Age and Ageing 2024; **53:** afae214
https://doi.org/10.1093/ageing/afae214

RESEARCH PAPER

Feasibility and acceptability of the HOLObalance telerehabilitation system compared with standard care for older adults at risk of falls: the HOLOBalance assessor blinded pilot randomised controlled study

Marousa Pavlou[1,2,3], Carol Ann Flavell[1], Fariba Mostajeran Gourtani[4], Christos Nikitas[5], Dimitris Kikidis[5], Athanasios Bibas[5], Dimitris Gatsios[6], Vassilis Tsakanikas[6], Dimitrios I. Fotiadis[6,7], Dimitrios Koutsouris[8], Frank Steinicke[4], Isabelle Daniela Walz[9,10], Christoph Maurer[9], Sofia Papadopoulou[5], Michalis Tsoukatos[5], Athanasios Pardalis[6], Doris-Eva Bamiou[2,3]

[1]Centre for Human and Applied Physiological Sciences, King's College London, London, UK
[2]Ear Institute, University College London, London, UK
[3]Department of Audiovestibular Medicine, Royal National ENT and Eastman Dental Hospitals, University College London Hospitals NHS Foundation Trust, London, UK
[4]Human-Computer Interaction Group, Department of Informatics, Universität Hamburg, Hamburg, Germany
[5] I st Department of Otorhinolaryngology, Head and Neck Surgery, National and Kapodistrian University of Athens, Hippocrateion General Hospital, Athens, Greece
[6]Unit of Medical Technology and Intelligent Information Systems, Department of Materials Science and Engineering, University of Ioannina, Ioannina, Greece
[7]Biomedical Research Institute, Ioannina, Greece
[8]Biomedical Engineering Laboratory, School of Electrical and Computer Engineering, National Technical University of Athens, Athens, Greece
[9]Department of Neurology and Neuroscience, Faculty of Medicine, Medical Center, University of Freiburg, Freiburg, Germany
[10]Department of Sport and Sport Science, University of Freiburg, Freiburg, Germany

Address correspondence to: Marousa Pavlou, Centre for Human and Applied Physiological Sciences, King's College London, London, UK. Email: marousa.pavlou@nhs.net

Abstract

Background: Falls have high socioeconomic costs. Information and communication technologies may support provision and monitoring of multisensory (MSR) physiotherapy programmes. The HOLOBalance platform used augmented reality holograms to provide patient-centred, individualised MSR.
Objectives: To determine the platform's safety, acceptability and feasibility, investigate functional gait and dynamic balance benefits and provide data for a definitive trial.
Design and setting: Single-blinded pilot randomised controlled feasibility study. Interventions were conducted at clinical sites or participants' homes in three European countries.
Participants: Community-dwelling older adults (median age 73 years; 64.2% female) at risk of falls were enrolled (May 2020-August 2021).
Methods: Participants were randomised to an 8-week clinic or home-based telerehabilitation MSR or OTAGO (control group) programme. Compliance, satisfaction, and adverse events determined feasibility. Clinical outcomes, assessed (blinded) within one-week prior to and post-intervention, included functional gait assessment (FGA), Mini BESTest and cognitive function.

Results: Randomisation to completion rate was 76.15% with 109 participants recruited (n = 289 screened). Drop-out rate was similar between groups. Adverse events were reported (n = 3) in the control group. Sixty-nine percent would recommend the HOLOBalance intervention. Findings were similar for the home and clinic-based arms of each intervention; data was combined for analysis. FGA (95%CI [1.63, 4.19]) and Mini-BESTest (95%CI [1.46, 3.93]) showed greater improvement in the HOLOBalance group with a clinically meaningful change of 4/30 noted for the FGA.
Conclusions: HOLObalance was feasible to implement and acceptable to older adults at risk of falls, with FGA and Mini-BEST improvements exceeding those for the OTAGO programme. A definitive trial is warranted.

Keywords: augmented reality; balance rehabilitation; older adults; falls risk; older people

Key Points

- Augmented reality rehabilitation is feasible and can be delivered in both a clinical and at-home setting for older adults who have fallen or have increased falls risk.
- Functional gait and dynamic balance improvements were greater for the HOLOBalance augmented reality rehabilitation system vs. OTAGO programme.
- Findings suggest that the HOLOBalance system may offer greater clinically meaningful improvements in falls risk within a reduced time frame, compared to standard care. A randomised controlled trial is warranted.

Introduction

Balance, vestibular disorders [1–5] and cognitive factors are leading causes for falls. Additionally, age-related decline in executive function and attention reduces dual-tasking balance and walking speed and is associated with higher falls rates and risk [6,7].

Balance relies on vestibular, visual and proprioceptive input processing and anticipatory postural adaptations to environmental challenges [8]. Individualised physiotherapy addressing balance control domains is an evidence-based reference standard for older adults with falls or increased falls risk [2]. Multisensory balance physiotherapy (MSR) combines conventional balance, with multisensory, dual-task and/or cognitive training exercises [9–12]. MSR has demonstrated safety, feasibility, acceptability, and strong efficacy in older adults with greater reduction in falls risk and rate compared to control interventions including wrist stabilisation exercises, modified OTAGO programme, or usual care [9,10,13,14]. The OTAGO programme is a muscle strengthening, balance retraining, and walking program for falls prevention in older adults. MSR combined with interactive technologies enhances quality of life, physical activity levels, and reduces depression [15,16].

Despite demonstrable efficacy of individualised MSR for older adults [2,14], successful implementation remains challenging [2,17–19]. Suitable resources and expert skills to implement these interventions are lacking [17,18]. Poor exercise performance monitoring and progression results in significantly worse outcomes in unsupervised vs. supervised interventions [20].

Technology-based solutions including virtual and augmented reality (VR, AR), gamification, sensor-based monitoring and real-time patient feedback can support MSR provision, mitigating these issues. These solutions provide motivation and promote exercise adherence, towards long-term behaviour change [21]. 'Designed for purpose' interactive technologies are needed, to support and guide clinicians' prescribing and monitoring of MSR programmes. Previous studies used commercial exergames that do not allow for customised, comprehensive MSR while various other fall detection and prevention technologies (i.e. tablet-based) for older adults are mostly static and provide no user-clinician interaction [22].

The HOLOBalance AR system [23] was designed to provide individualised MSR exercises and exergames that address the needs of older adults with increased falls risk and enables exercise performance monitoring and user-interaction with body worn sensors (pressure measuring insoles, inertial measurement unit (IMU), heart rate monitor).

