250 kHz，500 kHz，1MHz）の8点接触型電極法により左右腕，胴体，左右脚の抵抗値を基に筋肉量，体脂肪量を求めるBody Composition Analyzer（InBody720，Biospace社製）を用いて計測した．

握力はスメドレー式握力計を用いて利き手で2回測定し，大きい値を代表値とした．開眼片足立ちは60秒を上限値とし，ストップウォッチを用いて2回測定し，大きい値を代表値とした．歩行速度は3mと8mの地点にテープで印を付けた11mの歩行路を直線歩行し，3m地点と8m地点の間5mの歩行時間を測定し，歩行速度（m/分）を算出した．快適な速さでの歩行を1回（通常歩行速度），最大努力下での歩行（最大歩行速度）を2回測定し，最大歩行速度は最速値を代表値とした．TUGは椅子座位から3m前方のポールを回って着座するまでの時間をストップウォッチにて測定した．本研究では最大努力下で2回測定し，早い値を代表値とした．

SF-8は日本でも広く用いられている健康関連QOL尺度であり，SF-36の簡略版として健康関連の8領域［身体機能，日常生活役割機能（身体），体の痛み，全体的健康観，活力，心の健康，社会生活機能，日常生活役割機能（精神）］を測定することができる．WHO-5はWHOが開発した精神的健康状態を測定する尺度であり，5つの質問項目から構成されている．得点（素点）の範囲は0〜25点で，0点はQOLが最も不良であることを示しており，25点はQOLが最も良好であることを示している．13点未満の得点は精神的健康状態が低いことを表している[13]．

分析方法については，参加者の属性及び測定項目の群間差はχ^2乗検定，対応のないt検定によって検討した．プログラム前後における測定項目の変化（短期的効果）に関しては性，年齢を調整した一般線型モデルによって検討を行い，解析対象者は事前調査と第2回調査の両調査に参加した者とした．プログラム終了3カ月後を含めた変化（長期的効果）に関しては，第3回調査を含む3回の調査全てに参加した介入群を対象として，一般線型モデルによって時間の変化の主効果を検討した．統計解析はSPSS18.0を用いて行い，両側検定にて危険率5%未満を有意水準とした．

なお，本研究計画は平成21年度第一回東京都健康長寿医療センター研究所倫理委員会によって審査され，承認されており，研究内容はヘルシンキ宣言に基づくものである．

結　果

本プログラムへの参加に同意した60名（平均年齢±標準偏差：72.7歳±6.0）の調査結果の一覧を群別に表1に示した．事前調査の結果，基礎疾患の有無や既往歴，現病歴（高血圧，脂質異常症，糖尿病，心疾患，脳血管障害）に関しては群間差は認められなかった．また，事前健診の前6カ月間およびその後の介入期間の3カ月間に脳卒中発作，心血管イベントその他，特記すべき疾病の発症，症状の変化，治療内容の変化がないことを確認した．一方体重，BMI，筋肉量，中性脂肪，WHO-5に介入群と対照群の間に有意な差が認められた．そのため，統計解析においてはBMIを調整変数として追加投入することとした．

介入3カ月後の第2回調査結果を表2に示した．介入群においては3名が就労，多忙などの自己の都合によりプログラムの継続を辞退した．また介入群，対照群ともに3名が第2回調査を欠席したため51名（介入群：25名，対照群：26名）を解析対象とした．介入群の平均教室出席率は76%であった．介入プログラム及び施設，温泉入浴に起因した傷害，事故の発生は確認されなかった．

3カ月の介入の結果，介入群は対照群に比べ握力と開眼片足立ちに有意な改善が認められた（各々$p=0.028$；$p=0.003$）．他方，WHO-5や全体的健康感得点に関しては改善傾向が確認されたが有意差が認められるには至らなかった．

前期介入終了3カ月後の持続効果を表3に示した．交差後の対照群への介入（後期介入）では3名が自己の都合によりプログラム参加・継続を辞退した．第3回調査においては，介入群の2名が欠席したため，介入群23名を解析対象とした．対照群の平均教室出席率は81%であった．前期介入同様に，後期の介入においても傷害，事故の発生は確認されなかった．

前期介入終了3カ月後の第3回調査では，介入直後に確認された握力と開眼片足立ちの有意な改善の維持が認められ（各々$p=0.001$，$p=0.024$），第2回調査時に改善傾向が見られたWHO-5の有意な改善が示された（$p=0.027$）．また，有意差には至らなかったが最大歩行速度やTUGに改善傾向が認められた．一方，介入直後に比べHbA1cは有意な上昇が（$p<0.001$），日常生活機能（精神）得点においては有意な減少が確認された（$p=0.043$）．

考　察

本研究では，温泉施設を用いた運動教室，栄養教室，温泉入浴からなる複合プログラム“すぷりんぐ”が地域在住高齢者に与える効果，及び高齢者の健康増進を目的

表１ 対象者の事前調査時の群別属性

	介入群（n＝31） Mean±SD	対照群（n＝29） Mean±SD	P 値
男女比（人）	9：22	9：20	0.866
年齢	73.2±6.9	73.0±4.9	0.573
既往歴 高血圧（あり/なし）	13：18	12：17	0.965
既往歴 高脂血症（あり/なし）	11：20	13：16	0.460
既往歴 糖尿病（あり/なし）	5：26	7：22	0.438
既往歴 心疾患（あり/なし）	10：21	6：23	0.277
既往歴 脳血管障害（あり/なし）	2：29	2：27	0.973
身長（cm）	151.4±6.5	154.6±9.1	0.121
収縮期血圧（mmHg）	121.9±21.6	123.9±19.6	0.710
拡張期血圧（mmHg）	70.2±10.2	70.8±9.8	0.807
体重（kg）	50.6±10.2	58.0±9.5	0.006**
筋肉量（kg）	18.6±4.1	21.2±4.6	0.025*
体脂肪率（%）	29.6±8.6	31.9±6.0	0.233
BMI（kg/m²）	22.0±3.6	24.1±2.5	0.012*
通常歩行速度（m/分）	84.7±14.4	88.4±13.4	0.316
最大歩行速度（m/分）	122.2±29.1	124.7±25.8	0.737
握力（kg）	22.0±7.0	25.6±7.7	0.060†
開眼片足立ち（秒）	36.0±21.0	40.4±21.4	0.422
Time Up & Go test（秒）	6.03±1.57	5.76±1.25	0.460
T-CHO（mg/dL）	193.8±25.4	200.5±36.2	0.404
HDL-C（mg/dL）	55.5±14.5	56.7±18.6	0.774
TG（mg/dL）	139.3±64.4	187.7±85.8	0.016*
LDL-C（mg/dL）	113.6±20.4	114.0±31.0	0.947
Alb（g/dL）	4.1±0.2	4.2±0.2	0.077†
HbA1c（%）	5.4±0.5	5.5±0.6	0.560
WHO-5（点）	17.9±4.5	20.1±3.5	0.045*
SF-8 全体的健康感得点（点）	50.6±5.9	52.7±5.7	0.169
SF-8 身体機能得点（点）	51.1±4.4	52.7±3.1	0.118
SF-8 日常役割機能（身体）得点（点）	51.6±4.8	53.3±2.3	0.082†
SF-8 体の痛み得点（点）	49.6±9.4	52.4±8.0	0.217
SF-8 活力得点（点）	50.8±6.3	52.0±5.8	0.425
SF-8 社会生活機能得点（点）	50.1±8.0	53.0±4.7	0.096†
SF-8 心の健康得点（点）	51.8±6.7	54.1±5.0	0.147
SF-8 日常生活機能（精神）得点（点）	52.0±3.8	53.1±3.1	0.241
SF-8 身体的サマリースコア（点）	49.1±5.0	51.0±3.8	0.100
SF-8 精神的サマリースコア（点）	51.0±5.1	52.6±4.5	0.191

†：$P<0.10$，*：$P<0.05$，**：$P<0.01$

とした介入事業を温泉施設で行う意義について RCT によって検証することを目的とした．

介入群に関しては３カ月の介入によって握力と開眼片足立ちに有意な改善が認められた．本プログラムでは握力向上を目的としたゴムチューブを用いた上肢運動や，バランス機能の向上を目的とした体重移動を意識させる歩行運動を取り入れている．このような運動構成が握力と開眼片足立ちの有意な改善につながったものと推測される．高齢者における握力の低下は ADL の低下や転倒発生率，死亡率とも強い関連性が報告されており[14)～16)]，上肢を中心とした総合的な筋力として捉えられている[17)18)]．また，開眼片足立ち能力の低下に関しても転倒発生率や虚弱傾向，移動能力の低下との関連性について多くの報告があり[19)20)]，両者ともに高齢者の機能予後を見る上で重要な身体機能項目である．握力と開眼片足立ちに改善が認められたことから，本プログラムは短期的効果として地域在住高齢者に対する身体機能向上に寄与し，ひいては介護予防に貢献する可能性が示唆された．

プログラム終了３カ月後に行った第３回調査の結果，介入群では第２回調査にて有意な改善が見られた握力と開眼片足立ちの成績が維持され，WHO-5 は有意な改善が示された．待機期間中である第２回調査と第３回調査の間は，介入群は対照群同様に月１回の座学の健康教室を開催した．運営の都合上，介入群に対する健康教室は

表2　介入前後の比較

	事前調査 介入群（n＝25）	事前調査 対照群（n＝26）	第2回調査 介入群（n＝25）	第2回調査 対照群（n＝26）	P値 時間	P値 群	P値 交互作用
	Mean±SD	Mean±SD	Mean±SD	Mean±SD			
収縮期血圧（mmHg）	124.9±22.9	122.7±19.4	120.6±15.4	123.3±24.2	0.637	0.726	0.247
拡張期血圧（mmHg）	71.9±10.3	70.0±9.8	68.1±10.9	69.2±11.4	0.367	0.440	0.254
体重（kg）	52.0±10.3	57.6±9.9	52.2±10.2	57.9±10.0	0.119	0.034*	0.518
筋肉量（kg）	19.0±4.3	21.0±4.6	19.1±4.3	21.2±5.0	0.012*	0.054†	0.185
体脂肪率（%）	30.3±8.7	32.0±6.1	30.7±8.9	31.9±7.2	0.479	0.805	0.963
通常歩行速度（m/分）	86.5±13.0	88.0±14.0	87.6±14.5	86.2±13.8	0.641	0.962	0.413
最大歩行速度（m/分）	126.9±26.7	122.9±26.4	126.3±23.3	128.7±34.0	0.101	0.967	0.183
握力（kg）	22.7±7.4	25.7±8.0	24.4±7.9	25.8±8.1	0.117	0.147	0.028*
開眼片足立ち（秒）	37.9±20.7	43.4±20.3	43.6±23.3	38.0±21.6	0.676	0.979	0.003**
Time Up & Go test（秒）	5.66±1.00	5.80±1.32	5.54±1.50	5.46±1.13	0.024*	0.971	0.118
T-CHO（mg/dL）	189.9±22.4	198.8±37.6	197.6±33.1	202.1±35.6	0.424	0.343	0.687
HDL-C（mg/dL）	54.5±15.6	55.3±18.5	55.8±16.2	55.6±16.1	0.509	0.614	0.957
TG（mg/dL）	147.7±63.8	186.6±88.6	141.6±85.4	164.5±121.0	0.099†	0.326	0.316
LDL-C（mg/dL）	109.8±18.3	113.7±32.0	116.0±27.2	116.8±29.1	0.460	0.798	0.610
Alb（g/dL）	4.15±0.17	4.23±0.19	4.27±0.24	4.28±0.20	0.189	0.343	0.343
HbA1c（%）	5.4±0.5	5.5±0.6	5.5±0.5	5.6±0.7	0.085†	0.600	0.951
WHO-5（点）	18.1±4.5	20.0±3.7	20.1±4.5	20.2±4.0	0.706	0.251	0.073†
SF-8 全体的健康感得点（点）	51.0±5.7	52.2±5.6	51.7±5.6	50.4±5.2	0.033*	0.835	0.061†
SF-8 身体機能得点（点）	50.9±4.8	52.7±3.2	49.3±5.1	49.3±9.1	0.839	0.276	0.374
SF-8 日常役割機能（身体）得点（点）	51.5±5.2	53.5±2.2	49.6±7.2	49.0±8.8	0.722	0.427	0.324
SF-8 体の痛み得点（点）	52.0±8.2	52.7±7.7	51.1±9.7	51.0±8.8	0.419	0.723	0.847
SF-8 活力得点（点）	52.1±5.7	52.1±5.9	52.7±5.8	51.2±6.5	0.953	0.745	0.282
SF-8 社会生活機能得点（点）	51.0±7.2	53.4±4.0	51.0±6.4	51.1±6.8	0.456	0.260	0.314
SF-8 心の健康得点（点）	53.8±5.6	54.0±5.2	53.2±6.1	52.4±7.2	0.831	0.999	0.547
SF-8 日常生活機能（精神）得点（点）	52.3±3.8	53.0±3.3	52.3±3.5	52.5±2.9	0.797	0.444	0.610
SF-8 身体的サマリースコア（点）	49.3±5.3	51.1±3.8	48.0±6.4	47.6±8.2	0.531	0.426	0.246
SF-8 精神的サマリースコア（点）	52.4±4.4	52.5±4.5	52.9±5.0	52.4±4.9	0.819	0.951	0.593

