E-health StandingTall balance exercise for fall prevention in older people: results of a two year randomised controlled trial

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ABSTRACT

OBJECTIVE
To test whether StandingTall, a home based, e-health balance exercise programme delivered through an app, could provide an effective, self-managed fall prevention programme for community dwelling older people.

DESIGN
Assessor blinded, randomised controlled trial.

SETTING
Older people living independently in the community in Sydney, Australia.

PARTICIPANTS
503 people aged 70 years and older who were independent in activities of daily living, without cognitive impairment, progressive neurological disease, or any other unstable or acute medical condition precluding exercise.

INTERVENTIONS
Participants were block randomised to an intervention group (two hours of StandingTall per week and health education; n=254) or a control group (health education; n=249) for two years.

MAIN OUTCOME MEASURES
The primary outcomes were the rate of falls (number of falls per person year) and the proportion of people who had a fall over 12 months. Secondary outcomes were the number of people who had a fall and the number of injurious falls (resulting in any injury or requiring medical care), adherence, mood, health related quality of life, and activity levels over 24 months; and balance and mobility outcomes over 12 months.

RESULTS
The fall rates were not statistically different in the two groups after the first 12 months (0.60 falls per year (standard deviation 1.05) in the intervention group; 0.76 (1.25) in the control group; incidence rate ratio 0.82, 95% confidence interval 0.66 to 1.02, P=0.070). Additionally, the proportion of people who fell was not statistically different at 12 months (34.6% in intervention group, 40.2% in control group; relative risk 0.90, 95% confidence interval 0.72 to 1.12, P=0.348). However, the intervention group had a 16% lower rate of falls over 24 months (incidence rate ratio 0.84, 95% confidence interval 0.72 to 0.98, P=0.027) and a 20% lower rate of injurious falls over 24 months compared with the control group (incidence rate ratio 0.80, 95% confidence interval 0.66 to 0.98, P=0.031). Both groups had a similar proportion of people who fell over 24 months (relative risk 0.87, 95% confidence interval 0.74 to 1.02, P=0.077). In the intervention group, 68.1% and 52.0% of participants exercised for a median of 114.0 min/week (interquartile range 53.5) after 12 months and 120.4 min/week (38.6) after 24 months, respectively. Groups remained similar in mood and activity levels. The intervention group had a 0.03 (95% confidence interval 0.01 to 0.06) improvement on the EQ-5D-5L (EuroQol five dimension five level) utility score at six months, and an improvement in standing balance of 11 s (95% confidence interval 2 to 19 s) at six months and 10 s (1 to 19 s) at 12 months. No serious training related adverse events occurred.

CONCLUSIONS
The StandingTall balance exercise programme did not significantly affect the primary outcomes of this study. However, the programme significantly reduced the rate of falls and injurious falls over two years, with similar but not statistically significant effects at 12 months. E-health exercise programmes could provide promising scalable fall prevention strategies.

TRIAL REGISTRATION
ACTRN12615000138583

WHAT IS ALREADY KNOWN ON THIS TOPIC

Balance exercise programmes are among the most effective fall prevention strategies, with fall reduction rates of 23% in older people who live in the community

Despite strong evidence that falls can be prevented, sustained full adherence in effective trials is poor, with pooled adherence rates of 21% (range 0-68%) at 12 months

Previous studies have shown that e-health technology can deliver unsupervised balance exercises to older people, with good adherence rates

WHAT THIS STUDY ADDS

This study is a large, long term, and methodologically robust trial examining technology driven exercise as a strategy to prevent falls in older people

Over two years, the StandingTall programme significantly reduced the rate of falls and the rate of injurious falls with dose adherence rates of 30-40%

Introduction

Falls and fall related injuries have persisted over the past three decades as a leading cause of morbidity and mortality in older people.[1] With a rapidly ageing population globally, sustainable access to evidence based, cost effective fall prevention programmes is a priority. Evidence from high quality systematic reviews and meta-regressions has confirmed that well designed exercise programmes are among the most effective fall prevention strategies for community dwelling

older people, with fall reduction rates averaging 23%.[2] However, to achieve similar effectiveness at a population level, we need a programme that people can access easily and adhere to in the long term. Previous studies have found that older people prefer home based exercises and that the inclusion of balance exercises is associated with higher adherence.[3] Nevertheless, sustained adherence to prescribed home exercise programmes is low, with pooled estimates of 21% (range 0-68%).[4] Studies providing a physiotherapist led programme or a moderate level of home visits (that is, less than one home visit per month and more than two home visits in total) achieve higher levels of adherence[4]; however, such measures substantially increase the cost and reduce the feasibility as a population approach.

Digital technology can provide engaging and widely accessible methods for delivery of exercise programmes to enhance long term motivation and adherence at relatively low cost.[5] However, the provision of a well designed, unsupervised exercise programme that is tailored and progressive in nature, yet safe, could be a challenge. StandingTall is a home based, e-health balance exercise programme provided through an app that was developed by using principles of consumer design to ensure an appropriate and user friendly interface for older people. Behavioural change strategies are incorporated to enhance exercise uptake and long term adherence.[6]

This randomised controlled trial aimed to determine the effect of StandingTall on the recommended set of core outcomes for fall prevention trials in older people (fall rate, number of people who fall and those who have an injurious fall; and known fall risk factors, including balance, gait, concern about falling, health related quality of life, and physical activity levels).[7] The trial had a 24 month follow-up period and compared the outcomes of the intervention with a health promotion education control programme. We hypothesised that StandingTall would lead to a reduced fall rate compared with a control group with minimal intervention.

Methods
Study design
We conducted a prospective, assessor blinded, two arm, parallel randomised controlled trial with two year follow-up in Sydney, Australia. The trial was approved by the University of New South Wales ethics committee in December 2014 (HC#14/266) and was registered prospectively in the Australian and New Zealand Clinical Trials Registry (ACTRN12615000138583) on 13 February 2015. The study protocol was published in 2015.[8] The statistical analysis plan was preregistered in October 2018 through the OpenScience framework (https://osf.io/42gje/) before completion of data collection in November 2019. We used the CONSORT (consolidated standards of reporting trials) statement, ICMJE recommendations, and TiDieR (template for intervention description and replication) checklist when preparing this article.

