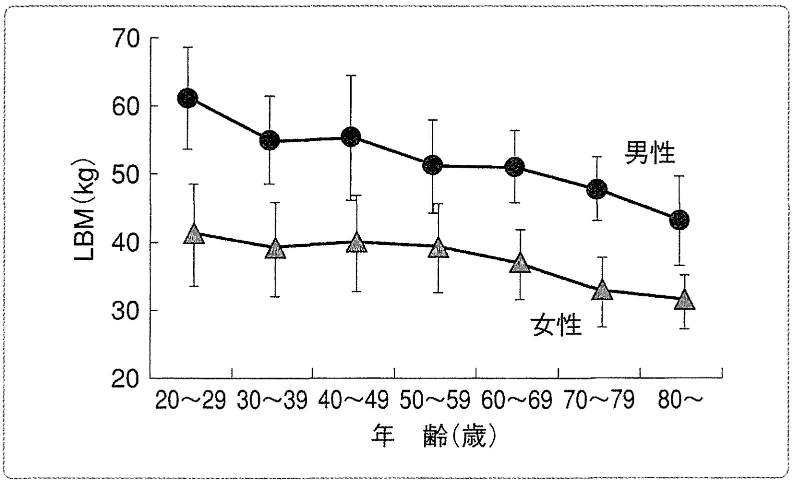

図１　DEXA 法による LBM の年代別の比較（文献１より引用）

ometry（DXA）法などが挙げられる．しかし，これらの測定には，高価な実験室装置や設備が要求され，計測に専門的な知識や資格が必要であり，大規模集団を扱う疫学調査の手法としては不向きである．骨格筋量を推定するための多様な手法が検討されているが，疫学研究に適用し得る代表的な方法を簡略に紹介する．

１）形態測定値による推定

形態測定値による筋肉量の評価については，1921 年の Matiegka[5]の試み以来，いくつかの研究が報告されている．1990 年，Martin ら[6]は，50〜94 歳の男性死体の筋肉量を妥当基準に設定し，筋肉量と四肢の周囲（前腕囲 r＝0.96，大腿囲 r＝0.94，下腿三頭囲 r＝0.84，腕囲 r＝0.82）との高い相関関係を示し，四肢の皮下脂肪厚値で補正すれば，精度が上昇することに着目し，男性の骨格筋量（total skeletal muscle mass：MM）を推定する次の式を提案している．

$$MM = STAT(0.0553\ CTG^2 + 0.0987\ FG^2 + 0.0331\ CCG^2) - 2445 \quad [SEE = 1.53\ kg,\ R^2 = 0.97] \cdots\cdots (1)$$

MM＝骨格筋量(g)，STAT＝身長(cm)，CTG＝大腿前部皮下脂肪厚で補正した大腿囲(cm)，FG＝補正なしの前腕囲(cm)，CCG＝下腿三頭皮下脂肪厚で補正した下腿三頭筋囲(cm)．

Lee ら[7]は，20〜81 歳の男性 135 名，女性 109 名を対象に，MRI より求めた骨格筋量（skeletal muscle mass：SM，妥当基準）を形態側値より推定する皮下脂肪厚－周径囲（モデル 1），体重－身長（モデル 2）を開発し，提案している．

モデル１：

$$SM(kg) = Ht \times (0.00744 \times CAG2 + 0.00088 \times CTG^2 + 0.00441 \times CCG^2) + 2.4 \times 性 - 0.048 \times 年齢 + 人種 + 7.8 \quad [R^2 = 0.91,\ SEE = 2.2\ kg] \cdots\cdots (2\text{-}1)$$

（性：男性＝1，女性＝0）（人種：アジア人＝−2.0，アフリカ系米国人＝1.1，白人・ヒスパニック人＝0）

モデル２

$$SM(kg) = 0.244 \times 体重 + 7.80 \times 身長\ 6.6 \times 性 - 0.098 \times 年齢 + 人種 - 3.3 \quad [R^2 = 0.86,\ SEE = 2.8\ kg] \cdots\cdots (2\text{-}2)$$

（性：男性＝1，女性＝0）（人種：アジア人＝−1.2，アフリカアメリカ人＝1.4，白人・ヒスパニック人＝0）

これらは，全身の骨格筋量を推定する式であり，推定式より求めた筋肉量に基づいたサルコ

表1　性・年齢・人種別にみたサルコペニアの有症率（文献4より引用）

年齢群（歳）	男性		女性	
	ヒスパニック (n=221)	白人 (n=205)	ヒスパニック (n=209)	白人 (n=173)
＜70	16.9	13.5	24.1	23.1
70～74	18.3	19.8	35.1	33.3
75～80	36.4	26.7	35.3	35.9
80＜	57.6	52.6	60.0	43.2

ペニア判定の試みはなかった．しかし，Baumgartner ら[4]は，1993～1995年に地域在住高齢男女808名（男性426名，女性382名）のDXA法より求めた四肢の骨格筋量(appendicular skeletal muscle mass：ASM）を，次の式より推定し，「ASM（kg)/身長^2（m^2)」の値が，18～40歳の健康成人の平均値の2SD以下をサルコペニアと定義している．

$$\text{ASM(kg)} = 0.248(\text{体重}) + 0.0483(\text{身長}) - 0.1584(\text{臀部囲}) + 0.0732(\text{握力}) + 2.5843(\text{性}) + 5.8828$$
$$[R^2=0.91,\ \text{SEE}=1.58\ \text{kg}] \cdots\cdots\cdots (3)$$

この式より求めたサルコペニアのカットオフ値は，男性7.26 kg/m^2，女性5.45 kg/m^{2}と設定し，有症率を調べたところ（表1），70歳以下の高齢者で13.5～24.1％の範囲であるが，80歳以上になると43.2～60.0％に高まるとともにdisabilityと密接に関連することを報告している．

Tanko ら[8]は，18～85歳の女性754名を対象とした研究において，DXA法より求めた18～39歳の健康な女性216名のASM(kg)/Ht^2(m^2)を基準値（6.8±0.7 kg）に用いている．この基準値の2SD以下をサルコペニアと定義した時のカットオフ値は，ASM=5.4 kg/m^{2}であり，ASMを推定する式を提案している．

$$\text{ASM} = -13.3 - 0.005(\text{年齢, 歳}) + 0.11(\text{体重, kg}) + 16.1(\text{身長, m})$$
$$[\text{SEE}=1.7\ \text{kg},\ R^2=0.76] \cdots\cdots\cdots\cdots (4)$$

