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Original Article

Effects of exercise improves muscle strength and fat mass in patients with high fracture risk: A randomized control trial

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KEYWORDS

Bone mineral density; Gender differences; Integrated care; Low extremities exercise; Muscle strength *Background*: The deterioration of the musculoskeletal system imposes significant impact on physical activity. Exercise is an important strategy which minimizes these changes. It is not clear which type of exercise provides better improvement on low physical performance, low muscle mass and low strength of sarcopenia. We aim to develop an integrated care (IC) model and compare its relative efficacy in limb fat free mass, muscle strength, and physical performance with low extremities exercise (LEE) in community dwelling older adults with high risk of fractures (Fracture Risk Assessment Tool (FRAX[®])) \geq 3% for hip fracture, \geq 20% for major osteoporotic fracture or 1-min osteoporosis risk test (\geq 1 point) or fall (\geq 2 falls in previous year). *Methods*: Patients were assigned randomized to participate in either IC or LEE group (n = 55 each) for 3 months. All participants received education including home-based exercise. The IC group consisted of different modalities of exercise while the LEE group performed machine-based low extremities exercise. Fat free mass, muscle strength, and physical performance were measured at their baseline and 3-months follow-up.

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Results: Mean age was 73.8 ± 7 years with 69.1% women. Entire cohort demonstrated significant increment in fat free mass, muscle strength (4 indicators) and physical performance (3 indicators). However, between group differences were not significant.

Conclusions: With regular supervise exercise; both groups are equally effective in decreasing fat mass and increasing physical performance, muscle mass and strength. However, the IC group required fewer resources and thus more financially feasible in a community setting. Copyright © 2017, Formosan Medical Association. Published by Elsevier Taiwan LLC. This is an

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Introduction

Maintenance in a healthy musculoskeletal system is important to older adults to remain independent in their daily activities. Aging, chronic diseases and other lifestyle factors can contribute to loss in muscle and skeletal integrity. Two important aging-associated diseases are sarcopenia and osteoporosis. Sarcopenia, which is characterized as loss of type 2 fibers and motor neurons, eventually leads to muscle weakness with age. This ultimately leads to subsequent physical disability and increased fall among older adults.¹ Osteoporosis, which is characterized by a compromise in bone strength, predisposes a person to increase fracture risk. Fragility fracture further deteriorates physical function and lead to other complications and morbidities such as malnutrition, depression, poor quality of life and death.^{2,3} In order to minimize fracturerelated morbidity and mortality, targeting improvement in muscle strength and promoting bone health is necessary.^{4,5}

Although osteoporosis medications (OM) and other newly developed medications are increasingly becoming more available, only patients experiencing fragility fracture and low bone mineral density (BMD) are reimbursed for treatment with OM in Taiwan.⁶ Furthermore, more than half of the fragility fractures were found in women whose BMD were higher than the definition of osteoporosis.⁷ Despite the fact these OMs improve BMD and decrease further fracture risks, limited studies investigated their effects on the muscle system, which is also an important integral contribution to fall prevention.⁸ Therefore, nonpharmacological therapy is also crucial to prevent sarcopenia, osteoporosis and subsequent fall-related fractures.

It has been proved that exercise can prevent or slow the progression of sarcopenia and osteoporosis. A communitybased group exercise is a practical method to improve the physical performance, muscle strength, and BMD. However, not all types of exercises lead to significant improvement in muscle strength and BMD. A meta-analysis reported that weight bearing training and progressive resistant training (PRT) are effective in maintaining BMD.⁹ Positive effects of PRT on muscle strength and mass were also demonstrated for older adults with frailty.¹⁰ However, the changes of functional performance such as balance, gait and mobility after these exercise trials were limited.¹¹ For this reason, multimodal exercise program was designed and shown to be effective in improvement on muscular strength and functional performance.^{12,13} However, most randomized controlled studies used weight machine for training exercise. Weight machines are not widely available to all older adults living in a community. In addition, most studies applied control group to demonstrate positive effects of exercise. There are very few trials comparing the effectiveness of different group exercise programs.^{14,15} Hence, we enrolled older people who are classified as high risk of fragility fracture or fall for two different exercise programs. The purposes of our study are as follows: 1) by comparing to a weight machine based training, we wish to demonstrate equal if not superior effectiveness of a community-based, integrated care program for improvement on muscle mass and strength and, BMD, 2) to explore these interventions leading to different effects between men and women.

Methods

Trial designs

The proposed study is a randomized controlled trial (RCT) with 3-month exercise interventions at National Taiwan University Hospital (NTUH) Bei-Hu Branch (BB site). Subjects were randomized to either integrated care (IC) or lower extremity exercise (LEE) groups. The research site is a community hospital affiliated to a medical center. The study was approved in 2014 by the Institutional Review Board of NTUH (Protocol ID: 201402022RINB, ClinicalTrials. gov: NCT02608749).

Patients and sample size

Subjects equal to or older than the age of 50 years, capable of visiting the researchers' outpatient clinics, able to exercise, and with one of the listed characteristics below were eligible for the current study. 1) participants of 2013 Wang Jhan-Yang Charitable Trust Fund (WJYCTF) sponsored "Osteoporosis and fall prevention education with high risk population management study" or 2) screening high risk from fall (≥ 2 /year), FRAX[®] ($\geq 3\%$ for hip fracture, $\geq 20\%$ for major osteoporotic fracture),¹⁶ or 1-min osteoporosis risk test (≥ 1 point).¹⁷ BMD evaluation with dual-energy Xray absorptiometry (DXA) before enrollment was highly recommended but not required. Based on our previous unpublished study results, LEE group subjects had on average 4.5 kg higher lower leg extension power than IC group (mainly Tai-Chi based exercise and some group activities). Assuming 1:1 ratio, and an 80% power, the

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