This study compared the HOLOBalance (intervention group) versus OTAGO programme (control group) [24] in community-dwelling older adults at risk of falls. Study aims were to (i) determine the system's safety, acceptability, and feasibility; (ii) assess if balance, gait, disability, cognitive function, and fear of falling can improve more compared to standard intervention and (iii) provide preliminary data for a definitive randomised controlled trial.

Methods

The study was conducted in academic clinical settings in Germany, Greece and the UK as described in the published protocol [23].

Trial design

A randomised controlled pilot study, adhering to the Consolidated Standards of Reporting Trials (CONSORT) [25]. A clinic and home-based MSR programme, delivered via HOLOBalance was compared with a standard care

(home-based) and modified (clinic-based) Otago programme [26]. Ethical approval was granted by Human Research Ethics Committees in Germany (265/19), Greece (9769/24-6-2019), and UK (19/LO/1908). All participants provided written informed consent on arrival at their baseline assessment session.

Patient and public involvement

Age UK London recruited older adults (n = 75) between April 2018 and November 2019 to attend plenary meetings, focus groups, and workshops. Older adults were involved in (i) testing potential sensors and headsets for the HOLObalance system and its feasibility for home use, (ii) completing questionnaires and providing feedback on the system's viability and study protocol and (iii) the user testing phase of the system. Feedback was positive, with older adults expressing a keen interest in the technology and willingness to use the device. Specific feedback regarding usability and design was considered by the research team to assist in HOLObalance system development (i.e. headset choice, sensors, sensor placement, home set-up and hologram images).

Study settings and enrolment

Between May 2020 and August 2021 (funding endpoint), participants were enrolled into the study from aged care organisations, support groups and academic clinics at each site.

Study criteria

Independently living, community-dwelling older adults aged 65-80 years at risk of falls (defined as Functional Gait Assessment (FGA) score $\leq$ 22/30 [27], Falls Efficacy Scale (FES-1) score $\geq$ 20/64 [26]; and/or reported $\geq$ 1 fall in previous year); able to walk $\geq$500 m continuously, independent or single-point stick assisted; able to understand and consent; no or mild cognitive impairment (Montreal Cognitive Assessment (MoCA) score > 22/30 [27,28]) were recruited.

Exclusion criteria were orthostatic hypotension ($\geq$20 mm Hg or $\geq$ 10 mm fall in systolic or diastolic blood pressure, respectively, within three-minutes of standing [29]; uncontrolled hypertension; significant visual impairment; short-form Geriatric Depression Scale score > 10/15 [30]; acute musculoskeletal injury; neurological condition; clinical drug trial participation within previous six months; currently receiving balance, or cognitive rehabilitation; implanted medical devices.

Sample size, randomisation and allocation concealment

No formal sample size calculation was performed. However, for quantitative studies, a sample of 30 per group may be adequate to establish feasibility [31]. This study therefore aimed to recruit n = 120 participants. Participants were randomised (www.sealedenvelope.com) on a 1:1:1:1 ratio into an in-home or in-clinic delivered HOLOBalance or Otago programme by researchers external to the study at each site. Allocation concealed in consecutively numbered opaque envelopes was presented to treating physiotherapists (n = 2 at each clinical site) and participants after baseline assessment. Assessors were blinded to intervention allocation. Training was provided to all physiotherapists and assessors to ensure a consistent approach to enrolling, assessment, and intervention implementation.

Interventions

All participants were asked to practise prescribed exercises for 30-minutes daily over 8-weeks. Physiotherapists pre-programmed the HOLOBalance in-home or clinic-based system with individualised evidence-based MSR exercises, cognitive, auditory, and gamified activities [23]. Range, degrees, movement speed, and number of repetitions were recorded with IMU sensors, positioned at the forehead within the head-mounted device and over the sacrum via an abdominal/pelvic belt. The home-based system provided real time instructions (see www.holobalance.eu).

Training goals and individual programmes were set via an electronic dashboard (Figure1A). For all exercises, participants' movement and physiological performance and symptoms provoked data was relayed, stored, and available via the dashboard as tables, graphs, or plots (Figure 1B). Data evaluation guided clinical decisions for weekly modification and progression of participants' programmes.

Control group participants received the OTAGO standardised written and pictorial instruction workbook of systematically progressed exercises [26].

Intervention delivery

Site-based physiotherapists conducted all study interventions. HOLOBalance in-clinic participants attended twice-weekly sessions, delivered by the 'holographic virtual physiotherapist' projected into a purpose-built 2 x 2 x 2 metre 'HOLOBox' (Figure 1C). Cognitive training (exergames; auditory training) was delivered via an AR headset [23]. The physiotherapist remained nearby to ensure participant safety with no therapist-participant interaction during the session. On non-attendance days, participants practised individualised MSR exercises at home.

The HOLOBalance in-home system was installed by a visiting physiotherapist, who provided verbal and written instructions for safe exercise performance, and training regarding application and use of wearables. MSR and cognitive training were delivered by a 'holographic virtual physiotherapist', through an AR headset (Figure 1D). Participants were contacted weekly by phone to address difficulties and discuss MSR modifications and progressions.

Otago [24], in-clinic participants completed exercises twice-weekly under physiotherapist supervision and at home on non-attendance days. The in-home group had an initial visit by the treating physiotherapist to ensure correct, safe practise of the exercises and completed these at home only. Participants logged their exercises in a diary for weekly

