

## 2. 音楽療法

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- 音楽療法とは心身の障害の軽減回復，機能の維持改善，生活の質の向上を目的に意図的，計画的に音楽を治療として用いることである。
- 音楽療法は受動的音楽療法と能動的音楽療法との2つに分けられる。
- 音楽療法の実践においては認定音楽療法士も存在し，全国的にもさまざまな取り組みがなされている。
- 認知症に対して能動的音楽療法によるエビデンスを示していく必要がある。

**Key Words** 認知症，受動的音楽療法，能動的音楽療法，認定音楽療法士，fNIRS

音楽療法とは音楽の持つ生理的，心理的，社会的働きを用いて，心身の障害の軽減回復，機能の維持改善，生活の質の向上，問題となる行動の変容などに向けて，音楽を意図的，計画的に使用することである。したがって認知症に対しても，治療上の効果を期待して行うこととなる。たとえ認知機能は改善せずとも，QOLの向上に繋がるなど，何らかの効果を示す根拠が必要である。音楽療法の実践においては認定音楽療法士も存在し，さまざまな取り組みがなされており，少なくとも認知症に対して能動的音楽療法による効果を示していく必要がある。これまでに当センターでは認知症高齢者に対して外来や病棟での音楽療法の長年の経験をもっている。さらに我々のグループでは音楽療法の実践と，脳血流を測定することで，音楽の持つ生理的かつ客観的評価をめざしている。本稿ではその現状と課題について総括する。

### □ 音楽療法とは？

日本音楽療法学会による定義によれば，音楽療法とは「音楽の持つ生理的，心理的，社会的働きを用いて，心身の障害の軽減回復，機能の維持改善，生活の質の向上，問題となる行動の変容などに向けて，音楽を意図的，計画的に使用すること」とされている。

音楽療法の歴史は古く，古来より音楽は人々の

心身を癒す目的で用いられてきた。旧約聖書には，ユダヤの王サウルのころの病を治すために，羊飼いのダビデが堅琴を弾いて治療したと記されている。音楽は人々の暮らしや宗教と深く結びつき現在に至っており，音楽によってところが鎮められたり，逆に鼓舞されたりするなどの効果があることを，人々は皆，経験的に知っていた。その後，第1次世界大戦で負傷した兵士に対する心身のケアに音楽療法が用いられ，アメリカ，ヨーロッパを中心に発展した。第2次世界大戦後，アメリカでは大学の教育プログラムの1つに音楽療法コースが設立されたが，日本でもアメリカの論文に影響を受けた櫻林仁が1962年、『生活と音楽』を記し，この頃からわが国における音楽療法は始まった。当初は障害児教育の分野で行われていたが，現代では精神科，高齢者，健常者など医療，福祉，教育の領域に活動の場を拡げている。

このように，音楽療法の対象領域が幅広いのは，音楽には多種多様なジャンル，楽曲があり，あらゆる年代のさまざまな好みや気分などのニーズに応えることができるため，幅広い対象者に，あらゆる目的に応じた音楽療法の提供が可能であるからである。

音楽療法は，その実施形態から大別すると，受動的音楽療法と能動的音楽療法との2つに分けられる。前者は，音楽を受動的に聴取することで治

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療効果を得ようとするもの、後者は対象者自身が歌ったり楽器を演奏したりすることで効果を得ようとするものであるが、それぞれ対象者、その目的に応じて使い分けられ、実施されている。

しかし、音楽療法で得られる効果は主観的には感じられるものであっても、客観的指標によってデータで示すことが難しいために、医療の代替、補助療法としては正規の立場を得られていないのが現状である。

#### □ わが国における音楽療法の現状と今後

1960年代以降、日本でも障害児、精神科、高齢者施設などの各領域で音楽療法が取り入れられるようになり、当初は臨床音楽療法協会とバイオミュージック学会とが、2001年に統合される形で日本音楽療法学会が設立され、現在では全国で6,000人を超える会員を擁する団体である。現在日本には、その日本音楽療法学会の認定音楽療法士が1,631名(2009年6月現在)いる。しかし、その多くは正職員という正規の立場を得られず、非常勤であったり、もしくは別の資格を有して(たとえば介護職員として)勤務するかたわらで音楽療法を行っていたり、ボランティアで行っているなど非常に不安定な立場にあり、専門職として認められていないのが現状である。現在、日本音楽療法学会は音楽療法士の国家資格化、音楽療法の保険点数化などを働きかけているが、今後、音楽療法が医療の代替、補助療法として認められるためには、客観的指標によって効果を証明し、そのデータを積み重ねていくこと、また音楽療法がどこでも同じレベルの療法が受けられるよう教育を充実させ、音楽療法士の質を向上、安定させることが必須である。

#### □ 音楽療法が認知症患者に貢献できること

客観的指標を用いて音楽療法の有効性を検討した研究のうち、とくに認知症領域での効果の証明に関与すると思われる研究の一例を報告する。

はじめに、前頭前野の賦活化に音楽聴取が貢献できることを示したデータの1例を示す(図1)。このデータは、日立メディコ社製光トポグラフィ(ETG-100)を用い、健常成人15名に対し

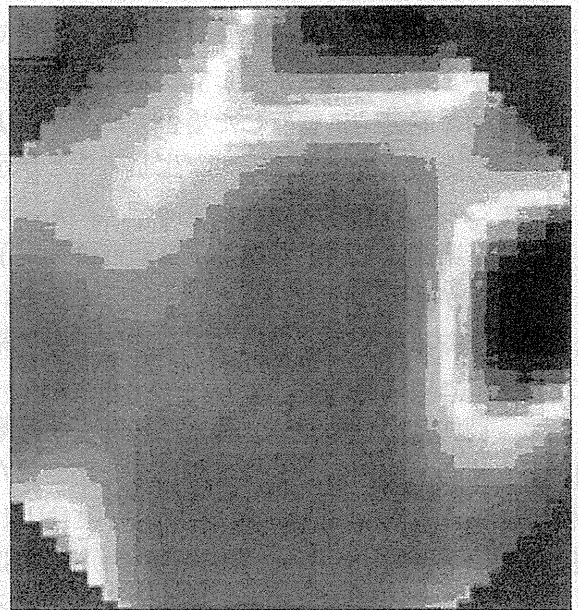


図1 タスクB(能動的)聴取時の前頭前野賦活化の一例

て行ったものである。タスクとして使用したのは、J.S. バッハ作曲 平均律クラヴィーア曲集第1巻 第1番ハ長調プレリュードの冒頭1分間であり、聴取A(受動的聴取)と聴取B(能動的聴取)をABABAの順に交互に聴取するブロックデザインで行った際の、前頭前野の賦活状態を捉えたものである。すなわち、被験者は同一の曲を、聴取AではBGMのように受け身に聴き流し、聴取Bでは楽曲に集中し、積極的、能動的に聴取するよう指示した。したがって、同一の曲を聴取する際に、AとBとでは聴取する態度のみを意図的に替えるという複雑なものであったため、その指示が正確に行える健常成人15名に対し行った。

図1は、受動的に聴き流した聴取Aより、能動的に聴取したBで賦活した部位が赤色で示されている。このように、タスクBでより前頭前野が賦活していることを示している。つまり、耳から入ってくる聴覚情報は全く同一の音楽でありながら、意図的に聴取する心構え、態度を替えるだけで、前頭前野の賦活状態は変化するということを示したデータである。この傾向は移動の差はあれ15例全例でみられ、統計的にも有意であった<sup>2)</sup>。

音楽を受動的に聴取することは、どんな状態であっても(ベッド上安静であっても、電車で通勤

中でも) 手軽に用いられる音楽療法の1つの形である。しかし、ただBGMとして聴き流した場合と、積極的に能動的に聴取した場合では、このように前頭前野の血流状態に違いが生じることが示された。このことから、認知症予防や、認知機能の改善に音楽療法を用いる場合、前頭前野を賦活させることが重要であるため、いかに音楽療法に能動的に、やる気を持って取り組むかがその効果を左右するといえる。

次に、認知症患者の意欲、積極性に関する事例を紹介する。認知症患者の前頭前野を測定した1例である。この研究は、島津製作所製fNIRS(近赤外線分光法)を用い、認知症患者がMMSEを行っている際の前頭前野を計測したものである。すなわち言葉に詰まるような、ご本人にとってわからないことを答えているときと、ご本人にとって答えやすい、すらすら解答が出てくるようなときとを比較したところ、後者のほうが脳局所の血流が増加した。このように、本人にとって得意なことを話すような状況であれば、話そうとする意欲が高まる。当然のことながら、発話が増え、発話が増えれば前頭前野は賦活するというを示している。これらの結果から、たとえ認知症症状があっても、一生懸命、何かに能動的に取り組めば、前頭前野は賦活されるということが示された。しかしそのためには、本人の好きなことや得意なことで、やる気が出るよう、意欲的に取り組めるようにすることが必要といえる。つまり、音楽療法の効果を高めたかったら、対象者の好みをきちんと把握して、好み、気分にあうもの、意欲的に取り組めるものを提供することが大切であるといえるのではないか。そのことが、音楽療法の効果をより高めるための留意点である。

#### □ 音楽療法の認知症領域での発展性

超高齢化社会に突入しようとしている日本で、平成22年現在の高齢化率は22.5%と、実に人口の4人に1人が65歳以上の高齢者になろうとしている。また、日本人の平均寿命が延び、高齢化社会が進むなか、65歳以上の高齢者のうち8.1%が認知症を有し、85歳以上では27.3%に上るといふ。

