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Effect of vibration training on fall risk factors in older people at high risk of falling randomised controlled trial

Submission date	Recruitment status
28/09/2007	No longer recruiting
Registration date	**Overall study status**
28/09/2007	Completed
Last Edited	**Condition category**
22/05/2017	Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0192187952

Study information

Scientific Title
Effect of vibration training on fall risk factors in older people at high risk of falling randomised controlled trial

Study objectives
1. To determine whether standing on a vibrating platform three times per week for 12 weeks improves muscular strength and balance, hence reducing risk factors for falling in older people at risk of falling (i.e., referred to a falls prevention programme as part of their routine care at Nottingham University Hospitals NHS Trust)
2. To determine whether there are any adverse effects of standing on a vibration platform three times per week for 12 weeks for older people at risk of falling
3. To consider whether standing on a vibration platform three times per week for 12 weeks:
3.1. Influences general health and well-being
3.2. Influences bone metabolism in older people at risk of falling

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nottingham Research Ethics Committee 2, 18/09/2006

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Injury, Occupational Diseases, Poisoning: Falls

Interventions
AIMS AND HYPOTHESIS
Falls in older people are a major public health concern in terms of morbidity, mortality and cost.

Previous studies suggest that multifactorial interventions can reduce falls. There are a number of factors associated with an increased risk of falling, one of which is physical function.
The hypothesis is that the intervention of vibration training three times per week can improve physical function and reduce fall risk factors in older people identified as being at high risk of falling. This will be tested by a randomised controlled trial.
To the knowledge of the chief investigator this hypothesis has not yet been tested in a community-based population referred for being at high risk of falling.

CONTRIBUTION OF USERS TO THE DESIGN
In order to involve users in the study design a number of clinics in which older people were using vibration training were visited. In addition, preliminary work has been conducted at Loughborough University to test the feasibility of vibration training in healthy older volunteers from the community. The opinions and responses of these volunteers who experienced vibration training has contributed to the design of the training protocol.

The study design is informed by a number of recent studies using vibration platforms. The length and number of vibration bouts in each session are similar to those used in previous studies with older people (Bruyere, et al. 2005; Russo, et al., 2003; Iwamoto, et al., 2003).

STUDY DESIGN
The study will be based at Nottingham University Hospitals NHS Trust Sherwood Day Service. During the duration of the study period (up to one year, since it is not known what proportion of patients will choose to participate) or until sufficient patients have been recruited, all new patients over 60 years old who are not known to have dementia and who are referred to the falls prevention programme will be provided with an information leaflet about the study as well as a health screen questionnaire to complete if they would like to take part in the study. Patients without vertigo, dementia or any contra-indication for vibration training (as directed by the British Standard for mechanical vibration and shock - Guidance on safety aspects of tests and experiments with people, which is written because there is much research into the effect of vibration on workers in industrial settings) will be invited to take part in the study during their next visit as part of their routine care (not normally less than one week after being given the information leaflet). Patients will have an opportunity to discuss this with friends and family and ask further questions about the study before making a decision. The patient information leaflet states clearly that patients may leave the study at any time without providing a reason. If a patient chooses to participate they will be required to sign a written consent form.

All patients will undergo an initial fall risk assessment at the Sherwood Day Service as part of their routine care. This involves several tests of physical function and a test of cognitive function called the mini mental state examination (MMSE). If patients score less than 20 in the MMSE they will be excluded from participating in the study.

Additional assessment of function in patients who have chosen to participate in the study will include:
1. Static balance as measured by excursions in centre of pressure (i.e., the amount of movement of body weight) over 30 seconds while standing on a force plate (a flat platform which detects force or body weight) during four conditions; eyes open, eyes closed, standing on foam, standing on foam with eyes closed.
2. The peak power produced during an attempt to move from a seated position to a standing position with arms crossed over chest. This is measured using a force plate.
3. Peak power produced during an attempt to jump vertically in the air. This is also measured using a force plate.
4. Dynamic balance in standing as measured by the time it takes to perform a simple

standardised sequence of steps over a thin piece of foam on the floor. This test called the Four Square Step Test involves forward, backward and sideways steps.
5. Leg power (i.e., speed and force of movement) as measured using a leg power rig which has been used previously with older people at risk of falling. The speed generated in a fly wheel attached to a foot peddle which is pushed by straightening the legs in a seated position is used as a measure of leg muscle power.
6. Health-related quality of life as assessed using a standardised questionnaire which is completed by the researcher who reads the questions to the patient.
7. Physical activity over the past week as assessed using a standardised questionnaire which is completed by the researcher who reads the questions to the patient.

Patients who have chosen to participate and have not been excluded from the study on the basis of the health screen questionnaire or their score in the MMSE cognitive function test will be randomly allocated into the control or one of two intervention groups for the study. This will be done by asking patients to choose one from a number of sealed envelopes with a group marked on paper inside the envelope.

All the patients participating in the study including those in the control group will be asked to undertake three sessions each week for 12 weeks. For the first 6 weeks one session will take place during their appointments to the Sherwood Day Service as part of their routine care and the other two sessions independent of their routine care. For the final 6 weeks all visits will be independent of routine care. On all three occasions the participants will stand on a platform with bent knees for up to 10 minutes. The participants in the control group will be stationary and the participants in the vibration groups will experience one of two types of vibration, either tilting or vertical. The length of the training intervals will increase during the 12 weeks and will be in part based on individual patients' capability and comfort.