†：P＜0.10，＊：P＜0.05，＊＊：P＜0.01

温泉施設から離れた別の温泉施設で行ったが，介入プログラム同様の高い出席率が得られ，対象者の健康意識の維持がうかがえた．施設の変更や，プログラムの終了にかかわらず介入終了後の長期的効果が示されたことから，本プログラムが日常生活における健康行動を促進するような行動変容を促すものであった可能性が考えられる．

行動科学に基づいた行動変容型プログラムは一般成人のみならず，高齢者に対しても身体活動を促進することが報告されている[21]．本プログラムでは教室終了毎に健康活動を自主化することを目的としたグループワークを実施した．その手法は自己効力感の向上に主眼を置いたBandura[22]の理論に依るものである．運動・栄養教室と併せて効果的に行動変容を促したことが，寒冷地であるため冬季に高齢者が閉じこもりがちになる草津町においても介入効果の維持に寄与したものと推察される．加えて，コミュニティーサロンともいえる温泉施設の性質が健康行動を促進する一因となっていた可能性も考えられる．自主的な運動活動などにおいては集団型で，かつ住民間の交流を図る形での活動運営が好ましいことが示唆されている[23]．本研究は，地域資源である温泉施設での健康増進プログラムが参加者同士の交流や利用のしやすさといった点から健康行動の動機付けができる可能性を示しており，温泉施設での健康増進を目的とした保健事業実施は，事業への参加・活動維持の面から大きな可能性を持っていると考えられる．

介護予防事業に代表されるような高齢者を対象とした介入事業においては特定高齢者の様な虚弱傾向にある高齢者の低い出席率，継続率が課題となっており，全国自治体を対象とした実態調査では，本人に生活機能低下の自覚がないことや，住民に身近な場所で開催できていないことが挙げられている[24][25]．本研究では，研究参加者の年齢層が65歳から93歳と幅広いにもかかわらず介入・対照両群において比較的高い介入教室への出席率が得られた．その理由の一つとして，公募により研究参加者を募ったため，健康に対する意識が高い高齢者が集

表3 事前検査から第3回調査までの推移

	事前調査 Mean±SD	第2回調査 Mean±SD	第3回調査 Mean±SD	P値
収縮期血圧（mmHg）	123.8±20.9	118.3±13.9	126.2±20.1	0.101
拡張期血圧（mmHg）	71.0±10.4	66.1±10.3	66.8±12.0	0.050†
体重（kg）	52.4±11.2	53.3±10.6	52.3±11.2	0.334
筋肉量（kg）	19.4±4.6	19.5±4.6	19.4±4.6	0.582
体脂肪率（%）	29.6±8.8	30.8±8.4	29.7±8.3	0.286
通常歩行速度（m/分）	84.9±13.4	88.1±15.3	91.3±16.9	0.052†
最大歩行速度（m/分）	124.8±28.1	126.9±22.7	127.4±21.7	0.740
握力（kg）	22.1±7.8	23.9±8.3	23.9±7.8	0.001**
開眼片足立ち（秒）	35.9±21.0	42.8±23.7	43.2±23.4	0.024*
Time Up & Go test（秒）	5.8±1.1	5.6±1.6	5.4±1.4	0.115
T-CHO（mg/dL）	187.4±23.2	194.4±34.3	194.1±27.6	0.426
HDL-C（mg/dL）	53.4±16.1	54.1±16.3	52.6±15.6	0.739
TG（mg/dL）	143.1±65.6	144.0±91.0	141.3±79.8	0.981
LDL-C（mg/dL）	109.2±19.1	114.6±28.5	115.0±23.9	0.385
Alb（g/dL）	4.15±0.17	4.26±0.24	4.18±0.23	0.182
HbA1c（%）	5.5±0.6	5.5±0.5	5.7±0.6	0.001**
WHO-5（点）	18.5±4.3	20.1±4.6	20.0±3.9	0.027*
SF-8 全体的健康感得点（点）	50.5±5.8	51.5±5.9	50.6±6.3	0.700
SF-8 身体機能得点（点）	50.6±5.1	49.6±4.9	49.6±5.5	0.592
SF-8 日常役割機能（身体）得点（点）	52.1±4.8	49.8±6.7	51.1±5.3	0.077†
SF-8 体の痛み得点（点）	51.5±8.4	50.8±8.9	51.3±8.8	0.866
SF-8 活力得点（点）	52.3±5.6	51.8±5.8	51.5±6.5	0.816
SF-8 社会生活機能得点（点）	50.8±7.7	51.8±5.6	51.4±6.8	0.602
SF-8 心の健康得点（点）	54.2±5.3	53.7±5.6	54.0±5.6	0.587
SF-8 日常生活機能（精神）得点（点）	52.6±3.6	52.6±3.3	50.8±5.4	0.043*
SF-8 身体的サマリースコア（点）	49.0±5.3	47.8±6.6	48.4±6.0	0.493
SF-8 精神的サマリースコア（点）	52.8±4.5	53.3±4.8	52.3±5.1	0.421

n=23，†：P<0.10，*：P<0.05，**：P<0.01

まっていたことも考えられる．しかしながら，一方で本プログラムが参加者の体力レベルに合わせて座位でも行いやすい運動で構成されていることから，年齢や体力レベルにかかわらず参加者が同一カリキュラムに参加することが可能であったためとも考えられる．また，本プログラムが代替医療，健康増進，リラクゼーション，地域交流などの多面的機能を持つ温泉施設を拠点としていたためとも推測される．つまり，高齢者の自主活動の場として一般的な公民館や地区会館などとは異なり，温泉施設は利用目的が健康志向に合致しやすいため，介入終了後も健康行動を継続しやすい可能性がある．更に，本プログラムは特殊な運動器具や広いスペースを必要としないため，今後は地域の公衆浴場の有効活用，活性化に寄与する可能性も推察される．しかしながら，高齢者の入浴においては温熱環境の急激な変化や浴室環境に起因した疾患・事故死が報告されている[26]．そのため，本プログラムの一般化に際しては，室内温度の一定化などの浴室内環境を考慮する必要があり，心疾患を中心とした循環器疾患者や虚弱な高齢者に対しては医師の判断が必要である．

本研究では第3回調査時にHbA1cに有意な上昇が認められた．機序は不明であるがHbA1cは冬季に上昇する傾向が大規模調査より示されており[27]，本研究で確認された上昇も季節変動の範囲であると考えられる．また，同様に第3回調査において日常生活機能（精神）得点に有意な減少が認められた．これは介入群の1名が第3回調査の直前に眼科手術を行ったためと推測され，この参加者は総じてQOL指標の成績が低く，分析から除外した場合には日常生活機能（精神）得点の低下は有意差が見られなくなった．

本研究では自己免疫疾患に有用であるとされる酸性塩化物硫酸塩泉を用いたが[1)3)]，本研究で得られた結果が泉質特有であったかは明らかではない．温泉入浴と運動・栄養介入の併用効果について泉質の違いによって検討している研究は極めて少ない．しかしながら異なる泉質を用いた場合でも一定の効果が得られていることを考慮す

ると，温熱効果なども含めた複合的な要因が作用していると考えられ，温泉ではない入浴施設でも効果が得られるのではないかと推測される[4)5)].

本研究の特徴は温泉施設を利用した複合プログラムが地域在住高齢者に与える効果をRCTによって検証している点である．しかしながら，本研究の限界としては温泉入浴のみの介入効果を検討していない点が挙げられる．大塚[28)]は運動・栄養教室と温泉入浴からなるプログラムを高齢者に実施し，開眼片足立ちや6分間歩行距離などの運動機能とQOL（Quality Of Life，生活の質）に改善が認められたことを報告している．この研究では温泉入浴のみの高齢者を対照群としているが，対照群にはQOLの改善が認められず，温泉入浴が高齢者のQOLに与える効果は乏しいことを指摘している．しかしながら，対照群は保健事業に参加せず，運動機能測定を拒否した高齢者で構成されており，研究結果にはサンプリングバイアスが生じている可能性がある．また，入浴頻度・期間が不明瞭なため，研究デザイン上のクオリティが担保されていない．また一般成人に関しては温泉入浴頻度が高いほどQOLが上昇傾向にあるとの報告も見られ[29)30)]，対象者の世代により得られた見解は異なる．本研究で，温泉入浴のみのプログラムを設定しなかった理由は以下の2つである．一つは，草津町をはじめ全国の温泉保養地に共通する過疎化の問題がある．介護予防事業は2006年度に創設された後，二次予防事業（旧特定高齢者施策）の全高齢者人口に占める出席率の目標は，5%であるのに対して実績の全国平均は0.5%と低調である．地元職員らの懸命な広報活動をもってしても，草津町の高齢者人口を勘案すると，温泉入浴のみ群を設定しうるほどの研究対象者の増員は望めなかった．第二の理由は，同町では各家庭への温泉の配給はないが，個人的に温泉を引き入れたり，無料の共同温泉浴場が町内に散在しており，高齢者の多くが，日常的に温泉を利用する環境下にあるため，温泉入浴の単独効果を検証しにくい点であった．

引き続き，同地域において追試験を行うとともに，新たに大都市部フィールドにおいて温泉入浴のみの群を設定した同様の介入試験を実施することが望まれる．

結　論

温泉施設を活用した複合介入プログラムである"すぷりんぐ"は身体機能を中心とした健康増進効果が期待でき，ひいては介護予防に貢献する可能性が示唆されるプログラムであるといえる．加えて，健康行動を継続する行動変容を促進する可能性が示され，その継続的効果とプログラム出席率・安全性が確保されていることから，温泉施設を高齢者に対する健康増進を目的とした介入事業の拠点とする意義は高いものと考えられる．

謝辞
本研究は平成21年度厚生労働科学研究費補助金［H21-循環器等（生習）-一般-002「温泉利用が健康増進に与える効果および安全性に関する研究」(研究代表者　藤原佳典)］，平成21年度介護予防実態調査分析支援事業および平成21年度日本健康開発財団研究助成「温泉施設を利用した筋肉減少症予防のための温泉・栄養・運動プログラム」(研究代表者　齋藤京子）の一環として実施した．本研究の実施に際し，多大なるご協力を頂いた，草津町保健センターの土屋由美子氏，干川なつみ氏，岡部たづる氏の各氏に深く感謝致します．

文　献

1) 大塚吉則，中谷　純，及川隆司：単純泉における温泉療法による脱ストレス作用と免疫機能の変化．日本温泉気候物理医学会雑誌　2002; 65: 121–127.
2) 上馬場和夫，許　鳳浩，矢崎俊樹，上岡洋晴：総合的な温泉療法の健康増進効果に関する検討．日本温泉気候物理医学会雑誌　2006; 69: 128–138.
3) 松原　勇：温泉を利用した健康増進についての包括的考察—国内の最近25年の論文の紹介を中心に—．石川看護雑誌　2010; 7: 97–107.
4) 上岡洋晴，岡田真平，武藤芳照，矢崎俊樹：温泉利用と生活・運動指導を組み合わせた総合的健康教育の有効性に関する研究．日本温泉気候物理医学会雑誌　2003; 66: 239–248.
5) Kamioka H, Nakamura Y, Yazaki T, Uebaba K, Mutoh Y, Okada S, et al.: Comprehensive health education combining hot spa bathing and lifestyle education in middle-aged and elderly women: one-year follow-up on randomized controlled trial of three- and six-month interventions. J Epidemiol 2006; 16: 35–44.
6) Borg G: Perceived exertion as an indicator of somatic stress. Scand. J Rehabil Med 1970; 2: 92–98.
7) 小野寺孝一，宮下充正：全身持久性運動における主観的強度と客観的強度の対応性—Rating of Perceivedexertionの観点から—．体育学研究　1976; 21: 191–203.
8) Cha K, Chertow GM, Gonzalez J, Lazarus JM, Wilmore DW: Multifrequency bioelectrical impedance estimates the distribution of body water. J Appl Physiol 1995; 79: 1316–1319.
9) Tromp AM, Pluijm SM, Smit JH, Deeg DJ, Bouter LM, Lips P: Fall-risk screening test: a prospective study on predictors for falls in community-dwelling elderly. J Clin Epidemiol 2001; 54: 837–844.
10) VanSwearingen JM, Paschal KA, Bonino P, Chen TW: Assessing recurrent fall risk of community-dwelling, frail older veterans using specific tests of mobility and the physical performance test of function. J Gerontol A Biol Sci Med Sci 1998; 53: M457–464.
11) Turner-Bowker DM, Bayliss MS, Ware JE Jr, Kosinski

M: Usefulness of the SF-8 Health Survey for comparing the impact of migraine and other conditions. Qual Life Res 2003; 12: 1003–1012.