Participants
We recruited community dwelling older people in the Sydney metropolitan area by using flyers, printed advertisements in local newspapers, presentations at residential and community senior centres, and word of mouth. Study participants lived on average 12 km (range 1.2-46.9 km) from Neuroscience Research Australia (Randwick, NSW). After initial screening by telephone, eligible people were invited to participate if they were aged 70 years or older, living in the community, independent in activities of daily living, able to walk household distances without the use of a walking aid, and willing and able to give informed consent and comply with the study protocol. People were excluded if they had an unstable or acute medical condition that precluded exercise participation, suffered from a progressive neurological condition (such as Parkinson's disease or multiple sclerosis), were cognitively impaired as defined by a Pfeiffer short portable mental status questionnaire score less than 8,[9] or were currently participating in a fall prevention programme. Eligibility was determined after informed verbal consent. People who were eligible and agreed to participate in the study were asked to provide informed written consent.

Randomisation and masking
Participants were randomised after completion of the baseline assessment. Permuted block randomisation with mixed block lengths of four and six was applied to form two groups of similar size (allocation ratio 1:1). People living in the same household were treated as one unit to avoid contamination. Allocation was performed centrally using a custom randomisation programme by an investigator not involved in participant assessments or delivery of the intervention. Allocation concealment was ensured because the randomisation code was only released after the baseline assessment was completed. Only the first 226 participants were invited for repeated physical tests to reduce costs and participants' time. Outcome assessors were blinded to study group assignment throughout the trial. Statistical analyses were performed blinded for intervention or control group allocation.

Procedures
All participants received a tablet computer with a health promotion education programme that focused on health related information relevant to older people, in addition to usual care, for two years. This health promotion education programme comprised weekly fact sheets (104 in total) with information on healthy diet, drugs, fall risk factors, and exercise. Tablet based health education alone was chosen as the active control intervention to regulate the use of technology and allow data collection (such as number of falls during the trial period) through a tablet computer for both groups. Participants received a manual on how to use the tablet computer. After their baseline assessment, participants received guidance on the basic features of the tablet computer and health promotion education programme.

The intervention group received the StandingTall programme, with exercise equipment (foam cushion, stepping box, exercise mat), in addition to the health promotion education programme and usual care that was received by the control group. The StandingTall intervention consisted of balance exercises delivered through a tablet computer in the participants' homes with embedded behavioural change techniques, including a weekly calendar for scheduling exercises, goal setting, and educational fact sheets. The exercises focus on standing balance, targeted stepping, and step-up (box) exercises. More information about the programme can be found in the study protocol[8] and online (https://www.standingtall.org.au/). Participants were asked to exercise for at least two hours per week for the duration of the trial, in line with the international recommendations for fall prevention at the time of the study.[2] The intervention was introduced gradually; participants started with 40 min/week of exercise, which was increased by 20 min fortnightly until participants reached the required amount of two hours per week in week 9.

StandingTall delivers individually tailored balance exercises that increase in difficulty over time; the programme also allows people to choose the time and duration of their exercise sessions. The intensity of the balance exercises is monitored by using a self-report modified rate of perceived exertion scale and is adjusted as performance changes throughout the trial without the need for supervision. Exercise adherence (volume and frequency) was monitored for two years after automatic data transfer to a server. During the first six months, participants were encouraged to inform the research team when they were going away or would not be able to exercise for a few weeks. Participants who did not inform the team and did not reach 100 min/week for two consecutive weeks were contacted by telephone so that the reason for non-adherence could be recorded, any issues related to the programme could be discussed, and the team could encourage adherence. These calls stopped after six months to gain a better understanding of behavioural change and long term exercise adherence.

Intervention group participants received two home visits. During the first visit, a qualified exercise physiologist instructed the participant on how to use the StandingTall programme; this visit occurred between one and three weeks after the baseline assessment and lasted approximately one hour. The second home visit after one month lasted approximately 30 min and ensured safe use of the programme and progression of training. Control group participants received two phone calls by qualified exercise physiologists at the same time points to discuss any issues with accessing the health education programme and using additional features of the tablet computer.

Outcomes

The primary outcome measures were the rate of falls and the proportion of people who fell over the first 12 months of the trial. A fall was defined as 'an unexpected event in which the participant comes to rest on the ground, floor or lower level'.[7] Falls were monitored by using prospective weekly fall diaries through the tablet computer (completed from baseline assessment for 24 months). Fall information was automatically uploaded to a database. Research staff contacted participants by telephone at the end of each month when their fall diaries were incomplete to record missing data. The falls database was checked, reviewed, and locked before group allocation was unmasked. Falls that occurred up to one year after randomisation were included in the primary analysis. Falls that occurred up to two years after randomisation were included as secondary fall outcomes. Injurious falls were defined as falls that resulted in any injury (eg, bruises, cuts or grazes, joint dislocations, sprains or strains, fractures, pain), or falls that required medical care (eg, visit to physician or emergency department).

Secondary outcome measures were assessed at baseline, at six months to examine acute effects, and at 12, 18, and 24 months to examine retention effects. These measures included common fall risk factors: laboratory based balance and neuropsychological assessments (at baseline and at six and 12 months after baseline assessment in the first 226 participants), and remote measures (taken at home) of wellbeing, quality of life, and activity levels (at baseline and at six, 12, 18, and 24 months after baseline assessment in all participants). Physiological fall risk was assessed using the physiological profile assessment.[10] Balance, functional mobility, and gait were evaluated by using tests of standing balance (standing with feet in different positions for a maximum of 30 s per condition: feet together, near tandem, and tandem on floor and foam cushion, and left and right foot on floor; sum of durations for all eight conditions), maximum forward-backwards and controlled leaning balance,[10 11] timed sit-to-stand[12] and up-and-go tests,[13] short physical performance battery,[14] and self-selected walking speed over 10 m.[15] Stepping performance was assessed with choice, Stroop and inhibitory stepping reaction time tests.[16 17] Cognitive function was measured with the Montreal cognitive assessment[18] for global cognition, trail making tests[19] for set shifting, and the Victoria Stroop task[20] for response inhibition. Psychological outcome measures were assessed by using the iconographical falls efficacy scale (concern about falling),[21] the nine item patient health questionnaire (mood)[22] and the COMPAS-W scale (wellbeing).[23] Health related quality of life was measured with the 12 item WHO disability assessment schedule,[24] the EuroQol five dimension five level (EQ-5D-5L) questionnaire,[25] and the AQOL-6D (20 item assessment of quality of life six dimensions) questionnaire.[26]

Detailed self-report information on frequency and duration of physical activity was evaluated with the incidental and planned exercise questionnaire.[27] Daily life activity was assessed with the McRoberts MoveMonitor (McRoberts, Netherlands) as the average duration of daily walking and standing, and the number of walking and standing bouts per day[28]; a

bout was defined as a period of consecutive activity. Because participants were instructed to remove the device before going to bed, we required a minimum wear duration of 12 hours per day on one or more days for daily life activity data to be included in the analysis. Daily life activity data were collected over a median of six days (interquartile range one day) for both groups.