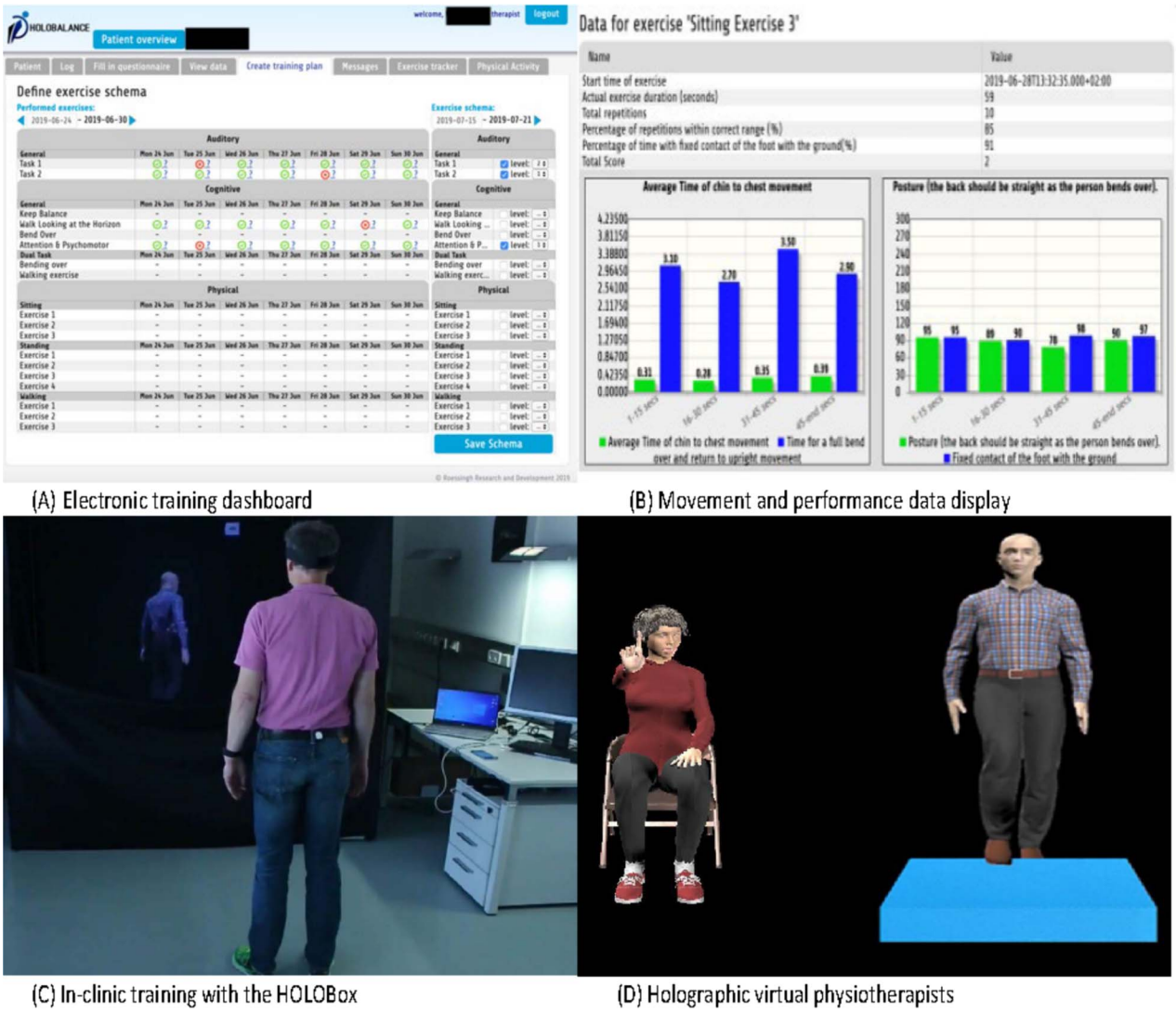

Figure 1. Image of HOLOBalance electronic dashboard (1A), sample of movement and performance data (B), example of in-clinic HOLOBalance training (C) and holographic virtual physiotherapist demonstrating MSR exercises (D).

telephone-based review. Instructions and progressions adhered to the programme's standardised process and clinical judgement.

Outcome measures

Primary outcomes were

(i) acceptability: recruitment (percentage of eligible participants enrolled); drop-out rates; intervention adherence (percentage of prescribed sessions completed) monitored automatically through the system for in-home HOLOBalance participants and via an exercise diary for control and HOLOBalance in-clinic groups for non-clinic attendance days;

(ii) Adverse events (AEs): participants were monitored for AEs via completion of adverse events forms on the system database, during telephone or face-to-face contacts as part of the intervention phase and during follow-up assessments. Falls were also monitored by the platform;

(iii) HOLOBalance feasibility: protocol deviation (PD) or study protocol implementation problems (e.g. logistical);

(iv) Exit interviews with 13 structured questions were completed with all HOLOBalance group completers. Four questions exploring participants' experience using the system (perceived benefits, frustrations, and recommendations) are presented.

Secondary outcomes

Clinical assessments were completed in a single session, at baseline and within one-week of intervention completion, by the same assessor, using a standardised sequential process for demographic, physical, and cognitive outcomes.

Objective measures included FGA [32,33] and Mini-BESTest [34,35] which assess complex gait/dynamic balance and MoCA [27,28] for cognitive function. Subjective measures included the FES-1 [26] to measure concerns about falling; Activities Specific Balance Confidence Scale (ABC)

[36] for balance confidence; World Health Organisation Disability Assessment Schedule 2 (WHODAS-2.0) [37] to assesses disability across multiple domains; and Behavioural Regulation in Exercise Questionnaire (BREQ-3) [38] to measure exercise motivation.

Statistical analysis

Primary outcome analysis was mainly descriptive with participant flow and screening, recruitment, adherence, and drop-out estimates reported. No formal hypotheses testing on within- and between-group change was conducted as the study was underpowered to test for effectiveness [39]. Secondary outcome measure data was presented as mean (95% confidence interval [lower range, upper range]). IBM SPSS Statistics (version 29) was used for chi-square or Mann–Whitney U tests to assess drop-out rate, demographic information, and ordinal and/or non-normally distributed variables between-groups at baseline. In view of non-significant differences between the two HOLOBalance (n = 30 at-home, 28 in-clinic) and two OTAGO groups (n = 26 at-home, 25 in-clinic), data was combined for each intervention and analysis performed on two groups. Missing data for collected variables was less than 5%, i.e. inconsequential [40]. Missing data from drop-out participants was excluded and not treated.

A Dovetail application (https://dovetail.com) that provides qualitative data analysis tools, analysed exit interview question responses, which were manually tagged, presented in chart form, and reported qualitatively as numbers, with inclusion of some verbatim exemplar statements.

Results

Recruitment, retention, drop-out rate and baseline characteristics

Older adults (n = 289) were assessed for eligibility with n = 180 excluded and n = 109 randomised into a control or intervention group (Figure 2). Ineligibility reasons included age-range (n = 26), falls risk (n = 23) or MoCA (n = 6) criteria not met, neurological diagnosis (n = 10); orthostatic hypotension (n = 5), significant visual impairment (n = 3), acute musculoskeletal injury (n = 2), unwilling to travel to clinic twice-weekly (n = 13); currently receiving balance/cognitive rehabilitation (n = 9). Table 1A-C details participants' baseline characteristics.