As physical function and response to training is likely to vary between individuals the sessions will be conducted and monitored on a personal basis. Patients will be asked to stop the bout or session at any stage which the training feels 'unpleasant'. Below is a draft training protocol; however, patients will not move on to the next phase until they have completed the previous without stopping. In this way the training will be tailored to the individuals' physical function and response to the vibration training. For example it is possible that some patients will not reach Phase 5 within the 12-week intervention period.

Draft Protocol:
Participants will undertake up to:
Week 1 - session 1 2 x 30secs (Phase 1a); session 2 3 x 30secs(Phase 1b); session 3 4 x 30secs (Phase 1c)
Week 2 - session 1 1 x 1min (Phase 2a); session 2 2 x 1min(Phase 2b); session 3 3 x 1min (Phase 2c)
Week 3 to 5 - all 3 sessions 4 x 1min (Phase 3)
Week 6 to 7 - all 3 sessions 5 x 1min (Phase 4)
Week 8 to 12 - all 3 sessions 6 x 1min (Phase 5)

The training protocol has been designed in part as a result of findings from a pilot study of subjective (i.e., what they thought about it) and objective response (i.e., how they moved) of people of various ages who experienced vibration training, which has been conducted at Loughborough University. During this study the vibration platforms for the study were tested to ensure the training programme will not exceed exposure limit values of the European Union Physical Agents (Vibration) Directive. This is a directive designed to prevent workers being exposed to excessive amounts of vibration in an occupational setting such as truck driving or drilling.

The patient information leaflet will advise patients to discontinue the vibration training if they encounter any adverse symptoms. Patients will be asked if they have experienced any such symptoms before participating in each training session. In addition, in order to monitor potential adverse effects of vibration, tactile sensitivity (i.e., sensitivity to touch) will be measured prior to the intervention and before and after a vibration training session during Week 4 and Week 8. Results from a pilot study at Loughborough University suggest that there is unlikely to be a change following short bouts of vibration as experienced in Phase 1 and Phase 2. Tactile sensitivity will be measured by touching the participants skin with monofilaments (thin plastic filaments of progressively decreasing thickness) and asking participants to say whether they can feel the filament.

All patients will undergo a fall risk reassessment at Week 6 and Week 13 as part of routine care. Participants will also undertake the seven additional measures (five functional performance tests and two questionnaires) at Week 13.

ANALYSIS

Repeated measures analysis of variance will be used to determine whether responses in outcome measures differ between control and vibration groups. These will include the seven additional measures as well as measures taken during the routine care as part of the Sherwood Day Service falls prevention programme. Possible confounding factors (e.g., medication use, physical activity scale) will be included as covariates.

REFERENCES

BRUYERE, O., WUIDART, M.A., DI PALMA, E., GOURLAY, M., ETHGEN, O., RICHY, F. and REGINSTER, J.Y., 2005. Controlled whole body vibration to decrease fall risk and improve health-related quality of life of nursing home residents. Archives of Physical Medicine and Rehabilitation, 86(2), pp. 303-307

IWAMOTO, J., TAKEDA, T., SATO, Y. and UZAWA, M., 2005. Effect of whole-body vibration exercise on lumbar bone mineral density, bone turnover, and chronic back pain in post-menopausal osteoporotic women treated with alendronate. Aging Clinical and Experimental Research, 17(2), pp. 157-163

RUSSO, C.R., LAURETANI, F., BANDINELLI, S., BARTALI, B., CAVAZZINI, C., GURALNIK, J.M. and FERRUCCI, L., 2003. High-frequency vibration training increases muscle power in postmenopausal women. Archives of Physical Medicine and Rehabilitation, 84;(12), pp. 1854-1857

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Change in physical function as measured by a fall risk assessment undertaken as part of routine care, which includes functional reach, chair stand, timed up and go test, and four test balance score.

Change in additional assessments of physical function:
1. Static balance as measured by postural sway during quiet stance on a force plate in four conditions: eyes open, eyes closed, standing on foam, standing on foam with eyes closed
2. Peak power during sit to stand on force plate
3. Peak power during a counter-movement vertical jump on a force platform
4. Dynamic standing balance as measured by time to complete the Four Square Step Test
5. Knee extensor power as measured by a leg power rig

Secondary outcome measures
Secondary outcome measures - adverse effects of vibration training:
1. Adverse symptoms reported
2. Changes in tactile sensitivity as measured using monofilaments

Changes in additional assessment of self-reported health-related quality of life as measured by interviewer-administered SF-36, a multi-item scale measuring physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health.

Changes in bone metabolism if measured by a blood sample analysis as part of routine care.

Overall study start date
18/09/2006

Completion date
17/09/2007

Eligibility

Key inclusion criteria
1. Patients over 60 years old
2. Not known to have dementia
3. Referred to the falls prevention programme

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
45

Key exclusion criteria
Patients scoring less than 20 in the mini mental state examination (MMSE)

Date of first enrolment
18/09/2006

Date of final enrolment
17/09/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nottingham University Hospitals NHS Trust
Nottingham
United Kingdom
NG5 1PB

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health (UK)

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Sponsor type
Government

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Funder(s)

Funder type
Government

Funder Name
Nottingham University Hospitals NHS Trust (UK), NHS R&D Support Funding

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
National Osteoporosis Society (UK)

Alternative Name(s)
NOS

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Funder Name
British Geriatric Society (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	results	01/01/2015	Yes	No