Process outcome measures included exercise duration and were captured through the tablet computer. Because participants were allowed exercise breaks when they were sick or went on holiday, we averaged weekly exercise duration as median values for participants as a robust measure of central tendency. We obtained subjective user experience by assessing usability, enjoyment, and exercise self-efficacy with the system usability scale,[29] the physical activity enjoyment scale,[30] the exercise self-efficacy scale,[31] and the attitudes to falls related interventions scale.[32]

All outcome measures were assessed by trained exercise physiologists or physiotherapists who were blinded to group allocation. We assessed safety in terms of adverse events, which were defined as any fall related to the prescribed exercise programme or involving the intervention equipment.

Statistical analysis

Sample size calculation—based on previous evidence, we carried out an a priori sample size calculation[8] in Stata using a custom code with 5000 simulations. The calculation showed that 500 participants were required to achieve 80% power to find a fall rate reduction of 33% (incidence rate ratio of 0.67) in the intervention versus the control group that is statistically significant at a P value less than 0.05 (considering an overdispersion of 1.2, 0.8 falls/person year in the control group, and a follow-up duration of 22 months to account for 20% dropout rate). We then ran power calculations in G*Power (version 3.1.7) for our secondary outcomes (considering an analysis of variance design with four measurements and 20% dropout rate). These calculations showed that we would have 90% power to detect a statistically significant (P<0.05) small reduction (effect size f=0.15) in concern about falling in the intervention group versus the control group, assuming a within subject correlation of 0.75.[8] A subsample of 200 participants with repeat physical assessments would provide us with 95% power to detect a statistically significant (P<0.05) large reduction (effect size f=0.38) in postural sway in the intervention group versus the control group, assuming a within subject correlation of 0.76.[8]

Analysis plan—analyses were conducted according to the predefined statistical analysis plan, as registered on the OpenScience framework (https://osf.io/42gje/). We coded data to maintain group allocation blinding during analysis. Effectiveness analyses of the primary outcome were conducted on an intention-to-treat basis by a statistician (BT or NB) and independently replicated by one of the investigators (KSvS). The α level was set to 5%. Analyses were performed with Stata (version 16, Stata Corp) and SPSS (version 25, IBM Corp).

Missing data—participants who were randomly assigned to a group were included in the analysis irrespective of their level of compliance with their group assignment, which was in line with intention-to-treat principles. The primary outcome measures (number of falls per person year and proportion of people who fell over 12 months) were analysed without imputation or adjustment for descriptive characteristics, and with correction for follow-up duration when appropriate. We assumed that the faller status of people with incomplete follow-up (n=66 at 12 months and n=188 at 24 months, distributed evenly over the two groups) was maintained during censoring. We used Little's missing completely at random test to determine the missing data patterns of secondary outcome measures. The secondary outcome measures were imputed using estimated means single imputation if they were missing completely at random; or under the assumption of missing at random using multiple imputation to create 20 imputation datasets under joint multivariate normal imputation[33] if they were not missing completely at random. Psychological wellbeing, health related quality of life, and physical activity questionnaire data were missing for 58 out of a total of 503 people at six months, for 82 people at 12 months, for 98 people at 18 months, and for 99 people at 24 months. Daily life activity monitoring data were unavailable for 21 people at baseline, 101 people at six months, 138 people at 12 months, 148 people at 18 months, and 156 people at 24 months. Clinic based balance and neuropsychological assessment data were missing for 42 people at six months and for 47 people at 12 months. These data were missing because of dropout, scheduling issues, non-adherence, or technical problems. Little's missing completely at random test indicated that all data were missing at random with respect to participant baseline characteristics.

Primary outcomes—primary outcomes were the number of falls per person year, and the proportion of people who fell over 12 months. The number of falls per person year was analysed using Poisson regression to estimate the difference in fall rates between the two groups. Incidence rate ratios and 95% confidence intervals are reported. Poisson regression was selected over negative binomial regression (as a priori registered in our statistical analysis plan, but not in our protocol paper) to allow for a direct comparison with our planned complier average causal effects analysis because this analysis was based on a Poisson model. Online appendix 1 presents the results of the negative binomial regression. Days of follow-up was included as an exposure term in these models; that is, the natural logarithm of the days of follow-up was added as an offset. We examined the proportion of people who fell in the two groups by using modified Poisson regression models for binary outcomes. Faller status was compared (no falls *v* at least one fall) and relative risks and 95% confidence intervals are reported.

Secondary outcomes—secondary fall outcomes were the number of falls, the complier averaged causal effect, the number of injurious falls, the proportion of

people who fell, and the proportion of people who had injurious falls at 24 months. We used instrumental variable regression to correct for imperfect participant adherence and to gain insight into efficacy by estimating the complier averaged causal effect. We used a 2000 times bootstrapped, two stage complier averaged causal effect estimator composed of a linear regression with adherence as the dependent variable and group as the independent variable to obtain an estimate for adherence. A robust Poisson regression was then performed, with falls as the dependent variable and the natural logarithm of follow-up in days as exposure to estimate the effect of the intervention among people with perfect adherence. The number of injurious falls per person year was analysed using Poisson regression to estimate the difference in injurious fall rates between the two groups. We analysed secondary non-fall outcome measures with robust generalised linear models using an exchangeable working correlation matrix and compared the change in scores over time at six, 12, 18, and 24 months between the two groups. When the residuals of the generalised linear models deviated from normality, we used a 1000 times bootstrap for each imputation dataset to obtain confidence intervals.

Patient and public involvement
StandingTall was developed using consumer design principles. A group of older people were involved during the development of the StandingTall application. They were asked to evaluate an early version on its usability and age appropriateness as a means to engage in fall prevention exercises using tablet based technology. A two week feasibility study was conducted in 10 community dwelling older people in November 2013. The average age of the participants was 77.5 years (range 67-82 years), and six participants were women. Physiological profile assessment scores ranged from mild to marked (median z score 1.68; range 0.79-2.94) and seven participants had experienced falls in the previous year. Adherence was high, with participants reporting that the programme was suitable for older people. There was no other formal patient and public involvement in this study.

Results
Between February 2015 and October 2017, 823 people were screened (fig 1). Of these, 503 people were included in the study and randomly assigned to the intervention group (n=254) or the control group (n=249). We lost 90 participants during the two year follow-up (intervention group, n=53; control group, n=37) and 46 participants in the intervention group discontinued the intervention but continued to contribute data. Table 1 presents baseline characteristics of all participants.

