The effect of progressive balance exercise on postural sway – a 4 week randomized controlled trial

Today most fracture prevention measures targets the bone and osteoporosis. However, only about 20% of individuals with fractures have osteoporosis and at least 90% of all fractures are caused by a fall. Therefore, the present project builds on previous findings from our group identifying postural sway as an important risk factor for falls and aims to intervene against this risk factor in a randomized controlled trial targeting subjects at the highest risk for falls.

Specific aims:

1. Examine whether four weeks progressive balance training can improve parameters of body sway in measurements of static standing balance
2. Investigate whether participants experience greater security to their own ability and less fear of future falls after 4 weeks of progressive balance training
3. Investigate how long a potential effect of progressive balance training may be noticeable on participants' experiences of greater security in their own ability and less fear of future falls
4. 3. Examine whether participation in balance training leads to reduced number of falls at follow-up after 6, 12 and 24 months

Background

Falls and fall-related injuries are major health concerns for elderly individuals; they cause functional decline and increased mortality, as well as incurring vast health care costs for society.[1-3] Occurrences and consequences of falls are expected to increase globally with the growing number of elderly individuals. Hence, the improved detection and prediction of potential fall risk markers are of individual and societal importance.

Falling can be the end result of intrinsic and extrinsic factors negatively affecting an individual's ability to maintain balance,[4] which are often revealed during sequences of body movement.[5] Balance can be both dynamically and statically measured, the latter involves having the individual in a stationary standing position, from which results researchers have proposed impaired postural stability as a risk factor for falling.[6,7] However, evidence regarding the association of postural instability with prospective falls is limited, and population-based cohort studies in this field are scarce.[8] Other shortcomings of previous studies include the use of retrospective study designs,[9] which increase the risks of recall bias and the identification of risk factors as the result of falls.[10,11]

Postural instability is preferably investigated using objective measures of posturography, the advantages of which over regular clinical assessments include the reduction of test performance variability and avoidance of subjective scoring systems.[12] Recently, researchers have analyzed the performance of the Wii Balance Board (WBB; Nintendo, Kyoto, Japan) in the measurement of postural instability; WBB-based assessment has shown excellent concurrent validity and the ability to complement existing fall assessments.[13,14]

As of 2012, all 70-year olds in the Umeå municipality are invited to participate in the Healthy Ageing Initiative (HAI) study, which has currently enrolled more than 3000 participants. Among other measurements, we include assessment of postural stability using a Wii Balance Board (WBB; Nintendo, Kyoto, Japan) device. With each participant in a quiet stance, balance trials consisting of 60-second eyes-open (EO) and eyes-closed (EC) trials are performed. Participants are instructed to maintain an upright position throughout the test, stand relaxed, and avoid any arm or head movement. The WBB measures total COP sway length, representing the sum of postural sway in the anteroposterior and mediolateral directions.

Preliminary results from our analysis of data consisting of 1900 70-year-old individuals revealed that participants with postural sway in the 5th quintile had almost twice the risk of

falling compared to the reference group, when the 1-year follow-up of prospective falls was performed.

Thus the aim of the present follow-up study is to investigate if we can reduce the increased postural sway of participants who have been identified as having abnormal balance values, based on previous measurements.

Project description

Study design

The present project is planned to be conducted as a 4-week randomized intervention study with a follow up time of 2 years.

Study population

Recruitment of individuals at high risk of falls from the Healthy Ageing Initiative

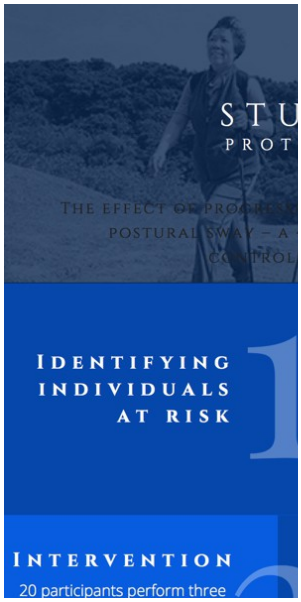
The Healthy Ageing Initiative (HAI) is an ongoing population based project aiming to reduce risk factors for non-communicable diseases (NCD) by risk factor evaluation and increased physical activity.[15] In short, HAI is inviting all 70 year olds in Umeå municipality to a health examination where traditional and potential novel risk factors for diabetes, CVD and fractures are investigated. These include objective measures of physical activity, blood pressure, blood-glucose, objective measured abdominal fat mass and ectopic fat, bone density and other features of bone quality, cognitive function, balance, walking ability, and different life style factors. At the second visit, all participants are informed about the results of tests performed and gets advice with a focus on physical activity, aiming at decreasing the risk of future diabetes, CVD and fractures. The counseling with focus on physical activity is based on motivational interviewing (MI) which is a directive patient-cantered counseling style to help the participants to explore and resolve their ambivalence about behavior change. They are

contacted at 6 months and 12 months per telephone for follow up and are contacted for an in-clinic follow up after 5 years.