高齢者の方々には、ただ長生きするのではなく、健康に心豊かに暮らせる老後が求められる。したがって、認知症の発症を少しでも遅らせること、認知症を発症せずに天寿を全うできる人を増やすこと、すなわち認知症の予防、進展抑制が大切であり、音楽療法はその一部に貢献できると考える。

音楽療法には、回想法と類似の効果があるといわれているが<sup>3)</sup>、見当識が失われていくなか、断片的な記憶の世界で生きる認知症患者にとって、昔懐かしい音楽は、過去と今の自分とがつながる時間ということができ、これが回想法と同様の効果を与えると考えられる。また、音楽を用いた回想法では、よりポジティブな回想を促すなどの効果もあるといわれている<sup>4)</sup>。

また、音楽を用いることで活動性が向上したり、身体運動を誘発するなど脳にも好ましい刺激となり、認知機能が向上したり、残存機能を最大限に高めたり、精神的安定を促したり、ひいては高齢者のQOLを向上することにつながるなどの効果も得られる。このような、音楽が脳や心身に与える物理的な刺激や、療法の場で患者とセラピストが交わす温かな時間、精神的充足、それら両面が脳の可塑性をも促進し、脳内のネットワークを再度、構築、強化し、認知機能を向上させることにつながると考えられる。このように、音楽療法は認知症患者にさまざまな効果をもたらすことから、高齢者領域での音楽療法の導入は今後さらに増加するのではないだろうか。しかし、個々にスポットをあてた療法としてではなく、ただ単に大勢の人を楽しませることを目的とした音楽レクリエーションのようなどころも多い。もちろん、レクリエーション自体を否定するつもりは全くないが、やはり療法として行うのであれば、セラピストが専門性を活かし、きちんとした目的を持ち、個々の患者の嗜好に合わせた音楽療法の提供が重要である。

#### まとめ

高齢化社会の現代、今後ますます認知症患者の増加が想定されるわが国で、寝たきりではなく元気に生き生きと暮らせることが求められる。高齢者を対象とした音楽療法では、機能の維持および

改善, 活動性の向上, 認知症予防, 認知症の進行を遅らせる, QOL の向上などが期待される。

音楽療法で認知症そのものを改善することは難しい。しかし, 認知症の中核症状である認知障害, 記憶障害, 見当識障害などは, 患者の心理状態や身体的状況によって左右されることから, それらの症状に音楽療法が貢献できることは少なくない。また, 認知症の進行を遅らせたり, 認知症予防に必要な前頭前野の賦活化は, 音楽を用いたアプローチであれば, より活動性を高めたり, 楽しんで行うことができるなどトレーニングが容易となる。たとえば, ある言葉のみを抜いて歌うトレーニングでは, 注意, 集中を促し, 認知機能の向上を目的とした活動となり, 季節に合った歌を歌うトレーニングでは, 見当識強化, そしてそこから回想法のような展開にもつながる。

こういった脳に刺激となるようなトレーニングも, 音楽療法であれば楽しんで取り組み, さらに意欲的に取り組みれば前頭前野も賦活化すると, 認知症患者に音楽療法を用いる利点は数多い。認知症そのものの改善には至らなくても, 対象者が健康に, 心豊かに, その人がその人らしく, 周囲との関係も良好に天寿を全うする……, そこに音楽療法が貢献できることは少なくない。

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## こうして乗り切る、切り抜ける 認知症ケア 家族とプロの介護者による究極の知恵袋

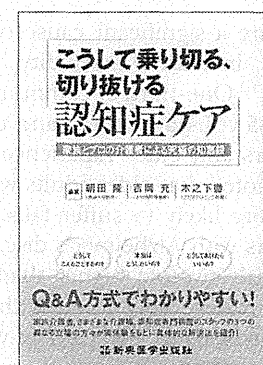
編著: 朝田 隆(筑波大学教授)  
吉岡 充(上川病院理事長)  
木之下徹(こだまクリニック院長)

本邦認知症 BPSD の第 1 人者が、実際に現場で日々なされている創意工夫をあますことなく紹介。知っているだけでラクになる知識が満載です。ドクターもケアスタッフも、家族もみんなで読んで下さい。

認知症ケアの現場でよく起こる「困った」「キレそう」な場面を厳選。介護に携わる人々による多方面からの視点を元に練られた、具体的で現実に役立つ対応策を Q&A で紹介。

### 主要目次

在宅の認知症の人への対応 / 介護スタッフ・関連職域の人たちの疑問や悩み / 病院・施設での認知症対応 / 起こりがちな病気と障害 / 用語解説



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ISBN978-4-88002-809-5



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## ORIGINAL ARTICLE

# Global brain atrophy is associated with physical performance and the risk of falls in older adults with cognitive impairment

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**Aim:** Falls are common in patients with cognitive disorder. The purpose of this study was to determine whether global brain atrophy is associated with cognitive function, physical performance and fall incidents in older adults with mild cognitive disorder.

**Methods:** A total of 31 older adults with mild cognitive disorders (mean age  $78.9 \pm 7.3$  years) were studied, and 10 of them had experienced falls and the others had not in the past 1 year. Cognitive function and physical performance were measured in these patients. Global brain atrophy was determined by the Voxel-Based Specific Regional Analysis System for Alzheimer's Disease software.

**Results:** Fallers showed significantly worse scores than the non-fallers in the Global Brain Atrophy Index, Clock Drawing Test (CDT), Verbal Fluency Test (animal), maximum walking time and Timed Up & Go (TUG) Test. The Global Brain Atrophy Index was correlated with the Verbal Fluency Test (animal;  $r = -0.522$ ), the Verbal Fluency Test with letter (ka;  $r = -0.337$ ), CDT ( $r = -0.547$ ), TUG ( $r = 0.276$ ) and Five Chair Stands Test ( $r = 0.303$ ) by age-adjusted correlation analyses. Stepwise regression analysis showed that the Global Brain Atrophy Index ( $\beta = 1.265$ , 95% CI 1.022–1.567) was a significant and independent determinant of falls ( $R^2 = 0.356$ ,  $P = 0.003$ ).

**Conclusion:** Global brain atrophy might be indicated as one of the risk factors for falls in older adults with mild cognitive disorders. *Geriatr Gerontol Int* 2012; ••: ••–••.

**Keywords:** falls, global brain atrophy, mild cognitive disorder.

## Introduction

Falls are a significant cause of injuries, loss of confidence, increased morbidity and mortality in older adults.<sup>1,2</sup> One-third of community-dwelling older adults aged 65 years and older, and up to 50% of those aged 80 years and older experience falls each year.<sup>3,4</sup> It has been noted that older adults with cognitive impairment are more likely to suffer falls.<sup>5</sup> In fact, the fall rate in patients with Alzheimer's disease (AD) was reported to be nearly twofold higher than age-matched controls.<sup>6</sup> Furthermore, older adults with cognitive disorders have impaired balance and gait,<sup>7</sup> as well as impaired executive functions.<sup>8</sup>

Although patients with cognitive disorders have a higher risk of falls, few studies have been reported on

the relationship between morphological changes of the brain and fall incidents. White matter lesions, frequently found in magnetic resonance imaging (MRI) of the aging brain,<sup>9</sup> are attributed to cerebral microangiopathic changes.<sup>10</sup> White matter lesions in older adults are also associated with gait and balance impairment,<sup>11,12</sup> cognitive impairment<sup>13</sup> and frequent falling.<sup>14</sup> A previous study suggested that periventricular white matter lesions might be related to falls in patients with a mild to moderate cognitive disorder.<sup>15</sup> Furthermore, white matter lesions can predict the incident of hip fracture in persons younger than 80 years-of-age.<sup>16</sup>

Previous reports showed that measures of cognitive performance in old age, such as scores on tests of intelligence, information processing speed and memory, are predicted by global and local brain atrophy.<sup>17</sup> However, there have been no studies to address the relationship between global brain atrophy and fall incidents. Therefore, the purpose of the present study was to determine whether global brain atrophy is associated with cognitive function, physical performance and fall incidents in older adults with mild cognitive disorders.

Accepted for publication 2 July 2012.

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## Methods

### Participants

Patients with a cognitive disorder who were referred to the memory clinic of the Department of Geriatric Medicine in Kyoto University Hospital, Kyoto, Japan, were enrolled in the present study. All patients underwent brain MRI, as well as a battery of laboratory tests. The diagnosis of AD and mild cognitive impairment (MCI) was made according to the following criteria: AD, Diagnostic and Statistical Manual of Mental Disorders, 4th edition and National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer's Disease and Related Disorders Association;<sup>18,19</sup> and MCI, Petersen's criteria.<sup>20</sup> In the present study, we did not set the upper limit of the Mini-Mental State Examination (MMSE) for the diagnosis of MCI. Of the 31 patients with a cognitive disorder, 20 were classified as mild AD and 11 were classified as MCI by the criteria. Those with MMSE scores below 19 were excluded from the present study.<sup>21</sup> Other exclusion criteria used in the present study were vascular dementia, dementia with Lewy bodies, lacunar infarcts, Fazekas grade 3 periventricular hyperintensity (PVH)/deep white-matter hyperintensity (DWMH),<sup>22</sup> severe cardiac, pulmonary or musculoskeletal disorders, and the presence of comorbidities associated with greater risk of falls, such as Parkinson's disease and stroke.

Written informed consent was obtained from each participant or his/her family members for the trial in accordance with the guidelines approved by the Kyoto University Graduate School of Medicine and the Declaration of Human Rights, Helsinki, 1975.

