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A feasibility study for improving balance in community-dwelling elders using trained volunteers within faith-based institutions

Submission date
15/09/2021

Recruitment status
No longer recruiting

Registration date
28/09/2021

Overall study status
Completed

Last Edited
04/11/2021

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
According to the Age UK (2010) report, every minute, six people over 65 years or older have a fall. This results in fractures, disability, isolation and institutionalisation in a majority of those who have had a fall. However, falls can be prevented or reduced by improving strength, balance and endurance by doing specific exercises. There are limited resources in the NHS to provide services to improve balance and reduce falls to everyone above 65 years living in the community. Therefore, initiatives using local resources are needed to improve this situation.
The aim of the study is to set up community-based programmes run by trained volunteers to improve balance in older people who are at risk of falling and to evaluate the feasibility and efficacy of this programme.

Who can participate?
Older people (aged 65 years or older) who feel they are off-balance at times, at an increased risk of falling but have not had a fall in the past 6 months

What does the study involve?
Healthy volunteers are trained to enable them to deliver balance training programmes locally. A group activity is set up for people who are above the age of 65 years. Participants will be tested using simple tests such as sit to stand five times in a row and if they can do that, they will be able to participate in the study. It is important to note that participation is entirely voluntary. This project will take place in the community such as the local churches. This will involve a group activity that will include balance education, group exercises once a week for 4 weeks, home exercises, individual balance assessments and advice. To assess if such a programme is feasible and effective, the researchers will compare this with a group of people who will not do exercises but listen to talks about general health issues and how to maintain a healthy lifestyle.

What are the possible benefits and risks of participating?
This work will help to identify whether local programs for improving balance using volunteers help to reduce the risk of falling in elders. The information gathered will be used to write to councils recommending to set up more programs like this to improve the health of elders in the

community. It is possible that participants will personally benefit by improving their knowledge about health issues or about falls and gain better balance if they are in the group having exercises.
There are no major risks associated with this balance improvement program. However, testing and training for balance have an inherent risk of falls as participants will be challenging their current level of balance. Volunteers or therapists will be there to support weaker participants while doing the tests and exercises. There is also the risk of overdoing exercises at home causing tiredness and muscle soreness. Participants will be told how much they should do and if participants follow the advice they will not have these effects.

Where is the study run from?
University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
August 2017 to December 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Sheeba Rosewilliam
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ERN_18-0001A

Study information

Scientific Title
Improving balance in community-dwelling elders using trained volunteers within faith-based institutions: a mixed-methods feasibility study

Study objectives
To investigate whether a community balance training programme, delivered by trained volunteers for elders in local churches, is feasible and acceptable.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 04/11/2021:
Approved 09/11/2018; COVID amendment: 19/10/2020, University of Birmingham STEM Ethics Committee (Dr Birgit Whitman, Research Support Group, C Block Dome (room 132), Aston Webb Building, University of Birmingham, Edgbaston, B15 2TT, UK; +44 (0)121 414 810; researchgovernance@contacts.bham.ac.uk), ref: ERN_18-0001A

Previous ethics approval:
Approved 09/11/2018; COVID amendment: 19/10/2020, University of Birmingham STEM Ethics Committee (Research Support Group, C Block Dome (room 132), Aston Webb Building, University of Birmingham, Edgbaston, B15 2TT, UK; +44 (0)121 414 810; s.m.waldron@bham.ac.uk), ref: ERN_18-0001A

Study design

Mixed methods feasibility study including a feasibility Interventional cluster randomized controlled trial and qualitative focus groups

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Prevention of falls in older people who are at risk of falls living in the community

Interventions
The churches that agreed to participate were randomised to either intervention or control by picking from a hat.

Intervention group participants received:
1. Education regarding balance problems for 45 minutes
2. Trial balance exercises with the clinician and volunteers
3. Volunteers training by the clinician in a 2-hour session
4. Group exercises for participants for 4 weeks supervised by volunteers. Physiotherapists monitored the sessions
5. Exercise booklet for exercises 5 times a week for 6 months
6. Leaflet with falls prevention tips

Control group participants received:
1. Talks and discussions regarding health conditions related to aging and diet for 6 weeks
2. Leaflet with fall prevention tips

For both the control and intervention groups the follow-up assessment was done at 6 months.