Participants in HAI identified as being in the highest quartile of measures of postural sway, indicating poor balance and high fall risk, are invited to participate by telephone contact, and will upon agreement be randomized into either the intervention group or control group. Participants will after the initial contact also receive written information about the study. We aim to recruit 90 individuals from the existing HAI study cohort

Study protocol

Please see figure 1 for figure of study protocol.



Intervention protocol

Group 1

Twenty participants are randomised into the intervention group. The intervention group will perform three supervised group training sessions a week, consisting of 30 minutes of balance training for 4 weeks.

Group 2

Forty participants are randomised into the control group and receive a health consultation that highlights the importance of physical activity and balance exercise according to standard practice within the HAI project. They are asked to return after 4 weeks for follow up.

Follow up

After 4 weeks, the groups are followed up with the same measures that are used in the Healthy Ageing Initiative that contains objective and functional balance tests, tests of muscle strength and a validated questionnaires on fear-of-falling and physical activity. Both groups will be offered the specific program for balance training post measurements, with instructions that it can be performed in the home setting according to the same principles offered to the intervention group. The groups are followed up after 6 and 12 months through 70-years-health checks on prospective falls and levels of physical activity.

Methods used for baseline and follow up

Measurements of postural stability

Postural stability is assessed using a Wii Balance Board (WBB) device (Nintendo, Kyoto, Japan) labeled “Nintendo RVL-WBC-01”, with a nominal sampling frequency of 100 Hz. The equipment is linked to a PC via Bluetooth connection “E1310E(00**)”, using drivers labeled

"Manage Library for Nintendo's Wiimote v1.7.00 by Brian Peek". The software was designed in Microsoft C# by Prof. Göran Westling, Umeå University. The equipment's power supply has been exchanged from battery to USB power. The validity and reliability of the WBB has been evaluated elsewhere, showing excellent conformation to other laboratory balance equipment, with mean differences in center of pressure (COP) variance ranging between 0.3 to 3%.[13]

Participants are examined during quiet stance involving trials of eyes open (EO) and eyes closed (EC) for 60 seconds each. Participants are instructed to maintain an upright position throughout the test and stand relaxed, while avoiding any arm or head movements. The WBB measures total COP sway length, representing the sum of postural sway in anteroposterior and

Measurements of physical activity and capacity

Participants will be asked to complete the short form of the International Physical Activity Questionnaire (IPAQ),[17] an instrument designed to estimate activity levels among adult populations in domains including: 1) leisure time PA, 2) domestic and gardening activities, 3) work- related PA and 4) transport-related PA. Individuals are asked to recollect the duration of activities (walking, moderate- and vigorous- intensity PA) during the last 7 days in each domain. Questionnaire responses are used to calculate MET-min data in accordance with IPAQ guidelines.[17]

Participants will also be asked to perform the Time-Up-and-Go (TUG) test,[18] commonly used by clinicians to assess lower leg muscle strength, gait performance and overall functional mobility in elderly individuals. Testing involves participants rising unaided from an armchair and walking forward 3 meters until they reach a selected line on the floor, at which point they turn and come back to a seated position. Research nurses provides instructions and measures total testing time using a stopwatch. The TUG test have previously demonstrated good inter-

rater reliability (ICC=0.99).[18] Testing of isometric muscle strength involves using a hydraulic hand dynamometer (Jamar, Patterson Medical, Warrenville, IL, USA) to measure participant's maximum grip strength in the non-dominant hand. Participants will be instructed to keep the arm angled at 90° and maintain the elbow in proximity to the waist during the test. The maximum value out of 2 consecutive attempts is subsequently recorded.

Measurement of Confidence in Balance Ability and Fear-of-Falling

Participants will also be asked to report confidence in balance ability and fear of falling. This will be accomplished through two questionnaires. The Falls Efficacy Scale International (FES-I) measures fear of falling and is comprised of 16 questions on a scale from 1-4.[19] The Original Falls Efficacy Scale (FES) is also included and measures confidence in balance ability, formed by answering 13 questions on a scale from 1-10.[20]

Anthropometric measures

Anthropometric data will be obtained using a scale (HL 120; Avery Berkel, Fairmont, MN, USA) to measure weight, and a gauge (Holtain Limited; Crymych, Dyfed, UK) to measure height.

Statistical analysis plan

Descriptive data will be presented as means + standard deviations and the Student's t-test will be used to analyze statistical differences between variables. Categorical variables are investigated using chi-squared tests. Potential differences between intervention and control group will be analyzed using paired and independent t-tests. All analyses will be performed with SPSS version 24 (IBM Corp, Armonk, NY, USA) and Stata version 13.1 (StataCorp, College Station, Texas, USA).

Ethical considerations

Importance

This study could potentially lead to increased understanding of how balance exercise can contribute to an improved balance in individuals with impaired balance and ability. We also intend to highlight the participant's confidence in, and experience of, their own balance ability, and if the fear of future falls is reduced. This is important knowledge in order to prevent falls and fall injuries in older individuals, which are expected to increase in number in society. Through improvements in balance, future falls can potentially be preventable, which contributes to less fall-related injuries and accidents, thereby maintaining functional ability in especially older individuals. The prevention of falls and fall injuries reduces the suffering of individuals, but can also reduce health care costs when care for fall injuries such as hip fractures can be reduced.

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