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Randomised controlled trial assessing the effect of a technology-assisted gait and balance training on mobility in older people after hip fracture: study protocol

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ABSTRACT

Introduction Deficits in balance and walking ability are relevant risk factors for falls during ageing. Moreover, falls are a risk factor for future falls, strongly associated with adverse health outcomes, such as fear of falling or fractures, particularly, hip fracture. For this reason, the development of prevention tools and innovative rehabilitation strategies is one of the main objectives in geriatrics. Effective interventions to promote hip recovery after hip fracture are characterised by intensive and repetitive movements. One treatment approach is to increase the number of steps during the rehabilitation sessions and to improve the balance and the endurance of the patients in the use of technological devices.

Methods and analysis This randomised controlled trial aimed to evaluate an innovative rehabilitation treatment of elderly patients with hip fractures. A total of 195 patients with hip fractures will be recruited and randomly divided into three groups: traditional rehabilitation programme, traditional rehabilitation programme plus TYMO system and traditional rehabilitation programme plus Walker View. Assessments will be performed at baseline, at the end of treatment, at 6 months, and at 1 and 2 years after the end of the treatment. Only subjects hospitalised 4 weeks prior to the beginning of the study will be taken into consideration. Twenty treatment sessions will be conducted, divided into three training sessions per week, for 7 weeks. The technological intervention group will carry out 30 min sessions of traditional therapy and 20 min of treatment with a technological device. The control group will perform traditional therapy sessions, each lasting 50 min. The primary outcomes are risk of falling, gait performance and fear of falling.

Ethics and dissemination The study was approved by the Istituto di Ricerca e Cura a Carattere Scientifica, Istituto Nazionale Ricovero e Cura Anziani Ethics Committee, with identification code number 19014. Trial results will be submitted for publication in journals and conferences.

Trial registration number NCT04095338.

Strengths and limitations of this study

- This study is a large, controlled, randomised study that analysed innovative clinical practices to treat hip fracture, designed to improve gait and to reduce the risk of falling.
- To our knowledge, this is the first clinical trial to compare traditional rehabilitation and technology-delivered gait performance and balance training in patients with hip fracture.
- The use of instrumented gait analysis, together with clinical outcomes, is the optimal approach to quantify study results.
- It is the first time that the follow-up lasts 2 years after the end of the treatment, representing both a strength and a risk due to an expected higher drop-out rate.

INTRODUCTION

Populations are growing older in countries throughout the world. By 2050, nearly 1.2 billion of the expected 1.5 billion people aged 65 years or older will reside in today's low-income regions. Just 22% of the world's older people will live in what we today call high-income countries.[1] This demographic transformation will profoundly affect the health and socioeconomic development of all nations.

Balance and deficit in walking are some of the main characteristics of ageing and are considered among the risk factors for falls.[2 3] Falls are a risk factor for future falls and are associated with other adverse health outcomes, such as fear of falling or fractures.[4–8] In particular, hip fractures can have a devastating impact on the ability of older patients to remain independent. Individuals following hip fractures experience greater postural sway, possibly due to reduced muscular strength and proprioception.[9] Reports show that one in three patients dies within the first year after injury, while survivors have poor quality of life.[10]

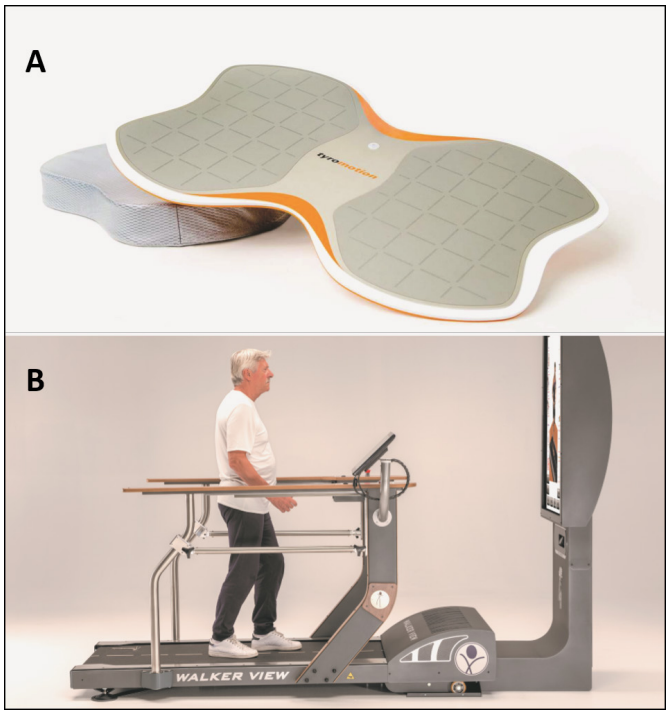

Figure 1 Technological devices used during the rehabilitation treatment: TYMO system (A) and Walker View (B). The image in the article is a commercial one of the Walker View system and not one of our patients.

