Effectiveness of the computerized balance rehabilitation after hip fracture surgery
A study protocol of a prospective and open-label clinical trial

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Abstract
Introduction: Although balance problems in older populations are directly correlated with hip fractures, the overall physical gain afforded by balance rehabilitation itself has not yet been fully investigated. Here we describe a protocol for an open-label clinical trial to evaluate the effectiveness of computer-based balance-specific exercise (BSE) on the performance and balance of elderly women who underwent hip fracture surgery (HFS).

Methods and analysis: Elderly female patients (≥65 years old) who underwent surgery for femoral neck, intertrochanteric, or subtrochanteric fracture regardless of surgery type will be included. The BSE will be conducted using a computed posturographic system for a 2-week intervention period following HFS. The primary outcome of this study is Berg balance scale score. All functional outcomes will be measured at 1 and 3 weeks and at 3 and 6 months after the surgical intervention. The data will be analyzed using the intention-to-treat principle.

Abbreviations: ADLs = activities of daily living, BBS = Berg balance scale, BSE = balance specific exercise, EQ-5D = Euro Quality of Life Questionnaire five-dimensional classification, FAC = functional ambulatory category, FRAL = fatigue, resistance, ambulation, illnesses, and loss of weight, GDS = Geriatric Depression Scale, HFS = hip fracture surgery, IRB = Institutional Review Board, MBI = modified Barthel index, MFES = Modified Falls Efficacy Scale, MMSE = Mini-Mental State Examination, MRMI = modified Rivermead mobility index, PT = physical therapy, QOL = quality of life, REC = Research Ethics Committee.

Keywords: balance, hip fractures, postoperative care, rehabilitation

1. Introduction
1.1. Background

A balance problem is both the cause and the result of hip fracture. In particular, elderly people who have undergone hip fracture surgery (HFS) suffer from balance problems. Radosavljevic et al reported a significant correlation between patient age and Berg balance scale (BBS) score at 3 months after HFS. Also, elderly individuals are afraid of falling after HFS and thus lack both balance confidence and functional balance. Portegies et al suggested that balance confidence was independently correlated with mobility in patients with fall-related hip fractures. One study also suggested that balance confidence was highly correlated with activities of daily living (ADLs). Therefore, balance impairment may be a long-term issue among older adults after HFS and may limit mobility and daily activities and increase the risk of subsequent falls. Thus, balance impairment should be evaluated as a major fall risk and balance rehabilitation is essential to the prevention of additional falls in elderly individuals after HFS. The American College of Sports Medicine and the American Heart Association have also suggested that community-dwelling older adults at substantial risk of falls should perform exercises that maintain or improve balance to reduce the risk of injury.

Most rehabilitation programs after HFS mainly focus on postoperative range of motion exercises, standing, gait training with progressive weight bearing, and strengthening exercises of the hip extensor and abductor muscles. These postoperative programs have been shown to improve the independence of ADLs and gait function after hip fracture. However, in long-term follow-up studies > 1 year, conventional rehabilitation programs had no significant effect on re-fracture and fall rates. Therefore, recent clinical trials about comprehensive rehabilitation after HFS included balance training to strengthen physical functioning and performance with the intention of improving gait and balance. One clinical trial also showed that the fall rate was reduced when individualized fall prevention programs were administered to elderly patients who were transferred to the...
rehabilitation department after HFS. However, those studies were limited to home-based exercises or outpatient rehabilitation programs after general rehabilitation of hip fracture and not about intensive balance training in the early postoperative stage. The overall physical gain by balance rehabilitation itself has not yet been fully investigated. Furthermore, balance training immediately after HFS is fundamentally limited for patients whose balance confidence is low and who still suffer from severe surgical-site pain. Therefore, clinical studies should be conducted to evaluate the effectiveness of systematic and safe balance rehabilitation in patients after hip fracture.

1.2. Objectives

We aim to evaluate the effectiveness of a computer-based balance specific exercise (BSE) on the performance and balance ability of the elderly women who underwent HFS. We will also investigate whether the intervention could reduce their fear of falling and improve their coping abilities.

2. Method

2.1. Trial design

This prospective and open-label clinical trial will be performed in a tertiary hospital setting. During the 2-week postoperative intervention period, patients will participate in the hospital’s exercise program starting 5 to 7 days after HFS. All participants will follow the computer-based BSE program. Functional outcomes will be measured at 1 and 3 weeks as well as at 3 and 6 months after surgery. The trial has been registered prospectively with the ClinicalTrials.gov Registry (NCT03618576) prior to participant recruitment. Important protocol modifications will be communicated to the trial registry.