この式に基づく有症率は，40～49歳で3.3％，50～59歳で3.8％と低いものの，60～69歳で9.4％，70歳以上で12.3％と上昇することを報告している[6]．

2）生体電気インピーダンス法（bioelectrical impedance analysis：BIA）による推定

ヒトの身体組成を，安全かつ迅速に測定できるBIA法については，多くの研究者によってその妥当性が検証されていることから，多人数を対象にする疫学研究で汎用されている手法である．BIA法をサルコペニア判定に適用するために，Janssen ら[9]は，18～86歳の男女388名を対象に，MRI法により求めた骨格筋量（SM）を妥当基準として，BIA法に基づく骨格筋量の推定式を提案している．

$$\text{SM mass(kg)} = (\text{身長}^2/R \times 0.401) + (\text{性} \times 3.825) + (\text{年齢} \times -0.071) + 5.102$$
$$[R^2=0.86,\ \text{SE}=2.7\ \text{kg}\ (9\%)] \cdots\cdots\cdots (5)$$

身長=cm, R=BIAレジスタンス(ohms), 性(男性=1，女性=0)，年齢=歳．

さらに，この式より求めたSMと生活機能障害との関連性を検討しており，障害発生のハイリスクカットオフ値は，男性8.50 kg/m^{2}以下（オッズ比4.71），女性5.75 kg/m^{2}以下（オッズ比3.31）と提案している[10]．

一方，Chien ら[11]は，Janssen らの式を台湾在住の高齢者に適応して，18～40歳の基準値は，

表 2　サルコペニア選定に用いた骨格筋量のカットオフ値

研究者	基準	男性	女性
Baumgartner, et al（1998）[4]	ASM/Ht^2，若年値の 2 SD 以下	7.26	5.45
Tanko, et al（2002）[8]	ASM/Ht^2，若年値の 2 SD 以下	*	5.40
Chien, et al（2008）[11]	SMI，若年値の 2 SD 以下	8.87	6.42
Janssen, et al（2000）[9]	SMI	8.50	5.75

ASM（kg）: appendicular skeletal muscle mass estimated by DXA，SM（kg）: skeletal muscle mass estimated by BIA，
SMI : SM/Ht^2，Ht : height

男性 10.87±1.00 kg/m^2，女性 7.88±0.73 kg/m^2 であることを示した．この基準値の 2 SD 以下をサルコペニアと定義し，男性 8.87 kg/m^2，女性 6.42 kg/m^{2}をカットオフ値と設定している．この基準によるサルコペニア有症率は，65 歳以上の男性 23.6%，女性 18.6% と報告している．

以上で紹介した地域高齢者の骨格筋量を推定する間接法は，周囲，皮下脂肪厚，身長，握力，BIA 法による抵抗値など簡単な測定値を利用すれば，骨格筋量の推定が可能な式である．

しかし，これらの式の採用に当たっては，杖使用者，車椅子使用者，変形性膝関節炎患者，あるいは脊柱彎曲を有する虚弱高齢者の形態を正確に測定できているかの問題がある．さらに，サルコペニアを判定するためのカットオフ値は研究者によって異なり，採用する定義によって有症率が異なる点を十分考慮すべきである（表 2）．すなわち，地域高齢者におけるサルコペニア発見は容易なことではないという認識が必要である．

2．介入の組み立て方

サルコペニア対処法を構築するためには，サルコペニアの問題点，危険因子，サルコペニア高齢者の特性，取り組みの効果の把握が必要である．

1）サルコペニアの問題点と関連要因

サルコペニアには，性，年齢，身長，体重，BMI，膝の高さ，テストステロン，脂肪量，身体活動，ビタミン D など様々な要因が複雑に関わっていることが多くの研究で指摘されている[12]．サルコペニア予防策を構築するためには，多くの危険因子の中で，可変因子の改善を目的とした取り組みが有効である．Fiatarone ら[13]は，骨格筋の不使用と低栄養の改善に焦点を当てた介入が有効であると提案している．なぜならば，不活動が生理機能に及ぼす影響についてはベッドレスト実験でよく知られており，6〜7 週間ベッドで安静をとらせると，筋中に多く含まれている窒素，カリウムの排泄量が増加し，筋の成分が臥床中に失われること，また，臥床中は特に下肢の筋力低下が著しく起こり，足関節背屈力は 13.3%，足関節低屈力は 20.8% 低下するとともに，大腿囲および下腿囲が減少することを検証している[14]．反対に，虚弱高齢者でも筋力強化運動を実践すれば，筋力や歩行機能の改善効果が得られると報告している[15]．

一方，骨格筋量減少と栄養との関連性についても様々な角度から分析され，特に骨格筋蛋白質の分解量が合成量を上回ることによって，徐々に骨格筋量が減少するのである．したがって，骨格筋蛋白質の合成を促進するか，分解を抑制することにより，合成量が分解量を上回る