12) 粟田主一：高齢者の自殺とその予防．精神神経学雑誌 2005; 107: 1099–1109.

13) 岩佐　一，権藤恭之，増井幸恵，稲垣宏樹，河合千恵子，大塚理加ほか：日本語版「WHO-5 精神的健康状態表」の信頼性ならびに妥当性　地域高齢者を対象とした検討．厚生の指標　2007; 54: 48–55.

14) Fried LP, Tangen CM, Walston J, Newman AB, Hirsch C, Gottdiener J, et al.: Cardiovascular Health Study Collaborative Research Group: Frailty in older adults: evidence for a phenotype. J Gerontol A Biol Sci Med Sci 2001; 56: M146–156.

15) Al Snih S, Markides KS, Ray L, Ostir GV, Goodwin JS: Handgrip strength and mortality in older Mexican Americans. J Am Geriatr Soc 2002; 50: 1250–1256.

16) Laukkanen P, Heikknen E, Kauppinen M: Muscle strength and mobility as predictors of survival in 75-84-year-old people. Age Ageing 1995; 24: 468–473.

17) Skelton DA, Greig CA, Davies JM, Young A: Strength, power and related functional ability of healthy people aged 65-89 years. Age Ageing 1994; 23: 371–377.

18) Kallman DA, Plato CC, Tobin JD: The role of muscle strength loss in the age-related decline in grip strength cross-sectional and longitudinal perspectives. J Gerontol A Biol Sci Med Sci 1990; 45: M82–M89.

19) Drusini AG, Eleazer GP, Caiazzo M, Veronese E, Carrara N, Ranzato C, et al.: One-leg standing balance and functional status in an elderly community-dwelling population in northeast Italy. Aging Clin Exp Res 2002; 14: 42–46.

20) de Rekeneire N, Visser M, Peila R, Nevitt MC, Cauley JA, Tylavsky FA, et al.: Is a fall just a fall: correlates of falling in healthy older persons. The health, aging and body composition study. J Am Geriatr Soc 2003; 51: 841–846.

21) Rejeski WJ, Brawley LR, Ambrosius WT, Brubaker PH, Focht BC, Foy CG, et al.: Older adults with chronic disease: benefits of group-mediated counseling in the promotion of physically active lifestyles. Health Psychol 2003; 22: 414–423.

22) Bandura A, Adams NE, Beyer J: Cognitive processes mediating behavioral change. J Pers Soc Psychol 1977; 35: 125–139.

23) 藤原佳典（研究代表者）：総括・分担研究報告書．平成20年度厚生労働科学研究費補助金政策科学総合研究事業「行政と住民ネットワークの連携による孤立予防戦略の検証」報告書，2009.

24) 厚生労働省老健局老人保健福祉課：第２回　介護予防継続的評価分析等検討会議事次第　介護予防事業の実施状況の調査結果（平成18年11月30日時点の調査）の概要． http://www.mhlw.go.jp/shingi/2007/02/s0227-3.html 2008.

25) 日本公衆衛生協会：「今後の介護予防事業のあり方に関する研究委員会」鈴木隆雄（委員長）：介護予防事業のあり方に関する研究報告書，2009.

26) 藤原佳典（研究代表者）：総括・分担研究報告書　平成21年度厚生労働科学研究費補助金循環器疾患等生活習慣病対策総合研究事業「温泉利用が健康増進に与える効果および安全性に関する研究」報告書，2010.

27) Tseng CL, Brimacombe M, Xie M, Rajan M, Wang H, Kolassa J, et al.: Seasonal patterns in monthly hemoglobin A1c values. Am J Epidemiol 2005; 161: 565–574.

28) 大塚吉則：温泉入浴に健康教室を組み合わせた高齢者の健康づくり．日本温泉気候物理医学会雑誌　2007; 44: 111–114.

29) 岡田真平：日帰り温泉施設の利用と健康状態，生活習慣，健康関連 QOL との関連：市民及び施設利用者を対象としたアンケート調査の結果から単純泉における温泉療法による脱ストレス作用と免疫機能の変化．信州公衆衛生雑誌　2007; 2: 46–47.

30) Sekine M, Nasermoaddeli A, Wang H, Kanayama H, Kagamimori S: Spa resort use and health-related quality of life, sleep, sickness absence and hospital admission: the Japanese civil servants study. Complement Ther Med 2006; 14 (2): 133–143.

Shimada *et al. BMC Geriatrics* 2011, **11**:40
http://www.biomedcentral.com/1471-2318/11/40

BMC Geriatrics

RESEARCH ARTICLE | Open Access

Relationship between subjective fall risk assessment and falls and fall-related fractures in frail elderly people

Hiroyuki Shimada[1*], Megumi Suzukawa[2], Tatsuro Ishizaki[3], Kumiko Kobayashi[4], Hunkyung Kim[5] and Takao Suzuki[6]

Abstract

Background: Objective measurements can be used to identify people with risks of falls, but many frail elderly adults cannot complete physical performance tests. The study examined the relationship between a subjective risk rating of specific tasks (SRRST) to screen for fall risks and falls and fall-related fractures in frail elderly people.

Methods: The SRRST was investigated in 5,062 individuals aged 65 years or older who were utilized day-care services. The SRRST comprised 7 dichotomous questions to screen for fall risks during movements and behaviours such as walking, transferring, and wandering. The history of falls and fall-related fractures during the previous year was reported by participants or determined from an interview with the participant's family and care staff.

Results: All SRRST items showed significant differences between the participants with and without falls and fall-related fractures. In multiple logistic regression analysis adjusted for age, sex, diseases, and behavioural variables, the SRRST score was independently associated with history of falls and fractures. Odds ratios for those in the high-risk SRRST group (≥ 5 points) compared with the no risk SRRST group (0 point) were 6.15 ($p < 0.01$) for a single fall, 15.04 ($p < 0.01$) for recurrent falls, and 5.05 ($p < 0.01$) for fall-related fractures. The results remained essentially unchanged in subgroup analysis accounting for locomotion status.

Conclusion: These results suggest that subjective ratings by care staff can be utilized to determine the risks of falls and fall-related fractures in the frail elderly, however, these preliminary results require confirmation in further prospective research.

Background

Falls and fall-related fractures are a common cause of disability in elderly people [1], and preventing falls is an urgent medical and social issue. Numerous studies have identified factors that predict an increased risk of falls, and many validated assessment tools have been developed to determine fall risks for elderly people [2,3]. Although falls can be caused by multiple factors, mobility impairments such as gait and balance disorders are among the most common predisposing conditions [4,5].

Our previous studies have identified the best mobility tests [6] and a physical performance test [7] for predicting falls in the elderly. These objective measurements can be used to identify people who are appropriate for and who will gain benefit from targeted falls prevention interventions. However, we found that about half of the frail elderly subjects could not complete physical performance tests such as the functional reach test and tandem walk test [7]. In addition, cognitive impairment, particularly confusion, impaired orientation, and misperception of functional ability, is one of the most important risk factors for falls in elderly people [8,9] and is likely to be an important inclusion in a screening tool. Successful strategies for preventing falls in frail elderly people with cognitive impairments are yet to be identified conclusively [10] and appropriate screening tools for these individuals are needed.

Some subjective assessments by care staff have been developed for identifying fall risks in frail elderly adults [11-13]. In a residential facility, staff members possess knowledge of their residents' potential fall risk over a

* Correspondence: shimada@ncgg.go.jp
[1]Section for Health Promotion, Department of Health and Medical Care, Center for Development of Advanced Medicine for Dementia, National Center for Geriatrics and Gerontology, Obu, Japan
Full list of author information is available at the end of the article

24-hour period, and this encompasses both predisposing and precipitating factors. Therefore, their global assessment of fall risk could have the highest predictive validity in relation to falls [13]. These global assessment scales are composed of one item, e.g. 'how do you judge the risk that Mr or Mrs × will fall within 6 months–high or low?' [11,13], which can be used easily in clinical settings, but a global assessment cannot identify specific fall risks and appropriate interventions in frail elderly persons who have multifactorial risks for falls. We determined seven specific tasks with high risks of falls based on a nationwide survey of falls in the frail elderly [7,14], and identified the relationship between these tasks and falls in our preliminary study [15]. However, it was not clear that these tasks were related independently with falls and fall-related fractures in a large population study.

The purpose of this study was to develop the subjective risk rating of specific tasks (SRRST) for screening for the risk of falls and fall-related fractures. Subjects were frail elderly people enrolled in the Tsukui Ordered Useful Care for Health (TOUCH) program which provides day-care services.

Methods

Participants

This study recruited 5,062 elderly participants (mean age, 82.6 ± 7.4 years) enrolled in the TOUCH program. To enrol in TOUCH, an individual must be aged 65 or older and have been certified as needing long-term care by the Japanese public long-term care insurance system [16]. The TOUCH sites are located throughout Japan and provide comprehensive, facility-based day-care services. TOUCH clients have some physical disability and frailty, as defined by the presence of weakness, reduced physical activity or slow gait, which is in accordance with the widely accepted definition of frailty [17]. We limited the participants of this study to those who were aged less than 65 years and who had missing value in measurements. Informed consent was obtained from all participants or a family member prior to their inclusion in the study and the Ethics Committee of the Tokyo Metropolitan Institute of Gerontology approved the study protocol.

Study procedures

This study was performed by cross-sectional design and falls and fall-related fractures were investigated retrospectively for a one-year period. Prior to the commencement of the study, all staff received a measurement manual which mentioned the correct protocols for administering all of the assessment measures included in the study.

Falls and fall-related fractures during the previous year

A fall was defined as "an event that resulted in a person coming to rest unintentionally on the ground or another lower level that did not result from a major intrinsic event or an overwhelming hazard" [18,19]. Falls and fall-related fractures were measured retrospectively for a one-year period via a self-report questionnaire and care records. A caregiver or family member provided information on the participant's annual incidence of falls and fall-related fractures when the trained nurses or care workers recognized that a participant had problems recalling such events.

Subjective risk rating of specific tasks (SRRST)

The SRRST was conducted by day-centre staff who had nursing, allied health or similar qualifications, and they were familiar with their clients. The staff answered the questions of the SRRST based on the present status of the participants. The SRRST consisted of the following items: 1) "Do you feel there is a risk of falls when the client (Mr or Mrs X) is walking?"; 2) "Do you feel there is a risk of falls when the client is transferring in bed room, toilet, or bath room?"; 3) "Do you feel there is a risk of falls when the client is toileting?"; 4) "Do you feel there is a risk of falls when the client is ascending or descending stairs?"; 5) "Do you feel there is a risk of falls when the client is wandering?"; 6) "Do you feel there is risk of falls because the client exhibits risky behavior?"; 7) "Do you feel there is a risk of falls because the client is agitated?". The response to each item in the SRRST was designated as "yes" (1 point) or "no or not applicable" (0 points) [15]. The information of the SRRST and history of falls was obtained at the same time. Prior to the commencement of the study, three raters completed the SRRST twice at weekly intervals (n = 4 × 2 × 30), and test-retest and inter-rater (one physical therapist, one nurse, and two caregivers) reliability comparisons of total scores revealed intraclass correlation coefficients (ICCs) of 0.84 to 0.96 and 0.81, respectively [20].

Potential confounding factors of falls

With reference to previous studies [2,21-24], we selected two demographic variables, eight primary diseases or general health statuses, and two behavioural variables as possible confounding factors of falls (Table 1). The demographic variables were sex and age. Primary diseases or general health status were recorded by the care staff, who identified the chronic condition from care records or symptoms. The following diseases and general health status were included in the analysis: history of stroke with symptoms of hemiparesis, knee osteoarthritis with pain, Parkinson disease, dementia, poor vision, urinary incontinence or frequency, psychotropic use, and walking aid use. Absence of habitual exercise and daily use of slippers or sandals were investigated as behavioural variables.