Effect on primary fall outcomes
Rate of falls at 12 months—the incidence rate of falls over the first 12 months was 0.61 (95% confidence interval 0.52 to 0.71) in the intervention group and 0.75 (0.64 to 0.85) in the control group. The difference

in fall rate was not statistically different, with an incidence rate ratio of 0.82 (95% confidence interval 0.66 to 1.02, P=0.070) in the intervention group compared with the control group (see fig 2).

Proportion of people who fell over first 12 months—overall, 188 participants (37.4% in total; 34.6% in the intervention group and 40.2% in the control group) fell at least once in the 12 month follow-up period. Participants in both groups were equally likely to fall at least once, with a relative risk of 0.90 (95% confidence interval 0.72 to 1.12, P=0.35) in the intervention group compared with the control group.

Effect on secondary fall outcomes
Rate of falls at 24 months—the incidence rate of falls over the 24 month follow-up was 1.17 (95% confidence interval 1.03 to 1.30) in the intervention group and 1.39 (1.25 to 1.53) in the control group. The difference in fall rate was statistically different, with an incidence rate ratio of 0.84 (95% confidence interval 0.72 to 0.98, P=0.03) in the intervention group compared with the control group.

Rate of falls through complier averaged causal effects at 24 months—complier averaged causal effect analysis revealed an incidence rate ratio of 0.67 (95% confidence interval 0.21 to 1.13, P=0.22) in the intervention group compared with the control group. This figure was similar to that reported in the intention-to-treat analysis.

Rate of injurious falls at 24 months—the incidence rate of injurious falls over the 24 month follow-up was 0.71 (95% confidence interval 0.60 to 0.81) in the intervention group and 0.88 (0.76 to 0.99) in the control group. The difference in injurious fall rate was statistically different, with an incidence rate ratio of 0.80 (0.66 to 0.98, P=0.03) in the intervention group compared with the control group.

Proportion of people who fell at 24 months—270 participants (53.7%) fell at least once in the 24 month follow-up. Participants in both groups were equally likely to fall at least once, with a relative risk of 0.87 (95% confidence interval 0.74 to 1.02, P=0.077) in the intervention group compared with the control group.

Proportion of people who had injurious falls at 24 months—210 participants (41.7% in total; 37.4% in the intervention group and 46.2% in the control group) experienced an injurious fall during the 24 month follow-up. Participants in both groups were equally likely to have injurious falls, with a relative risk of 0.87 (95% confidence interval 0.71 to 1.06, P=0.17).

Effect on secondary outcomes of wellbeing, quality of life, and activity levels
We found no significant difference in psychological wellbeing or physical activity levels at six, 12, 18, and 24 months in the two groups (table 2). We found a small improvement of 0.03 (95% confidence interval 0.01 to 0.06) on the EQ-5D-5L utility score at six months in the intervention group compared with the control group. All other health related quality of life measures showed no difference between the two groups at all time points.
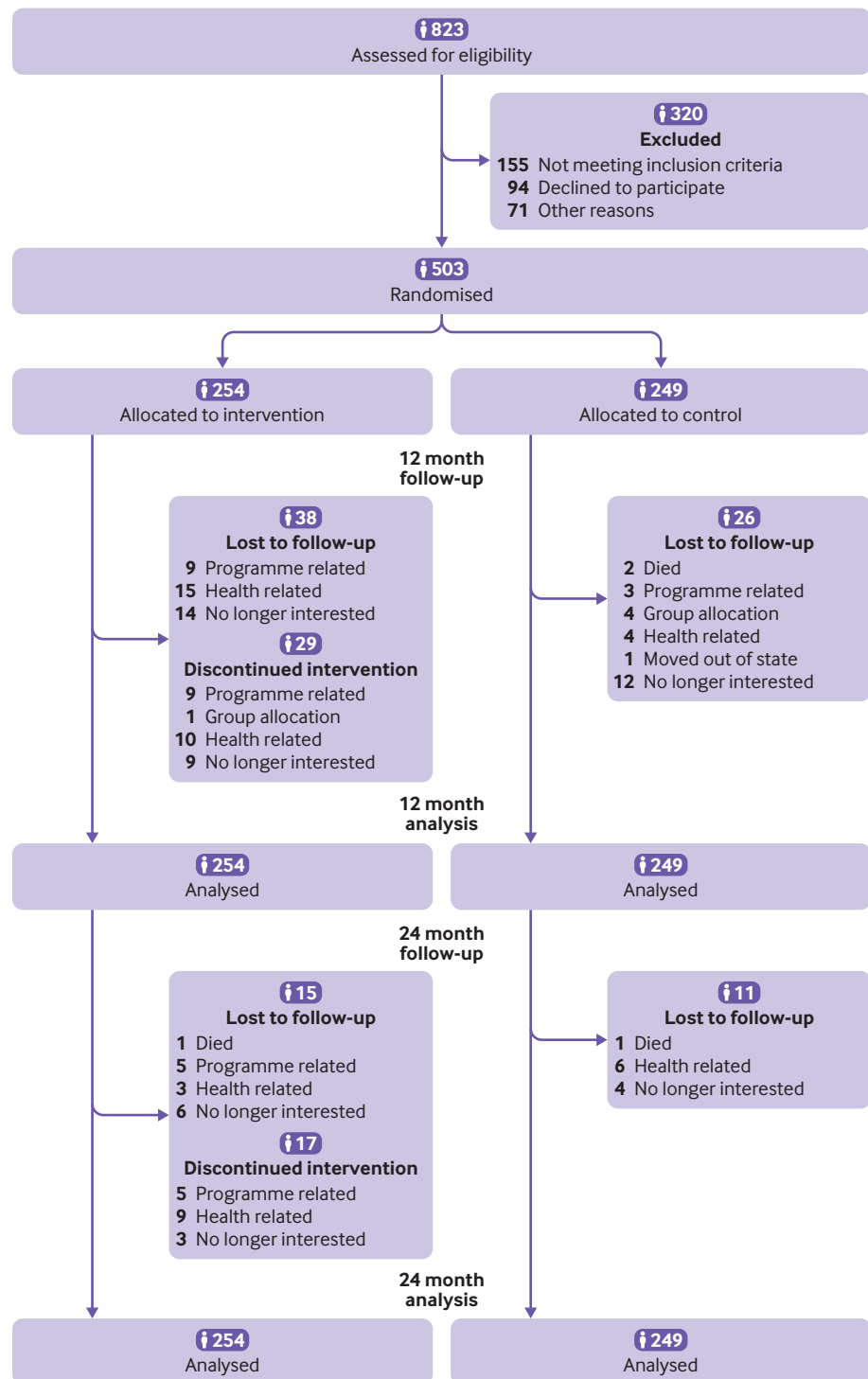
Fig 1 | Flowchart of study recruitment and retention