### MRI

MRI scans were carried out with a 1.5-T superconductive MRI unit (Magnetom Symphony; Siemens Medical, Erlanger, Germany). Whole-brain volumetric imaging with 3-D gradient refocused echo sequence (magnetization prepared rapid gradient echo, or MPRAGE) was carried out for voxel-based morphometry analysis using the following parameters: field of view (FOV) 22 × 22 cm, matrix 256 × 256, 120 contiguous 1.25-mm thick sagittal slices, TR/TE/TI 1700/3.93/800 ms and FA 15°.

### Voxel-based morphometry

The voxel-based analysis system in the present study has been validated.<sup>23</sup> Currently, their software is distributed in Japan under the name, Voxel-Based Specific Regional Analysis System for Alzheimer's Disease (VSRAD). VSRAD automatically calculated the following analysis results, which reflect the severity of gray

matter loss in the global brain by comparing the original normal database template. The severity of global brain gray matter loss was estimated with the Global Brain Atrophy Index, which was calculated as a percentage rate of voxels with a Z-score >2 compared with the whole brain.

### Fall experience

Fall events in the past 1 year were recorded based on an interview with the family members. A fall was defined as "an event that results in a person coming to rest inadvertently on the ground or other lower level regardless of whether an injury was sustained, and not as a result of a major intrinsic event or overwhelming hazard".<sup>5</sup> The date, number, characteristics (e.g. while rising from a lying or sitting position, while turning in the opposite direction, while tripping over an obstacle) and consequences (e.g. bruise, fracture) of the falls were recorded using a standardized questionnaire.

### Cognitive function measures

Cognitive functions were assessed by MMSE, Clock Drawing Test (CDT), Trail Making Test part A (TMT-A), Verbal Fluency Test (animal) and Verbal Fluency Test with letter (ka). MMSE is a short screening test to assess cognitive impairment, which consists of five areas: orientation, registration, attention and calculation, and recall language. The CDT is a sensitive test for executive function and early cognitive impairment. The participant was asked to draw a clock with all the numbers on it and to set the time to 10 min past 11. We used a 10-point scoring system by Rouleau *et al.*<sup>24</sup> The TMT-A assesses working memory capacity. Patients need to connect the numbers in order, beginning with 1 and ending with 25, as fast as possible. Word fluency is a sensitive test to detect early changes in cognitive function. In the Verbal Fluency Task (animal), patients were instructed to name as many animals as possible within 1 min. In the Verbal Fluency Task, the subject was asked to say as many words as possible beginning with the letters "ka" in 1 min.<sup>25</sup>

### Physical performance measures

The participants were subjected to five physical function tests that are widely used to identify frail elderly. For each performance task, the participants performed two trials, and the better performance of two trials was used as scores in the analysis. The physical performance assessment, such as 10-m walking time,<sup>26</sup> Timed Up & Go (TUG) Test,<sup>27</sup> Functional Reach (FR),<sup>28</sup> One-Leg Stand (OLS) test<sup>29</sup> and Five Chair Stands (SCS) Test,<sup>30</sup> was carried out as previously described.

### Physical activity measures

In physical activity, a valid, accurate and reliable pedometer, Yamax Power walker EX-510 (Yamasa, Tokyo, Japan) was used to measure free-living step counts.<sup>31</sup> Participants were instructed to wear the pedometer in their pocket on the side of the dominant leg for 14 consecutive days except when bathing, sleeping and carrying out water-based activities. This pedometer has a 30-day data storage capacity. We calculated the averages of their daily step counts for 2 weeks.

### Statistical analysis

The *t*-test and  $\chi^2$ -test were used to compare the results of measurements between faller and non-faller groups. The relationship between the global brain atrophy and the other measurements was investigated with the Spearman's correlation coefficient. The partial correlation coefficient between the global brain atrophy and the other measurements were adjusted for age. Multivariate logistic regression analysis using a stepwise method was carried out to investigate whether age, sex, body mass index (BMI), Global Brain Atrophy Index, word fluency animals, CDT, maximum walking time and TUG were independently associated with the fall

incident. Data were analyzed using the Statistical Package for Social Science, Windows version 20.0 (SPSS, Chicago, IL, USA).

### Results

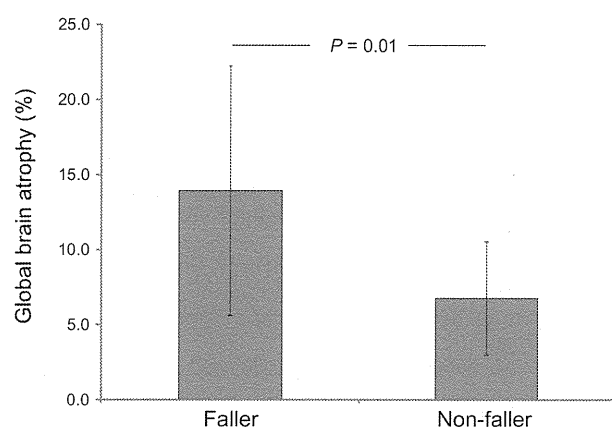
There were no significant differences in age (fallers  $78.2 \pm 7.1$  years, non-fallers  $77.7 \pm 5.4$  years,  $P = 0.53$ ), percentage of female (fallers 80.0%, non-fallers 71.4%,  $P = 0.48$ ), height (fallers  $150.7 \pm 11.9$  cm, non-fallers  $153.2 \pm 7.9$  cm,  $P = 0.37$ ), weight (fallers  $52.9 \pm 12.4$  kg, non-fallers  $50.5 \pm 7.8$  kg,  $P = 0.74$ ) or BMI (fallers  $23.2 \pm 3.7$ , non-fallers  $21.5 \pm 2.8$ ,  $P = 0.39$ ) between the two groups (Table 1).

The fallers had significantly worse scores than the non-fallers in the Global Brain Atrophy Index (fallers  $13.9 \pm 8.3$ , non-fallers  $6.8 \pm 3.8$ ,  $P = 0.01$ ), CDT (fallers  $8.2 \pm 1.1$ , non-fallers  $9.3 \pm 0.8$ ,  $P = 0.01$ ), Verbal Fluency Test (animal; fallers  $6.2 \pm 2.7$ , non-fallers  $9.5 \pm 3.9$ ,  $P = 0.02$ ), maximum walking time (fallers  $10.4 \pm 4.4$ , non-fallers  $7.5 \pm 1.7$ , effect size 0.64,  $P = 0.03$ ) and TUG (fallers  $13.5 \pm 7.0$ , non-fallers  $8.9 \pm 1.9$ ,  $P = 0.01$ ). However, the other measurements were not significantly different between the two groups ( $P > 0.05$ ; Table 1, Fig. 1).

**Table 1** Comparison of demographic characteristics and measurements between the groups

	Faller <i>n</i> = 10		Non-faller <i>n</i> = 21		E/S	<i>P</i> -value
	Mean	SD	Mean	SD		
Characteristics						
Age	78.2	7.1	77.7	5.4	0.08	0.53
BMI	23.2	3.7	21.5	2.8	0.45	0.39
Sex (female), <i>n</i> (%)	8 (80.0%)		15 (71.4%)			0.48
Disease (MCI), <i>n</i> (%)	5 (50.0%)		6 (28.5%)			0.32
Brain volume						
Global brain atrophy, %	13.9	8.3	6.8	3.8	0.86	0.01
Cognitive function						
Mini-Mental State Examination, points	24.7	3.8	23.7	2.5	0.27	0.59
Word Fluency Test (animals), number	6.2	2.7	9.5	3.9	0.84	0.02
Letter Fluency Test (ka), number	6.0	2.4	6.0	2.6	0.00	0.88
Clock Drawing Test, points	8.2	1.1	9.3	0.8	0.92	0.01
Trail Making Test Part-A, sec	78.7	43.2	72.3	16.1	0.15	0.53
Physical function						
Comfortable walking time, sec	12.1	4.0	10.1	2.5	0.53	0.07
Maximum walking time, sec	10.4	4.4	7.5	1.7	0.64	0.03
Timed Up & Go Test, sec	13.5	7.0	8.9	1.9	0.65	0.01
Functional Reach, cm	18.8	8.5	22.2	6.4	0.41	0.36
One-Leg Standing time, sec	6.5	11.3	16.7	18.8	0.91	0.06
Five Chair Stands, sec	11.9	2.8	10.5	3.2	0.48	0.18
Activity						
Physical activity, steps	3167.9	2213.1	4499.8	2934.4	0.45	0.21

MCI, mild cognitive impairment.



**Figure 1** Comparison of Global Brain Atrophy Index (%) between the groups. The fallers ( $n = 10$ ) had significantly worse scores than the non-fallers ( $n = 21$ ) in the Global Brain Atrophy Index.

To determine the association of global brain atrophy with their demography, cognitive function, physical performance and physical activity, we determined Pearson's correlation coefficients. Table 2 shows that the Global Brain Atrophy Index was correlated with age ( $r = 0.435$ ,  $P < 0.05$ ), Verbal Fluency Test with letter (animal;  $r = -0.641$ ,  $P < 0.05$ ), Verbal Fluency Test with letter (ka;  $r = -0.320$ ,  $P < 0.05$ ), CDT ( $r = -0.338$ ,  $P < 0.05$ ), comfortable walking time ( $r = 0.555$ ,  $P < 0.05$ ), maximum walking time ( $r = 0.543$ ,  $P < 0.05$ ), TUG ( $r = 0.630$ ,  $P < 0.05$ ), OLS ( $r = -0.581$ ,  $P < 0.05$ ), 5CS ( $r = 0.437$ ,  $P < 0.05$ ) and physical activity ( $r = -0.389$ ,  $P < 0.05$ ; Table 2).