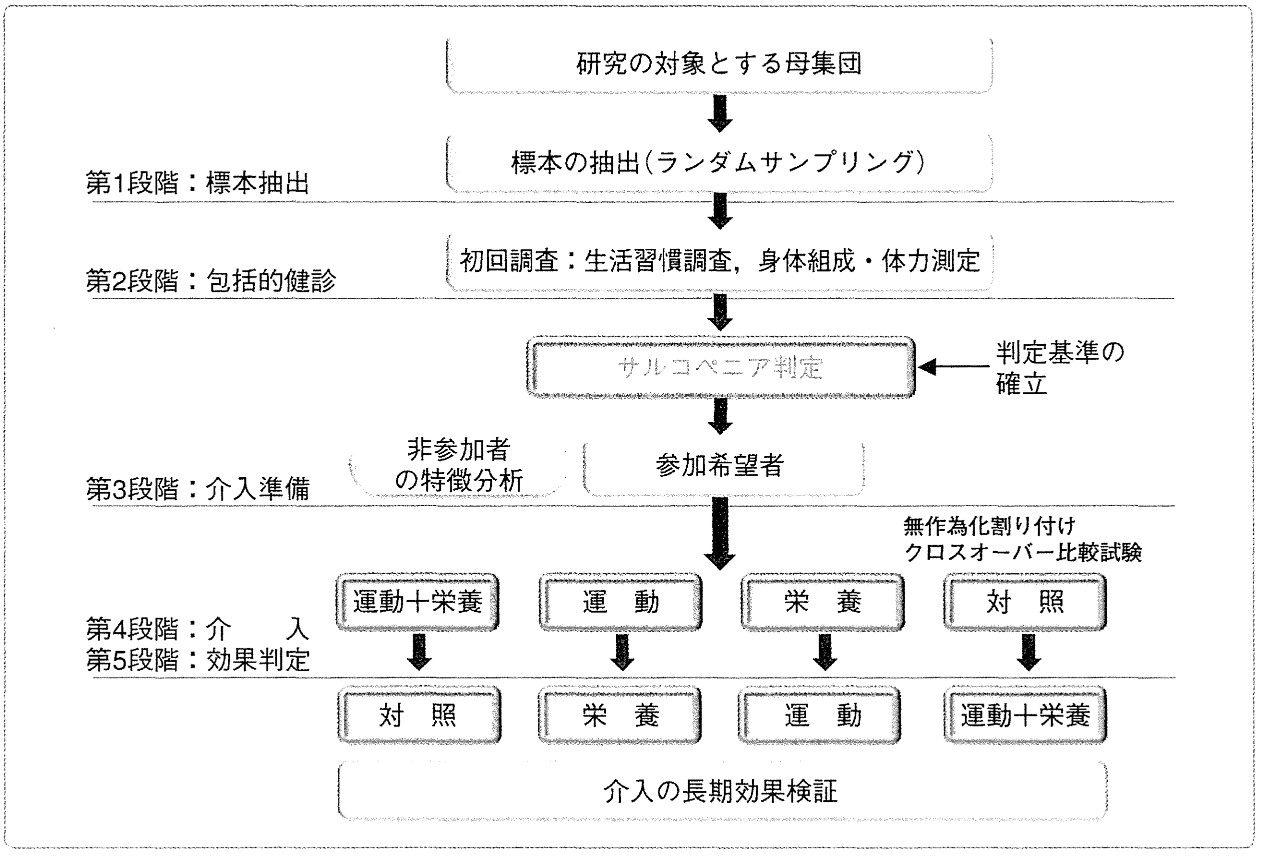

図 2　大規模集団を用いた対処の構築手順

状態にできれば，筋量の減少を食い止める有効な対策となる．これらの背景に基づき，アミノ酸投与が骨格筋蛋白質代謝に与える影響について多く検討されている[16]．

2）対処の構築方法

対処が必要となった集団や個人に対し，介入実施の第一歩は，まず倫理委員会の承諾を得た上で，対象となり得る条件を持っている人に対し，対処の趣旨，目的，方法などの概略を説明し，対処への協力を依頼し，参加承諾を得ることである．

地域在住サルコペニア高齢者に対する対処法を確立するためには，概ね 5 段階の手続きが要求される．対処の標準的な手順を図 2 に示す．

①第 1 段階：無作為標本抽出

i ）地域在住高齢者におけるサルコペニア有症率を検討するためには，悉皆調査がベストである．しかし，悉皆調査が不可能な大規模集団については，住民基本台帳などに基づく標本代表性を維持するため，性・年齢層化無作為標本抽出を推奨する．

ii ）抽出された標本に対して，調査研究への協力を要請する．参加承諾を得るためには，調査の趣旨，目的，方法などを詳細に説明し，参加意欲を高める．

②第 2 段階：初回調査準備および実施

i ）初回調査参加者を確定する．

ii ）調査日数，スタッフ確保および事前訓練，調査項目，調査場所を確定する．

iii ）調査実施，緊急発生時の対応マニュアルなどを用意する．

iv ）調査結果の使用についての同意を得る．

③第 3 段階：介入準備

i ）サルコペニア選定基準に基づき，サルコ

表 3　サルコペニア群と正常群の調査項目の比較（文献 17 より引用）

項　目	サルコペニア群	正常群	p 値
年　齢（歳）	79.49±2.93	78.51±2.77	<0.001
下腿三頭筋周囲（cm）	30.17±2.03	33.92±2.60	<0.001
BMI（kg/m^2）	18.98±2.01	23.74±2.84	<0.001
筋肉量（kg）	26.92±2.61	31.73±3.16	<0.001
健康度自己評価，健康（%）	75.7	85.8	<0.001
外出頻度，少ない（%）	4.6	2.5	0.051
運動習慣，有（%）	27.3	33.5	0.039
既往歴：有（%）			
高血圧	51.0	58.0	0.029
高脂血症	32.2	40.5	0.009
貧血症	4.6	2.2	0.022
骨粗鬆症	38.2	30.7	0.014
骨　折	28.6	22.9	0.038

ペニア高齢者を選定する．

ii）介入期間，頻度，時間，プログラムの内容を確定し，介入参加者を募集する．

iii）介入参加希望者を対象に説明会を開催し，プログラムの内容を具体的に説明する．介入最終参加者を決め，介入参加への同意を得る．

iv）無作為割付けにより群分けをする．群配置による不利益が生じないように crossover モデルを採用する．不参加者の特性把握および不参加者に対する支援策を考える．

v）outcome measure を決める．

④第 4 段階：介　入

i）導　入：柔軟体操を中心とした軽い運動の指導によって，運動に慣れ，身体を動かす楽しさを感じ，運動に対する動機づけを高めることができる．個々人の特徴を把握し，無理のない範囲で指導する．

ii）展　開：筋力強化運動，各種器具（バンド，ダンベル，アンクルウエイト，ボール）を活用する指導を行い，運動幅を拡げる．

iii）定　着：運動の効果を意識し，習慣化を図る，目標到達度を自己評価する．

⑤第 5 段階：効果判定

i）短期効果判定および結果返却：体組成，身体機能，意識，老年症候群の変化について検討し，結果を返却する．

ii）長期効果判定：追跡期間の設定（3 カ月，6 カ月，1 年，2 年）および最終アウトカムについて評価する．

3）効果検証

加齢に伴って低下した筋肉量や筋力を回復させるためには，筋力強化運動が有効であることは多くの研究で指摘されている．一方，アミノ酸投与によって，筋蛋白質合成能力が促進される可能性も示唆されている．これらの研究を踏まえて，筆者らは，サルコペニアを単なる骨格筋量の減少という解釈にとどめず，骨格筋量の減少に伴う身体機能の低下，体格までも考慮し