Effect on secondary outcomes of balance and neuropsychological assessments

The 226 participants (45% of the total sample; 114 in intervention group and 112 in control group) who were invited for laboratory reassessments were on average 1.1 years older (78.0 (standard deviation 5.4) years *v* 76.9 (5.5) years in those not invited; t(501)=−2.29, P=0.02) and scored 0.40 points higher on physiological fall risk (measured with physiological profile assessment: 1.10 (standard deviation 0.82) *v* 0.70 (0.90) in those not invited; t(501)=−5.06, P<0.001). No other important differences in baseline characteristics were found between these groups. We observed a significant improvement in standing balance at six and 12 months (11 s, 95% confidence interval 3 to 19 s, and 10 s, 1 to 19 s, respectively) in the intervention group compared with the control group (table 3). We found no significant difference in physiological fall risk,

Table 1 | Baseline characteristics of all participants (n=503). Values are means (standard deviations) unless stated otherwise

Variable	Intervention group (n=254)	Control group (n=249)
Age (years)	77.1 (5.5)	77.7 (5.5)
Female sex (n (%))	177 (69.7)	162 (65.1)
Body mass index	27.3 (4.5)	27.0 (4.9)
Education (years)	14.4 (4.1)	14.6 (4.4)
Living alone (n (%))	113 (44.5)	104 (41.9)
Owns a computer (n (%))	214 (85.0)	220 (88.4)
Uses walking aid (n (%))	18 (7.1)	20 (8.0)
No of falls in previous year (median (IQR))	0 (1)	0 (1)
EQ-5D-5L VAS* (median (IQR))	90 (15)	85 (15)
No of medical conditions (median (IQR))	0 (1)	0 (1)
No of prescription drugs† (median (IQR))	3 (3)	3 (3)
Montreal cognitive assessment‡ (median (IQR))	27 (3)	27 (3)
Trail making test B minus A (s; median (IQR))	55.3 (36.2)	54.8 (44.8)
Patient health questionnaire§ (median (IQR))	2 (4)	2 (4)
Iconographical falls efficacy scale¶ (icon-FES)	53 (16)	55 (16)
Physiological fall risk (PPA score)	0.99 (0.74)	1.19 (0.87)
Timed up and go (s)	8.5 (3.3)	8.6 (3.0)

EQ-5D-5L VAS=EuroQol five dimension five level visual analogue scale; IQR=interquartile range; PPA=physiological profile assessment.
*Score range 0-100.
†Aailable for 335 (66.6%) people.
‡Score range 0-30 (best score 30).
§Score range 0-27 (best score 0).
¶Score range 30-120 (best score 30).

maximum forward-backwards and controlled leaning balance, functional mobility and gait tests, stepping performance, or cognitive and executive functions at six or 12 months between the two groups.

Subgroup analyses

Planned subgroup analyses in participants who did or did not experience falls in the past 12 months or had low or high physiological fall risk, concern about falling, or executive function scores (median splits on physiological profile assessment, iconographical falls efficacy scale, and trail making test B) at baseline suggested no mediation on rate of falls (all P=0.058; see online appendix 2). The subgroup analysis suggested mediation by baseline status of physiological fall risk on physiological fall risk and by baseline status of concern about falling on concern about falling (P=0.004 and P=0.027, respectively; see online appendix 3). People with lower physiological fall risk at baseline had a significantly greater improvement in physiological fall risk at six months of 0.52 points (95% confidence interval 0.17 to 0.88 points). People

with higher concern about falling at baseline had a significantly lower improvement in concern about falling at 12 months of −5 points (−9 to −1 points).

Process outcomes

Adverse events—five falls occurred in three participants from the intervention group while exercising, which led to minor injuries (grazes, bruising, cuts). These falls were directly related to the intervention. Three falls occurred during exercise sessions and two were caused by tripping over exercise equipment.

Adherence—in the intervention group, a total of 51 participants (20.1%) had a median adherence of 0 min/week at six months, 81 (31.9%) at 12 months, 104 (40.9%) at 18 months, and 122 (48.0%) at 24 months, either because of dropout or non-usage attrition (see fig 1). The remaining participants exercised for a median of 105.0 min/week (interquartile range 58.5, n=203) over the first six months, 114.0 min/week (53.5, n=173) over the first 12 months, 120.0 min/week (39.3, n=150) over 18 months, and 120.3 min/week (38.6, n=132) over the full 24 months. Overall,

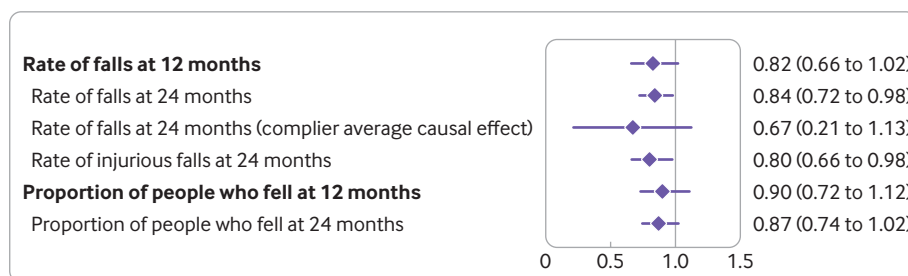|		
Rate of falls at 12 months		0.82 (0.66 to 1.02)
Rate of falls at 24 months		0.84 (0.72 to 0.98)
Rate of falls at 24 months (complier average causal effect)		0.67 (0.21 to 1.13)
Rate of injurious falls at 24 months		0.80 (0.66 to 0.98)
Proportion of people who fell at 12 months		0.90 (0.72 to 1.12)
Proportion of people who fell at 24 months		0.87 (0.74 to 1.02)

Fig 2 | Effect of StandingTall, a home based, e-health balance exercise programme, on rate of falls, rate of injurious falls, and proportion of people who fell at 12 months and 24 months. Values are incidence rate ratio (rate of falls) or relative risk (proportion of people who fell) with corresponding 95% confidence interval. Vertical line indicates no difference between groups (incidence rate ratio or relative risk=1). Primary outcome measures are given in bold

40.0%, 34.1%, 33.1%, and 29.8% of participants in the intervention group achieved the prescribed dose over six, 12, 18, and 24 months, respectively.