2.2. Participants and eligibility criteria

Elderly female patients (≥65 years old) who have undergone surgery for femoral neck, intertrochanteric, or subtrochanteric fractures regardless of surgery type (internal fixation, bipolar hemiarthroplasty, or total hip arthroplasty) will be included. Patients who have experienced the following will be excluded: hip surgery for infection, arthritis, implant loosening, or avascular necrosis; femoral shaft fracture, acetabular fracture, isolated fracture of the greater or lesser tuberosity, or periprosthetic fracture; pathologic fracture; combined multiple fracture; revision surgery; severe cognitive dysfunction (obey command ≤1 step); cannot stand by supporting a fixed walker at 5 days postoperative; and refusal to participate in a clinical trial.

2.3. Sample size and recruitment

Because this study is a preliminary and open-label trial, sample size calculation is not needed. A total of 40 subjects will be consecutively recruited. All participants will be enrolled at one tertiary hospital. On the fifth day after HFS, patients who meet the inclusion but not the exclusion criteria will be preliminarily screened by researchers in cooperation with orthopaedic surgeons. Patients who agree to participate in the study will be enrolled.

2.4. Intervention

The post-HFS rehabilitation program will be delivered by a rehabilitation physician, physical therapist, occupational therapist, nutritionist, clinical nurse specialist, and social worker. The program consists of total 10 days of physical therapy (PT) sessions (twice per day for 60 minutes) during the 2 weeks after surgery. PT intensity (weight-bearing, strengthening, gait training, aerobic, and functional exercises) will be gradually increased based on the patient’s functional level. Intensive patient education will also be provided by multidisciplinary rehabilitation members. BSE will be conducted with a computerized posturographic system for diagnosing balance and movement skills (Balance Master System NeuroCom; Natus Medical Inc., Pleasanton, CA) designed to objectively quantify balance and postural function of different origins, as described previously. Briefly, subjects will be prepared by being introduced to the supported standing position with the objective of looking for a symmetrical load on their legs. In the introductory session, dynamic exercises for small- and medium-sized muscle groups and lower extremity joints will be performed. Movements will be conducted at an average speed with maximum possible amplitudes. After the 5-minute introductory session, subjects will perform the main exercise for 20 minutes while maintaining the tandem position or maintaining their position with and without the use of a proprioceptive bubble. Subjects will be asked to walk on a rectilinear trajectory with or without crutches while changing speed and direction or while performing motor-cognitive tasks such as turning their head to the right and left side following a physiotherapist’s input. At the final 5-minute session, the training load will be gradually reduced and conducted at a slow speed and maximum amplitude.

2.5. Outcome measures

The following demographic data will be collected at baseline: age, sex, fracture location and laterality, surgery type, and underlying disease. Functional outcomes will be measured at 1 (before intervention) and 3 (after 2 weeks’ intervention) weeks and at 3 and 6 months after surgery. The primary outcome of this study will be balance and fall risk assessed using the BBS (range, 0–56; a lower score indicates a worse outcome). The secondary outcomes will be as follows: physical functioning and walking ability assessed according to the FAC (range, 0–5; a lower score indicates a worse outcome), Koval walking ability scores (range, 1–7; with a higher score indicating a worse outcome), which rate physical functioning according to walking dependency, MRMI (range, 0–40; a lower score indicates a worse outcome), and the MFES (range: 0–140; a lower score indicates a worse outcome); cognition evaluated using the Korean version of MMSE (range, 0–30; a lower score indicates a worse outcome); mood evaluated using the Korean version of GDS (range, 0–30; a lower score indicates a worse outcome); QOL evaluated using the EQ-5D (range, 0–1; a lower score indicates a worse outcome); ADLs determined using the Korean version of MBI (range, 0–100; a lower score indicates a worse outcome) and the Korean version of the Instrumental ADL (range, 0–3; a higher score indicates a worse outcome); and frailty, assessed based on the Korean version of the Fatigue, Resistance, Ambulation, Illness, and Loss of weight scale (FRAIL) using the Korean version of the FRAIL scale (range, 0–5; a lower score indicates a worse outcome).