Table 1 Number of participants with falls and fall-related fractures and odds ratios of potential risk factors

	Single fall		Recurrent falls		Fractures	
	Number (%)	Odds ratio (95% CI)	Number (%)	Odds ratio (95% CI)	Number (%)	Odds ratio (95% CI)
Subjective risk rating of specific tasks						
Risk of falls during walking, yes	1068 (41.5)†	2.21 (2.01-2.43)	633 (24.6)†	3.15 (2.71-3.66)	123 (4.8)†	1.83 (1.36-2.46)
Risk of falls during transferring, yes	823 (41.7)†	1.80 (1.66-1.96)	504 (25.5)†	2.43 (2.14-2.76)	103 (5.2)†	1.89 (1.43-2.51)
Risk of falls during toileting, yes	568 (42.9)†	1.66 (1.53-1.80)	361 (27.3)†	2.18 (1.93-2.47)	65 (4.9)†	1.49 (1.11-2.00)
Risk of falls during stair ascending/ descending, yes	1140 (39.2)†	2.13 (1.93-2.36)	685 (23.6)†	3.55 (2.99-4.22)	139 (4.8)†	2.10 (1.53-2.90)
Risk of falls during wandering, yes	453 (44.9)†	1.68 (1.55-1.83)	2.89 (28.7)†	2.16 (1.90-2.44)	66 (6.5)†	2.18 (1.63-2.91)
Risk of falls because of risky behaviors, yes	672 (41.6)†	1.66 (1.53-1.80)	424 (26.3)†	2.24 (1.98-2.54)	79 (4.9)†	1.55 (1.17-2.06)
Risk of falls because of agitation, yes	479 (45.0)†	1.70 (1.57-1.85)	316 (29.7)†	2.32 (2.05-2.62)	55 (5.2)†	1.55 (1.14-2.11)
Potential confounding factors						
Age, years‡ Falls or fractures	82.9 ± 7.5		83.0 ± 7.5		84.3 ± 6.9†	
No falls or fractures	82.5 ± 7.4		82.6 ± 7.4		82.6 ± 7.4	
Sex, female	1062 (30.1)	0.97 (0.89-1.06)	560 (15.8)	0.90 (0.79-1.03)	151 (4.3)†	1.77 (1.24-2.52)
Stroke, yes	345 (32.0)	1.07 (0.97-1.18)	175 (16.2)	0.99 (0.85-1.16)	41 (3.8)	1.03 (0.74-1.45)
Knee osteoarthritis and pain, yes	659 (36.7)†	1.36 (1.26-1.48)	362 (20.1)†	1.41 (1.25-1.60)	77 (4.3)	1.26 (0.95-1.67)
Dementia, yes	670 (34.3)†	1.23 (1.13-1.34)	387 (19.8)†	1.40 (1.23-1.58)	80 (4.1)	1.18 (0.89-1.57)
Poor vision, yes	239 (37.9)†	1.30 (1.16-1.45)	131 (20.8)*	1.32 (1.12-1.56)	26 (4.1)	1.13 (0.74-1.73)
Parkinson disease, yes	163 (44.7)†	1.53 (1.35-1.73)	104 (28.5)†	1.85 (1.55-2.20)	16 (4.4)	1.20 (0.73-1.98)
Use of psychotropics, yes	525 (37.0)†	1.33 (1.22-1.45)	283 (19.9)†	1.33 (1.17-1.52)	57 (4.0)	1.12 (0.82-1.51)
Urinary incontinence or frequency, yes	702 (36.2)†	1.35 (1.25-1.47)	403 (20.8)†	1.53 (1.35-1.73)	82 (4.2)	1.24 (0.94-1.65)
Absence of habitual exercise, yes	975 (33.7)†	1.31 (1.20-1.43)	561 (19.4)†	1.58 (1.38-1.81)	110 (3.8)	1.06 (0.80-1.41)
Use of slippers or sandals, yes	415 (36.3)†	1.27 (1.16-1.39)	185 (16.2)	0.99 (0.85-1.14)	63 (5.5)†	1.73 (1.28-2.32)
Use of walking aid, yes	887 (36.7)†	1.49 (1.37-1.63)	492 (20.3)†	1.60 (1.41-1.82)	109 (4.5)†	1.51 (1.14-2.01)

*p < .05, †p < .01, ‡Mean ± standard deviation.

Statistical analysis

Each SRRST item and potential confounding factor was compared between the participants with and without a single fall, recurrent falls, and fall-related fractures using *t*-tests for age and chi-square tests for categorical variables. Odds ratios (ORs) of potential risk factors were also calculated for categorical variables.

Multiple logistic regression analysis was performed to explore the independent associations between total SRRST score and falls and fall-related fractures with potential confounding factors. Multiple logistic regression models included total SRRST score as an independent variable, which was categorized into no risk (0 point), low risk (1 to 2 points), moderate risk (3 to 4 points), and high risk (≥ 5 points). The SRRST categories were assessed by their P-values for trend and were used to calculate the OR and 95% confidence interval (95% CI) relative to the category of 'no risk' for each higher category. Covariates were added sequentially to the logistic model to evaluate the associations at different levels of adjustment. Model 1 included the SRRST category plus age and sex, and model 2 included the model 1 variables plus other possible confounding factors. The participants were divided into dependent walking and independent walking groups for subgroup analysis. Logistic regression analysis (model 2) was performed in each group. The validity of the model was quantified using the C-Index and Hosmer-Lemeshow statistic for goodness of fit. Sensitivity and specificity statistics were used to determine the ability of classification in the SRRST. Sensitivity and specificity for falls and fall-related fractures were calculated in each SRRST score. Cut-points for maximizing the sensitivity and specificity for each score were determined using the closest-to-(0, 1) criterion [25]. All data management and statistical computations were performed using the SPSS 17.0 software package (SPSS Inc., Chicago, IL, USA).

Results

The participants were recruited from 88 TOUCH demonstration sites (35% of all sites) and completed the investigation. About 65% of the TOUCH sites (about 19,800 elderly people) could not complete the investigation. Table 2 shows the characteristics of the participants (Table 2).

Table 2 Characteristics (number and percent) of the participants (n = 5,062)

Age*	83 (41)
Women	3,541 (70.0)
Single fall during a one-year period	1,536 (30.3)
Recurrent falls during a one-year period	828 (16.4)
Fall-related fracture during a one-year period	188 (3.7)
Femoral fracture	74 (1.5)
Fracture of the skull, trunk, pelvic, and lower legs	68 (1.3)
Fracture of the arms	46 (0.9)
Stroke	1,077 (21.3)
Knee osteoarthritis with pain	1,798 (35.5)
Dementia	1,953 (38.6)
Poor vision	630 (12.4)
Parkinson disease	365 (7.2)
Use of psychotropics	1,420 (28.1)
Urinary incontinence or frequency	1,941 (38.3)
Absence of habitual exercise	2,889 (57.1)
Use of slippers and sandals	1,144 (22.6)
Use of a walking aid	2,418 (47.8)
Mobility status	
Independent gait	2,930 (57.9)
Independent transfers	953 (18.8)
Independent sit up	589 (11.6)
Dependent sit up	590 (11.7)

* median (range).

Number of participants with falls and fall-related fractures

Of the 5,062 elderly people, 1536 (30.3%) reported a single fall in the previous year, 828 (16.4%) had recurrent falls, and 188 (3.7%) experienced fall-related fractures. Of the participants with fractures, 74 (39.4%) had a femoral fracture, 68 (36.2%) participants had a fracture of the skull, trunk, pelvic, or lower leg, and 46 (24.5%) experienced a fracture of the arm.

Comparison between participants with and without falls and fall-related fractures

All SRRST items showed significant differences between those with and without a fall, recurrent falls, and fall-related fractures. In terms of potential confounding variables, there were significant differences for all except history of stroke when single fallers and non fallers were compared. When recurrent fallers were compared with non-recurrent fallers there was a significant difference for all potential confounders except for history of stroke and daily use of slippers or sandals. Compared with participants without fractures, those with fractures were significantly more likely to report daily use of slippers or sandals or use of walking aids (Table 1).

Among the SRRST items, ORs of the participants with risk to those without risk were 1.66 to 2.21 for a single fall, 2.16 to 3.55 for recurrent falls, and 1.49 to 2.18 for fall-related fractures. The ORs of significant confounders were 1.23 to 1.53 for a single fall, 1.32 to 1.85 for recurrent falls, and 1.51 to 1.73 for fall-related fractures. The highest ORs for a single fall, recurrent falls, and fall-related fractures were recognized for the SRRST items of risk of falls during walking, stair ascending/descending, and wandering, respectively (Table 1).

Risk factors for falls

The multiple logistic regression models showed significant relationships between falls and fall-related fractures and SRRST categories (Table 3). Participants who had higher fall risk on the SRRST had higher rates of falling and fall-related fractures (Figure 1). In model 1, which adjusted for age and sex, the OR for a single fall, recurrent falls, and fall-related fractures increased as the SRRST score increased, and P for trend of all models showed significance. The ORs of the high-risk group compared with the no-risk group were 7.56 (95% confidence interval (95% CI); 6.07-9.42) for single fall; 17.71 (95% CI; 12.32-25.45) for recurrent falls, and 4.65 (95% CI; 2.73-7.94) for fall-related fractures (P for trend < 0.01). The results remained essentially unchanged after controlling for other confounders (Table 3, model 2). The highest ORs of factors related to single fall, recurrent falls, and fall-related fractures were for the high-risk group in the SRRST in all logistic models. The p-values of the Hosmer-Lemeshow statistics were > 0.05 in both logistic models ($p = 0.12$-0.72) and the C-index showed moderate model-fit in nearly all cases (0.67-0.74). In the subgroup analysis, the significant odds ratios remained essentially the same in the dependent walking and independent walking groups, with the exception of fall-related fracture. Regarding fall-related fractures in the dependent walking group, there were no significant odds ratios when the low and moderate risk groups were compared to the no-risk group of the SRRST (Figure 2).

Sensitivity and specificity

Table 4 shows the sensitivity and specificity of each SRRST score for falls and fall-related fractures. Cut-points for maximizing the sensitivity and specificity were 2/3 point in all of a single fall, recurrent falls and fall-related fractures. Sensitivity and specificity of 2/3 cut-point in a single fall, recurrent falls and fall-related fractures were 0.66 and 0.63, 0.75 and 0.60, and 0.68 and 0.55, respectively.

Discussion

There are many distinct and multifactorial causes for falls in elderly people, including low muscle strength, balance and gait disturbances, cognitive function decline, environmental hazards, and low or high activity levels. Objective measures such as physical tests can provide

Table 3 Odds ratios for falls and fall-related fractures by SRRST category and confounders

	Single fall		Recurrent falls		Fractures	
	Model 1 Odds ratio (95% CI)	Model 2 Odds ratio (95% CI)	Model 1 Odds ratio (95% CI)	Model 2 Odds ratio (95% CI)	Model 1 Odds ratio (95% CI)	Model 2 Odds ratio (95% CI)
Subjective risk rating of specific tasks						
No risk, 0 points	1.00‡	1.00‡	1.00‡	1.00‡	1.00‡	1.00‡
Low risk, 1-2 points	2.65 (2.14-3.28)†	2.40 (1.94-2.98)†	4.17 (2.88-6.06)†	3.88 (2.67-5.64)†	1.80 (1.03-3.15)*	1.77 (1.01-3.12)*
Moderate risk, 3-4 points	5.06 (4.11-6.23)†	4.21 (3.39-5.23)†	9.11 (6.36-13.05)†	7.94 (5.5-11.47)†	3.24 (1.91-5.48)†	3.22 (1.86-5.57)†
High risk, ≥ 5 points	7.56 (6.07-9.42)†	6.15 (4.85-7.8)†	17.71 (12.32-25.45)†	15.04 (10.29-22)†	4.65 (2.73-7.94)†	5.05 (2.83-9.03)†
P for trend	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01
Potential confounding factors						
Age, years	1.01 (1.00-1.01)	1.01 (1.00-1.02)	1.01 (0.99-1.02)	1.00 (0.99-1.02)	1.02 (1.00-1.05)*	1.03 (1.01-1.05)*
Sex, female	0.97 (0.84-1.11)	0.94 (0.81-1.09)	0.91 (0.77-1.08)	0.89 (0.74-1.06)	1.72 (1.19-2.50)†	1.76 (1.20-2.58)†
History of stroke with symptoms of hemiparesis		1.04 (0.88-1.22)		0.88 (0.72-1.08)		1.32 (0.91-1.93)
Knee osteoarthritis with pain		1.28 (1.12-1.47)†		1.31 (1.11-1.54)†		1.00 (0.73-1.37)
Parkinson disease		1.44 (1.14-1.81)†		1.51 (1.16-1.96)†		1.10 (0.64-1.88)
Dementia		0.93 (0.81-1.08)		0.95 (0.80-1.14)		0.87 (0.62-1.22)
Poor vision		1.05 (0.87-1.27)		1.00 (0.80-1.25)		0.87 (0.56-1.34)
Urinary incontinence or frequency		1.09 (0.95-1.26)		1.06 (0.89-1.26)		0.96 (0.69-1.34)
Use of psychotropics		1.22 (1.06-1.40)†		1.07 (0.90-1.28)		0.95 (0.68-1.32)
Use of walking aid		1.20 (1.05-1.38)†		1.14 (0.96-1.35)		1.07 (0.78-1.47)
Absence of habitual exercise		1.04 (0.90-1.19)		1.15 (0.96-1.37)		0.81 (0.59-1.12)
Daily use of slippers or sandals		1.23 (1.06-1.43)†		0.81 (0.67-0.98)*		1.67 (1.21-2.30)†
C-index, value (95% CI)	0.68 (0.66-0.70)†	0.70 (0.68-0.71)†	0.72 (0.71-0.74)†	0.74 (0.72-0.75)†	0.67 (0.63-0.71)†	0.69 (0.65-0.73)†
Hosmer-Lemeshow test, p value	0.51	0.48	0.72	0.57	0.72	0.12

*p < .05, †p < .01.
‡Odds ratios in the SRRST category were calculated in the low, moderate, and high risk relative to the no risk.

accurate information in accordance with the task tested, but predictive validity of these tests are inadequate in frail elderly people with multiple risks of falls. This may be explained by the multifactorial nature of falls, which makes the notion of a single screening tool with excellent predictive accuracy an unrealistic goal. Nordin (2008) reported that staff members' assessment of their residents' fall risk as well as history of previous falls appeared superior to performance-based measures of falls in frail elderly people [13]. We therefore examined the utility of an objective assessment tool to identify useful measures for screening frail elderly people for fall risk.