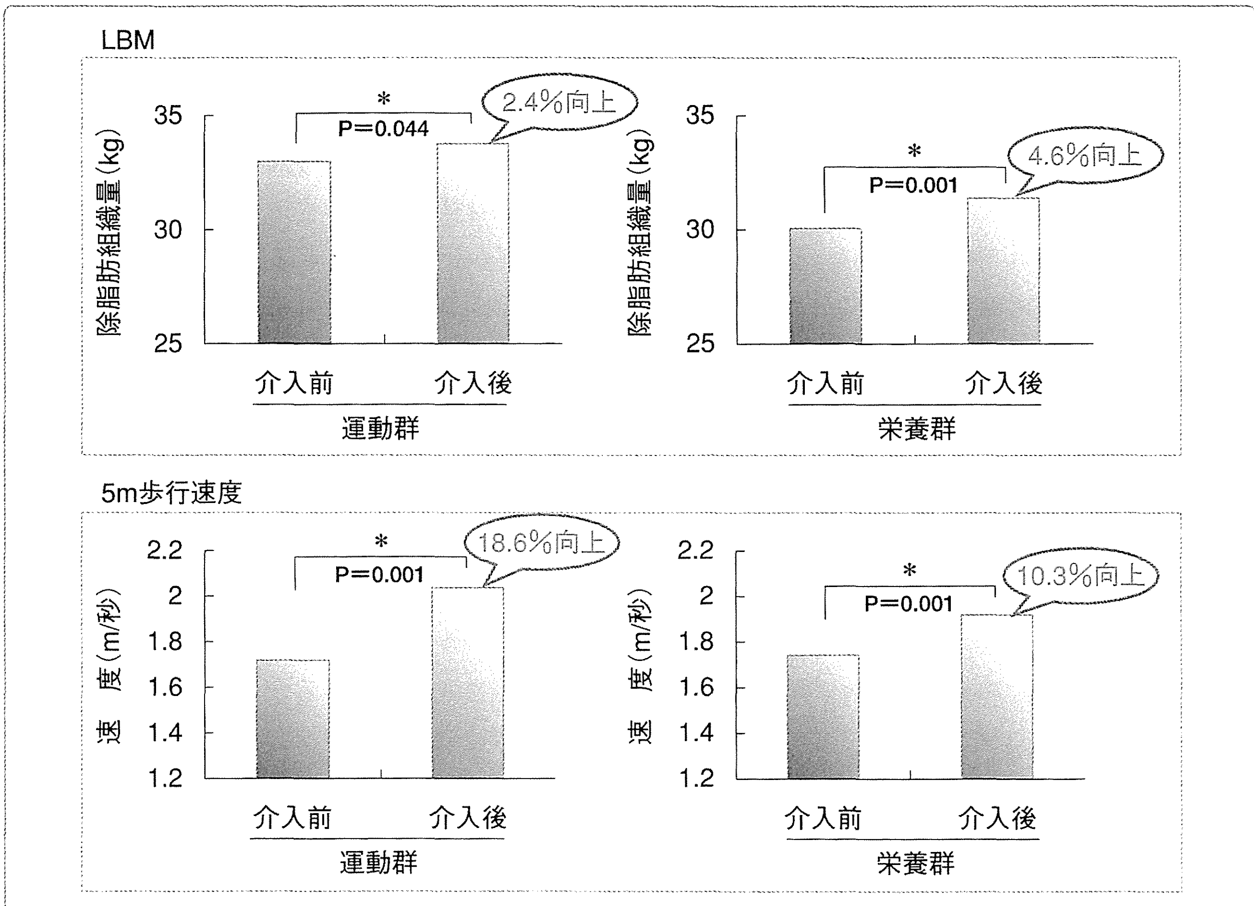

図3　3カ月間の介入がLBMおよび歩行速度に及ぼす影響

た概念を導入することが妥当であると判断した．この判断に基づき，大都市部在住75歳以上の後期高齢女性1,399名を対象に包括的健診を実施し，「骨格筋量の減少」，「BMIの低下」，「筋力あるいは歩行機能の低下」3つの基準に該当する場合をサルコペニアと定義し，該当者304名（21.7%）を抽出し，対処法を構築した事例を紹介する．

① サルコペニア高齢者の特徴

サルコペニアと判定された304名と，サルコペニアと判定されなかった正常者1,095名の調査項目を比較したところ（表3），サルコペニア群は正常群に比べて，年齢が高く，下腿三頭筋周囲，BMI，筋肉量が有意に低値を示し，高年齢の痩せ型で筋肉量が少ない者は，サルコペニアの可能性が高まることが示唆された．聞き取り調査項目においては，健康度自己評価，定期的な運動習慣を持っている者の割合は低く，外出頻度が少ない者の割合は高かった．一方，既往歴においては，貧血症，骨粗鬆症，骨折歴は有意に高い割合を示したが，高血圧症，高脂血症は正常群より低い割合を示している[17]．以上のことから，サルコペニアと判定された高齢者は活動量が少なく，自分の健康に対する自信感を喪失している者が多く，骨粗鬆症に伴う骨折危険性の上昇が示唆された．

② 取組みの実際と効果

サルコペニアと判定された304名について，「サルコペニア改善介入参加者」を募集し，参加希望者をRCTにより運動群と栄養群に分けた．運動群には週2回，1回当たり60分間の筋力強化と歩行機能の改善を目的とした包括的運動を，栄養群はロイシン高配合のアミノ酸3gを1日2回補充する指導を，3カ月間実施した．介入