2.6. Data analysis

Data will be collected using a standardized data entry form and entered into the data management system. The intention-to-treat
principle will be used for the data analysis. Participant characteristics will be described using means and standard deviations for continuous data and frequencies and percentages for categorical data. To compare paired data (before and after) between 2 different points, we will use the paired t-test and the Wilcoxon signed-rank test for continuous and nonparametric data, respectively. To compare categorical data, we will use McNemar’s test. Statistical significance will be defined as a P value <.05. All statistical analyses will be performed using SPSS version 19.0 for Windows (IBM Corp., Chicago, IL).

2.7. Ethics and dissemination

The study will be performed according to the relevant guidelines of the Declaration of Helsinki 1964 as amended in Tokyo, 1975; Venice, 1983; Hong Kong, 1989; and Somerset West, 1996.[23] Written informed consent for all interventions and examinations will be obtained at patient admission. The ethics board will be informed of all serious adverse events and any unanticipated adverse effects that occur during the study. The study protocol has been registered at Clinicaltrials.gov and will be updated accordingly. The study methods were designed in accordance with the SPIRIT guidelines for reporting randomized trials.[26] Direct access to the source data will be provided for monitoring, audits, REC/IRB review, and regulatory authority inspections during and after the study. All patient information will be coded anonymously with only the study team having access to the original data. The study results will be disseminated in peer-reviewed publications and conference presentations.

3. Discussion

The balance problems of older populations are directly correlated with fragility fractures such as hip fractures that can cause serious morbidity and mortality. Therefore, it is necessary to anticipate and seek to solve such problems. Several types of balance training have been introduced in clinical settings. The main feature of the training is to allow maintenance of body position, both statically and dynamically, over the base of support within defined stability limits.[27] Balance training has historically consisted of walking up and down stairs,[28–30] and/or walking on uneven surfaces (a rugged floor or fluffy sponge).[31] Monticone et al.[32] suggested that balance task-specific training was superior to general exercises for improving physical function, balance, and ADLs in elderly patients who have undergone internal fixation following hip fracture. A computerized balance-training machine with a force plate that detects weight loads and a monitor giving visual feedback was recently used to train elderly subjects.[33] Dodd et al.[34] showed that the training was feasible and useful after HFS in the elderly. However, no clinical trials of computerized balance training in elderly individuals after HFS have been reported to date. Our study will be the first to our knowledge to examine the efficacy and safety of computer-based BSE in this population.