To age-adjust the association of Global Brain Atrophy Index with their demography, cognitive function, physical performance and physical activity, we analyzed partial correlation coefficients. Table 2 shows that global brain atrophy was correlated with BMI ( $r = 0.308$ ), Verbal Fluency Test (animal;  $r = -0.522$ ,  $P < 0.05$ ), Verbal Fluency Test with letter (ka;  $r = -0.337$ ,  $P < 0.05$ ), CDT ( $r = -0.547$ ,  $P < 0.05$ ), TUG ( $r = 0.276$ ,  $P < 0.05$ ) and 5CS ( $r = 0.303$ ,  $P < 0.05$ ; Table 2).

Stepwise regression analysis showed that the Global Brain Atrophy Index ( $\beta = 1.265$ , 95% CI 1.022–1.567) was a significant and independent determinant of falls ( $R^2 = 0.356$ ,  $P = 0.003$ ; Table 3).

## Discussions

The present study showed that the fall incident might relate to global brain atrophy in older adults with mild cognitive disorders. The fallers also showed a significantly higher Global Brain Atrophy Index, and lower physical and cognitive performance scores than the non-fallers. Age-adjusted correlation analyses showed

**Table 2** Correlation coefficients for global brain atrophy and other measurements

	Global brain atrophy	Global brain atrophy (adjusted for age)
Characteristics		
Age	0.435	
Cognitive function		
Mini-Mental State Examination	0.019	-0.147
Word Fluency Test (animals)	-0.641	-0.522
Letter fluency Test (ka)	-0.320	-0.337
Clock Drawing Test	-0.338	-0.547
Trail Making Test Part-A	0.067	0.053
Geriatric Depression Scale	0.210	0.181
Physical function		
Comfortable walking time	0.555	0.205
Maximum walking time	0.543	0.221
Timed Up & Go Test	0.630	0.276
Functional reach	-0.121	-0.009
One-Leg Standing time	-0.581	-0.204
Five Chair Stands	0.473	0.303
Activity		
Physical activity	-0.389	-0.169

**Table 3** Logistic regression analysis

Independent variables	Adjusted $R^2$ value = 0.356	
	Standard regression value	95% CI
Age	-	-
Sex	-	-
BMI	-	-
Brain atrophy index	1.265	1.022–1.567
Word Fluency (animals)	-	-
Clock Drawing Test	-	-
Maximum walking time	-	-
Timed Up & Go Test	-	-

BMI, body mass index.

that the Global Brain Atrophy Index was weakly correlated with several cognitive and motor performances. Furthermore, stepwise regression analysis showed that the Global Brain Atrophy Index was a significant



and independent determinant of the fall incident. Taken together, these findings led us to conclude that measuring global brain atrophy is potentially important to predict falls in patients with mild cognitive disorders.

The mechanisms by which global brain atrophy associates with fall incident and poor physical performance are not well understood. It is possible that global brain atrophy is related to poor neural connectivity. However, we assume that global brain atrophy is mostly attributed to the volume loss in the frontal lobe, because Rosano *et al.* suggested that a smaller prefrontal region was associated with slower gait speed.<sup>32</sup> In contrast, it has been shown that atrophy of dorsolateral prefrontal regions is associated with poorer executive function.<sup>33</sup> Previous imaging research has also shown that brain atrophy is associated with impaired physical and executive functions.<sup>17,34</sup> As expected, physical and executive functions have been associated with an increased fall risk in older adults.<sup>35,36</sup> These reports and the present study suggested that the function of the frontal lobe is associated with the risk of falls, and brain atrophy index can be a biomarker to predict falls.

There are several limitations in the present study. First, the limited sample size might introduce some error of inference, reduce the power of the analysis and limit generalization. Second, global brain atrophy might not be able to predict falls in more robust older adults, as the present study was based on the participants having experienced falls in the previous year. Further study is required to confirm our finding in patients who do not have an experience of falls. Finally, detailed information on falls was lacking. Therefore, the relationship between the decline of frontal lobe function and fall incidents requires further investigation. Thus, the results of the present study should be interpreted with caution.

In conclusion, this is the first study to show that global brain atrophy is associated with fall incident, motor and cognitive performance in older adults with mild cognitive disorders. From the present results, global atrophy might be indicted as one of risk factors for falls in older adults with mild cognitive disorders. Further investigation, such as a prospective study, is required to confirm the present study.

## Acknowledgments

This work was supported by the Grants-in-aid for Scientific Research from the Japan Society for the Promotion of Science, from the Ministry of Education, Culture, Sports, Science, and Technology.

## Disclosure statement

None of the authors have conflicts of interest or financial disclosures.

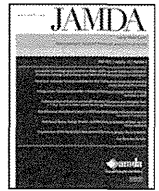
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## Original Study

## Community-Based Exercise Program is Cost-Effective by Preventing Care and Disability in Japanese Frail Older Adults

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## A B S T R A C T

**Keywords:**

Care prevention program  
long term care insurance  
older adults  
Japanese

**Background:** In Japan, older adults are assessed by frailty checklist for care prevention. However, the effect of care prevention programs in community-dwelling frail older adults is still unclear.

**Objectives:** The purpose of this study was to investigate whether the care prevention program would reduce care and disability and to measure its cost-effectiveness in frail older adults.

**Design:** This is a prospective study using propensity score matching.

**Setting and subjects:** A total of 610 community-dwelling older adults were recruited in 2 cities of Japan.

**Intervention:** Subjects in the exercise group (n = 305) attended physical exercise sessions once a week for 16 consecutive weeks. The exercise sessions were in a standardized format consisting of moderate-intensity aerobic exercise, progressive strength training, flexibility and balance exercises, and cool-down activities. The control group (n = 305) received only screening evaluation.

**Measurements:** Primary outcome was long term care insurance requirement certification during the 1-year follow-up period. Secondary outcome measurements were changes of frailty checklist, and care and medical cost.

**Results:** Twenty-five subjects (8.1%) in the exercise group and 55 (18%) in the control group were newly certified for long-term care insurance service requirement in 1 year after the intervention (RR = 2.16, 95% CI = 1.46–3.20). Consequently, the health care cost for the subjects in the exercise group was significantly lower than in the control group ( $P < .001$ ). Moreover, subjects in the exercise group had significant improvements in total scores of the frailty checklist compared with the control group that worsened after 1 year (exercise group: from  $7.41 \pm 3.98$  to  $7.11 \pm 4.00$ , control group: from  $7.34 \pm 4.27$  to  $8.02 \pm 4.81$ ,  $F = 12.84$ ,  $P < .001$ ).

**Conclusion:** These results suggested that physical exercise is effective in preventing the progression of frailty and further disability in older adults living in the community. We could save health care costs by our care prevention program.

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The aged population in Japan is increasing faster than in any other country. Frailty in older adults is a serious problem in aged countries, such as in Japan. In general, frailty can be defined as a vulnerable state that places older adults at high risk for adverse health outcomes, such as falls, hospitalization, and mortality.<sup>1</sup> Therefore, to prevent the adverse outcomes of frailty, multicomponent exercise programs have been implemented and provided a beneficial effect on activities of daily living (ADLs) and instrumental ADL disability for community-dwelling moderately frail older adults.<sup>2</sup>

Japan implemented a long term care insurance (LTCI) system in April 2000 to deal with the extremely rapid aging process of our population. Before 2000, long term care services were provided

under a tax-based social welfare system targeting seniors with limited economic resources and family support.<sup>3</sup> After LTCI implementation, however, LTCI services have been provided to the elderly who are certified, as a support requirement or care requirement according to their care needs and certification assessment.<sup>4</sup> The selection process for classifying dependent older adults is first based on a questionnaire that evaluates a person's current mental and physical condition (74 items), and then the first decision is reached by computerized algorithm. The second decision is made by a long term care approval board based on the first computer decision, doctor's recommendation, and the home-visit report. Finally, people who are certified as dependent older adults are subdivided into 7 levels (requiring support levels 1 and 2 and care levels 1 to 5) depending on their conditions. They are provided home- and community-based or institutional services according to the care needs. Individuals who are not eligible for long term care or support care may use preventive care services.

The authors declare no conflicts of interest.

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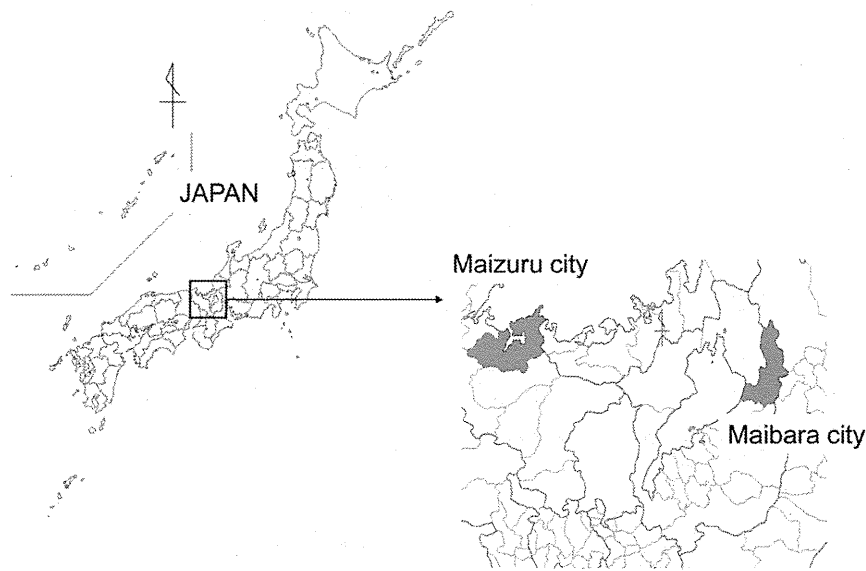


Fig. 1. Location of Maibara and Maizuru City in Japan.