前後における身体組成，体力，老年症候群の改善の度合いを検討した．その結果，LBM は運動群で 2.4%，栄養群で 4.6% の有意な向上が観察された（図 3）．歩行速度は，運動群で 18.6%，栄養群で 10.3% の顕著な向上が確認され（図 3），地域在住サルコペニアの改善には，運動のみならずアミノ酸補充も有効であることが示唆された．しかし，サルコペニア高齢者に多く観察される尿失禁は，運動群で 38.9% から 19.4%（P=0.021）と有意に改善されたが，栄養群では有意な改善がみられなかった[18]．以上のことから，サルコペニア高齢者の LBM あるいは体力の改善を目的とした場合には，運動指導あるいは栄養補充の両方とも有効な手法であるが，サルコペニア高齢者に有症率の高い老年症候群の改善には，運動介入の効果が優れる可能性が示唆された．

おわりに

骨格筋量の減少に伴う筋力の衰えを意味するサルコペニアは，後期高齢者において有症率が上昇し，身体機能の障害や死亡と強く関連していることが指摘されている．サルコペニアと関連する要因は様々で複雑であるが，不活動や栄養など可変要因の改善に焦点を当てた予防策の効果を検討したところ，骨格筋量の増加，体力の向上には，運動指導，栄養指導ともに有効であった．しかし，サルコペニア高齢者に多くみられる老年症候群の解消には，運動指導がより有効であることが示唆された．

近年，サルコペニア高齢者を対象とした介入成果は報告されつつあるが，十分とはいえず，今後の研究成果に期待を寄せる．

文　献

1）金　憲経，田中喜代次，天貝　均，他：身体組成の加齢に伴う変化：DXA 法による検討．体育研 44：500-509，1999

2）Rossenberg IH：Summary comments. Am J Clin Nutr 50：1231-1233, 1989

3）Cawthon PM, Marshall LM, Michael Y, et al：Frailty in older men：Prevalence, progression, and relationship with mortality. J Am Geriatr Soc 55：1216-1223, 2007

4）Baumgartner RN, Koehler KM, Gallagher D, et al：Epidemiology of sarcopenia among the elderly in New Mexico. Am J Epidemiol 147：755-763, 1998

5）Matiegka J：The test of physical efficiency. Am J Phys Anthropol 4：223-230, 1921

6）Martin AD, Spenst LF, Drinkwater DT, et al：Anthropometric estimate of muscle mass in men. Med Sci Sports Med 22：729-733, 1990

7）Lee RC, Wang Z, Heo M, et al：Total-body skeletal muscle mass：Development and cross-validation of anthropometric prediction domels. Am J Clin Nutr 72：796-803, 2000

8）Tanko LB, Movsesyan L, Mouritzen U, et al：Appendicular lean tissue mass and prevalence of sarcopenia among healthy women. Metabolism 51：69-74, 2002

9）Janssen I, Heymsfield SB, Baumgartner RN, et al：Estimation of skeletal muscle mass by bioelectrical impedance analysis. J Appl Physiol 89：465-471, 2000

10）Janssen I, Baumgartner RN, Ross R, et al：Skeletal muscle cutpoints associated with elevated physical disability risk in older men and women. Am J Epidemiol 159：413-421, 2004

11）Chien MY, Huang TY, Wu YT：Prevalence of sarcopenia estimated using a

bioelectrical impedance analysis prediction equation in community-dwelling elderly people in Taiwan. J Am Geriatr Soc 56：1710-1715, 2008
12) Iannuzzi-Sucich M, Prestwood KM, Kenny AM：Prevalence of sarcopenia and predictors of skeletal muscle mass in healthy, older men and women. J Gerontol A Biol Sci Med Sci 57：M772-M777, 2002
13) Fiatarone MA, O'Neill EF, Ryan ND, et al：Exercise training and nutritional supplementation for physical frailty in very elderly people. N Engl J Med 330：1769-1775, 1994
14) Deitrick JE, Whedon GD, Shorr E：Effects of immobilization upon various metabolic and physiologic functions of normal men. Am J Med 4：3-36, 1948
15) Borst SE：Interventions for sarcopenia and muscle weakness in older people. Age ageing 33：548-555, 2004
16) Katsanos CS, Kobayashi H, Sheffield-Moore M, et al：A high proportion of leucine is required for optimal stimulation of the rate of muscle protein synthesis by essential amino acids in the elderly. Am J Physiol Endocrinol Metab 291：E381-E387, 2006
17) 金　憲経，吉田英世：高齢者におけるサルコペニア発生の現状と関連要因．Geriat Med 48：191-195，2010
18) Kim H, Yoshida H, Saito K, et al：Effects of exercise and amino acid supplementation on body composition and physical function in community-dwelling Japanese sarcopenic women：A randomized controlled trial. J Am Geriatr Soc 58：S100, 2010

［金　憲経/吉田英世］

International Journal of Nursing Studies 48 (2011) 1165–1172

Contents lists available at ScienceDirect

International Journal of Nursing Studies

journal homepage: www.elsevier.com/ijns

The effects of multidimensional exercise treatment on community-dwelling elderly Japanese women with stress, urge, and mixed urinary incontinence: A randomized controlled trial

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ARTICLE INFO

Article history:
Received 1 October 2010
Received in revised form 16 December 2010
Accepted 18 February 2011

Keywords:
Cure
Elderly women
Multidimensional exercise
Pelvic muscle exercises
Urinary incontinence