For these reasons, the development of prevention tools and innovative strategies in the rehabilitation field should be one of the main objectives in the treatment of the diseases afflicting the elderly, such as hip fractures.[11] Evidence suggests that rehabilitation plays a crucial role in guaranteeing recovery and enhancing quality of life following hip fracture. This pathological condition is routinely treated by rehabilitative approaches aimed at improving the static/dynamic balance, the recovery of walking and the prevention of falls.[12–14] From the literature, it is evident that there is no standard rehabilitation practice common to all. No standard set of key outcomes or measures was used across the previously designed investigations. The ingredients of programmes and practices evaluated were dissimilar and varied in their intensity, duration and timing of the initiation.[15]

One of the few practices that seems to be effective in hip fracture rehabilitation is a specific task repetitive training since, by increasing therapy dosage, intensity and number of repetitions, the plasticity and the functional recovery are promoted.[16] A treatment approach to increase the number of steps during rehabilitation sessions and to improve balance and endurance of the patients is the use of robotic systems. In this study, the technological devices used for the rehabilitation treatment are the TYMO system (Tyromotion, Austria), a wireless static and dynamic platform for evaluating and rehabilitating posture (figure 1A), or the Walker View (TecnoBody, Italy) a treadmill equipped with a sensorised belt with eight load cells and a 3-D camera (figure 1B). The two intervention groups will be treated with only one of the two technological devices, combined with traditional therapy.

Study aims and objectives

This study aimed to evaluate an innovative rehabilitation treatment based on technological devices for older patients with hip fractures, designed to improve gait performance and to reduce risk of falling. The primary aim was to evaluate the effect of the rehabilitation treatment on balance and gait performance of older people with hip fracture, as a result of the use of the TYMO system or the Walker View, at the end of the treatment and at 6 months and 1 and 2 years of follow-up, by using the Performance-Oriented Mobility Assessment (POMA) scale.

The secondary aims were

1. To evaluate the effect of the rehabilitation treatment on gait speed of older people with hip fracture, as a result of the use of the TYMO system or the Walker View, at the end of the treatment and at 6 months and 1 and 2 years of follow-up, by using instrumental gait analysis.
2. To evaluate the effect of the rehabilitation treatment on the fear of falling of older people with hip fracture, as a result of the use of the TYMO system or the Walker View, at the end of the treatment and at 6 months and at 1 and 2 years of follow-up, by using Short Falls Efficacy Scale–International (FES-I) Short Form Scale.

METHODS AND ANALYSIS

Trial design

This study is a randomised, single blind (outcome assessors) controlled trial. A total of 195 patients with hip fractures will be recruited and randomly divided into three groups: (1) traditional rehabilitation programme, (2) traditional rehabilitation programme plus TYMO system and (3) traditional rehabilitation programme plus Walker View. Assessments will be performed at baseline, at the end of treatment, and at 6 months and 1 and 2 years after the end of the treatment. In addition, the study design includes the use of a standardised questionnaire and instrumental gait analysis, in order to collect data on the improvements with a mix-method approach. This methodology is routinely applied in our institute.

Study setting

The study will be conducted at the Clinical Unit of Physical Rehabilitation, Istituto di Ricerca e Cura a Carattere Scientifica, Istituto Nazionale Ricovero e Cura Anziani (IRCCS INRCA), in the Ancona and Fermo branches, Italy. Assessments and treatments will be conducted in the robotics laboratories. Patients will be selected from the clinic at the two hospitals' physical rehabilitation clinic after receiving the appropriate treatment to be stabilised and discharged.

Patient and public involvement

No patients were involved.

Trial status

At the time of the submission of this study protocol, data collection was ongoing. The first patient was recruitment on 26 November 2019. The study is expected to end in August 2021.

Participants

The inclusion criteria[12 17] are

- Age 65 years and over.
- Capacity to provide consent.
- Traumatic event within 60 days.
- Romberg test: negative.
- Functional Ambulation Category (FAC) score of ≥2.
- Rankin Scale score of ≤3.