Intervention Type
Behavioural

Primary outcome measure
Feasibility measures:
1. Number of volunteer helpers trained, measured using registers during programme delivery for the 5 weeks
2. Volunteers' time commitment measured using observation during programme delivery for the 5 weeks
3. Number of sessions run over the project period collected using registers at week 6 and 6

months
4. Recruitment rate recorded as the number of participants who consented to participate at various sites by week 0 (start of the programme at a specific site)
5. Views of participants, volunteers and church leaders about the sustainability of the program and the volunteers' ability to deliver the programme, collected using focus groups following programme delivery

Secondary outcome measures
1. Dynamic balance measured using timed up and go test at baseline, week 6 and 6 months
2. Dynamic balance measured using five-time sit to stand at baseline, week 6 and 6 months
3. Postural control under various sensory conditions measured using Modified Clinical Test of Sensory Interaction in Balance (CTSIB-M) at baseline, week 6 and 6 months
4. Static balance measured using single-leg stance test and tandem stance test at baseline, week 6 and 6 months
5. Fear of falling measured by Falls Self-Efficacy Scale questionnaire at baseline, week 6 and 6 months
6. Balance confidence measured using Modified Activity Specific Balance scale questionnaire at baseline, week 6 and 6 months
7. Emotional and social loneliness measured using DeJong Loneliness scale questionnaire at baseline, week 6 and 6 months
8. Rate of falls measured using the number of falls self-reported by participants at 6 months

Overall study start date
01/08/2017

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. 65 years or above
2. Able to perform five times sit-to-stand test (Bohannon, 2006)
3. Able to consent
4. Had no falls in the previous 6 months
5. Individuals of either gender
6. Who can walk within their homes
7. With the mental capacity to consent
8. With a self-perceived need to improve their balance

Participant type(s)
Other

Age group
Senior

Sex
Both

Target number of participants

4 clusters with sample size of 60 participants

Total final enrolment
62

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
01/12/2018

Date of final enrolment
01/11/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Church 1
Wolverhampton
United Kingdom
WV8 1PF

Study participating centre
Church 2
Wolverhampton
United Kingdom
WV8 1EU

Study participating centre
Church 3
Wolverhampton
United Kingdom
WV8 2ER

Study participating centre

Church 4
Wolverhampton
United Kingdom
WV8 1EH

Sponsor information

Organisation
University of Birmingham

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Sponsor type
University/education

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ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Other

Funder Name
Investigator intiated and funded

Results and Publications

Publication and dissemination plan
1. Publish in open access journals
2. Present at rehabilitation conferences
3. Protocol available on request

Intention to publish date
01/08/2021

Individual participant data (IPD) sharing plan
Current individual participant data (IPD) sharing statement as of 04/11/2021:
Individual participant data that underlie the results reported in the publication after deidentification (text, tables, figures, and appendices) will be available upon request from Sheeba Rosewilliam (s.b.rosewilliam@bham.ac.uk) after analysis for 2 years for investigators whose proposed use of the data has been approved by an independent review committee identified for this purpose. Consent has been gained from participants to share anonymised data. Proposals may be submitted up to 24 months following article publication.

Previous individual participant data (IPD) sharing statement:
Individual participant data that underlie the results reported in the publication after deidentification (text, tables, figures, and appendices) will be available upon request from Samantha Waldron (s.m.waldron@bham.ac.uk) after analysis for 2 years for investigators whose proposed use of the data has been approved by an independent review committee identified for this purpose. Consent has been gained from participants to share anonymised data. Proposals may be submitted up to 24 months following article publication.

IPD sharing plan summary
Available on request

Study outputs
Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	25/07/2018	27/09/2021	No	Yes
Participant information sheet	version 5	25/07/2018	27/09/2021	No	Yes