In 2006, the LTCI system was revised and new preventive benefits were introduced. The aim of this system was to allocate the limited resources to impaired elderly by providing services intended to improve physical strength, nutritional status, oral function, and mental health.<sup>5</sup> The LTCI system also increased emphasis on preventive care services for those with lower needs and those at risk for needing care in the future, in which pre-frail and frail older adults can be selected by a frailty checklist. The local governments provide a frailty checklist to uncertified older adults, and all older adults are required to fill out a basic yes or no questionnaire consisting of assessments of their lifestyle, motor abilities, nutrition, oral function, seclusion, forgetfulness, and emotions. According to the results of impairment on a specific domain, the government provides several intervention programs to prevent care and disability of older adults; however, the effect of the care prevention program on frail older adults is still unclear.

The aim of the current study, therefore, was to evaluate the effect of an exercise intervention on care and disability classified by LTCI service requirement certification and health care cost in community-dwelling older adults. We hypothesized that subjects who attend the care prevention program have a lower chance of being certified for the LTCI service requirement than nonparticipants, and as a result, the intervention can save health care costs.

## Methods

### Subjects

We analyzed the cohort data from a prospective study: the Japan Multi-center Aging Cohort for Care prevention. In this study, in 2009, we recruited community-dwelling older adults who were

Table 1  
Frailty Checklist of Japan

Domain	Question	Items	Yes	No
Lifestyle	1	Do you ride the bus or train alone?	0	1
	2	Do you buy household goods for everyday use?	0	1
	3	Do you withdraw and deposit savings?	0	1
	4	Do you visit your friends' homes?	0	1
	5	Do you give advice to family and friends?	0	1
Motor abilities	6	Can you climb stairs without holding onto a handrail or the wall?	0	1
	7	Can you get up from a chair without grabbing something?	0	1
	8	Are you able to keep walking for about 15 minutes?	0	1
	9	Have you fallen in the past year?	1	0
Nutrition	10	Are you very worried about falling?	1	0
	11	Have you ever lost more than 2–3 kg of weight in a 6-month period?	1	0
Oral function	12	BMI is less than 18.5.	1	0
	13	I cannot eat hard foods as well as 6 months ago.	1	0
	14	Have you ever choked on tea or soups?	1	0
Seclusion	15	Are you concerned with being thirsty?	1	0
	16	Do you leave your home at least once a week?	0	1
Forgetfulness	17	Compared to last year, has the number of times you go out decreased?	1	0
	18	Are you told that you are forgetful or you always tell me the same thing?	1	0
	19	Do you look up phone numbers and make phone calls yourself?	0	1
Emotions	20	Do you sometimes forget the date and month?	1	0
	21	(In the past 2 weeks) I do not feel fulfillment in my daily life.	1	0
	22	(In the past 2 weeks) The activities I used to enjoy are no longer enjoyable.	1	0
	23	(In the past 2 weeks) The activities I used to carry out with ease have become troublesome.	1	0
	24	(In the past 2 weeks) I do not think I am a useful person.	1	0
	25	(In the past 2 weeks) I feel tired for no reason.	1	0

BMI, body mass index.

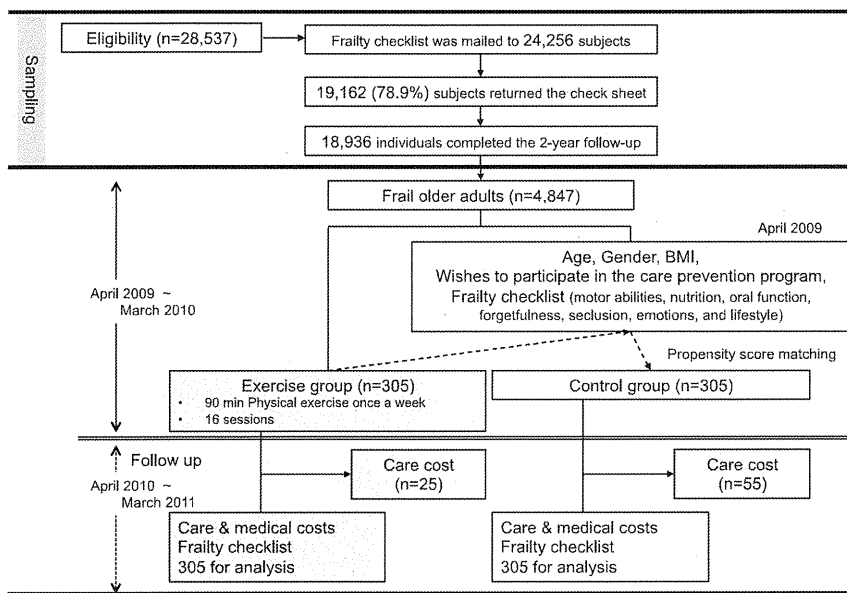


Fig. 2. A flow chart showing the distribution of subjects throughout the trial.

independent in ADLs in 2 cities (Maibara City in Shiga Prefecture and Maizuru City in Kyoto Prefecture) (Figure 1). The exclusion criteria were older adults who were already ADL-dependent and were eligible to receive benefits from LTCI services.

A total of 28,537 residents were eligible for this study in April 2009. The self-administered frailty checklist was mailed to 24,256 subjects, and the response rate was 78.9%. We further excluded individuals who died or moved from the cities in the 2-year follow-up, and analyzed 18,936 elderly. Subjects for the care prevention program were recruited using direct mail. We screened subjects in an initial interview and recruited frail older adults 65 years or older.

This study was conducted in accordance with the guidelines proposed by the Declaration of Helsinki, and the study protocol was reviewed and approved by the Ethics Committee of Kyoto University Graduate School of Medicine.

**Frailty Checklist**

The frailty checklist includes simple yes/no questions concerning lifestyle (questions 1 to 5), motor abilities (questions 6 to 10), nutrition (questions 11 to 12), oral functions (questions 13 to 15), seclusion (questions 16 to 17), forgetfulness (questions 18 to 20), and emotions (questions 21 to 25) (Table 1). We calculated the scores in each of these 7 domains.

**Table 2**  
Baseline Characteristics of the Study Subjects in Exercise and Control Groups

	Exercise Group (n = 305)		Control Group (n = 305)		P Value
	Mean	SD	Mean	SD	
Age, y	79.7	6.3	80.3	6.6	.275
Gender, female	231 (75.4%)		238 (78.0%)		.560*
Height	151.5	8.0	151.1	8.3	.509
Weight	53.1	10.0	51.8	10.2	.128
BMI, kg/m <sup>2</sup>	23.0	3.4	22.6	3.5	.129
Falls in past year	107 (35.1%)		114 (37.4%)		.670*
Total scores of frailty checklist	7.41	3.98	7.34	4.27	.814

BMI, body mass index.  
\*Chi-square test.

Impaired physical condition was defined as having 3 points or more in motor ability items according to the Japanese Ministry of Health, Labor, and Welfare. Malnutrition was defined as having 2 points in nutrition items, poor oral health as having 1 point or more in oral function items, seclusion as having 1 point or more in seclusion items, cognitive decline as having 1 point or more in forgetfulness items, and depressive mood as having 2 points or more in emotion items. Frailty was defined by scores of 10 or more points on questions 1 to 20.

**Definition of Frail Older Adults in this Study**

In this study, we defined frail older adults as those who need to maintain or to improve daily functions. These individuals are not eligible for the LTCI service requirement as defined by the government, but have a high risk of becoming dependent based on the results of the frailty checklist.<sup>5</sup> Those older adults are defined as having impaired motor abilities, malnutrition, poor oral health, or impaired lifestyle as described in the previous paragraph.

**Care Prevention Program**

The subjects received 90 minutes of group training sessions once a week for 16 consecutive weeks. The exercise class was supervised by a physiotherapist. The exercise sessions were conducted according

**Table 3**  
Comparison of New LTCI Service Requirement Certification Between the 2 Groups

	Exercise Group, n (%)	Control Group, n (%)	RR	95% CI
LTCI requirement	25 (8.1%)	55 (18.0%)	2.16	1.46–3.20
Support level				
1	11	15		
2	7	14		
Care level				
1	4	13		
2	3	7		
3	0	3		
4	0	3		
5	0	0		

CI, confidence interval; LTCI, long term care insurance; RR, relative risk.