The exclusion criteria are

- Failure to meet the inclusion criteria.
- Concomitant participation in other studies.
- History of syncopal episodes.
- Presence of non-pharmacologically compensated behavioural syndromes.
- Presence of pain that prevents walking or standing.
- Presence of neurological pathologies that compromise balance (multiple sclerosis, Parkinson's disease, stroke, myelosion, ataxias or poliomyelitis).
- Spinal stenosis.
- Radiculopathy.
- Neuropathies in the lower limbs.
- Disabling disabilities that impair walking (eg, congenital malformations of the foot).
- Heterometry of >2 cm.
- Lack of written informed consent.
- Clinical Dementia Rating (CDR) score of ≥3.
- Severe systemic diseases with life expectancy of <1 year.

Sample size

The POMA,[18] a test widely used to assess walking ability and associated with equilibrium, was used to calculate the sample size.[19] Assuming a small effect size of 10%,[20] it is estimated that the overall sample size needed to capture this effect size is of 153 subjects, assuming a statistical power of 80%, a significance level of 0.05, three groups and five repeated assessments (a baseline and four follow-ups) in an analysis of variance (ANOVA) model within–between interactions. Even assuming a 25% drop-out rate, the total number required would be 195 subjects (65 for each arm).

It is hypothesised that this sample dimension is more than sufficient to grasp a variation also for secondary outcomes for which a treatment effect size is assumed of a similar or higher magnitude than that identified for the primary outcome.[17 21]

Recruitment

Patients are selected by the outpatient department at the Clinical Unit of Physical Rehabilitation, IRCCS INRCA, in the Ancona and Fermo branches. Patients are contacted to schedule a visit with the physician. Once the compliance with the inclusion and exclusion criteria of the study has been verified and informed consent has been obtained in triplicate, the doctor, together with a physiotherapist and a biomedical engineer, proceeds with the baseline evaluation and with acquisition of gait assessment parameters through gait analysis at the Movement Analysis Laboratory of the Clinical Unit of Physical Rehabilitation of the Ancona branch. Functional and cognitive evaluation scale scores are obtained by a physiotherapist and a psychologist, respectively. A copy of the informed consent is reported in online supplementary file 1.

A randomisation technique based on a single sequence of random assignments is used. A list of random numbers generated by the computer is used and subjects are assigned a number based on their order of inclusion in the study. According to this technique, the 195 subjects will be randomly assigned to one of the three study groups.

At the end of the treatment and after 6 months and 1 and 2 years, patients will be contacted again to schedule subsequent follow-up visits and upgrades.

Recruitment will run from August 2019 to August 2021.

Intervention

For the study, outpatients are involved 4 weeks after hospitalisation in the Clinical Unit of Physical Rehabilitation, IRCCS INRCA, in the Ancona and Fermo branches. Participants have already received the standard treatment. Twenty treatment sessions will be conducted, divided into three training sessions per week, for 7 weeks. The technological intervention groups, using the TYMO system or the Walker View, carry out 30 min sessions of traditional therapy, plus 20 min of treatment with a technological device. The control group performs 50 min traditional therapy sessions. Cardiac activity monitoring is conducted during robotic treatments in order to detect the heart rate during physical activity.[22]

Individual participants must complete at least 80% of the overall planned sessions. The recovery of two sessions will be possible.

All patients included in the study perform traditional rehabilitation treatments consisting of

- Passive mobilisation for the recovery of the complete articular range.
- Scar removal massage therapy and possible draining massage of the lower limb.
- Muscle strengthening with isometric and isotonic exercises.
- Proprioceptive exercises in standing position for load balancing and balance control.
- Step training with progressive reduction of walking aids.
- Recovery of autonomy in stair ascent and descent.
- Recovery of autonomy in daily life activities.

The technology-delivered gait and balance training consists of using either of two different devices: the TYMO system or the Walker View.

The TYMO system is a wireless platform for balance and the postural control training. The TYMO system is connected to a screen and provides virtual reality games,

Table 1 Outcomes and clinical assessments

Outcomes	Clinical assessment	Expected improvement at the end of treatment (%)
Primary: improvement of the overall mobility (balance+walking ability)	POMA	10
Secondary: improvement of gait speed	Instrumental gait analysis	12
Secondary: decrease of fear of falling	FES-I Short Form	15

FES-I, Short Falls Efficacy Scale–International; POMA, Performance-Oriented Mobility Assessment.

adaptable to the functional capacity of the patient. Through the games proposed, the physiotherapist will decide to work in a dimension (anteroposterior or mediolateral) or in two dimensions (combining the anteroposterior and mediolateral movements).