ABSTRACT

Background: Urinary incontinence is one of the most prevalent health problems and a significant cause of disability and dependence in the elderly. Pelvic floor exercise is effective in reducing stress urinary incontinence, but few studies have investigated the effect of behavioral management on urge and mixed incontinence.
Objectives: To determine the effects of multidimensional exercise treatment on reducing urine leakage in elderly Japanese women with stress, urge, and mixed urinary incontinence.
Design: Randomized controlled, follow-up trial.
Settings: Urban community-based study.
Participants: 127 community-dwelling women aged 70 and older with stress, urge, and mixed urinary incontinence were randomly assigned to the intervention ($n = 63$) or the control group ($n = 64$).
Methods: Urine leakage and fitness data were collected at baseline, and after the intervention and follow-up. The intervention group received a multidimensional exercise treatment twice a week for 3-month. After treatment, the participants were followed for 7-month.
Results: There were significant differences in changes of functional fitness and incontinence variables between the intervention and control groups. The intervention group showed urine leakage cure rates of 44.1% after treatment and 39.3% after follow-up ($\chi^2 = 21.96$, $p < 0.001$); whereas, the control group showed no significant improvement. The multidimensional exercise treatment was significantly effective in decreasing all three types of urinary incontinence. However, the effects of the exercise treatment were greater on stress urinary incontinence than on urge or mixed urinary incontinence. At the 7-month follow-up, while cure rates of all three types of urinary incontinence were significantly maintained, a slight reversal was seen only in the urge and mixed urinary incontinence ($\chi^2 = 10.28$, $p = 0.008$). According to the logistic regression model, urine leakage volume (adjusted odds ratio OR = 0.69, 95% confidence interval CI = 0.39–0.98), compliance (OR = 1.03, 95%CI = 1.01–1.16), and BMI reduction (OR = 0.67, 95%CI = 0.48–0.89) were significantly associated with the cure of urine leakage after intervention. The cure rate of urine leakage after the follow-up was significantly associated with compliance (OR = 1.13, 95%CI = 1.02–1.29) and BMI reduction (OR = 0.78, 95%CI = 0.60–0.96).
Conclusions: The intervention group showed higher urine leakage cure rates than control group. This result suggests that multidimensional exercise strategies may be effective for all three types of urinary incontinence. BMI reduction and compliance to the intervention was the consistent predictor for the effectiveness of the exercise treatment.

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0020-7489/$ – see front matter
doi:10.1016/j.ijnurstu.2011.02.016

What is already known about the topic?

- Several factors such as overweightness, high body mass index, and increased abdominal fat have been associated with higher risk of urinary incontinence.
- Behavioral management is effective in the treatment of stress urinary incontinence and is therefore recommended as a first-line therapy.
- Compliance has a positive influence on the effects of the exercise treatment.

What this paper adds

- Multidimensional exercise treatment targeting pelvic floor muscles and abdominal fat and/or BMI reduction are equally effective in reducing stress, urge, and mixed urinary incontinence after the intervention and follow-up.
- BMI reduction as well as compliance to the prescribed exercise regimen was the most consistently significant predictors of the short- and long-term effectiveness to the behavioral therapy.
- Multidimensional exercise treatment should be considered for the elderly as a strategy for reducing incontinence and improving functional capacity.

1. Introduction

Urinary incontinence (UI) in elderly people is a common condition that contributes greatly to the loss of independence, decrease in quality of life, restriction of social activities, and increase in risk for hospitalization or long-term care. The estimated prevalence of UI ranged from 17 to 55% depending on the definition of UI, the population characteristics, and the methodological approach (Thom, 1998). A number of methods are used to treat or deal with UI. Pelvic floor muscle (PFM) exercise, devised by Kegel (1948), is recommended as a first line of treatment in the management of stress UI and many investigators have validated the short- and long-term effects on stress UI (Cammu and Van Nylen, 1995; Goode et al., 2003; Kim et al., 2007). PFM exercise is hypothesized to enhance urethral resistance by increasing the strength and endurance of the periurethral and perivaginal muscles and by improving the anatomic support given to the bladder neck and proximal urethra (Kegel, 1951; Bo et al., 1999). One previous study found that PFM exercise reduces urine leakage in urge and mixed UI because of inhibition of the bladder reflex associated with PFM contraction; however, this study had no control group (Nygaard et al., 1996).

Several studies have reported that obesity and high BMI are associated with UI (Bump et al., 1992; Brown et al., 1999). One study reported objective and subjective resolution of stress and urge UI after surgically inducing weight loss in morbidly obese women (Bump et al., 1992). These results suggest that weight reduction is desirable for UI treatment (Subak et al., 2005; Auwad et al., 2008; Wing et al., 2010). We hypothesized that fitness exercises focused on strengthening the abdominal muscles would reduce abdominal fat and/or BMI, and thereby reduce abdominal wall pressure, intravesicular pressure, and the risk of UI in elderly women.

We conducted a randomized controlled trial to measure the effects of a multidimensional exercise treatment (FPM and fitness exercises) on urine leakage episodes in community-dwelling elderly Japanese women with stress, urge, and mixed UI, and to identify the factors that influence the effectiveness of the trial.

2. Methods

2.1. Subjects

The subjects in this study were randomly selected from the Basic Resident Register of 5935 women aged 70 and older that resided in the Itabashi ward (district) of Tokyo as of April 1, 2006. Information about the study was mailed to potential subjects. The baseline survey was conducted in November 2006, and 957 (16.1%) women participated. Out of the participants, 416 (43.5%) were experiencing some urinary incontinence, and 194 (46.6%) were classified as experiencing urine leakage more than once a week.

The inclusion criteria were: (1) suffering from urge, stress, or mixed UI; (2) being ≥70 years old; (3) having urine leakage episodes more than once a week; and (4) completing a 1-week urinary diary. The exclusion criteria included (1) an unclear UI type; (2) having urine leakage episodes less than once a week; (3) not completing the 1-week urinary diary; (4) impaired cognition (a Mini-Mental State Examination score of <24) (Folstein et al., 1975; McDowell et al., 1999) and (5) unstable cardiac conditions such as ventricular dysrhythmias, pulmonary edema, or other musculoskeletal conditions. Sixty seven (34.5%) of the potential participants were excluded because they were classified into one or more of the exclusion criteria. The study protocol was approved by the Clinical Research Ethics Committee of Tokyo Metropolitan Institute of Gerontology (TMIG). The procedures were fully explained to all participants, and written informed consent was obtained (Fig. 1).

2.2. Randomization

Randomization was performed after the baseline assessment and completion of the 1-week urinary diary, and any variable that identified personal information was not included in the randomization process. The assigned identification numbers of 127 participants (stress = 37, urge = 47, and mixed = 43) were divided into two groups based on the computer-generated random numbers. One group was randomly assigned to the intervention group ($n = 63$), and the other to the control group ($n = 64$). There was no attempt to equalize the size of the groups based on their characteristics or to recruit subjects with specific characteristics. The randomization procedure was blinded, and the investigators that evaluated the effects of the exercise treatment were blind to the allocation of interventions.