Recruitment was 39.7% in Athens, Freiburg 52.6% and London 7.7%. Recruitment differences were associated with Covid-19 restrictions on human research, with the London site disproportionately affected. Target sample size was not achieved by n = 11. Randomisation to completion rate was 76.15%. Higher mean adherence was noted for the HOLOBalance (83.2%;SD 17.6%) vs. control (66.3%,SD 26.1%) group. Drop-out rate was similar between interventions (Table 1A-C). Drop-out reasons are included in Figure 2. No PDs were reported.

Adverse events

No Serious AEs were reported. Three AEs were reported. In the control group, two participants dropped-out due to Covid-19 and n = 1 dropped out due to severe dizziness, with AEs reported as unrelated to the intervention as the OTAGO programme does not include exercises at intensities that may induce significant dizziness.

Exit interview results

All HOLOBalance group completers answered exit interview questions. System experience was rated as very good to good by 38%, 27% reported technical problems, 11% stated it required improvements and 7% reported exercise related issues (overlong pause between exercises; additional progressions required). Problems or frustrations experienced with the exercises or games included technical difficulties (76%) with connectivity and insoles (31%), head-mounted display or sensor issues, disappearing hologram, lack of feedback, or system delay (22%). One participant stated, 'Positive experience even though there were problems with the connectivity of the sensors which caused delays.'

Seventy-one percent reported improved balance with 33% attributing this to the HOLOBalance exercises and 18% to other improvements including decreased fear of falling, dizziness or stress, more stable gait, or increased balance awareness. 'My balance is much better because of my participation' was a standout statement from one participant. Two participants (4%) believed their balance had either not changed or worsened. Overall, 69% of participants would recommend the system to others as they believed it is helpful with one participant stating, 'Yes because I had improvement and I have friends with similar problems'. However, 31% would not yet recommend it since they believed it must be improved primarily regarding technical difficulties stated above and for a more user-friendly home-based system.

Between-group findings for secondary outcomes.

A greater mean pre-post treatment change was observed in the HOLObalance vs. OTAGO intervention (Table 2A) for the FGA (mean difference 2.91, 95% CI [1.63. 4.19]) and Mini-BESTest (mean difference 2.69, 95% CI [1.46. 3.93]). Between-group pre-post treatment change was similar in both groups or much less than that for the FGA and Mini-BEST for all other secondary outcomes (Table 2A).

Discussion

The HOLOBalance proof of concept study evaluated the efficacy of AR delivered, sensor-based monitored, with real-time feedback MSR compared to the widely used OTAGO programme. The first platform iteration demonstrated moderately strong approval by older adult users with 69% reporting they would recommend it to others, and greater improvements for complex gait and dynamic balance outcomes for the HOLOBalance vs. OTAGO programme at eight-weeks.

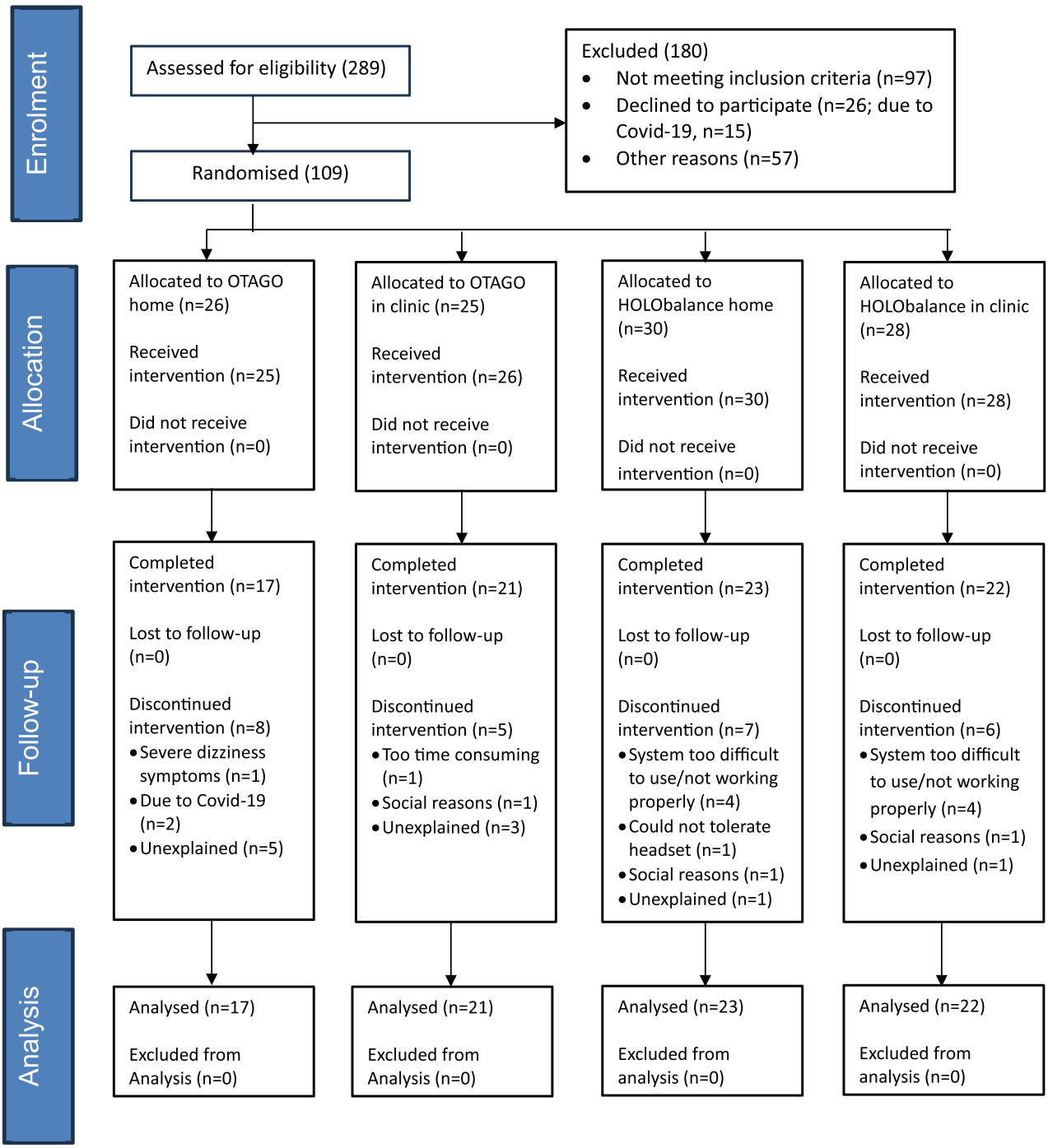

Figure 2. CONSORT diagram to demonstrate participant flow through the HOLOBalance study (modified from CONSORT 2010) [25].