The Walker View is a treadmill equipped with a sensorised belt with eight load cells and a three-dimensional (3-D) camera to detect length, speed and symmetry of the pace and load, range of the trunk, hips and knees. Patients are asked to walk at a comfortable speed while the physiotherapist is able to work on different parameters, such as step length, load distribution and step height. The setting takes into account the clinical conditions of each patient, allowing the customisation of the intervention. The Walker View offers visual and auditory feedback to the patient so they can correct gait in real time. Details of the exercises carried out by the three groups are shown in the online supplementary file 2.

Outcomes

All outcome measures follow a standardised operating procedure. Table 1 shows the primary outcome and secondary outcomes with the expected result at the end of the treatment. The expected improvement is derived from the analysis of similar studies,[20] collected for the evaluation of the sample size for each outcome.

Further evaluations will be carried out as follows:

- Length and asymmetry of the step, through instrumental gait analysis.
- Walking and functional status, through the FAC and Barthel Index (BI) Scale.
- Acceptance of the technology, through the Psychosocial Impact of Assistive Device Scale questionnaire.
- Quality of life, through the Short Form (SF)-12 questionnaire.

Mini-Mental State Examination (MMSE): The MMSE was designed as a clinical method for grading cognitive impairment. The score ranges from 0 to 30: scores of ≥24 indicate normality; scores between 18 and 23 indicate mild cognitive impairment; scores between 11 and 17 indicate average cognitive deficits; and scores of ≤10 indicate severe cognitive impairments. The reported score is corrected for age and education.[23]

Rankin Scale: The Rankin Scale is a simple scale for the evaluation of the outcomes following a stroke. Reliability is well defined. The individual categories are essentially based on patient mobility. There are six grades of classification from 0 to 5, where 0 means independence.[24]

Barthel Index: BI is an ordinal scale used to measure a subject's performance in everyday life activities. The index analyses 10 variables that describe the activities of daily life and mobility. Each item is assigned a score between 0 and 10, depending on the degree of the patient's functionality: full, reduced or no functionality. A high overall score is associated with a greater probability of being able to live at home independently after discharge from the hospital.[25]

Functional Ambulation Category: The scale is used to classify the severity level of gait disturbances in neurological disorders. It provides a hierarchical classification from level 0 (impossible walking) to level 5 (no limitation).[26]

SF-12 Health Survey: The SF-12 questionnaire was originally developed in the USA to provide a short alternative form to the SF-36 questionnaire. The SF-12 is composed of 12 items that produce two measurements related to two different aspects of health: physical health and mental health. The subject is asked to answer on how he feels and how he is able to carry out the usual activities, evaluating the current day and the four previous weeks.[27]

Tinetti's Scale or POMA: The Tinetti scale is a tool used to evaluate balance and gait performance. The test is used clinically to determine the mobility status of a subject or to assess changes in balance and gait time. The total POMA consists of two subscales: the balance evaluation scale ('balance scale' or POMA-B) and the gait evaluation scale ('gait scale' or POMA-G). The maximum score is 28 points: in detail, the maximum score of the POMA-B is 16, while for the POMA-G, the maximum score is 12.[18]

Short Falls Efficacy Scale–International: The scale measures the 'fear of falling'. The scale can be self-administered or administered during the interview. The cut-offs for the fear of falling are divided as follows: a score of 7–8 indicates low concern; a score between 9 and 12 indicates moderate concern; and a score between 14 and 28 indicates high concern.[28]

Psychosocial Impact of Assistive Device Scale: It is a self-completion questionnaire to be completed by the user and it assesses the impact that the device has on the person. Through 26 questions, it tries to detect how the device has brought about a perception of change with respect to one's availability for new experiences (6 questions), skills (ability to cope with daily activities and challenges, 12 questions) and self-esteem (security and self-confidence, 8 questions). Every question is answered on a visual scale from −3 (the device has strongly limited my independence) to +3 (the device has greatly improved my independence).[29]

Assistive Device Predisposition Assessment: The purpose of the tool is to assess user expectations about technological devices.[30]