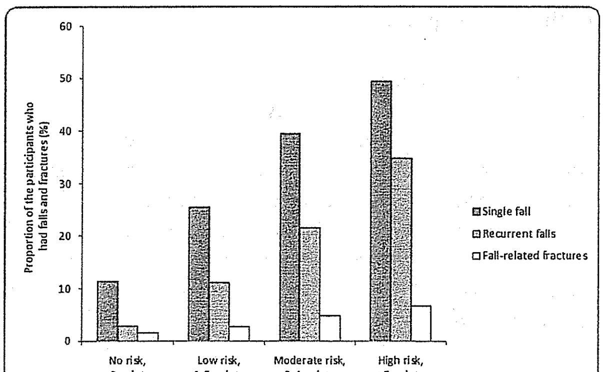

Figure 1 Proportion of the participants who had single fall, recurrent falls, and fall-related fractures according to fall risk. Frail, elderly participants were categorized into four **fall risk** groups by SRRST score. The rate of single fall, recurrent falls, and fall-related fractures increased in accordance with the risk of falls based on the SRRST score.

In the comparative analysis, when compared with non-fallers, participants who had experienced falling were more likely to have a fall risk (with the exception of history of stroke and use of slippers and sandals). In contrast, when compared with those without fall-related fractures, participants who had fall-related fractures did not show significant differences in many potential confounding factors, although all SRRST items showed significant differences. These results suggest that the subjective assessment used in the SRRST was useful to examine the risk of fractures in the frail elderly.

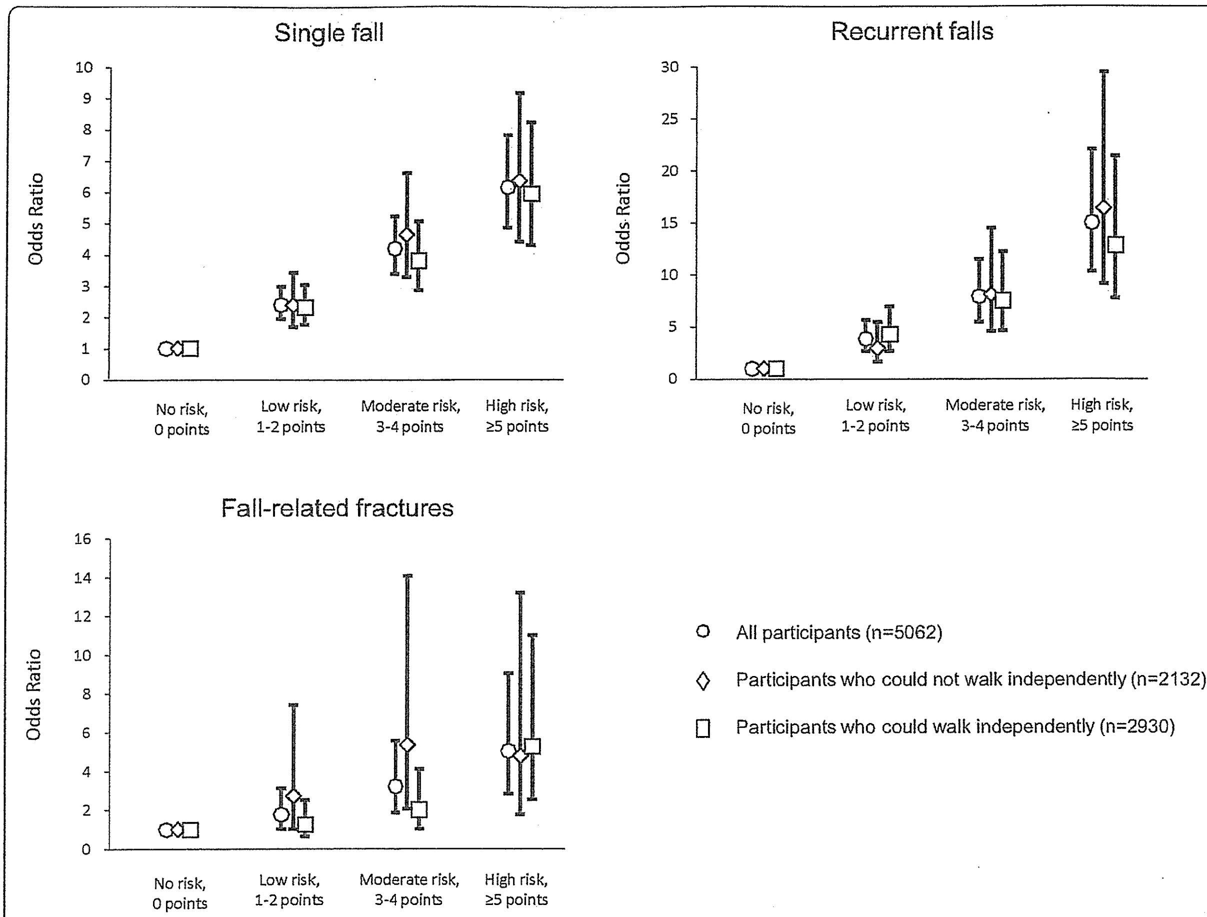

Figure 2 Odds ratios and 95% confidence intervals of SRRST categories for a single fall, recurrent falls, and fall-related fractures. Models were adjusted for all confounding factors (model 2). The participants were divided into dependent-walking and independent-walking groups.

Table 4 Sensitivity and specificity of SRRST scores for falls and fall-related fractures

SRRST score	Single fall		Recurrent falls		Fractures	
	Sensitivity (95% CI)	Specificity (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)
0/1 point	0.91 (0.90 to 0.92)	0.30 (0.29 to 0.32)	0.96 (0.94 to 0.97)	0.28 (0.26 to 0.29)	0.90 (0.85 to 0.94)	0.24 (0.23 to 0.26)
1/2 point	0.80 (0.78 to 0.82)	0.47 (0.45 to 0.49)	0.87 (0.85 to 0.90)	0.44 (0.42 to 0.45)	0.79 (0.72 to 0.84)	0.39 (0.38 to 0.41)
2/3 point	0.66 (0.63 to 0.68)	0.63 (0.61 to 0.64)	0.75 (0.72 to 0.78)	0.60 (0.58 to 0.61)	0.68 (0.61 to 0.74)	0.55 (0.53 to 0.56)
3/4 point	0.48 (0.46 to 0.51)	0.76 (0.75 to 0.78)	0.58 (0.55 to 0.62)	0.74 (0.73 to 0.76)	0.50 (0.43 to 0.57)	0.70 (0.68 to 0.71)
4/5 point	0.30 (0.28 to 0.32)	0.87 (0.86 to 0.88)	0.39 (0.36 to 0.42)	0.86 (0.85 to 0.87)	0.32 (0.26 to 0.39)	0.82 (0.81 to 0.83)
5/6 point	0.14 (0.13 to 0.16)	0.94 (0.93 to 0.95)	0.22 (0.20 to 0.25)	0.93 (0.92 to 0.94)	0.13 (0.09 to 0.19)	0.91 (0.90 to 0.92)
6/7 point	0.07 (0.06 to 0.09)	0.97 (0.97 to 0.98)	0.10 (0.08 to 0.12)	0.97 (0.96 to 0.97)	0.02 (0.01 to 0.05)	0.96 (0.95 to 0.96)

Multiple regression models revealed that the SRRST score was associated with falling as well as fall-related fracture, even when adjusted for many confounding factors. Odds ratios were markedly higher for recurrent falls than for single fall and fall-related fractures. A previous study suggested that infrequent or isolated falls are more unpredictable events than multiple falls and less likely to result from underlying neurologic or musculoskeletal problems [18]. The incidence of fall-related fractures is also influenced by low bone density which was not measured in this study [26-28]. These factors may have weakened the relationships between the SRRST and a single fall and fall-related fractures. Higher odds ratios, however, remained between the SRRST and history of falling and fractures than previously reported odds ratios calculated from the cut-off points of objective performance tests in frail elderly people who participated in the TOUCH [7]. Cut-points for maximizing the sensitivity and specificity were 2/3 point in all of a single fall, recurrent falls and fall-related fractures. Care providers may require attention to risk of falls and fall-related fractures in the frail elderly adults who have a score 3 points and over in the SRRST.

Why did staff assessments show close relationships with falls and fall-related fractures? Falling is induced by multidimensional factors, and the primary cause of falling may vary among frail elderly adults who have many risk factors for falls. Thus, it is difficult to determine the primary risks for falls in all frail elderly adults using objective measures that can identify only specific issues. In contrast, subjective evaluations can determine combined risks of falling based on various information such as physical functions, daily activity status, and risky behaviors, although these evaluations cannot give clear, specific and objective risks for falling. The combined information is important for identifying risks of falls and preventing falls in frail elderly people, because correct risk-assessments by care staff may lead to successful assessment and interventions for preventing falls [29,30]. We reported previously that an intervention study using supervision technique based on the assessment of fall-risk behaviors can reduce the risk of falling in institutionalized elderly people [31]. Thus, we considered that the assessment and intervention used in the SRRST may be useful for preventing falls in frail elderly people. Furthermore, the SRRST has the strength of being designed for frail elderly people. Although risk factors for falls differ between elderly adults who can and cannot stand unaided [32], nearly all risks identified by the SRRST showed significant odds ratios for falls and fall-related fractures in the dependent walking and independent walking groups. Future research should include a prospective measurement of falls in order to more accurately determine the validity of the SRRST for this population and perform an intervention study to reveal the effects of the SRRST on intervention.

One of the limitations of our study is that we performed a cross-sectional study and analysed retrospectively recalled falls. This is known to be a less accurate measure than prospectively recalled falls [33]. It is possible that underreporting of falls by participants may have led an underestimation of the rates of falls. Therefore, further investigation of the validity of these tests in predicting falls in frail elderly people using a prospective study design is recommended. Second, the investigations of the SRRST and history of falls were investigated at the same time. Thus, the information of the history of falls might affect subjective judgments of the testers. However, correct judgments of the SRRST may require multidimensional information included the history of falls in the elderly adults and testers, i.e. care providers, may know history of falls of their clients through daily care. In other words, testers who had information of falls history in the subjects could measure correctly the risk of falls using the SRRST.

Conclusion

In conclusion, this study developed the SRRST as a subjective assessment for identifying risk of falls in the frail elderly people. Numerous studies developed fall risk assessment tools which evaluate using objective physical or cognitive measurements [2]. Unfortunately, some frail elderly adults cannot perform objective assessments to screen fall risks although these assessment tools may judge almost frail elderly as high risk individuals and identify multiple risks for falling [7]. The SRRST can evaluate easily the specific fall risks and have high feasibility in the elderly. This study provides the evidence that subjective assessment by staff was associated with risk of falling and fall-related fractures in frail elderly people. We encourage providing a fall prevention strategy to the frail elderly who had some risks for falls in your subjective judgments. Future research need to determine the predictive validity of incidence of falls and fractures in the frail elderly people.

Abbreviations

SRRST: Subjective Risk Rating of Specific Tasks; TOUCH: Tsukui Ordered Useful Care for Health; ICC: intraclass correlation coefficient; OR: Odds Ratio; 95% CI: 95% confidence interval.

Acknowledgements

This work received financial support from a Grant-in-Aid for Scientific Research from the Ministry of Education, Culture, Sports, Science and Technology of Japan (Tokyo, Japan).