2.3. Outcome measures

The primary outcome of this trial was the cure rate of urine leakage episodes, which was assessed by the self-

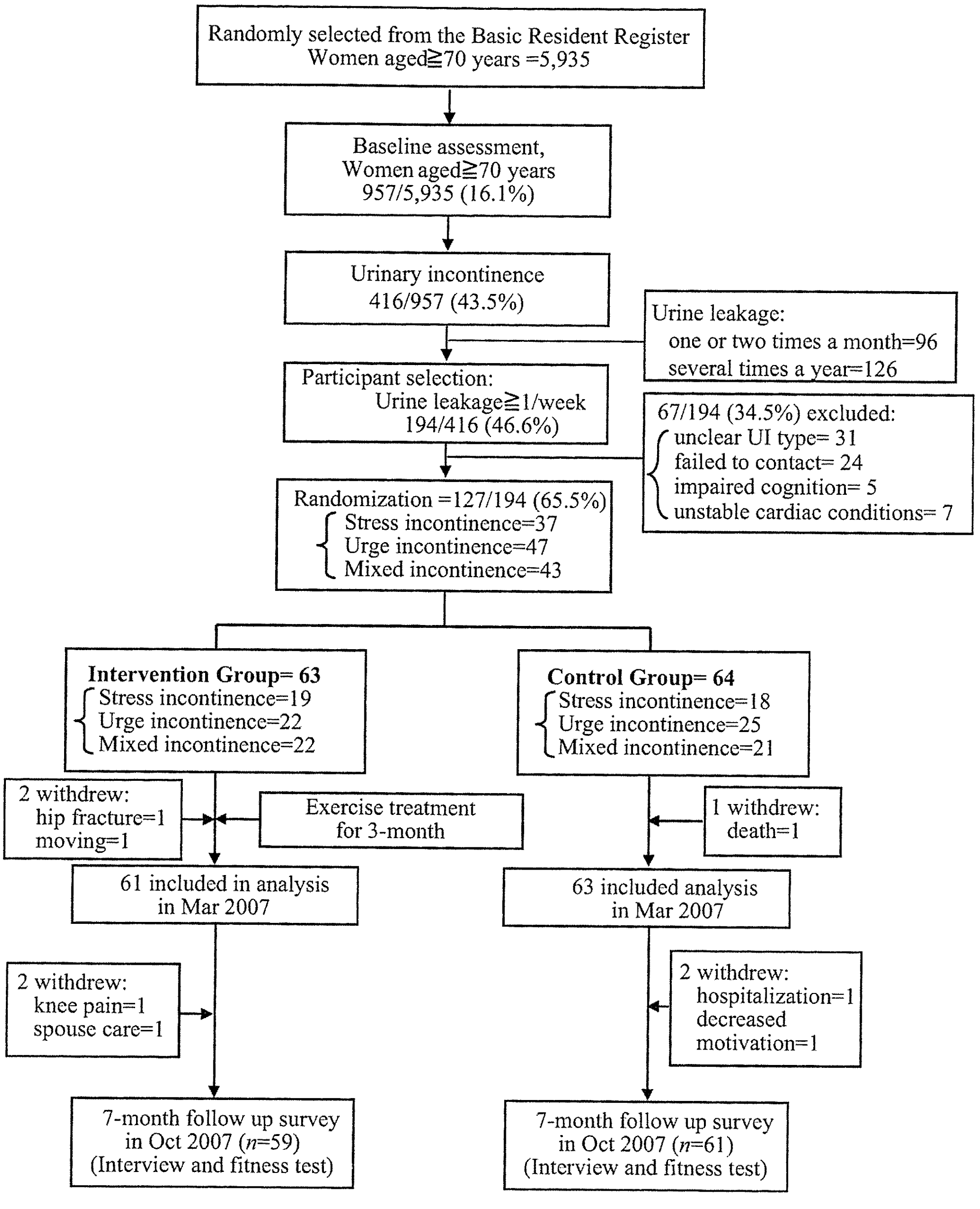

Fig. 1. Flow of the participants through the randomized controlled trial of exercise treatment and analyses.

reported urinary diary data (Wyman et al., 1988; Locher et al., 2001). The effects of the exercise treatment on urine leakage episodes were assessed based on the changes in the 5-point scale (1 = no urine leakage, 2 = less than once a week, 3 = once a week, 4 = two or three times a week, and 5 = everyday) recorded in the 1-week urinary diary, which was obtained pretreatment, after the 3-month exercise and 7-month follow-up. Complete cessation of urine leakage episodes was defined as cured.

2.3.1. Interview survey and urinary diary

A face-to face interview was conducted to assess temporary UI conditions based on the modified International Consultation on Incontinence Questionnaire (ICIQ) (Avery et al., 2004). The ICIQ was easily completed with low levels of missing data (mean 1.6%), good construct validity, and acceptable convergent validity. Reliability was good with moderate to very good stability in test-retest analysis and a Cronbach's alpha of 0.95 (Avery et al., 2004; Gotoh et al., 2009). The first question was "Have you experienced urine leakage during the previous year?" If the person responded that urine leakage episodes occurred more than once a week, to confirm the pretreatment frequency of urine leakage episodes, potential subjects were provided with a 1-week urinary diary. The subjects documented the time of every void and urine leakage episode, as well as the amount and circumstance of each episode. To confirm the changes of frequency, the urine leakage scores were calculated based on the self-reported 1-week urinary diary as follows: 0 = no urine leakage, 1 = less than once a week, 2 = once a week, 3 = two or three times a week, and 4 = every day.

UI type was classified based on inquiries about urine leakage in relation to 8 possible antecedents (Avery et al., 2004). Stress UI was recorded when urine leakage was associated with increased abdominal pressure such as coughing, sneezing, or participating in some other physical activity. Urge UI was recorded when urine leakage was reported to be associated with running water or an urge to void and not being able to reach the toilet in time. When the characteristics of both stress and urge UI types were present, it was defined as mixed UI.

The subjects were asked about the onset age and duration of UI, frequency of daytime and nighttime voiding, and chronic medical conditions.

2.3.2. Functional fitness test

Measurements of height and body weight were converted to body mass index (BMI, kg/m^2), waist circumference, and fitness test variables including grip strength, usual and maximum walking speed, and seated hip adductor muscle strength. The procedures for the fitness tests have been described in detail in a previous report (Kim et al., 2007).

2.4. Intervention

2.4.1. Intervention group

The participants attended an exercise treatment session 2 times a week for 3-months at the TMIG health promotion classes. The protocols of the PFM and fitness exercises have been published previously (Kim et al., 2007). The following exercises were performed by the participants.