Author contributions

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References

[1] Radosavljevic N, Nikolic D, Lazovic M, et al. Estimation of functional recovery in patients after hip fracture by Berg Balance Scale regarding the sex, age and comorbidity of participants. Geriatr Gerontol Int 2013;13:365–71.
[2] Hadjistavropoulos T, Delbaere K, Fitzgerald TD. Reconceptualizing the role of fear of falling and balance confidence in fall risk. J Aging Health 2011;23:3–23.
[3] Portegies E, Edgerton J, Salpakoski A, et al. Balance confidence was associated with mobility and balance performance in older people with fall-related hip fracture: a cross-sectional study. Arch Phys Med Rehabil 2012;93:2340–6.
[4] Edgerton J, Salpakoski A, Rantanen T, et al. Balance confidence and functional balance are associated with physical disability after hip fracture. Gait Posture 2013;37:201–5.
[5] Siivonen S, Kulmala J, Kallinen M, et al. Postural balance and self-reported balance confidence in older adults with a hip fracture history. Gait Posture 2009;30:363–6.
[6] Nelson ME, Rejeski WJ, Blair SN, et al. Physical activity and public health in older adults: recommendation from the American College of Sports Medicine and the American Heart Association. Circulation 2007;116:1094–105.
[7] Chudyk AM, Jutai JW, Petrella RJ, et al. Systematic review of hip fracture rehabilitation practices in the elderly. Arch Phys Med Rehabil 2009;90:246–62.
[8] Stenvall M, Olofsson B, Nyberg L, et al. Improved performance in activities of daily living and mobility after a multidisciplinary postoperative rehabilitation in older people with femoral neck fracture: a randomized controlled trial with 1-year follow-up. J Rehabil Med 2007;39:232–8.
[9] Latham NK, Harris BA, Bean JF, et al. Effect of a home-based exercise program on functional recovery following rehabilitation after hip fracture: a randomized clinical trial. JAMA 2014;311:700–8.
[10] Binder EF, Brown M, Sinacore DR, et al. Effects of extended outpatient rehabilitation after hip fracture: a randomized controlled trial. JAMA 2004;292:837–46.
[11] Hill AM, McPhail SM, Waldron N, et al. Fall rates in hospital rehabilitation units after individualised patient and staff education programmes: a pragmatic, stepped-wedge, cluster-randomised controlled trial. Lancet 2013;381:2592–9.
[12] Lee SY, Beom J, Kim BR, et al. Comparative effectiveness of fragility fracture integrated rehabilitation management for elderly individuals after hip fracture surgery: a study protocol for a multicenter randomized controlled trial. Medicine (Baltimore) 2018;97:e10763.
[13] Efstigmeeva I, Lesnyak O, Bulink IE, et al. Effect of twelve-month physical exercise program on patients with osteoporotic vertebral fractures: a randomized, controlled trial. Osteoporos Int 2016;27:2315–24.
[14] Berg K, Wood-Dauphinee S, Williams JL. The Balance Scale: reliability assessment with elderly residents and patients with an acute stroke. Scand J Rehabil Med 1995;27:37–36.
[15] Colles FM, Wade DT, Bradshaw CM. Mobility after stroke: reliability of measures of impairment and disability. Int Disabil Stud 1990;12:6–9.
[16] Koval KJ, Skovron ML, Aharonoff GB, et al. Ambulatory ability after hip fracture. A prospective study in geriatric patients. Clin Orthop Relat Res 1993;310:150–9.
[17] Lennon S, Johnson L. The modified rivermead mobility index: validity and reliability. Disabil Rehabil 2000;22:833–9.
[18] Edwards N, Lockett D. Development and validation of a modified falls efficacy scale. Disabil Rehabil Assist Technol 2008;3:193–200.
[19] Kang Y, Na DL, Hahn S. A validity study on the Korean Mini-Mental State Examination (K-MMSE) in dementia patients. J Korean Neurol Assoc 1997;15:500–8.
[20] Jung IK, Kwak DI, Joe SH, et al. A study of standardization of Korean form of Geriatric Depression Scale (KGDS). J Korean Geriatr Psychiatry 1997;1:61–72.
[21] Group TE. EuroQol—a new facility for the measurement of health-related quality of life. Health policy 1990;16:199–208.
[22] Jung HY, Park BK, Shin HS, et al. Development of the Korean version of Modified Barthel Index (K-MBI): multi-center study for subjects with stroke. J Korean Acad Rehab Med 2007;31:283–97.
[23] Won CW, Yang KY, Rho YG, et al. The development of Korean activities of daily living (K-ADL) and Korean instrumental activities of daily living (K-IADL) scale. J Korean Geriatrics Soc 2002;6:107–20.
[24] Jung HW, Yoo HJ, Park SY, et al. The Korean version of the FRAIL scale: clinical feasibility and validity of assessing the frailty status of Korean elderly. Korean J Intern Med 2016;31:394–600.
[25] Dale O, Sala M. The Helsinki Declaration, research guidelines and regulations: present and future editorial aspects. Acta Anaesthesiol Scand 1996;40:771–2.
[26] Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. Int J Surg 2012;10:28–35.
[27] Chiarovano E, de Waele C, MacDougall HG, et al. Maintaining balance when looking at a virtual reality three-dimensional display of a field of moving dots or at a virtual reality scene. Front Neurol 2015;6:164.
[28] Moseley AM, Sherrington C, Lord SR, et al. Mobility training after hip fracture: a randomised controlled trial. Age and ageing 2009;38:74–80.
[29] Sherrington C, Lord SR. Home exercise to improve strength and walking velocity after hip fracture: a randomized controlled trial. Arch Phys Med Rehabil 1997;78:208–12.
[30] Sherrington C, Lord SR, Herbert RD. A randomized controlled trial of weight-bearing versus non-weight-bearing exercise for improving physical ability after usual care for hip fracture. Arch Phys Med Rehabil 2004;85:710–6.
[31] Jogi P, Overend TJ, Spaulding SJ, et al. Effectiveness of balance exercises in the acute post-operative phase following total hip and knee arthroplasty: A randomized clinical trial. SAGE Open Med 2015;3:2050312115570769.
[32] Monticone M, Ambrosini E, Brunati R, et al. How balance task-specific training contributes to improving physical function in older subjects undergoing rehabilitation following hip fracture: a randomized controlled trial. Clin Rehabil 2018;32:340–51.
[33] Ben Achour Lebib S, Missaoui B, Miri I, et al. Role of the Neurocom Balance Master in assessment of gait problems and risk of falling in elderly people. Ann Readapt Med Phys 2006;49:210–7.
[34] Dodd K, Hill K, Haas R, et al. Retest reliability of dynamic balance during standing in older people after surgical treatment of hip fracture. Physiother Res Int 2003;8:93–100.