Author details

[1]Section for Health Promotion, Department of Health and Medical Care, Center for Development of Advanced Medicine for Dementia, National Center for Geriatrics and Gerontology, Obu, Japan. [2]Faculty of Health Sciences, Department of Rehabilitation, Course of Physical Therapy,

University of Human Arts and Science, Saitama, Japan. [3]Human Care Research Team, Tokyo Metropolitan Institute of Gerontology, Tokyo, Japan. [4]Tsukui Corporation, Yokohama, Japan. [5]Research Team for Promoting Independence of the Elderly, Tokyo Metropolitan Institute of Gerontology, Tokyo, Japan. [6]National Institute for Longevity Sciences, National Center for Geriatrics and Gerontology, Obu, Japan.

Authors' contributions

HS and MS were responsible for the study concept and design. HS was responsible for the draft of the manuscript. MI, TI, KH, and TS were responsible for the critical revision of the manuscript for important intellectual content. KK was responsible for the coordination of acquisition of data. All authors were responsible for the final approval of the manuscript.

Competing interests

The authors declare that they have no competing interests.

Received: 9 August 2010 Accepted: 12 August 2011
Published: 12 August 2011

References

1. Ministry of Health, Labor and Welfare: **National nutrition survey in Japan 2002.** Tokyo: Ministry of Health, Labor and Welfare; 2002.
2. Lord SR, Sherrington C, Menz HB, Close JCT: **Falls in older people: risk factors and strategies for prevention.** Cambridge: Cambridge University Press, 2 2007.
3. Scott V, Votova K, Scanlan A, Close J: **Multifactorial and functional mobility assessment tools for fall risk among older adults in community, home-support, long-term and acute care settings.** *Age Ageing* 2007, **36(2)**:130-139.
4. Robbins AS, Rubenstein LZ, Josephson KR, Schulman BL, Osterweil D, Fine G: **Predictors of falls among elderly people. Results of two population-based studies.** *Arch Intern Med* 1989, **149(7)**:1628-1633.
5. Lord SR, Menz HB, Tiedemann A: **A physiological profile approach to falls risk assessment and prevention.** *Phys Ther* 2003, **83(3)**:237-252.
6. Tiedemann A, Shimada H, Sherrington C, Murray S, Lord S: **The comparative ability of eight functional mobility tests for predicting falls in community-dwelling older people.** *Age Ageing* 2008, **37(4)**:430-435.
7. Shimada H, Suzukawa M, Tiedemann A, Kobayashi K, Yoshida H, Suzuki T: **Which neuromuscular or cognitive test is the optimal screening tool to predict falls in frail community-dwelling older people?** *Gerontology* 2009, **55(5)**:532-538.
8. Salgado R, Lord SR, Packer J, Ehrlich F: **Factors associated with falling in elderly hospital patients.** *Gerontology* 1994, **40(6)**:325-331.
9. Stevenson B, Mills EM, Welin L, Beal KG: **Falls risk factors in an acute-care setting: a retrospective study.** *Can J Nurs Res* 1998, **30(1)**:97-111.
10. Jensen J, Nyberg L, Gustafson Y, Lundin-Olsson L: **Fall and injury prevention in residential care–effects in residents with higher and lower levels of cognition.** *J Am Geriatr Soc* 2003, **51(5)**:627-635.
11. Lundin-Olsson L, Jensen J, Nyberg L, Gustafson Y: **Predicting falls in residential care by a risk assessment tool, staff judgement, and history of falls.** *Aging Clin Exp Res* 2003, **15(1)**:51-59.
12. Izumi K, Makimoto K, Kato M, Hiramatsu T: **Prospective study of fall risk assessment among institutionalized elderly in Japan.** *Nurs Health Sci* 2002, **4(4)**:141-147.
13. Nordin E, Lindelöf N, Rosendahl E, Jensen J, Lundin-Olsson L: **Prognostic validity of the Timed Up-and-Go test, a modified Get-Up-and-Go test, staff's global judgement and fall history in evaluating fall risk in residential care facilities.** *Age Ageing* 2008, **37(4)**:442-448.
14. Suzukawa M, Shimada H, Makizako H, Watanabe S, Suzuki T: **[Incidence of falls and fractures in disabled elderly people utilizing long-term care insurance].** *Nippon Ronen Igakkai zasshi* 2009, **46(4)**:334-340.
15. Suzukawa M, Shimada H, Tamura M, Suzuki T, Inoue N: **The relationship between the subjective risk rating of specific tasks and falls in frail elderly people.** *J Phys Ther Sci* 2011, **23(3)**:425-429.
16. Tsutsui T, Muramatsu N: **Japan's universal long-term care system reform of 2005: containing costs and realizing a vision.** *J Am Geriatr Soc* 2007, **55(9)**:1458-1463.
17. Fried LP, Ettinger WH, Lind B, Newman AB, Gardin J: **Physical disability in older adults: a physiological approach. Cardiovascular Health Study Research Group.** *J Clin Epidemiol* 1994, **47(7)**:747-760.
18. Nevitt MC, Cummings SR, Kidd S, Black D: **Risk factors for recurrent nonsyncopal falls. A prospective study.** *JAMA* 1989, **261(18)**:2663-2668.
19. Cumming RG, Sherrington C, Lord SR, Simpson JM, Vogler C, Cameron ID, Naganathan V, Prevention of Older People's Injury Falls Prevention in Hospitals Research Group: **Cluster randomised trial of a targeted multifactorial intervention to prevent falls among older people in hospital.** *BMJ* 2008, **336(7647)**:758-760.
20. Hashidate H, Shimada H, Shiomi T, Sasamoto N: **Usefulness of the subjective risk rating of specific tasks for falling in frail older people.** *J Phys Ther Sci* 2011, **23(3)**:519-524.
21. Rubenstein LZ, Josephson KR: **The epidemiology of falls and syncope.** *Clin Geriatr Med* 2002, **18(2)**:141-158.
22. Tinetti ME, Speechley M, Ginter SF: **Risk factors for falls among elderly persons living in the community.** *N Engl J Med* 1988, **319(26)**:1701-1707.
23. Fleming BE, Pendergast DR: **Physical condition, activity pattern, and environment as factors in falls by adult care facility residents.** *Arch Phys Med Rehabil* 1993, **74(6)**:627-630.
24. Kiely DK, Kiel DP, Burrows AB, Lipsitz LA: **Identifying nursing home residents at risk for falling.** *J Am Geriatr Soc* 1998, **46(5)**:551-555.
25. Perkins NJ, Schisterman EF: **The inconsistency of "optimal" cutpoints obtained using two criteria based on the receiver operating characteristic curve.** *Am J Epidemiol* 2006, **163(7)**:670-675.
26. Dargent-Molina P, Favier F, Grandjean H, Baudoin C, Schott AM, Hausherr E, Meunier PJ, Bréart G: **Fall-related factors and risk of hip fracture: the EPIDOS prospective study.** *Lancet* 1996, **348(9021)**:145-149.
27. Cummings SR, Nevitt MC, Browner WS, Stone K, Fox KM, Ensrud KE, Cauley J, Black D, Vogt TM: **Risk factors for hip fracture in white women. Study of Osteoporotic Fractures Research Group.** *N Engl J Med* 1995, **332(12)**:767-773.
28. Chandler JM, Zimmerman SI, Girman CJ, Martin AR, Hawkes W, Hebel JR, Sloane PD, Holder L, Magaziner J: **Low bone mineral density and risk of fracture in white female nursing home residents.** *JAMA* 2000, **284(8)**:972-977.
29. Shimada H, Obuchi S, Furuna T, Suzuki T, Nishizawa S, Kojima M: **Risk factors of falls in the elderly people with dementia.** *Gerontol Geriat Int* 2003, **3**:S198.
30. Shimada H, Ota M, Yabe N, Obuchi S, Furuna T, Kojima M, Suzuki T: **[Effect of predict falls for behavioral analysis in the elderly with dementia].** *Rigaku ryohogaku* 2004, **31**:124-129.
31. Shimada H, Tiedemann A, Lord SR, Suzuki T: **The effect of enhanced supervision on fall rates in residential aged care.** *Am J Phys Med Rehabili* 2009, **88(10)**:823-828.
32. Lord SR, March LM, Cameron ID, Cumming RG, Schwarz J, Zochling J, Chen JS, Makaroff J, Sitoh YY, Lau TC, Brnabic A, Sambrook PN: **Differing risk factors for falls in nursing home and intermediate-care residents who can and cannot stand unaided.** *J Am Geriatr Soc* 2003, **51(11)**:1645-1650.
33. Cummings SR, Nevitt MC, Kidd S: **Forgetting falls. The limited accuracy of recall of falls in the elderly.** *J Am Geriatr Soc* 1988, **36(7)**:613-616.

Pre-publication history

The pre-publication history for this paper can be accessed here:
http://www.biomedcentral.com/1471-2318/11/40/prepub

doi:10.1186/1471-2318-11-40
Cite this article as: Shimada *et al.*: Relationship between subjective fall risk assessment and falls and fall-related fractures in frail elderly people. *BMC Geriatrics* 2011 11:40.

Effects of Exercise and Amino Acid Supplementation on Body Composition and Physical Function in Community-Dwelling Elderly Japanese Sarcopenic Women: A Randomized Controlled Trial

Hun Kyung Kim, PhD, * *Takao Suzuki, MD, PhD,* † *Kyoko Saito, PhD,* * *Hideyo Yoshida, MD, PhD,* * *Hisamine Kobayashi, DVM,* ‡ *Hiroyuki Kato, MS,* ‡ *and Miwa Katayama, DVM* ‡

OBJECTIVES: To evaluate the effectiveness of exercise and amino acid supplementation in enhancing muscle mass and strength in community-dwelling elderly sarcopenic women.

DESIGN: Randomized controlled trial.

SETTING: Urban community in Tokyo, Japan.

PARTICIPANTS: One hundred fifty-five women aged 75 and older were defined as sarcopenic and randomly assigned to one of four groups: exercise and amino acid supplementation (exercise + AAS; n = 38), exercise (n = 39), amino acid supplementation (AAS; n = 39), or health education (HE; n = 39).

INTERVENTION: The exercise group attended a 60-minute comprehensive training program twice a week, and the AAS group ingested 3 g of a leucine-rich essential amino acid mixture twice a day for 3 months.

MEASUREMENTS: Body composition was determined using bioelectrical impedance analysis. Data from interviews and functional fitness parameters such as muscle strength and walking ability were collected at baseline and after the 3-month intervention.

RESULTS: A significant group × time interaction was seen in leg muscle mass ($P = .007$), usual walking speed ($P = .007$), and knee extension strength ($P = .017$). The within-group analysis showed that walking speed significantly increased in all three intervention groups, leg muscle mass in the exercise + AAS and exercise groups, and knee extension strength only in the exercise + AAS group (9.3% increase, $P = .01$). The odds ratio for leg muscle mass and knee extension strength improvement was more than four times as great in the exercise + AAS group (odds ratio = 4.89, 95% confidence interval = 1.89–11.27) as in the HE group.

CONCLUSION: The data suggest that exercise and AAS together may be effective in enhancing not only muscle strength, but also combined variables of muscle mass and walking speed and of muscle mass and strength in sarcopenic women. J Am Geriatr Soc 60:16–23, 2012.

Key words: sarcopenic women; exercise; amino acid supplementation; muscle mass; muscle strength

Sarcopenia, defined as age-related involuntary loss of skeletal muscle mass and strength,[1,2] has been associated with physical disability, functional decline, falls, impaired mobility, and mortality in elderly people.[3,4] Therefore, treating or reversing sarcopenia is important in the maintenance of health and life expectancy in the elderly population. Although many factors, such as chronic disease, physical inactivity, and decreased muscle protein synthesis, may contribute to loss of muscle mass,[5–7] it has been suggested that only skeletal muscle disuse and undernutrition are potentially preventable or reversible with targeted interventions.[8]

Many studies have shown a strong relationship between resistance exercise and strength improvement, through which the efficacy of resistance exercise for the prevention and treatment of sarcopenia has been confirmed.[9] The previous studies have also shown that ingestion of essential amino acids can induce muscle protein anabolism in elderly adults.[10,11] One study showed that the combination of resistance exercise and essential amino acid supplementation (AAS) augmented muscle protein

From the *Research Team for Promoting Independence of the Elderly, Tokyo Metropolitan Institute of Gerontology, Tokyo, Japan; †National Institute for Longevity Sciences, Aichi, Japan; and ‡Ajinomoto Co. Inc., Kawasaki, Japan.