**Table 4**  
Frailty Checklist Scores in Each Group at Baseline and After Intervention

	Baseline		After Intervention		Group × Time Interaction	
	n (%)	P Value	n (%)	P Value	F Value	P Value
Motor ability domain score						
Exercise (n = 305)	181 (59.5)	.414	177 (58.0)	.087		
Control (n = 305)	185 (60.7)		158 (51.7)			
Nutrition domain score						
Exercise (n = 305)	10 (3.4)	.348	11 (3.5)	.364		
Control (n = 305)	13 (4.3)		8 (2.6)			
Oral function domain score						
Exercise (n = 305)	114 (37.5)	.210	113 (37.0)	.073		
Control (n = 305)	104 (34.0)		94 (30.7)			
Forgetfulness domain score						
Exercise (n = 305)	139 (45.6)	.430	120 (39.3)	.037		
Control (n = 305)	142 (46.7)		145 (47.6)			
Seclusion domain score						
Exercise (n = 305)	66 (21.6)	.349	19 (6.2)	<.001		
Control (n = 305)	61 (20.0)		50 (16.5)			
Emotions domain score						
Exercise (n = 305)	144 (47.3)	.407	133 (43.6)	.008		
Control (n = 305)	140 (46.0)		167 (54.7)			
Lifestyle domain score						
Exercise (n = 305)	47 (15.5)	.517	36 (11.7)	.003		
Control (n = 305)	46 (15.1)		64 (21.0)			
Total score						
Exercise (n = 305)	7.41 ± 3.98		7.11 ± 4.00		12.84	<.001*
Control (n = 305)	7.34 ± 4.27		8.02 ± 4.81			

\*Two-way analysis of variance adjusted for age and gender.

to a standardized format consisting of 20 minutes of moderate-intensity aerobic exercise, 30 minutes of progressive strength training, 20 minutes of flexibility and balance exercises, and 20 minutes of cool-down activities. The aerobic exercise was composed of global movement of the legs, trunk, and arms involving all joints and major muscle groups in activities such as dance. Strength training consisted of progressive resistive exercises using an elastic band. A sequence of progressively difficult exercises was also performed to improve static and dynamic balance. The control group received screening evaluation only.

#### Propensity Score Matching

We used propensity score matching to assemble a cohort of the exercise group, then the 2 groups would be well matched on all measured baseline characteristics, such as age, gender, body mass index, wishes to participate in the care prevention program, motor abilities, nutrition, oral function, forgetfulness, seclusion, and emotions. We estimated the scores of the exercise group for each subject using a multivariable logistic regression model. We were able to match 305 pairs of exercise and control subjects who had similar propensity scores.

#### Outcome Measures

Primary outcome was the new LTCI service requirement certification at 1 year after the conclusion of the intervention. Secondary outcomes were changes of frailty checklist, LTCI cost, and medical

cost. The LTCI cost indicates use of home care services, nursing care, or day care services and nursing home. The utilization records of LTCI benefit services during 1 year were collected from the local governmental office. The medical cost covers almost all medical treatment, including diagnostic tests, medications, surgery, supplies and materials, physicians, and other personal cost.

#### Statistical Analysis

Baseline characteristics of the intervention and control groups were examined for comparability of the 2 groups. Differences in the demographic variables between the 2 groups were analyzed using the Student *t* test or chi-square test. Relative risk was then calculated, and the chi-square test was used to evaluate the effect of the care prevention program on the new LTCI service requirement and the influence on each domain of frailty checklist. Analysis of covariance was used to determine the effect of the care prevention program on total points of frailty checklist, using age as covariates. Post hoc Tukey tests were used to assess whether group or time periods showed significant differences. Multiple logistic regressions using a stepwise method was performed to investigate which of age, gender, or the decline in frailty checklist for each category was independently associated with the change of frailty checklist (improvement, maintenance, or deterioration). Finally, differences in the care and medical cost between the 2 groups were analyzed using the Student *t* test. Data were entered and analyzed using the Predictive Analytics Software (Windows version 18.0, SPSS, Inc., Chicago, IL). A *P* value less than .05 was considered statistically significant for all analyses.

**Table 5**  
Change of Each Domain in Frailty Checklist After Exercise Intervention

Dependent Variables	Adjusted Odds Ratio (95% Confidence Interval)						
	Motor Abilities	Nutrition	Oral Functions	Forgetfulness	Seclusion	Emotions	Lifestyle
Change in checklist	2.29 (1.58–3.31)	5.32 (1.52–18.62)	—	1.77 (1.22–2.57)	—	—	—

1 = improvement, 0 = maintenance or deterioration.

**Table 6**  
Comparison of Long Term Care Insurance and Medical Costs Between the 2 Groups

	Exercise Group, n = 305	Control Group, n = 305	P Value
	Mean ± SD	Mean ± SD	
Care costs* dollars	1126.8 ± 1797.9	4430.7 ± 6324.7	<.001
Medical costs dollars	2458.7 ± 1968.7	3458.0 ± 5847.1	<.001

One dollar = 88 yen.

\*Exercise group: n = 25, control group: n = 55.

## Results

Of the 610 individuals, all subjects completed the 1-year follow-up: 305 in the exercise group, and the others in the control group (Figure 2). All 16 scheduled intervention sessions were completed. The median relative adherence was 100% (25th–75th percentile, 88%–100%) in the exercise group. No fall incidents or health problems, such as cardiovascular or musculoskeletal complications, occurred during training sessions or testing. Minor problems were muscle ache and fatigue. All problems were managed easily using adjustment of the intervention, and they improved during the intervention. Subjects in the exercise and control groups were comparable and well matched with regard to their baseline characteristics (Table 2).

During 1 year after the intervention, 25 subjects (8.1%) in the exercise group and 55 (18.0%) in the control group were newly certified for the LTCI service requirement. Therefore, the relative risk for new LTCI service requirement in the control group compared with the exercise group was 2.16 (95% confidence interval [CI] = 1.46–3.20) (Table 3).

At baseline, all domains of the frailty checklist were not significantly different between the 2 groups (Table 3). Subjects in the exercise group had significant improvements in total scores of the frailty checklist compared with the control group that worsened after 1 year (exercise group: from  $7.41 \pm 3.98$  to  $7.11 \pm 4.00$ , control group: from  $7.34 \pm 4.27$  to  $8.02 \pm 4.81$ ,  $F = 12.84$ ,  $P < .001$ ) (Table 4) as well as in forgetfulness, seclusion, emotion, and daily life domains ( $P < .05$ ); however, the other domains were not significantly different between them ( $P > 0.05$ ).

Stepwise logistic regression analysis revealed that motor ability domain (OR = 2.29, 95% CI 1.58–3.31), nutrition domain (OR = 5.32, 95% CI 1.52–18.62), and forgetfulness domain (OR = 1.77, 95% CI 1.22–2.57) were significant and independent determinants of the change in frailty checklist ( $P < .001$ ) (Table 5).

Finally, we calculated the cost-effectiveness of this intervention, and found that subjects in the exercise group spent significantly lower care cost than the control group (exercise group: \$1126.8 ± 1797.9, control group: \$4430.7 ± 6324.7,  $P < .001$ ) (Table 5), whereas subjects in the exercise group spent significantly less on medical costs than the control group (exercise group: \$2458.7 ± 1968.7, control group: \$3458.0 ± 5847.1,  $P < .001$ ) (Table 6).

## Discussion

In this study, we addressed the role of the physical exercise program for frail older adults, and have shown that the subjects who received physical exercise sessions demonstrated a lower incidence of new LTCI service requirement, improved frailty checklist, and reduced care and medical costs.

The current results indicated that the care prevention program had a beneficial effect on frailty in older adults. Specifically, the physical exercise program showed more beneficial effects on older adults with impaired motor ability, malnutrition, and forgetfulness. Previous studies also confirmed the benefits of physical exercise

training on frail older adults.<sup>6,7</sup> In addition, a systematic review by Daniels and colleagues<sup>2</sup> suggested that multicomponent exercise programs have a positive effect on ADL and instrumental ADL disability for community-living moderate physically frail older adults. These reports and our findings suggested that the physical exercise program is effective in preventing frailty.

Moreover, our results indicated that the care prevention program could reduce health care costs. Owing to the positive effect on cognition, seclusion, depression, and instrumental ADLs, the program might also be associated with fewer medical costs. In addition, intervention by the prevention program showed a lower incidence of new LTCI service requirement certification, resulting in lower care costs. On the other hand, Frick and colleagues<sup>8</sup> reported that the physical exercise program was not cost-effective by evaluating the cost-effectiveness of fall-prevention programs for fall-related hip fractures in older adults. These results suggest that all the physical exercise programs are not always cost-effective. Further study is required to determine how to perform cost-effective interventions in frail older adults.

There were several limitations of this study that warrant mention. First, we did not measure physical performance, and used only the frailty checklist to define frailty. There is a possibility that the frailty checklist may not be the best instrument to define frailty, such as the Short Physical Performance Battery that evaluates balance, gait, strength, and endurance by examining an individual's ability.<sup>9</sup> Second, our study design was not a randomized controlled trial. Therefore, these findings should be interpreted with caution.

This is the first study to demonstrate that the care prevention program is effective to improve the scores of the frailty checklist. In addition, subjects who received the care prevention program demonstrated a lower incidence of new certification of LTCI service requirement with a lower cost during the follow-up period. These results implicated the importance of care prevention programs to reduce care and disabilities in older adults. A larger study is needed to confirm the present results and to evaluate the most effective exercises for the prevention of disability in older adults.

## Acknowledgments

The authors acknowledge Ms. Sayuri Takahashi, Ms. Tomoko Kodama, and Mr. Seiji Moriguchi for their contribution to the data collection. We also thank Priscila Yukari Sewo Sampaio for critical reading of our manuscript.

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ORIGINAL ARTICLE: EPIDEMIOLOGY,  
CLINICAL PRACTICE AND HEALTH

# Complex obstacle negotiation exercise can prevent falls in community-dwelling elderly Japanese aged 75 years and older

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**Objectives:** The aim of the present study was to evaluate whether a complex course obstacle negotiation exercise (CC), a 24-week exercise program, can reduce falls and fractures in older adults, as compared with a simple course obstacle negotiation exercise (SC).