HOLOBalance platform approval agrees with previous studies which suggest that combined contextual information for fall risk assessment, fall prevention instructions, and patient attributes improves acceptance of such technologies by older adults [41,42].

MSR provision using information and communication technologies is a rapidly evolving field [43]. Remote assessment and management of patients with balance disorders and falls is now mandatory standard practice [44] in line with worldwide strategic priorities for digital healthcare [45]. These technologies support multifaceted individualised rehabilitation but require evaluation for feasibility, acceptability, effectiveness, and safety [46] prior to clinical implementation. Study data support the HOLOBalance system's feasibility and safety with no PDs or AEs directly related to the intervention. Standard operating procedures, training

Table 1. Participant characteristics for the combined group data for the OTAGO and HOLOBALANCE programmes (A), and separately for the OTAGO (B) and HOLObalance (C) at home and in clinic group data

A.

Variable	OTAGO combined groups; (n = 51)	HOLOBalance combined groups (n = 58)
Age (y) (median, range)	73.06 (65– 80)	72.00 (65– 80)
Sex (n)	51	58
Female (n, %)	31 (60.80%)	39 (67.20%)
Male (n, %)	20 (39.20%)	19 (32.80%)
Education (n, %)		
–*Left formal education before age 16*	1 (2.00%)	4 (6.90%)
–*Left formal education at age 16*	2 (3.90%)	5 (8.6%)
–*Left formal education before age 18*	11 (21.60%)	11 (19.00%)
–*Undergraduate degree/Higher National*	13 (25.5%)	13 (22.4%)
–*Diploma*	6 (11.8%)	13 (22.4%)
–*Master's degree/Post-graduate Diploma*	10 (19.6%)	6 (10.30%)
–*PhD*	8 (15.7%)	6 (10.30%)
–*Missing*		
Falls in last 12 months (n, %)	24 (47.1%)	33 (56.9%)
Drop-out rate (n, %)	13 (25.5%)	13 (22.4%)

B.

Variable	OTAGO at home (n = 25)	OTAGO In clinic (n = 26)
Age (y) (median, range)	75.00 (67– 80)	71.00 (65– 80)
Sex (n)	25	26
Female (n, %)	16 (64.00%)	15 (57.70%)
Male (n, %)	9 (36.00%)	11 (42.30%)
Education (n, %)		
–*Left formal education before age 16*	0 (0.00%)	1 (3.85%)
–*Left formal education at age 16*	0 (0.00%)	2 (7.69%)
–*Left formal education before age 18*	6 (24.0%)	5 (19.23%)
–*Undergraduate degree/Higher National Diploma*	6 (24.0%)	7 (26.92%)
–*Master's degree/Post-graduate Diploma*	3 (12.0%)	3 (11.54%)
–*PhD*	4 (16.0%)	6 (23.08%)
–*Missing*	6 (24.0%)	2 (7.69%)
Participants had a fall/s in last 12 months (n, %)	10 (40.0%)	14 (53.8%)
Drop-out rate (n, %)	8 (32.0%)	5 (19.0%)

C.

Variable	HOLObalance at home (n = 30)	HOLOBalance in clinic (n = 28)
Age (y) (median, range)	70.00 (65– 79)	73.00 (65– 80)
Sex (n)	30	28
Female (n, %)	17 (56.70%)	22 (78.60%)
Male (n, %)	13 (43.30%)	6 (21.40%)
Education (n, %)		
–*Left formal education before age 16*	1 (3.33%)	3 (10.71%)
–*Left formal education at age 16*	4 (13.33%)	1 (3.57%)
–*Left formal education before age 18*	2 (6.67%)	9 (32.14%)
–*Undergraduate degree/Higher National*	7 (23.33%)	6 (21.43%)
–*Diploma*	9 (30.0%)	4 (14.29%)
–*Master's degree/Post-graduate Diploma*	4 (13.33%)	2 (7.14%)
–*PhD*	3 (10.0%)	3 (10.71%)
–*Missing*		
Participants had a fall/s in last 12 months (n, %)	16 (53.33%)	17 (60.71%)
Drop-out rate (n, %)	7 (23.33%)	6 (21.43%)

for all research staff, and regular staff meetings were an integral part of the project with an aim to help prevent PDs. Despite no PDs reported, it is possible that some may have been missed. Future HOLObalance studies will include a toolkit developed to support a holistic approach in PD management including specific guidance for consistent classification and categorization of PDs and thresholds at which non-important PDs may become important [47].

Table 2. Mean (95% CI) pre-post change difference for between and within intervention groups for all secondary outcome measure data

A. Between-group pre-post change difference for combined OTAGO and HOLObalance data.

Outcome variable	Mean between-group difference	CI 95%
MINIBEST	2.69	1.46, 3.93
FGA	2.91	1.63, 4.19
ABC	−0.12	−3.84 to 3.6
FES1	0.24	−2.74 to 2.26
MOCA	−0.28	−1.23 to 0.67
WHODAS 2.0	−1.96	−5.54 to 1.62
BREQ 3	1.81	−0.7 to 4.32