Attitudes and usability—attitudes to falls related interventions and exercise self-efficacy scale scores at baseline were similar for both groups (P=0.595 and P=0.681, respectively), with medians of 42 (interquartile range 9) and 86 (22) in the control group versus 42 (8) and 87 (23) in the intervention group. We repeated both measures and also obtained system usability scale and physical activity enjoyment scale scores for the intervention group at six, 12, 18, and 24 months. Attitudes to falls related interventions score declined over time (P<0.001) from a median of 42 (interquartile range 8) at baseline, to 40 (10) at six months, 39 (11) at 12 months, 39 (14) at 18 months, and 35 (18) at 24 months; these results suggest

reduced intentions to continue the intervention. Exercise self-efficacy scale score also declined over time (P<0.001) from a median of 87 (interquartile range 23) at baseline, to 75 (28) at six months, 70 (27) at 12 months, 69 (39) at 18 months, and 59 (41) at 24 months; these results suggest reduced exercise self-efficacy. Physical activity enjoyment scale and system usability scale scores remained stable over time (P=0.36 and P=0.70, respectively), with medians of 27 (interquartile range 14) and 4.4 (0.8), respectively.

Discussion
Principal findings
We observed no significant effects on our primary outcomes—rate of falls and proportion of people who fell—at 12 months. However, at 24 months we did observe a significant reduction in fall rate (16%)

Table 2 | Effect on secondary outcome measures in all participants. Values are means (standard deviations) unless stated otherwise

Variable	Control group					Intervention group					Change in intervention group v control group, β (95% CI), P value			
	0M	6M	12M	18M	24M	0M	6M	12M	18M	24M	0-6M	0-12M	0-18M	0-24M
Psychological wellbeing														
PHQ-9* (median (IQR))	2 (4)	3 (5)	3 (4)	4 (3)	3 (5)	2 (4)	2 (4)	3 (4)	3 (5)	3 (4)	0 (0 to 0), P=NA	0 (0 to 0), P=NA	0 (0 to 0), P=NA	0 (0 to 0), P=NA
Icon-FES†	55 (16)	53 (16)	55 (16)	57 (20)	58 (18)	53 (16)	52 (17)	51 (16)	52 (19)	53 (18)	2 (−2 to 6), P=0.331	−1 (−5 to 3), P=0.597	−2 (−6 to 2), P=0.254	−2 (−6 to 2), P=0.400
COMPAS-W‡	100 (11)	100 (11)	100 (11)	100 (12)	100 (11)	101 (12)	102 (12)	102 (12)	102 (13)	102 (12)	1 (−1 to 4), P=0.342	1 (−1 to 4), P=0.324	1 (−2 to 3), P=0.614	1 (−1 to 4), P=0.313
Health related quality of life														
WHODAS§ (median (IQR))	6.3 (12.5)	7.2 (15.6)	8.8 (14.7)	8.1 (16.5)	6.3 (16.5)	4.1 (10.4)	4.9 (12.9)	6.3 (13.4)	6.2 (14.5)	7.7 (14.6)	−1.6 (−4.1 to 0.8), P=NA	−0.2 (−2.7 to 2.3), P=NA	0.3 (−2.5 to 3.1), P=NA	0.2 (−2.0 to 2.5), P=NA
EQ-5D-5L VAS¶ (median (IQR))	85 (15)	87 (16)	83 (19)	80 (16)	80 (20)	90 (15)	90 (14)	89 (11)	87 (15)	88 (14)	−2 (−6 to 3), P=NA	0 (−4 to 4), P=NA	−2 (−6 to 2), P=NA	1 (−4 to 6), P=NA
EQ-5D-5L utility** (median (IQR))	0.89 (0.03)	0.87 (0.04)	0.87 (0.05)	0.86 (0.06)	0.86 (0.05)	0.89 (0.04)	0.87 (0.05)	0.87 (0.05)	0.87 (0.06)	0.88 (0.05)	0.03 (0.01 to 0.06), P=NA††	−0.01 (−0.04 to 0.03), P=NA	0.01 (−0.02 to 0.05), P=NA	0.01 (−0.02 to 0.04), P=NA
AQOL-6D utility** (median (IQR))	0.88 (0.16)	0.87 (0.15)	0.87 (0.16)	0.86 (0.20)	0.86 (0.16)	0.89 (0.14)	0.90 (0.15)	0.89 (0.16)	0.90 (0.19)	0.89 (0.15)	0.01 (−0.02 to 0.04), P=NA	−0.01 (−0.04 to 0.02), P=NA	0.14 (−0.94 to 1.24), P=NA	0.01 (−0.02 to 0.03), P=NA
Physical activity levels														
IPEQ planned activity (h; median (IQR))	5.3 (6.7)	5.0 (7.6)	4.9 (5.8)	4.2 (7.3)	4.4 (6.0)	5.4 (7.6)	5.7 (9.1)	5.9 (7.4)	5.0 (7.4)	5.0 (6.5)	0.5 (−0.8 to 1.8), P=NA	0 (−4.3 to 4.2), P=NA	−1.6 (−5.6 to 2.4), P=NA	1.1 (−3.6 to 5.7), P=NA
IPEQ incidental activity (h; median (IQR))	34.0 (28.9)	38.0 (30.1)	32.0 (33.6)	36.9 (24.3)	33.8 (35.4)	33.0 (35.2)	38.0 (32.9)	32.0 (33.8)	36.9 (24.4)	37.8 (34.6)	−2.8 (−7.8 to 2.3), P=NA	−0.9 (−6.8 to 5.0), P=NA	−1.7 (−7.0 to 3.7), P=NA	−1.9 (−7.3 to 3.4), P=NA
IPEQ planned exercise (h; median (IQR))	3.0 (4.9)	3.1 (4.7)	3.0 (4.5)	2.7 (4.5)	2.6 (3.9)	2.8 (4.9)	3.5 (5.3)	3.6 (4.9)	2.7 (4.4)	3.0 (4.7)	0.6 (−0.4 to 1.7), P=NA	0.9 (−0.1 to 2.0), P=NA	0.1 (−0.9 to 1.2), P=NA	0.6 (−0.5 to 1.6), P=NA
MM walking time (h)	1.26 (0.47)	1.20 (0.47)	1.16 (0.51)	1.13 (0.49)	1.19 (0.54)	1.35 (0.59)	1.31 (0.54)	1.25 (0.61)	1.21 (0.55)	1.21 (0.61)	0.02 (−0.11 to 0.14), P=0.790	0.01 (−0.13 to 0.14), P=0.901	−0.01 (−0.14 to 0.12), P=0.875	−0.07 (−0.19 to 0.06), P=0.301
MM walking bouts	423 (142)	429 (153)	418 (163)	396 (161)	411 (175)	441 (162)	459 (182)	444 (179)	424 (171)	413 (184)	11 (−31 to 54), P=0.583	8 (−34 to 51), P=0.692	10 (−36 to 56), P=0.644	−16 (−58 to 27), P=0.452
MM standing time (h)	2.52 (0.75)	2.55 (0.92)	2.52 (0.87)	2.42 (0.86)	2.44 (0.93)	2.59 (0.87)	2.65 (1.11)	2.62 (0.99)	2.48 (1.01)	2.34 (0.96)	0.03 (−0.23 to 0.30), P=0.788	0.03 (−0.23 to 0.28), P=0.825	−0.01 (−0.26 to 0.23), P=0.913	−0.16 (−0.41 to 0.09), P=0.190
MM standing bouts	870 (289)	880 (314)	877 (312)	824 (297)	848 (353)	880 (320)	948 (366)	934 (361)	876 (355)	825 (355)	59 (−24 to 142), P=0.156	47 (−38 to 132), P=0.263	42 (−48 to 132), P=0.338	−32 (−116 to 52), P=0.433