**Methods:** This trial was carried out on older adults, aged 75 years and above in Japan. In total, 157 participants were randomized into the CC group ( $n = 78$ ) and the SC group ( $n = 79$ ). Participants were enrolled in the exercise class using the CC program or the SC program for 24 weeks. The outcome measure was the number of falls and fracture rates in CC and SC groups for 12 months after the completion of the 24-week exercise class.

**Results:** Two participants (2.8%) in the CC group and 19 (26.0%) in the SC group experienced falls during 12 months. During the 12-month follow-up period after the intervention, the incidence rate ratio (IRR) of falls in the SC group against the CC group was 9.37 (95% CI = 2.26–38.77). One participant (1.4%) in the CC group and eight (10.9%) in the SC group had experienced fractures during 12 months after the exercise class. The IRR of fractures in the SC group compared with the CC group was 7.89 (95% CI = 1.01–61.49).

**Conclusions:** The results of the present trial show that the participants who received individualized obstacle avoidance training under complex tasks combined with a traditional intervention had a lower incidence rate of falls and fractures during the 12 months after the intervention. *Geriatr Gerontol Int* 2012; 12: 461–467.

**Keywords:** fall prevention, obstacle negotiation exercise, older adults, randomized controlled trial.

## Introduction

Falls are relatively common events in older people. One-third of community-dwelling people, aged 65 years and older, and up to 50% of those aged 80 years and older

experience a fall each year.<sup>1,2</sup> A previous study also reported that in community-dwelling elderly individuals, over 50% of the falls are a result of trips and slips that usually occur during walking.<sup>3</sup> In many of these cases, there is an external factor, such as an obstacle, that provokes and contributes to the fall.<sup>4</sup> In addition, the incidence of osteoporotic fractures is reported to increase with age,<sup>5</sup> and more than 50% of all fragility fractures in the community arise in women aged 75 years and older.<sup>6</sup> A recent systematic review of fall prevention programs has convincingly shown that exercise interventions are effective for reducing the risk of

Accepted for publication 6 November 2011.

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falls and fall injuries.<sup>7,8</sup> However, the kind of exercise intervention most effective for fall prevention is not fully addressed.

Concurrent cognitive or motor tasks, such as talking or carrying objects, are crucial for mobility in daily life. Because of the increasingly recognized role of cognition in postural control and gait, many researchers have used complex task paradigms incorporating a concurrent cognitive task to improve their studies investigating fall risk.<sup>9</sup> Changes in performance during multitasking are significantly associated with an increased risk for falls in older adults.<sup>9</sup> The ability to modulate attention might also play an important role in the acquisition of complex task coordination skills. Therefore, we developed a trail walking exercise (TWE), in which a person walks from numbered flags in either an ascending or descending order, to evaluate cognitive and motor function simultaneously.<sup>10</sup> Our previous randomized controlled trial (RCT) showed that TWE has the benefit of decreasing the incidence of falls in community-dwelling elderly adults.

In everyday life, when walking in a challenging and distracting environment, older people might have to avoid ground level obstacles when their attention is divided. In this instance, obstacle-avoidance performance is likely to be further impaired, as shown by most multitask research among older adults.<sup>11-13</sup> In addition, Jasmine *et al.* reported that when their attention is divided, older people negotiate obstacles more slowly and contact more obstacles.<sup>14</sup> Therefore, in the present study, we added obstacles to the area of TWE (complex course obstacle negotiation) to mimic a "real world" walking environment with a high fall risk.

The present RCT examined the effect of fall and fall-related fracture prevention programs on attention demands of obstacles during walking under complex task conditions in community-dwelling elderly Japanese adults aged 75 years and older. The aim of the present study was to evaluate whether the complex course obstacle negotiation exercise (CC), a new 24-week exercise program, would be effective in reducing falls and fall-related fractures in community-dwelling older adults. We hypothesized that complex task walking is improved to a greater extent with the CC program than with the simple course obstacle negotiation exercise (SC). From these results, we can assume that the CC program is more effective in preventing falls and fall-related fractures than is the SC program.

## Methods

### Participants

Participants were recruited using an advertisement in the local press. The following criteria were used to screen participants in an initial interview: age 75 years

and older, community-dwelling, had visited a primary care physician within the past 3 years, had no severe cognitive impairment (Rapid Dementia Screening Test [RDST] score of 4 or less),<sup>15</sup> can walk independently (or with a cane), willingness to participate in group exercise classes for at least 6 months, has access to transportation, has no significant hearing and vision impairments, and had no regular exercise in the past 12 months.

The interview was also used to exclude participants based on the following exclusion criteria: severe cardiac, pulmonary or musculoskeletal disorders; comorbidities associated with greater risk of falls, such as Parkinson disease and stroke; and use of psychotropic drugs. Written informed consent was obtained from each participant for the trial in accordance with the guidelines approved by the Kyoto University Graduate School of Medicine and the Declaration of Human Rights, Helsinki, 1975.

### Study design and randomization

Participants were randomized into two groups. Opaque envelopes bearing group names were numbered and the 157 participants were then randomly assigned to either the CC ( $n = 78$ ) or SC ( $n = 79$ ) group.

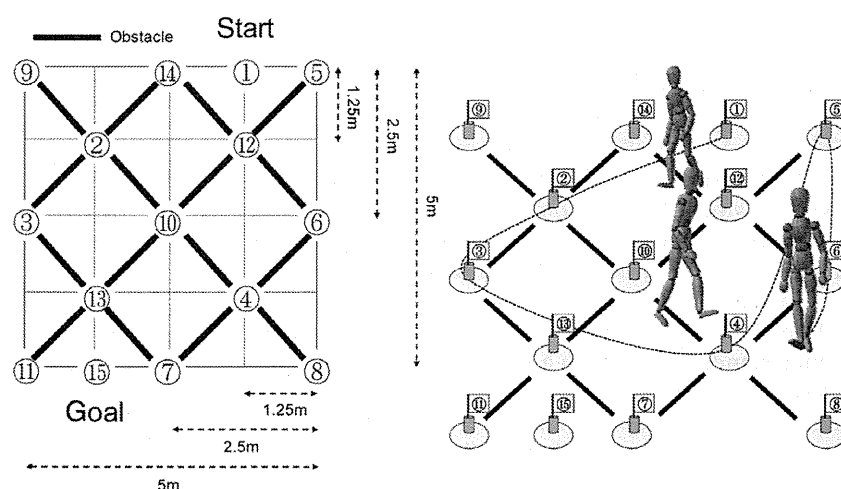
### Intervention

All participants received 45 min of group training sessions once a week for 24 weeks. Participants were randomly assigned to one of the two training groups: standardized training with CC and standardized training with SC.

The exercise class was individualized for each group and supervised by a physiotherapist. Each exercise class used a standardized format that included 10 min of moderate-intensity aerobic exercise, 15 min of progressive strength training, 10 min of flexibility and balance exercises, and 10 min of cool-down activities. The aerobic exercise consisted of movement of the legs, trunk and arms to involve all joints and major muscle groups in activities, such as dancing. Strength training consisted of progressive resistive exercises using an elastic band. A sequence of progressively more difficult exercises was also carried out to improve static and dynamic balance. Although exercises could be carried out in a sitting position, the importance of carrying the exercises out in a standing position to improve balance was stressed. Physiotherapists evaluated the participants twice during the study period to ensure adherence with exercise protocols during classes.

### Complex course with obstacle negotiation exercise

In the CC training field, the flags and obstacles were positioned as shown in Figure 1.<sup>10</sup> Flags were randomly



**Figure 1** Schematic representation of the complex course obstacle negotiation exercise. Participants were asked to pass sequentially from numbers 1 to 15 as quickly and as correctly as possible during obstacle avoidance.

moved for each trial. Participants in the CC group were asked to sequentially pass from number 1 to 15 while avoiding the obstacles (Fig. 1). A 30-cm diameter circle was drawn on the ground around each flag, and the participants were required to step in the circle to pass the flag. The height of the flag was 30 cm. The tester gave the following instructions to participants, "Please move to flag number 15 as quickly and correctly as possible while avoiding obstacles". Throughout the weeks, the obstacles were made increasingly more difficult for participants to notice. The obstacles consisted of 16 wooden white (contrasting the floor colour) blocks (3, 100 and 1 cm in height, length and width, respectively) in weeks 1–6, wooden black blocks (2, 100 and 1 cm in height, width and depth, respectively) in weeks 7–12, wooden dark brown blocks (1, 100 and 1 cm in height, length and width, respectively) in weeks 13–18 and wooden brown (matching the floor colour) blocks (0.5, 100 and 1 cm in height, length and width, respectively) in weeks 19–24. Flag and obstacle positions were changed on each day of training. Participants carried out two sets of the CC program per training session.

#### *Simple course with obstacle negotiation exercise*

Participants were asked to walk along a walkway at a self-selected speed and to avoid contact with the obstacles. These sessions were designed as controls for the additional physical activity in the CC session. Participants walked along a level walkway, 15 m in length. The obstacles used in the simple course were as follows: six wooden white (contrasting the floor colour) blocks (3, 100 and 1 cm in height, length and width, respectively) in weeks 1–6, wooden black blocks (2, 100 and 1 cm in height, length and width, respectively) in weeks 7–12, wooden dark brown blocks (1, 100 and 1 cm in height, width and depth, respectively) in weeks 13–18,

wooden brown (matching the floor colour) blocks (0.5, 100 and 1 cm in height, length and width, respectively) in weeks 19–24. These obstacles were placed across the walkway at intervals randomly ranging from 30 to 150 cm for each day of training. Each participant carried out six walking trials.