B. Pre-post intervention change for the OTAGO and HOLObalance at home and in clinic data.

Outcome variable	OTAGO (combined) Mean (95%CI)	OTAGO (home) Mean (95%CI)	OTAGO (in-clinic) Mean (95%CI)
MINIBEST	0.63(−0.31 to1.57)	0.44 (−1.12 to 2.01)	0.82(−0.37 to 2.02)
FGA	1.4(0.33, 2.46)	1.06(−0.31 to 2.43)	1.70(−0.02 to 3.42)
ABC	2.77(−0.42 to 5.11)	2.02(−0.73 to 4.77)	3.50(−0.55 to 7.49)
FES-1*	−1.00(−2.48 to 0.48)	−0.44(−2.72 to 1.85)	−1.69(−3.72 to 0.33)
MoCA	1.03(0.37, 1.69)	1.11(0.30, 1.93)	0.95(0.16 to 2.05)
WHODAS 2.0*	−1.18(−3.28 to 0.92)	−1.33(−4.36 to 1.70)	−1.00(−4.37 to 2.37)
BREQ 3	−0.23 (−1.78 to 1.31)	−0.46(−2.78 to 1.35)	0.01(−2.70 to 2.69)
Outcome variable	HOLObalance (combined) Mean (95%CI)	HOLObalance (home) Mean (95%CI)	HOLObalance (in-clinic) Mean ± SD
MINIBEST	3.32(2.49, 4.15)	3.17(2.18, 4.16)	3.48(2.02, 4.93)
FGA	4.31(3.52, 5.10)	4.00(2.91, 5.09)	4.64(4.64, 3.42)
ABC	2.65(−0.19 to 5.49)	1.60(−2.32 to 5.50)	3.81(−0.63 to 8.26)
FES-1*	−1.24(−3.04, −0.56)	−1.48(−3.89 to 0.94)	−1.00(−6.04 to 0.75)
MoCA	0.75(0.07, 1.44)	0.64(−0.11 to 1.38)	0.86(−0.36 to 2.08)
WHODAS 2.0*	−3.14(−5.88 to 0.40)	−2.55(−6.60 to 1.50)	−3.82(−7.89 to 0.24)
BREQ 3	1.58(−0.36 to 3.51)	1.48(−1.81 to 4.77)	1.69(−0.43 to 3.81)

Adverse events were less than anticipated. Study participants were independently ambulating, community-dwelling older adults who were at higher risk for outdoor vs. indoor falls [48]. As this study occurred during the Covid-19 pandemic, many individuals, particularly older adults, had reduced physical activity, reduced time spent outdoors and increased social isolation which may have resulted in reduced falls risk during this time and therefore decreased incidence of AEs.

Between-group drop-out rates were similar, and better than the 30% previously reported for MSR and OTAGO programmes in similar populations [10]. Encouragingly, adherence and drop-out rates were similar between home and supervised participants in each group. Adherence predictors for fall prevention programs are poorly understood [49]. It remains unknown whether the weekly telephone call to all participants affected retention and adherence.

Technical issues were reported by 27% of participants and were the main reason for 31% not yet recommending the system to others. Key issues were connectivity and insoles, head-mounted display or sensor problems, disappearing hologram, lack of feedback, or system delay. For the upcoming iteration, the number of body sensors has been reduced and insoles replaced with four IMU sensors positioned at the ankles, lower back and head. A pilot study (unpublished to date) compared the insoles/sensors used in HOLObalance vs. IMU motion sensor data and found it to be comparable. The headset is being replaced by a lighter weight version that provides a similar AR experience to the one used in this study. Technical partners are continuously addressing system connectivity, delays, and feedback issues. Enhanced algorithms, including adaptive buffering and predictive data streaming, have been implemented to minimise latency and ensure more stable connectivity. These algorithms dynamically adjust to network conditions, reducing lag and ensuring seamless data transmission between components. Additionally, real-time feedback mechanisms have been optimised using advanced machine-learning techniques to analyse user actions and provide immediate, context-sensitive guidance. These enhancements are expected to significantly improve user satisfaction and system reliability.

OTAGO studies report good adherence [24] and effectiveness in reducing falls, improving balance, and health-related quality of life in community-dwelling older adults [50]. In our study, the OTAGO, group, showed minimal, pre-post treatment change for both FGA and Mini-BESTest.

A ceiling effect is unlikely, as baseline scores were similar between-groups and minimal FGA change with OTAGO vs. MSR has been reported previously [10]. Baseline mean Mini-BESTest scores indicated increased falls risk [35] for both groups; but only for the OTAGO group at final assessment. The disparity between current and previous OTAGO findings is likely due to the outcome measure used, with most studies including the Berg Balance Scale, which does not measure gait parameters and shows floor and ceiling effects that negatively affect the ability to detect change [51]. The Mini-BESTest and FGA are more appropriate to assess balance impairments [52,53] and functional mobility tasks [33] in older community-dwelling adults. The Mini-BEST test will be the primary outcome in the confirmatory HOLObalance study which will be conducted at five clinical sites based in the UK and continental Europe.

Pre-post treatment changes were equal to or approaching the minimal clinically important difference (MCID) needed to determine intervention efficacy [54] in the intervention group only. In older adults, the FGA MCID is an average 4-point improvement [55]. Mini-BESTest has a minimal detectable change (MDC) of 3.8 [56] to 3.5 points with an MCID of 4-points [57]. For the HOLOBalance group, a 4.3 and 3.3 point pre-post treatment change was noted for the FGA and Mini-BESTest, respectively, compared to a $\leq$ 1-point change on both measures for the OTAGO group. In the HOLOBalance group, pre-post change neared the Mini-BESTest MDC, with final scores within normal ranges [35]. Observed improvements were achieved with an 8-week vs. a 12-week or longer programme as recommended by the 2022 world guidelines for falls prevention and management [2]. The decreased treatment time to achieve improvement in falls risk, provision of supervised treatment at-home, clear instructions and progressions, and multi-level exercises are benefits of the system's first iteration. HOLOBalance may provide a solution for barriers to provision of falls prevention interventions including lack of professional knowledge and skills, time constraints, transport access, and frequent unsuitability of falls prevention interventions for frail adults [58,59].

Mean baseline MoCA, balance confidence, and WHODAS-2 scores were within normal ranges for both groups, limiting capacity for change. Mean baseline scores indicated moderate fear of falling for both groups with minimal pre-post-treatment change. Existing fall prevention strategies reduce concerns about falling in older adults [2]. However, outcome measures, follow-up times, and study populations differed to the current study, reducing comparability. Fear of falling can be influenced by other psychological concepts [60]. It is possible that Covid-19's impact on mental health [61] may have affected outcome.

COVID-19 provided research challenges [61] affecting recruitment rates particularly for participants with greater balance deficit or multimorbidity who were 'shielding', which may reduce generalisability of study findings. The lack of longer-term follow-up, formal assessment of individual functional goals, and missing data analysis are also study limitations. Study strengths included use of appropriate balance outcome measures and conduct in three different countries' health systems. Findings of pre-post intervention benefits at or nearing MCID and MDC levels even after 8-weeks, low drop-out rate and moderately strong prototype platform acceptance were encouraging.

Conclusion

Augmented reality MSR is feasible and acceptable for older adults with increased falls risk or history. Early results suggest it improves functional gait and dynamic balance. HOLOBalance holds promise for a rapidly ageing society with increasingly stretched healthcare resources. A fully powered trial with cost–benefit analysis is warranted to determine its efficacy as a falls prevention and rehabilitation clinical tool.