AQOL-6D=20 item assessment of quality of life six dimensions; COMPAS-W=COMPAS-W scale; EQ-5D-5L=EuroQol five dimension five level; Icon-FES=iconographical falls efficacy scale; IPEQ=incidental and planned exercise questionnaire; IQR=interquartile range; M=months; MM: McRoberts MoveMonitor; PHQ-9=nine-item patient health questionnaire; WHODAS=12-item WHO disability assessment schedule.
P=NA indicates bootstrapped outcomes, which did not allow P values to be estimated.
*Score range 0-27 (best score 0).
†Score range 30-120 (best score 30).
‡Score range 26-130 (best score 130).
§Score range 0-100% (best score 0).
¶Score range 0-100 (best score 100).
**Score range 0-1 (best score 1).
††P<0.05 or confidence intervals not crossing 0.

and in injurious fall rate (20%). The effect size of an 18% reduction in fall rate at 12 months was similar to that at 24 months, although it was not statistically significant (P=0.07). The observed reduction in fall rate is comparable to that reported in previous studies—21% reduction with individually delivered exercise programmes over 12 months and 14% over 24 months.[2 34] However, the 20% reduction in the rate of injurious falls over 24 months seems to be higher than the 12% reduction previously reported in other studies.[35] These findings indicate that technology can be used to deliver an e-health balance exercise programme to older people that is effective at reducing fall rates and injurious fall rates over 24 months.

Secondary outcome analyses were not able to clearly highlight the pathway through which the reduction in rate of falls and injurious falls was achieved. While a number of research studies testing the effects of exercise interventions on balance in older people have shown an effect, systematic review findings have suggested that the evidence for a moderate effect is weak.[36] In a subgroup of 226 participants, we observed a major improvement in standing balance at six and 12 months; however, this observation was not confirmed through other balance and functional mobility measures. We did not repeat these assess-

ments at 24 months when a significant reduction in falls was observed. The StandingTall programme includes a monthly balance assessment that consists of maintaining a standing posture with the feet in different positions; it is possible that the repeated practice carried over to laboratory assessments for participants in the intervention group. This trial might have been underpowered for detecting differences in fall risk factors because our sample had a lower fall risk than anticipated. The a priori sample size calculation was based on a sample with a mean physiological fall risk score (physiological profile assessment) of 1.9 (standard deviation 1.1), which is a full point higher than that of the current sample (0.88, standard deviation 0.88).[8] Interestingly, our preregistered subgroup analyses found no significant modification of fall rates, but did suggest significant modification of the assessment outcomes at 12 months, with people with lower physiological fall risk and lower concern about falling benefitting more. Further research is required to confirm the effectiveness of StandingTall in older people with an increased risk of falling. Quality of life measured with the EQ-5D-5L utility index also showed a small, but potentially clinically relevant[37] improvement at six months, however no significant differences were found at 12 or 24 months.

Table 3 | Effect on secondary outcome measures in a subsample of 226 participants. Values are means (standard deviations) unless stated otherwise

Variable	Control group			Intervention group			Change in intervention group v control group, β (95% CI), P value	
	0M	6M	12M	0M	6M	12M	0-6M	0-12M
Physiological fall risk								
PPA score	1.19 (0.87)	1.17 (0.77)	0.97 (0.93)	0.99 (0.74)	0.82 (0.82)	0.76 (0.92)	−0.15 (−0.39 to 0.09), P=0.214	−0.01 (−0.27 to 0.26), P=0.955
Balance, functional mobility, and gait								
Standing balance (s; median (IQR))	188 (69)	189 (81)	186 (73)	193 (95)	209 (71)	198 (70)	11 (3 to 19),* P=NA	10 (1 to 19),* P=NA
Maximum lean range AP (cm)	15 (3)	16 (4)	18 (4)	15 (3)	17 (4)	19 (4)	1 (0 to 2), P=0.206	1 (0 to 2), P=0.213
Coordinated lean (score; median (IQR))	7 (13)	9 (15)	8 (11)	7 (11)	6 (11)	5 (12)	−2 (−4 to 0), P=NA	−1 (−3 to 1), P=NA
Timed up-and-go test (s)	8.6 (3.0)	8.7 (3.6)	8.6 (4.1)	8.5 (3.3)	8.5 (3.4)	8.2 (3.3)	−1.8 (−4.4 to 0.7), P=0.146	−1.5 (−3.7 to 0.8), P=0.190
5 times sit-to-stand test (s)	12.4 (4.3)	12.1 (5.2)	11.5 (4.7)	12.4 (5.4)	12.1 (4.6)	11.0 (3.8)	0.1 (−1.0 to 1.2), P=0.864	−0.4 (−1.5 to 0.6), P=0.411
10 m walk (s)	9.0 (2.0)	9.1 (3.1)	8.8 (3.0)	8.9 (2.1)	8.7 (2.4)	8.6 (2.5)	−0.3 (−0.8 to 0.3), P=0.322	−0.1 (−0.6 to 0.5), P=0.802
Short physical performance battery (score; median (IQR))	11 (2)	11 (2)	11 (2)	11 (2)	11 (1)	11 (2)	0 (0 to 0), P=NA	0 (0 to 1), P=NA
Stepping performance								
Choice stepping reaction time (s)	1.16 (0.20)	1.17 (0.17)	1.18 (0.23)	1.13 (0.18)	1.15 (0.19)	1.17 (0.18)	0.01 (−0.05 to 0.06), P=0.744	0.03 (−0.03 to 0.08), P=0.380
Inhibitory stepping reaction time (s)	1.32 (0.40)	1.32 (0.43)	1.32 (0.38)	1.26 (0.37)	1.36 (0.49)	1.29 (0.36)	0.10 (−0.04 to 0.23), P=0.143	0.03 (−0.11 to 0.17), P=0.645
Stroop stepping reaction time (s)	1.25 (0.42)	1.24 (0.39)	1.22 (0.39)	1.21 (0.34)	1.28 (0.38)	1.19 (0.34)	0.17 (−0.14 to 0.48), P=0.302	0.26 (0.12 to 0.40), P=0.116
Cognitive performance and executive functions								
TMT-A (s; median (IQR))	31.9 (11.8)	27.5 (14.4)	39.6 (12.8)	29.8 (12.7)	29.7 (11.8)	28.4 (13.9)	1.8 (−0.7 to 4.2), P=NA	0.6 (−2.0 to 3.1), P=NA
TMT-B (s; median (IQR))	85.2 (50.7)	90.1 (54.3)	84.3 (55.8)	87.7 (43.2)	87.5 (53.5)	87.8 (51.8)	1.5 (−8.0 to 11.0), P=NA	5.1 (−5.1 to 15.3), P=NA
TMT-B minus TMT-A (s; median (IQR))	54.8 (44.8)	60.5 (44.0)	56.2 (44.1)	55.3 (36.2)	55.9 (38.9)	59.7 (41.9)	−0.3 (−10.5 to 9.6), P=NA	4.5 (−5.8 to 15.0), P=NA
Victoria Stroop ratio	2.13 (0.87)	1.87 (0.92)	1.98 (0.91)	1.95 (0.74)	1.89 (0.89)	1.98 (0.96)	0.20 (−0.13 to 0.53), P=0.224	0.18 (−0.15 to 0.51), P=0.270
Victoria Stroop errors (median (IQR))	4 (5)	3 (5)	3 (4)	3 (5)	3 (5)	2 (4)	0 (0 to 0), P=NA	0 (0 to 0), P=NA