Address correspondence to Hun Kyung Kim, Research Team for Promoting Independence of the Elderly, Tokyo Metropolitan Institute of Gerontology, 35-2 Sakaecho, Itabashi-ku, Tokyo 173-0015, Japan. E-mail: kimhk@tmig.or.jp

DOI: 10.1111/j.1532-5415.2011.03776.x

0002-8614/12/$15.00

synthesis, suggesting it as a strategy to reverse sarcopenia[12] but in a small sample size. There are few randomized controlled trials (RCTs) on the effects of exercise and AAS on body composition and functional capacity.

The purpose of this study was to investigate the effects of exercise and AAS on muscle mass, strength, and walking ability in sarcopenic women.

METHODS

Subjects

A letter outlining the comprehensive geriatric health examination survey, describing its objective and the way that the personal data would be used, was mailed to the women randomly selected from the Basic Resident Register of 5,932 people aged 75 and older residing in the Itabashi ward of metropolitan Tokyo inviting them to participate in the study. Two thousand eighteen people responded to the mailed letters of invitation to participate in the study, with 1,670 people agreeing and 348 people declining to participate. The baseline assessment was conducted at the Tokyo Metropolitan Institute of Gerontology (TMIG) from October 12 to November 3, 2008. One thousand three hundred eighty-three women aged 75 and older were screened; 287 who originally agreed to participation were absent. Written informed consent was obtained for baseline screening; six people did not sign the informed consent form and were not included in this study.

Three hundred four of 1,377 women (22.1%) were operationally defined as sarcopenic (Figure 1), with selection based on categorization into one or more of the following inclusion criteria groups: appendicular skeletal muscle mass/height^2 less than 6.42 kg/m^2 and knee extension strength less than 1.01 Nm/kg[13,14] (n = 68), appendicular skeletal muscle mass/height^2 less than 6.42 kg/m^2 and usual walking speed less than 1.22 m/s (n = 65),[14] body mass index (BMI) less than 22.0 kg/m^2[14] and knee

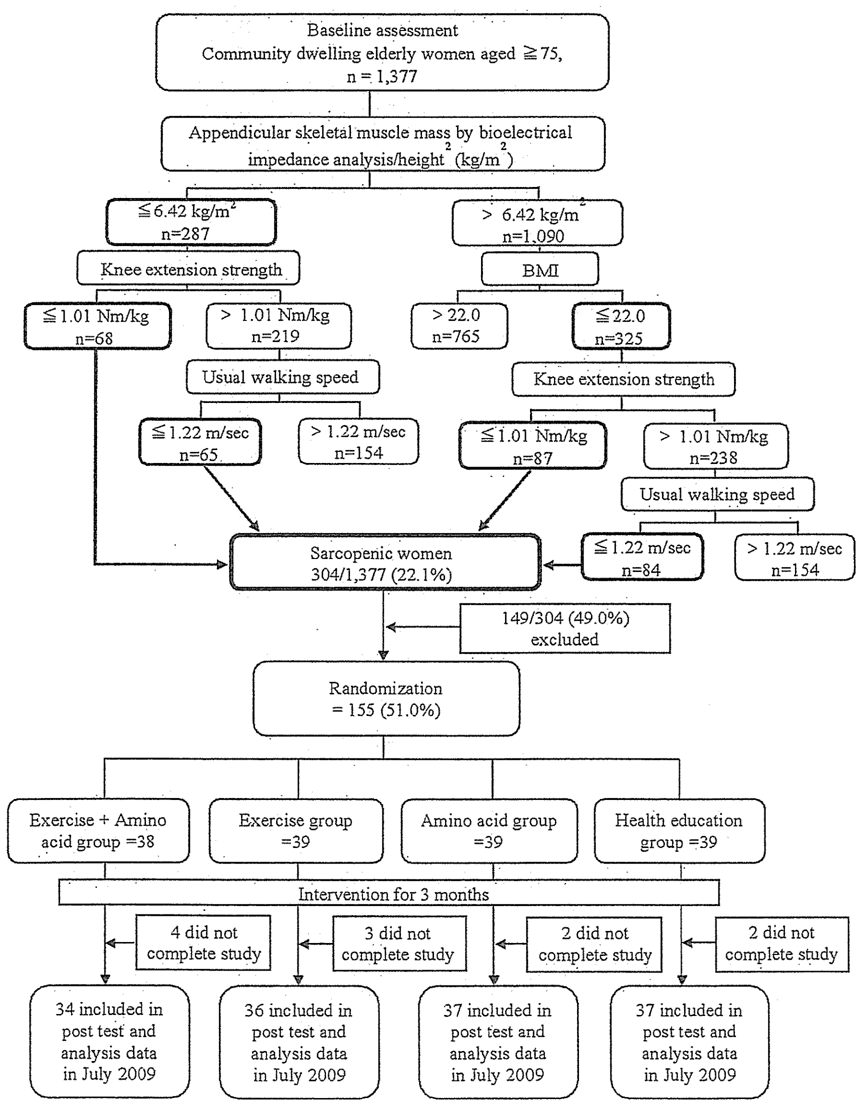

Figure 1. Algorithm for the selection of women who were operationally defined as sarcopenic and flowchart of participants in the randomized controlled trial of exercise and amino acid supplementation.

extension strength less than 1.01 Nm/kg (n = 87), and BMI less than 22.0 kg/m^2 and usual walking speed less than 1.22 m/s (n = 84). Exclusion criteria were severe knee or back pain; severely impaired mobility; impaired cognition (Mini-Mental State Examination (MMSE) score < 24);[16] missing baseline data; and unstable cardiac conditions such as ventricular dysrhythmias, pulmonary edema, or other musculoskeletal conditions. One hundred forty-nine (49.0%) of the potential sarcopenic participants were excluded because they were classified into one or more of the exclusion criteria or declined participation. The Clinical Research Ethics Committee of TMIG approved the study protocol. The intervention procedures were fully explained to all participants, and written informed consent was obtained (Figure 1).

Randomization

Randomization was performed after the baseline assessment; any variable that identified personal information was not included in the randomization process. Computer-generated random numbers were assigned to 155 participants who were then sorted and divided into four equal groups. The groups were randomly assigned to one of the four interventions groups: exercise + AAS (n = 38), exercise (n = 39), AAS (n = 39), or health education (HE; n = 39). All participants agreed to the group allocations that were mailed to them. There was no attempt to equalize the size of the groups based on their characteristics or to recruit subjects with specific characteristics. The co-investigators were blind to the randomization procedure and group allocations, separate physical therapy staff members who were also blind to the allocation of treatments collected data.

Outcome Measures

Outcome measures were evaluated according to data collected from interviews, body composition assessments using bioelectrical impedance analysis (BIA), and physical fitness tests at baseline and after the 3-month intervention.

Interview Survey

Face-to-face interviews were conducted to assess the individual's history of fractures and falls over the previous year, number of falls, cause of falls, urinary incontinence, exercise habits, smoking status, and MMSE score.

Body Composition Assessment

Measurements of height and weight were used to calculate BMI (kg/m^2). Body composition was measured using a segmental multifrequency BIA instrument that operated at frequencies of 5, 50, 250, and 550 kHz (Well-Scan 500, Elk Corp., Tokyo, Japan). Participants removed their socks, stood on two metallic electrodes on the floor scale barefoot, and held metallic grip electrodes placed in the palm of the hand with the fingers wrapped around the handrails. Using segmental body composition and muscle mass values of both legs, both arms, and the trunk, appendicular skeletal muscle mass and leg muscle mass values were obtained

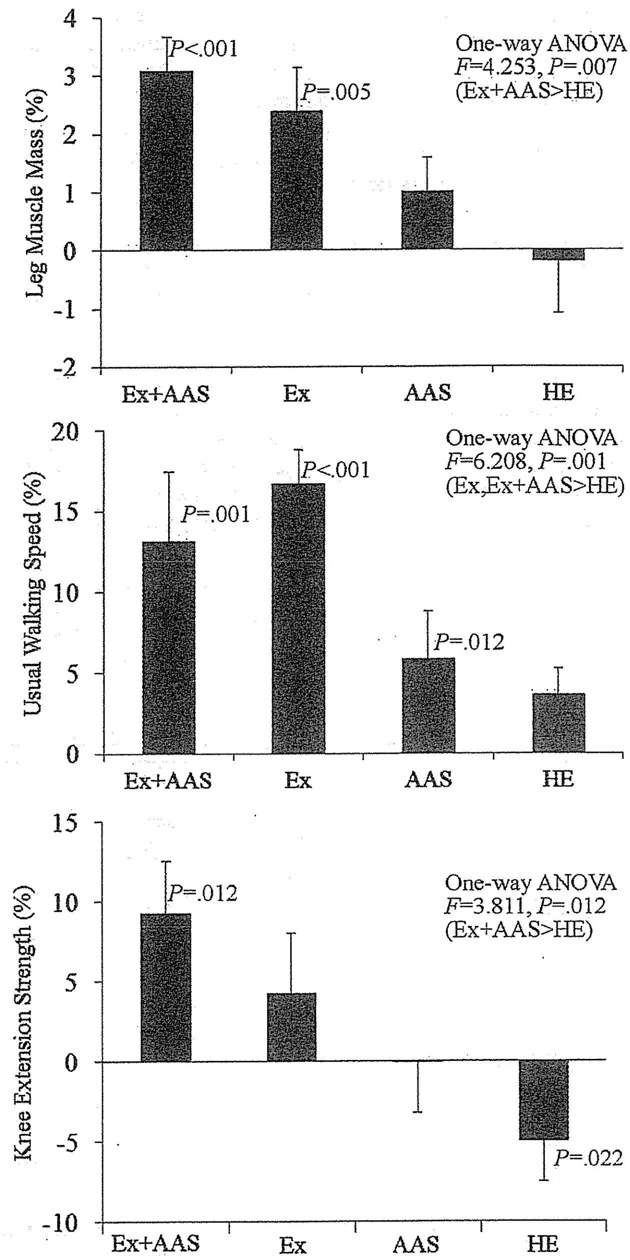

Figure 2. Mean percentage changes (standard errors) in leg muscle mass, usual walking speed, and knee extension strength after exercise (Ex), amino acid supplementation (AAS), both (Ex + AAS), or health education (HE). Bars indicate average changes from baseline to after the 3-month intervention. ANOVA = analysis of variance.

and used for analysis by summing the appropriate segmental muscle mass values.[13,17,18] Reliability of body composition measurements in all 155 participants in this study was not analyzed, although for the AAS group (n = 39), measurements were taken for a second time 1 week after baseline testing, and reliability was examined; the intraclass correlation coefficients (ICC) were: 0.98 for the right arm, 0.97 for the left arm, 0.97 for the right leg, 0.96 for the left leg, and 0.93 for the trunk.

Functional Fitness Test

Calf girth and functional fitness variables including usual and maximum walking speeds and knee extension strength were measured. In measures of walking speed, participants were allowed to use assistive walking devices only if they expressed strong concerns about walking without a device or if there was any danger of falling. The knee extension strength measurement was taken twice, and the higher value divided by body weight (Nm/kg) were analyzed. The procedures for the functional fitness tests have been described in detail in previous reports.[19,20]

Intervention

Exercise

A comprehensive physical fitness and muscle mass enhancement training program of moderate intensity was provided for the participants in the exercise groups. The exercise intervention consisted of 60-minute exercise sessions held at the TMIG twice per week for 3 months. Each exercise intervention group was divided into two subgroups, with participants exercising together within their assigned group in one of four exercise sessions offered per day.

Each exercise session consisted of a 5-minute warm-up, 30 minutes of strengthening exercise, 20 minutes of balance and gait training, and 5 minutes of cool down. The strengthening exercises were performed in a progressive sequence from seated to standing positions. For each type of exercise, participants were instructed to complete up to eight repetitions of the movements. When the exercises were properly executed without significant fatigue or loss of proper execution, the resistance was increased. The progressive resistance was provided through the use of resistance bands or ankle weights. Intensity was maintained at approximately 12 to 14 on the Borg Rate of Perceived Exertion scale.[21] The principal investigator, along with the exercise instructor and assistant trainers, assessed each individual's ability to increase intensity.

Chair exercise: The chair-seated exercises were used in the early stages of the program because the participants were frail older adults and it provided a secure and stable position. Repetitions of toe raises, heel raises, knee lifts, knee extensions, and others were performed while seated on a chair. Hip flexions, lateral leg raises, and repetitions of other exercises were performed standing upright behind the chair and holding the back of the chair for stability.

Ankle-weight exercise: To strengthen lower extremities, a fixed weight was placed on the ankle while participants performed strengthening exercises. Weights of 0.50, 0.75, 1.00, and 1.50 kg were prepared and used in accordance with each participant's strength level as the resistance progressively increased. The exercises performed using these ankle weights included seated knee flexion and extension and standing knee flexion and extensions.