Declaration of Conflicts of Interest: None declared.

Declaration of Sources of Funding: The project HOLOgrams for personalised virtual coaching and motivation in an ageing population with BALANCE disorders (HOLOBALANCE) was supported by the European Union's Horizon 2020 research and innovation programme under [grant 769574].

Trial Registration: NCT04053829.

References

1. Lord SR, Sherrington C, Menz H *et al. Falls in Older People: Risk Factors and Strategies for Prevention*. 2nd edition. Cambridge University Press, Cambridge, England, 2007. https://doi.org/10.1017/CBO9780511722233.
2. Montero-Odasso M, van der Velde N, Martin FC *et al.* World guidelines for falls prevention and management for older adults: a global initiative. *Age Ageing*. 2022;**51**:afac205.
3. Liston MB, Bamiou DE, Martin F *et al.* Peripheral vestibular dysfunction is prevalent in older adults experiencing multiple non-syncopal falls versus age-matched non-fallers: a pilot study. *Age Ageing*. 2014;**43**:38–43.
4. Baldursdottir B, Petersen H, Jonsson PV *et al.* Sensory impairments and wrist fractures: a case-control study. *J Rehabil Med*. 2018;**50**:209–15.
5. Agrawal Y. Editorial: age-related vestibular loss: current understanding and future research directions. *Front Neurol*. 2017;**8**:443.
6. Agrawal Y, Carey JP, Della Santina CC *et al.* Disorders of balance and vestibular function in US adults: data from the National Health and nutrition examination survey, 2001-2004. *Arch Intern Med*. 2009;**169**:938–44.
7. Hirashima K, Higuchi Y, Imaoka M *et al.* Dual-tasking over an extended walking distance is associated with falls among community-dwelling older adults. *Clin Interv Aging*. 2015;**10**:643–8.
8. Horak FB. Postural orientation and equilibrium: what do we need to know about neural control of balance to prevent falls? *Age Ageing*. 2006;**35**:ii7.

9. Baldursdottir B, Whitney SL, Ramel A *et al.* Multi-sensory training and wrist fractures: a randomized, controlled trial. *Aging Clin Exp Res*. 2020;**32**:29–40.
10. Liston MB, Alushi L, Bamiou DE *et al.* Feasibility and effect of supplementing a modified OTAGO intervention with multisensory balance exercises in older people who fall: a pilot randomized controlled trial. *Clin Rehabil*. 2014;**28**:784–93.
11. Kristinsdottir EK, Baldursdottir B. Effect of multi-sensory balance training for unsteady elderly people: pilot study of the "Reykjavik model". *Disabil Rehabil*. 2014;**36**:1211–8.
12. Whitney SL, Ellis J, Otis L *et al.* A multidimensional exercise program in the home for older adults designed to improve function. *Home Health Care Manag Pract*. 2019;**31**:147–54.
13. Beling J, Roller M. Multifactorial intervention with balance training as a core component among fall-prone older adults. *J Geriatr Phys Ther*. 2009;**32**:125–33.
14. Sherrington C, Fairhall NJ, Wallbank GK *et al.* Exercise for preventing falls in older people living in the community. *Cochrane Database Syst Rev*. 2019;**2019**:CD012424.
15. Li J, Erdt M, Chen L *et al.* The social effects of Exergames on older adults: systematic review and metric analysis. *J Med Internet Res*. 2018;**20**:e10486.
16. Verheijden Klompstra L, Jaarsma T, Strömberg A. Exergaming in older adults: a scoping review and implementation potential for patients with heart failure. *Eur J Cardiovasc Nurs*. 2014;**13**:388–98.
17. Treml J, Husk J, Lowe D *et al. Falling Standards, Broken Promises: Report of the National Audit of Falls and Bone Health*, Royal College of Physicians, London, 2013.
18. Riglin J, Clinical Associates Falls RCP, Lowe J *et al. Older people's Experience of Therapeutic Exercise as Part of a Falls Prevention Service*, Royal College of Physicians, London, 2016.
19. Montero-Odasso MM, Kamkar N, Pieruccini-Faria F *et al.* Evaluation of clinical practice guidelines on fall prevention and Management for Older Adults: a systematic review. *JAMA Netw Open*. 2021;**4**:e2138911.
20. Lacroix A, Hortobágyi T, Beurskens R *et al.* Effects of supervised vs. unsupervised training programs on balance and muscle strength in older adults: a systematic review and meta-analysis. *Sports Med*. 2017;**47**:2341–61.
21. Nishchyk A, Chen W, Pripp AH *et al.* The effect of mixed reality Technologies for falls prevention among older adults: systematic review and meta-analysis. *JMIR Aging*. 2021; **4**:e27972.
22. Oh-Park M, Doan T, Dohle C *et al.* Technology utilization in fall prevention. *Am J Phys Med Rehabil*. 2021;**100**:92–9.
23. Liston M, Genna G, Maurer C *et al.* Investigating the feasibility and acceptability of the HOLOBalance system compared with standard care in older adults at risk for falls: study protocol for an assessor blinded pilot randomised controlled study. *BMJ Open*. 2021;**11**:e039254.
24. Thomas S, Mackintosh S, Halbert J. Does the 'Otago exercise programme' reduce mortality and falls in older adults?: a systematic review and meta-analysis. *Age Ageing*. 2010;**39**:681–7.
25. Schulz KF, Altman DG, Moher D *et al.* CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *Int J Surg*. 2011;**9**:672–7.
26. Delbaere K, Close JCT, Mikolaizak AS *et al.* The falls efficacy scale international (FES-I). A comprehensive longitudinal validation study. *Age Ageing*. 2010;**39**:210–6.
27. Nasreddine ZS, Phillips NA, Bédirian V *et al.* The Montreal cognitive assessment, MoCA: a brief screening tool for mild cognitive impairment. *J Am Geriatr Soc*. 2005;**53**:695–9.
28. Clarnette R, O'Caoimh R, Antony DN *et al.* Comparison of the quick mild cognitive impairment (Qmci) screen to the Montreal cognitive assessment (MoCA) in an Australian geriatrics clinic. *Int J Geriatr Psychiatry*. 2017;**32**:643–9.
29. Bradley JG, Davis KA. Orthostatic hypotension. *Am Fam Physician*. 2003;**68**:2393–8.
30. van Marwijk HW, Wallace P, de Bock GH *et al.* Evaluation of the feasibility, reliability and diagnostic value of shortened versions of the geriatric depression scale. *Br J Gen Pract*. 1995;**45**:195–9.
31. Whitehead AL, Julious SA, Cooper CL *et al.* Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable. *Stat Methods Med Res*. 2016;**25**:1057–73.
32. Wrisley DM, Marchetti GF, Kuharsky DK *et al.* Reliability, internal consistency, and validity of data obtained with the functional gait assessment. *Phys Ther*. 2004;**84**:906–18.
33. Wrisley DM, Kumar NA. Functional gait assessment: concurrent, discriminative, and predictive validity in community-dwelling older adults. *Phys Ther*. 2010;**90**:761–73.
34. Franchignoni F, Horak F, Godi M *et al.* Using psychometric techniques to improve the balance evaluation systems test: the mini-BESTest. *J Rehabil Med*. 2010;**42**:323–31.
35. Magnani PE, Genovez MB, Porto JM *et al.* Use of the BESTest and the mini-BESTest for fall risk prediction in community-dwelling older adults between 60 and 102 years of age. *J Geriatr Phys Ther*. 2020;**43**:179–84.
36. Powell LE, Myers AM. The activities-specific balance confidence (ABC) scale. *J Gerontol A Biol Sci Med Sci*. 1995; **50A**:M28–34.
37. World Health Organization, Ü.T, Kostanjsek N, Chatterji S *et al. Measuring Health and Disability: Manual for WHO Disability Assessment Schedule (WHODAS 2.0)*. Geneva, Switzerland: World Health Organization, 2010.
38. Markland D, Tobin V. A modification of the behavioral regulation in exercise questionnaire to include an assessment of amotivation. *J Sport Exerc Psychol*. 2004;**26**:191–6.
39. Eldridge SM, Chan CL, Campbell MJ *et al.* CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *BMJ*. 2016;**2**:64.
40. Schafer JL. Multiple imputation: A primer. *Stat Methods Med Res*. 1999;**8**:3–15.
41. Tyagi S, Lim DSY, Ho WHH *et al.* Acceptance of tele-rehabilitation by stroke patients: perceived barriers and facilitators. *Arch Phys Med Rehabil*. 2018;**99**:2472–2477.e2.
42. Yusheng Wu A, Munteanu C. *Understanding Older Users' Acceptance of Wearable Interfaces for Sensor-Based Fall Risk Assessment. in CHI Conference on Human Factors in Computing Systems*. Montreal QC, Canada: Association for Computing Machinery, 2018, New York, NYUnited States.
43. Gaspar AGM, Lapão LV. eHealth for addressing balance disorders in the elderly: systematic review. *J Med Internet Res*. 2021;**23**:e22215.
44. Shaikh AG, Bronstein A, Carmona S *et al.* Consensus on virtual management of vestibular disorders: urgent versus expedited care. *Cerebellum*. 2021;**20**:4–8.