AP=anteroposterior; M=months; PPA=physiological profile assessment; TMT=trail making test.
P=NA indicates bootstrapped outcomes, which did not allow estimation of P values.
*P<0.05 or confidence intervals not crossing 0.

Adherence to the intervention was higher than reported for previous exercise trials, with 40% of participants being fully adherent over the first six months and 30% being fully adherent over the full 24 months compared with pooled estimates of 21% in previous trials.[32] These rates are particularly encouraging because adherence was recorded automatically and is therefore a true representation of the actual amount of balance training people received; often adherence rates have lower accuracy because of self-reports or estimates based on number of sessions attended.[32] Eighty per cent of participants in the intervention group had a median adherence of 105 min/week over six months, and over half sustained a median adherence of 120 min/week over 24 months, despite the low level of contact during the study (two home visits in the first month and incidental follow-up calls during the first six months). We acknowledge that when an exercise programme is rolled out to the community with potentially even less follow-up, adherence might be lower. Enjoyment and usability of the StandingTall intervention remained high throughout the study duration. Weekly median exercise durations suggest that the exercises might have become part of the lifestyle of participants who remained in the study. While intentions and self-efficacy towards completing two hours of exercise per week declined over time, this is probably a more realistic reflection of actual long term self-efficacy. The relatively high adherence and zero serious adverse events show promise for upscaling the intervention to a population level.

Strengths and limitations of this study

The strengths of this study were its large sample size, pragmatic design using a programme that could be delivered as part of routine care, broad inclusion criteria and use of methods designed to reduce the risk of bias such as concealed random allocation to groups, blinded outcome assessment, intention-to-treat analyses, and preregistered statistical analysis plan (see assessment in online appendix 4). The primary study limitations were, firstly, the reliance on self-reported falls; however, the weekly e-diaries completed by both groups should have removed any reporting bias. Secondly, similar to many other exercise trials, participant masking was not possible; this might have led to bias by expectation, considering that many outcomes were self-rated. Thirdly, our study design intentionally included more than one outcome measure to account for the many causes of falls, and in theory, the subsequent multiple testing of the results could introduce error. Fourthly, the community dwelling older people who participated in our study were highly educated, had a high percentage of computer ownership, and lived in more affluent areas of Sydney; our results might not generalise to usage in more rural or less affluent areas. Finally, it is possible that our weekly education fact sheets have induced a behaviour change in our control group, reducing our statistical power.

Implications for policy and practice

New methods for delivery of quality healthcare are required to increase the effectiveness of fall prevention programmes while containing costs and using scarce human resources to maximum effect. The ultimate success of a health promotion programme depends on its effectiveness and its reach and acceptability in the community. A recently published multifactorial fall prevention trial in 5451 older people at high risk of fall injuries showed that all participants had poor balance, and 95% agreed to take up an exercise programme.[38] However, the authors indicated that uptake and adherence to community based exercise programmes was low, and the evidence base of these available exercise programmes was uncertain.[38] Standing-Tall fills an important gap by helping older people to exercise at home; that is, those who are unable (or unwilling) to attend out-of-house or group exercises, or those who wish to combine group and home based exercises. In their global action plan on physical activity 2018-2030, the World Health Organization advocated exercise as a protective factor in the development of non-communicable diseases such as diabetes, cardiovascular disease, and stroke.[39] Recent evidence also shows that exercise can delay the onset of dementia and improve mental health in older people.[40] Also, in light of the covid-19 pandemic, as face-to-face delivery has been curtailed and deconditioning is widespread, e-health can offer an engaging, home based alternative to reduce the long term adverse health effects caused by extended periods of isolation in older people. E-health programmes such as StandingTall can provide older people with an opportunity to stay active, preventing physical deconditioning and concomitant falls, functional dependence, and increased healthcare use while maintaining covid-19 safety recommendations.

Conclusions

Our results show that a tailored e-health exercise programme is an effective intervention in preventing falls in older people. StandingTall is a scalable intervention and can be easily incorporated into clinical practice, providing healthcare professionals with a platform to remotely set up, monitor, and tailor the programme for their patients. StandingTall offers full user autonomy and requires minimal interaction with healthcare professionals. An economic evaluation is planned to determine whether StandingTall represents value for money.

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The authors report that the physiological profile assessment (NeuRA FallScreen) is commercially available through Neuroscience Research Australia.

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Supplementary information: online supplementary material