Exercises using a resistance band: Resistance bands were used to strengthen the upper and lower body. Lower body exercises included leg extension and hip flexion. Upper body exercises included double-arm pull downs and biceps curls.

Balance and gait training: The balance training was focused on improvement of static, dynamic, and lateral balancing ability. Exercises included standing on one leg, multidirectional weight shifts, tandem stand, and tandem walk. Participants practiced proper gait mechanics that focused on the maintenance of stability during walking and increasing stride length, toe elevation of the forward limb, heel elevation of the rear limb, frequency of stepping, and heel–floor angle. Exercises included raising the toes (dorsiflexion) during the forward swing of the leg, kicking off the floor with the ball of the foot, walking with directional changes, and gait pattern variations.

Amino Acid Supplementation

Essential AAS was provided for the participants in the AAS groups every 2 weeks. Packets of powdered amino acid supplements (42.0% leucine, 14.0% lysine, 10.5% valine, 10.5% isoleucine, 10.5% threonine, 7.0% phenylalanine, and 5.5% other) were provided for the participants to be taken with water or milk, and they were instructed to take the 3-g supplement two times a day (6 g daily) every day for 3 months.[22] To monitor their amino acid intake accurately, participants were given record sheets that were collected every 2 weeks on which they recorded what time of day they took the supplement and the amount of amino acid taken every day.

Health Education

Participants in the HE group took a class once a month for 3 months, a total of three times. The classes focused on cognitive function, osteoporosis, and oral hygiene. Participants were asked to continue their regular lifestyle habits, and no specific instructions on diet or physical activity were given.

Data Analysis

Sample size calculations using univariate one-factor repeated-measures analysis of variance (ANOVA) to examine significant differences in means at baseline and after the 3-month intervention ($\alpha = 0.05$, power = 0.80) with an effect size of 0.15 required a sample size of 28 participants. Esimating a potential attrition rate of 25%, 38 subjects per group were required.[23] One-way ANOVA was used to test any differences in baseline measures and percentage changes between groups, and chi-square tests were performed on categorical variables. Percentage changes in muscle mass and functional fitness after the intervention were calculated using the following formula: % change = ((postintervention value–baseline value)/(baseline value) $\times$ 100). Two-way repeated-measures ANOVA was used to evaluate the differences in the effect of the intervention on the outcome measures between groups, and a post hoc test was done on variables showing significant differences to determine which groups were different. Multiple logistic regressions were performed to compare the effects of the four intervention groups on each outcome variable after 3 months of intervention. All analyses were performed using SPSS version 15.0 of Windows (SPSS, Inc., Tokyo, Japan).

RESULTS

The baseline demographic, fitness, and interview variables of the participants in the four groups are summarized in Table 1. All of the baseline characteristics were similar between the groups.

The mean attendance rates during the 3-month intervention were 70.3% in the exercise + AAS group, 80.5% in the exercise group, 72.2% in the AAS group, and 71.8% in the HE group. Eleven participants (exercise + AAS = 4, exercise = 3, AAS = 2, HE = 2) were unable to complete the study after randomization because of spouse care (n = 3), admission to nursing home (n = 2), lack of motivation (n = 2), severe knee or back pain (n = 1), death (n = 1), falls and hip fracture (n = 1), and hospitalization (n = 1; Figure 2).

In comparing the pre- and postintervention changes in body composition and functional fitness of the groups (Table 2), there was a significant group × time interaction for leg muscle mass ($F = 4.253$, $P < .007$; exercise + AAS > HE), usual and maximum walking speeds (exercise and exercise + AAS > HE), and knee extension strength ($F = 3.558$, $P = .02$; exercise + AAS > HE).

The within-group analysis showed significant changes in leg muscle mass in the exercise + AAS ($P < .001$) and exercise ($P = .005$) groups and changes in usual walking speed in the exercise + AAS ($P = .001$), exercise ($P < .001$), and AAS groups ($P = .01$). Knee extension strength improved significantly only in the exercise + AAS group ($P = .01$), no improvement was seen in exercise or AAS, and a statistically significant decrease was observed in the HE group ($P = .02$; Figure 1).

Table 3 shows the effects of the type of intervention on changes in combined variables of muscle mass and physical function. Significant increases in leg muscle mass and knee extension strength (odds ratio (OR) = 4.89, 95% confidence interval (CI) = 1.89–11.27) and leg muscle mass and usual walking speed (OR = 4.11, 95% CI = 1.33–13.68) were observed in only the exercise + AAS group.

DISCUSSION

Although many definitions of sarcopenia have been reported,[1 3,24] there has recently been a focus not only on the loss of appendicular skeletal muscle mass, but also on functional decline.[25] In this study, sarcopenic women were operationally defined based on declines in muscle strength or walking ability that accompany the loss of skeletal muscle mass or low BMI. Because defining sarcopenia was beyond the scope of this study, the focus of the discussion will be on the effects of the intervention. To evaluate the intervention effects, the changes observed in the single variables as well as the combined variables will be discussed.

Many studies have focused on exercise or nutrition as interventions to reverse sarcopenia, but the results of these studies have not always been consistent.[8,9,12,26]

This study demonstrated that appendicular muscle mass and walking speed increased with the combination of exercise and essential amino acid ingestion, as well as with the separate exercise and amino acid interventions, but muscle strength improved only with the combination of exercise and amino acid ingestion.

A recently published meta-analysis[9] and a Cochrane review article also confirmed that resistance training two to three times a week can improve physical function and functional limitations and can reduce disability and muscle weakness in older people.[27] Previous studies have demonstrated that resistance training in elderly people produces

Table 1. Selected Variable Characteristics of Participants at Baseline According to Study Group

Characteristic	Exercise + AAS (n = 38)	Exercise (n = 39)	AAS (n = 39)	Health Education (n = 39)	F-Value*	P-Value*
Age, mean ± SD	79.5 ± 2.9	79.0 ± 2.9	79.2 ± 2.8	78.7 ± 2.8	0.577	.63
Height, cm, mean ± SD	147.1 ± 6.7	147.7 ± 4.4	145.8 ± 4.5	146.5 ± 4.9	0.960	.41
Body weight, kg, mean ± SD	39.5 ± 5.5	41.1 ± 4.7	40.1 ± 3.2	40.4 ± 3.9	0.874	.46
Body mass index, kg/m^2, mean ± SD	18.3 ± 2.5	18.9 ± 2.0	18.9 ± 1.6	18.8 ± 1.7	0.745	.53
Calf girth, cm, mean ± SD	18.3 ± 2.5	18.9 ± 2.0	18.9 ± 1.6	18.8 ± 1.7	0.745	.53
Lean body mass, kg, mean ± SD	29.1 ± 3.4	30.0 ± 2.6	28.8 ± 2.0	29.3 ± 2.4	1.505	.22
Muscle mass, kg, mean ± SD	26.9 ± 3.1	27.7 ± 2.3	26.5 ± 1.8	27.0 ± 2.2	1.538	.21
Appendicular muscle mass, kg, mean ± SD	13.3 ± 1.6	13.7 ± 1.3	13.1 ± 1.0	13.3 ± 1.2	1.502	.22
Legs muscle mass, kg, mean ± SD	9.8 ± 1.2	10.1 ± 1.0	9.7 ± 0.7	9.9 ± 0.9	1.570	.20
Usual walking speed, m/s, mean ± SD	1.26 ± 0.27	1.29 ± 0.28	1.29 ± 0.20	1.18 ± 0.22	1.701	.17
Maximal walking speed, m/s, mean ± SD	1.62 ± 0.37	1.67 ± 0.31	1.67 ± 0.27	1.55 ± 0.32	1.150	.33
Knee extension strength, Nm, mean ± SD	45.9 ± 11.3	46.6 ± 11.1	46.7 ± 7.8	47.4 ± 10.5	0.139	.94
Falls, %	21.1	17.9	15.4	20.5	0.519	.91
Exercise habit, %	26.3	25.6	38.5	33.3	2.029	.57
Urinary incontinence, %	44.7	38.5	41.0	25.6	3.414	.33
Osteoporosis history, %	36.8	43.6	48.7	30.8	2.987	.39
Heart disease history, %	10.5	15.4	12.8	17.9	0.977	.81
Diabetes mellitus history, %	7.9	5.1	5.1	12.8	2.156	.54

* One-way analysis of variance for continuous variables and chi-square test for categorical variables.

AAS = amino acid supplementation; SD = standard deviation.

Table 2. Comparison of Muscle Mass and Functional Fitness Variables Between Groups After 3-Month Intervention

Variable	Group	Mean ± Standard Deviation: Baseline	Mean ± Standard Deviation: After 3-Month Intervention	Analysis of Variance (Group × Time), P-Value	Post Hoc Analysis*
Muscle mass, kg	Exercise + AAS	26.76 ± 2.77	27.26 ± 3.04	F = 1.076, .36	
	Exercise	28.09 ± 1.90	28.51 ± 2.39		
	AAS	26.25 ± 1.81	26.53 ± 2.10		
	HE	27.48 ± 2.04	27.66 ± 2.23		
Appendicular muscle mass, kg	Exercise + AAS	13.25 ± 1.35	13.59 ± 1.53	F = 1.354, .26	
	Exercise	13.90 ± 1.06	14.19 ± 1.33		
	AAS	12.86 ± 0.99	13.03 ± 1.10		
	HE	13.57 ± 1.16	13.67 ± 1.05		
Legs muscle mass, kg	Exercise + AAS	9.76 ± 1.01	10.07 ± 1.13	F = 4.253, .007	Exercise + AAS > HE
	Exercise	10.28 ± 0.81	10.53 ± 1.05		
	AAS	9.55 ± 0.73	9.65 ± 0.83		
	HE	10.14 ± 0.87	10.11 ± 0.81		
BMI, kg/m²	Exercise + AAS	18.30 ± 2.64	18.14 ± 2.68	F = 0.606, .61	
	Exercise	18.80 ± 1.30	18.50 ± 1.41		
	AAS	18.84 ± 1.43	18.56 ± 1.62		
	HE	18.83 ± 1.75	18.77 ± 1.67		
Usual walking speed, m/s	Exercise + AAS	1.27 ± 0.25	1.43 ± 0.29	F = 4.213, .007	Exercise and Exercise + AAS > HE
	Exercise	1.31 ± 0.24	1.50 ± 0.23		
	AAS	1.30 ± 0.18	1.36 ± 0.18		
	HE	1.19 ± 0.21	1.22 ± 0.23		
Maximum walking speed, m/s	Exercise + AAS	1.64 ± 0.34	1.92 ± 0.37	F = 9.374, <.001	Exercise and Exercise + AAS > HE
	Exercise	1.72 ± 0.27	2.04 ± 0.27		
	AAS	1.71 ± 0.28	1.92 ± 0.27		
	HE	1.57 ± 0.31	1.64 ± 0.31		
Knee extension strength, Nm/kg	Exercise + AAS	1.15 ± 0.27	1.23 ± 0.29	F = 3.558, .02	Exercise + AAS > HE
	Exercise	1.12 ± 0.30	1.14 ± 0.26		
	AAS	1.15 ± 0.25	1.14 ± 0.25		
	HE	1.14 ± 0.26	1.00 ± 0.26		

* A post hoc analysis was performed using the Scheffe method.
AAS = amino acid supplementation; HE = health education; BMI = body mass index.

Table 3. Change in Leg Muscle Mass and Functional Fitness After Intervention According to Study Group

Dependent Variable*	Adjusted Odds Ratio (95% Confidence Interval): AAS	Exercise	Exercise + AAS
Change in leg muscle mass and knee extension strength	1.99 (0.72–5.65)	2.61 (0.88–8.05)	4.89 (1.89–11.27)
Change in leg muscle mass and usual walking speed	1.35 (0.45–4.08)	2.41 (0.79–7.58)	4.11 (1.33–13.68)

Reference: health education.
* 1 = improve, 0 = no change or decrease.
AAS = amino acid supplementation.

9% to 15% increases in strength and approximately 5% in thigh muscle volume.[28,29] Also, many studies have shown that resistance training in elderly people must be conducted at high intensities and volumes to see improvements.[9,27] In contrast, less-intense resistance exercise programs have produced little or no strength gains.

The data in this study show improvements of 2.4% in leg muscle mass, 2.0% in appendicular muscle mass, and 4.3% in leg strength in the exercise group. The moderate-intensity exercise provided in this trial produced strength gains that were smaller than those seen in previous studies, but the combination of moderate intensity exercise and AAS increased muscle mass 3.1% and muscle strength 9.3%, gains that are comparable with those observed in previous studies of high-intensity exercise.[28]

The results of the current study showed that total muscle mass, appendicular muscle mass, and walking speed significantly increased in the exercise group, suggesting that exercise is effective in the improvement of muscle mass and functional fitness, but increases in muscle