Table 2 Schedule of assessment and outcome measures

Outcome	Study aim/outcome	Clinical assessment	R	T1	FW1	FW2	FW3
Cognitive state		Mini-Mental State Examination	✓				
Gait parameters	Secondary outcome	Functional Ambulation Category	✓	✓	✓	✓	✓
Disability state		Rankin Scale	✓				
Cognitive state		CDR	✓				
Functional state	Secondary outcome	Barthel Index	✓	✓	✓	✓	✓
Quality of life	Secondary outcome	SF-12 Health Survey	✓	✓	✓	✓	✓
Sociodemographic characteristics		Checklist	✓				
Attitude to technology		Assistive Device Predisposition Assessment–Scala E	✓				
Fall risk	Primary aim/outcome	POMA	✓	✓	✓	✓	✓
Gait parameters	Secondary aim/outcome	Gait Analysis	✓	✓	✓	✓	✓
Fear of falling	Secondary aim/outcome	Short Falls Efficacy Scale–International	✓	✓	✓	✓	✓
Acceptance of technology		Psychosocial Impact of Assisted Device Scale		✓			

CDR, Clinical Dementia Rating; FW1, first follow-up at 6 months since the end of treatment; FW2, second follow-up at 1 year since the end of treatment; FW3, third follow-up at 2 years since the end of treatment; POMA, Performance-Oriented Mobility Assessment; R, Recruitment; SF, Short Form; T1, end of treatment.

CDR Scale: This questionnaire assesses the patient's dementia status. The CDR is a 5-point scale used to characterise six domains: memory, orientation, judgement and problem solving, business, home and hobby and personal care.[31]

Gait analysis and instrumental postural analysis: Gait analysis is the systematic study of human locomotion, augmented by instrumentation for measuring body movements, body mechanics and the activity of the muscles.[32] Gait analysis is performed on the selected patients at the Gait Analysis Laboratory in the Department of Physical Rehabilitation at the branch of IRCSS INRCA Ancona. Instrumented gait analysis is performed using BTS GAITLAB (BTS Bioengineering, Italy) system with six infrared cameras (100 Hz) and two force plates (50 Hz). The system is used to acquire both kinematic and kinetic data. 3-D kinematic data are recorded with the help of 22 reflective infrared markers using the Helen Hayes protocol.[33] The floor-mounted force plates are used to acquire the kinetic data. The subjects walked at a self-selected speed along a straight stretch 7 m long. The parameters obtained from gait analysis are used to answer the first two objectives of this study protocol, namely, to verify how technological treatment improves gait performance in patients with hip fracture.

A summary of all data collected and when these are collected is provided in table 2.

Data management

Personal data collected during the trial will be handled and stored in accordance with the General Data Protection Regulation 2018. The use of the study data will be controlled by the principal investigator. All data and documentation related to the trial will be stored in accordance with applicable regulatory requirements, and access to data will be restricted to authorised trial personnel.

Data analysis

Continuous variables will be reported as either mean and SD or median and IQR on the basis of their distribution (assessed using Shapiro-Wilk test). Comparison of variables between groups will be performed by unpaired Student t-test or Mann-Whitney U test according to their distribution. Categorical variables will be expressed as absolute numbers and percentage, and statistical significance will be assessed by χ^2 test or Fisher exact test.

In a second step, the analysis of the follow-up data will be carried out in order to evaluate the effectiveness of the intervention. This analysis phase will involve the use of multivariate statistical techniques, in particular, repeated measures ANOVA, in order to compare the changes over time in the outcome measures between the intervention group and the control group. The statistical significant will be set at $p<0.05$.

ETHICS AND DISSEMINATION

Ethics

The study was approved by IRCCS INRCA Ethics Committee during the session of 17 July 2019, with identification code number 19016. Any protocol modifications will be reported to the same ethics committee. The principals of the Declaration of Helsinki and Good Clinical Practice guidelines will be adhered to.

Administrative structures

The trial will be run by principal investigator and coinvestigators (a physiatrist, a biomedical engineer, a psychologist and a statistician) and two therapists. There is no external funding for the realisation of the study.

Dissemination

The dissemination programme will involve peer-reviewed journal and national and international conferences. The results will be disseminated to all participants.

Contributors EM and RBo led the design and writing of the pilot randomised controlled trial protocol. VDD and GRR helped with the development of the participant identification plan and provided advice on other key study issues. EC, NR and RBa helped with the design of the intervention. MDR will lead the collection, management and statistical analysis of the data. FL and RL contributed feedback on the trial design. All the authors contributed important intellectual content to the written protocol and approved the final version for publication.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this research.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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