part of your district/region/hospitals business as usual	Hospital and community based workers survey Targeted healthcare services manager interview Targeted healthcare services manager interview
Implementation cost		Implementation cost of each intervention component from a health sector perspective % participants willing to pay a small one-off amount of \$5 to access the <i>Standing Tall</i> programme* % participants interested in accessing the programme and advice from a helpline service as part of an annual subscription*	Study and financial records Participant survey at 6 months Participant survey at 6 months
Adverse events*		Adverse events while exercising using the <i>Standing Tall</i> programme or thought to be directly related to the <i>Standing Tall</i> programme	Participant, support person and exercise specialist report

*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.

†For the purposes of qualitative follow-up, support person refers to exercise specialists, caregivers, family and friends.

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 (eg, 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 (ie, 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 an SD of 43.1 min (estimated from an earlier trial²⁵), a sample size of 83 participants yield estimates of the mean with a CI width less than or equal to ± 10 min in 80% of studies. To allow for an approximately 20% lost 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 (IQR) 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 audiorecorded, 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 managers. 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 on reasonable request.

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LMC, JC, KH and CT are coinvestigators, MET is project manager in Australia, HH-H is Project Manager in the UK and SO is the Australian Project Officer. DJB, 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, LMC, JC, SRL, TL, DJB, JB, JC, JD, HH-H, WH, KH, PJ, RL, GM, MM, LM, CMS, LW, NW, AZ and KD revised the manuscript and all authors approved the submitted manuscript.

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Competing interests WH and MM work for ARTD Consultants who are a consultancy firm paid to evaluate the study.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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