45. Global strategy on digital health 2020–2025. Geneva: World Health Organization, 2021. Licence: CC BY-NC-SA 3.0 IGO.
46. Directorate-General for Health and Food Safety. *Regulation (EU) 2021/2282 on Health Technology Assessment*, European Parliament and the Council of the European Union, Brussels, 2021.
47. Galuchie L, Stewart C, Meloni F. Protocol deviations: a holistic approach from defining to reporting. *Ther Innov Regul Sci*. 2021;**55**:733–42.
48. Kelsey JL, Berry SD, Procter-Gray E *et al.* Indoor and outdoor falls in older adults are different: the maintenance of balance, independent living, intellect, and zest in the elderly of Boston study. *J Am Geriatr Soc*. 2010;**58**:2135–41.
49. Rivera-Torres S, Fahey TD, Rivera MA. Adherence to exercise programs in older adults: informative report. *Gerontol Geriatr Med*. 2019;**5**:2333721418823604.
50. Mgbeojedo UG *et al.* Effects of Otago exercise program on physical and psychosocial functions among community-dwelling and institutionalized older adults: a scoping review. *Inquiry*. 2023;**60**:469580231165858.
51. Downs S, Marquez J, Chiarelli P. The berg balance scale has high intra- and inter-rater reliability but absolute reliability varies across the scale: a systematic review. *J Physiother*. 2013;**59**:93–9.
52. Whitney SL, Wrisley DM, Brown KE *et al.* Is perception of handicap related to functional performance in persons with vestibular dysfunction? *Otol Neurotol*. 2004;**25**:139–43.
53. Robinett CS, Vondran MA. Functional ambulation velocity and distance requirements in rural and urban communities. *Clin Rep Phys Ther*. 1988;**68**:1371–3.
54. Guyatt G, Walter S, Norman G. Measuring change over time: assessing the usefulness of evaluative instruments. *J Chronic Dis*. 1987;**40**:171–8.
55. Beninato M, Fernandes A, Plummer LS. Minimal clinically important difference of the functional gait assessment in older adults. *Phys Ther*. 2014;**94**:1594–603.
56. Marques A, Almeida S, Carvalho J *et al.* Reliability, validity, and ability to identify fall status of the balance evaluation systems test, mini-balance evaluation systems test, and brief-balance evaluation systems test in older people living in the community. *Arch Phys Med Rehabil*. 2016;**97**:2166–2173.e1.
57. Godi M, Franchignoni F, Caligari M *et al.* Comparison of reliability, validity, and responsiveness of the mini-BESTest and berg balance scale in patients with balance disorders. *Phys Ther*. 2013;**93**:158–67.
58. Factors influencing the implementation of falls prevention practice in primary care. *J Am Assoc Nurse Pract*. 2021;**33**:117–8.
59. Meekes WMA, Leemrijse CJ, Korevaar JC *et al.* Implementing falls prevention in primary care: barriers and facilitators. *Clin Interv Aging*. 2022;**17**:885–902.
60. Hughes CC, Kneebone II, Jones F *et al.* A theoretical and empirical review of psychological factors associated with falls-related psychological concerns in community-dwelling older people. *Int Psychogeriatr*. 2015;**27**:1071–87.
61. Leite NJC, Raimundo AMM, Mendes RDC *et al.* Impact of COVID-19 pandemic on daily life, physical exercise, and general health among older people with type 2 diabetes: a qualitative interview study. *Int J Environ Res Public Health*. 2022;**19**:3986.

Received 24 January 2024; editorial decision 30 May 2024