#### *Falls and fall-related fractures*

The primary outcome of this trial was the occurrence of falls and fall-related fractures during the follow-up period of 12 months after the intervention was completed. Falls were defined as all situations in which a participant suddenly and involuntarily came to rest on the ground or at a surface lower than their original station.<sup>16</sup> Falls resulting from extraordinary environmental factors (e.g. traffic accidents or falls while riding a bicycle) were excluded. The participants were asked to record any falls in fall diaries mailed every month by research assistants. If participants failed to send the fall diaries, research assistants collected data on falls over the telephone. All participants who had fallen were interviewed during these calls using a structured questionnaire about a fall event and its consequences. The diagnosis of fractures was based on radiological evidence of fracture.

#### *Secondary outcome measures*

For all participants, the following six measurements were obtained: 10-m walking time,<sup>17</sup> the timed up and go (TUG) test,<sup>18</sup> the functional reach (FR) test,<sup>19</sup> the one-leg stand (OLS) test,<sup>20</sup> the SC test, and the CC test. A physiotherapist blinded to group allocation administered these measures at baseline, on completion of the 24-week intervention. All baseline measures were completed before randomization. Before the study started,



all staff members received training on correct protocols for administering all assessment measures included in the study from one of the authors (MY). If a walking aid was normally used at home, this aid was used during the TUG test, 10-m walking, SC test and CC test.

In the 10-m walking, participants walked 15 m at a speed at which they felt comfortable. A stopwatch was used to record the time required to reach the 10 m point that was marked in the middle of this walk. The time recorded in two trials was averaged as the walking score.

In the TUG test, participants were asked to stand up from a standard chair with a seat height of 40 cm, walk a distance of 3 m at a maximum pace, turn, walk back to the chair, and sit down. The time recorded from two trials was averaged to obtain the TUG score.

In the FR test, each participant was positioned next to a wall with one arm raised at 90° and fingers extended. A meter stick was mounted on the wall at shoulder height. The distance that a participant could reach while extending forward from an initial upright posture to the maximal anterior leaning posture without moving or lifting the feet was visually measured in centimetres according to the position of the tip of the third finger against the mounted meter stick. The distances measured in two trials were averaged to obtain the FR score.

In the OLS test, participants were instructed to start from a standing position with a comfortable base as support with eyes open and arms at their sides. They were then instructed to stand unassisted on either leg. OLS was measured in seconds from the time one foot was lifted from the floor to when it touched the ground or the standing leg.

In the SC test, participants were asked to walk along the walkway at a self-selected speed and to avoid contact with the obstacles. Participants walked along a level walkway, 10 m in length. The simple course consisted of six wooden white (contrasting the floor colour) blocks (3, 100 and 1 cm in height, length and width, respectively). These obstacles were placed across the walkway at intervals of 2 m. Time to complete each walking trial was recorded using a stopwatch. The number of obstacles contacted was recorded. The SC test was carried out only once for each participant at each time-point.

In the CC test, the field test was the same as that used for the CC exercise (Fig. 1). The complex course consisted of 16 wooden white (contrasting the floor colour) blocks (3, 100 and 1 cm in height, length and width, respectively). The test-retest reliability using the intra-class correlation coefficient was 0.935. The positions in which the flags and obstacles were placed are shown in Figure 1. The tester gave the following instruction to the participants: "Please move to number 15 as quickly and as correctly as possible while avoiding obstacles". Time to complete each walking trial was recorded using

a stopwatch. The number of obstacles contacted was recorded. The CC test was carried out only once for each participant at each time-point.

### *Required sample size*

A previous study showed that approximately 30% of the Japanese community-dwelling adults, 65 years of age or older, fall at least once a year. This result was consistent with a previous report.<sup>2</sup> We designed the current study to detect a 30% difference in fall rate between the groups (CC group = 10% and SC group = 30%), for which a sample size of 72 per group ( $\alpha = 0.05$  and power = 80%) was necessary. With an estimated dropout rate of 5%, a final sample size of 76 per group was required.

### *Statistical analysis*

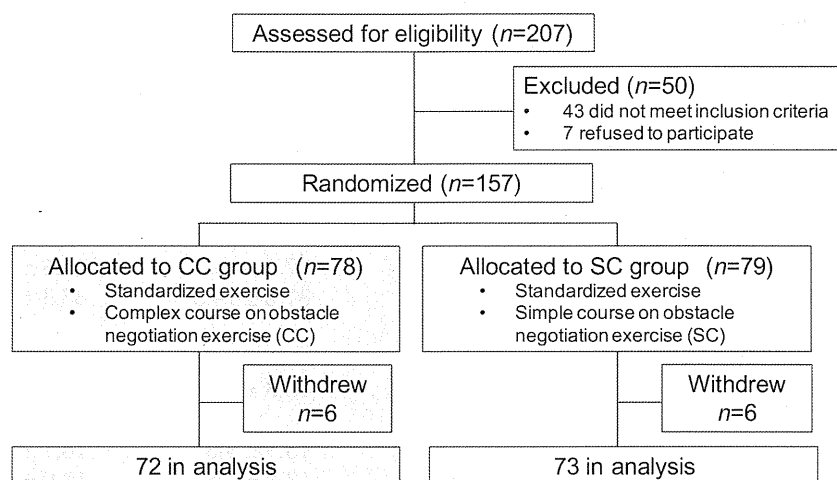
Baseline characteristics of CC and SC groups were compared to examine the comparability of the two groups. Differences in the physical function variables between the two groups were analyzed using the Student's *t*-test or  $\chi^2$ -test.

The number of falls and fall-related fractures was calculated from the beginning of the study to the participant's death, withdrawal from the trial or the end of the 12-month follow-up period. Confidence intervals (CI) for the falls and fall-related fracture rates were calculated assuming that the number of falls and fall-related fractures followed a negative binomial distribution. Incidences of falls and fall-related fractures with 95% CI were calculated for participants in the CC and SC groups, and compared using negative binomial regression analysis. Results were presented using incident rate ratios (IRR) with their 95% CI. The effect of exercise on outcome measurements was analyzed using a mixed 2 × 2 (group [CC and SC groups] × time [pre-training, post-training]) analysis of variance. Post-hoc Tukey tests were used to assess which group or time periods showed significant differences.

Data were entered and analyzed using the SPSS (Windows version 18.0, SPSS, Chicago, IL, USA). A *P*-value of <0.05 was considered statistically significant for all analyses.

## **Results**

Overall, 207 people were screened, and 157 (75.8%) who met the inclusion criteria for the trial and agreed to participate were enrolled (Fig. 2). Of the individuals not meeting the inclusion criteria (*n* = 50), most were excluded because they had exercised regularly in the 6 months before screening. Seven people who were eligible for the study withdrew their participation after a



**Figure 2** A flow chart showing the distribution of participants throughout the trial.

**Table 1** Baseline characteristics of the study participants in complex course obstacle negotiation exercise and simple course obstacle negotiation exercise groups

Characteristic	CC group <i>n</i> = 72	SC group <i>n</i> = 73	<i>P</i>
Age (years)	85.8 ± 5.9	85.3 ± 5.7	0.71
Bodyweight, (kg)	44.9 ± 9.8	47.8 ± 9.4	0.36
Height (cm)	145.1 ± 9.0	147.8 ± 9.2	0.22
Female, <i>n</i> (%)	63 (88.7%)	64 (86.5%)	0.59
RDST (points)	7.5 ± 2.2	7.6 ± 2.5	0.80
Medication ( <i>n</i> )	3.7 ± 2.9	3.8 ± 3.3	0.89
Walking aids, <i>n</i> (%)	34 (47.2%)	30 (41.1%)	0.28
Falls in the last year, <i>n</i> (%)	28 (38.9%)	29 (39.7%)	0.59

CC, complex course obstacle negotiation exercise; RDST, Rapid Dementia Screening Test; SC, simple course obstacle negotiation exercise.

telephone screening. Of the 157 individuals selected for the study, 145 (92.3%) completed the 12-month follow up: 72 in the CC group (92.3%) and 73 in the SC group (92.4%).

All 24 scheduled intervention sessions were completed. The median relative adherence was 96% (25<sup>th</sup> to 75<sup>th</sup> percentile, 88–100%) in the CC group and 96% (88–100%) in the SC group. No fall incidents occurred during training sessions or testing. No health problems, including cardiovascular or musculoskeletal complications, occurred during training sessions or testing. Minor problems observed in both groups were muscle ache after the first training sessions and fatigue. All problems were managed easily using adjustment of the intervention, and they improved during the intervention. Participants in the CC and SC groups were comparable and well matched with regard to their baseline characteristics (Table 1).

Two participants (2.8%) in the CC group and 19 (26.0%) in the SC group had experienced falls during the 12 months after the exercise program. During the 12-month follow-up period, the IRR of falls in the SC group against the CC group was 9.37 (95% CI 2.26–38.77). One participant (1.4%, distal radius *n* = 1) in the CC group and 8 (10.9%, distal radius *n* = 2; proximal humerus *n* = 3; hip *n* = 3) in the SC group experienced fall-related fractures during the 12-month follow-up period. The IRR of fall-related fractures in the SC group against the CC group was 7.89 (95% CI 1.01–61.49).

Participants in the CC group had significantly greater improvements in secondary outcome measures including the performance time and the number of obstacles contacted under the CC condition (*P* < 0.05) (Table 2). However, other secondary outcome measures were not significantly different between the two groups (*P* > 0.05).