2.4.2. Stretching exercise

Before the PFM exercise and muscle strengthening training, the participants performed 5–10 min of warm-up and stretching exercises, including shoulder rotation, waist rotation, and others.

2.4.3. PFM exercises

The subjects were trained to exert force only on the PFM without excessively straining the abdomen. The exercise regimen was designed to strengthen the fast- and slow-twitch muscle fibers located on the pelvic floor. The participants were initially instructed to perform 10 fast contractions (3 s) with a 5-s relaxation and 10 sustained contractions (8–10 s) with a 10-s relaxation between the contractions. The PFM exercise was performed in the sitting, lying, and standing positions with the legs apart, while emphasizing contraction of the PFM and relaxation of the other muscles.

2.4.4. Fitness exercises

Strength training of the thigh and abdominal muscles was performed between the PFM exercises. The fitness exercise included: lifting the foot (or both feet) and pointing toes then slowly pulling toes back toward the shin, slowly lifting one knee (or both knees), tilting the pelvis backward and forward, lifting the buttocks while on the back with the knees bent, raising one leg while lying on the back, and others. The ball exercises included actions like sitting on the ball, rolling the ball and the pelvis forward and backward, and moving from side to side, squeezing the thighs, lifting the ball with the legs, and others.

2.4.5. Control group

The control group received general education classes once a month for three months, where participants were educated on cognitive function, osteoporosis, and oral hygiene.

2.5. Follow-up

During the 7-month follow-up period, the participants attended 1-h exercise classes once a month at the TMIG health promotion center. The home-based program consisted of two to three sets of the 13 exercises and the PFM exercises that they had learned during the group exercise sessions. They were encouraged to perform the home-based exercises at least three times per week for approximately 30 min per day. To accurately monitor the exercise times and the number of sets performed during the follow-up period, a pamphlet illustrating the PFM and strengthening exercises and a recording sheet were distributed to the subjects. The subjects were asked to document the time and sets of exercises performed at home each day, the urine leakage episodes, and the amount and circumstances of each episode. The record sheets were collected once a month at the group exercise class and analyzed to calculate the mean exercise frequency per week and the mean exercise time per day. When a participant was absent from an exercise class, we mailed the record sheet to the individual.

2.6. Data analysis

The sample size was calculated to allow detection of a 20.0% reduction in urine leakage episodes between groups with 80% power and a significance level of 0.05 (Burgio et al., 2002).

The mean differences between groups were analyzed using the *t*-test for continuous variables and the chi-square test for categorical variables. To evaluate the differences between the groups in the effects of the intervention on selected continuous variables and urine leakage score at the baseline, after the 3-month exercise, and at the 7-month follow-up, a repeated-measures two-way analysis of variance (ANOVA) was performed. Significant interactions were analyzed to determine whether the effects were greater in the intervention or control group. A repeated-measures one-way ANOVA was also performed to evaluate the within group. A *post hoc* analysis was performed using the Scheffe method. The generalized estimating equation was used to compare the effects between the groups after 3-month exercise and at the 7-month follow-up on the cure rate of UI. The Kruskal–Wallis test was used to evaluate the differences of UI type in the effect of the exercise treatment on urine leakage episodes. The Cochran Q-test was used to evaluate the within-group differences in the effect of the exercise program on urine leakage episodes for baseline, 3-month exercise, and follow-up data.

Multiple logistic regressions were performed to identify variables that were associated with cured urine leakage after 3-month of exercise and at the 7-month follow-up after intervention. All analyses were performed using SPSS software, Windows version 15.0 (SPSS, Inc., Tokyo, Japan).

Table 1
Selected variables characteristics of participants at baseline by study group.

Variables[a]	Intervention group ($n = 63$)	Control group ($n = 64$)	p Value[b]
Age (yr)	76.1 ± 4.3	75.7 ± 4.4	0.625
Height (cm)	148.4 ± 5.8	148.9 ± 6.2	0.639
Body weight (kg)	51.8 ± 8.7	54.0 ± 7.9	0.202
BMI (kg/m^2)	23.4 ± 3.3	24.3 ± 3.0	0.195
Waist circumference (cm)	78.9 ± 10.2	78.5 ± 9.9	0.853
Grip strength (kg)	19.2 ± 4.6	18.6 ± 4.7	0.561
Adductor muscle strength (kg)	20.6 ± 6.9	21.5 ± 4.8	0.502
Usual walking speed (m/s)	1.2 ± 0.3	1.1 ± 0.3	0.282
Maximal walking speed (m/s)	1.7 ± 0.4	1.7 ± 0.4	0.423
Onset age of incontinence (yr)	71.3 ± 7.6	71.0 ± 7.1	0.865
Period of incontinence (year)	4.8 ± 6.4	4.6 ± 6.0	0.890
Frequency of toilet in daytime (times)	7.7 ± 3.1	7.4 ± 2.3	0.525
Frequency of toilet in night (times)	1.9 ± 1.2	1.8 ± 1.3	0.581
Frequence of urine leakage (%)			
Everyday	46.0	50.0	0.714
1 every two days	11.1	7.8	
More than once a week	42.9	42.2	
Amount of urine leakage, large (%)	23.8	32.8	0.210
Chronic medical conditions, yes (%)			
Hypertension	57.1	57.8	0.918
Hyperlipemia	36.5	40.6	0.712
Diabetes	17.5	15.6	0.780

[a] Data are presented as M (mean) and SD (standard deviation) for continuous variables, and percentage for categorical variables. BMI = body mass index.
[b] Two group t-tests for continuous variables and chi-square test for categorical variables.

3. Results

3.1. Subjects characteristics and compliance

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

The attendance rate during the 3-month exercise treatment ranged from 63.5% to 81.1%, with a mean of 70.3%. Seven participants (intervention group = 4, control group = 3) were unable to complete the study after

Table 2
Comparison of functional fitness and incontinence variables between intervention ($n = 59$) and control ($n = 61$) after 3-months of exercises and the 7-month follow-up.

Variables[a]	G[b]	Baseline	3-month exercise	7-month follow-up	ANOVA[c] G × T	p Value
Body Weight (kg)	I	52.0 ± 8.9	51.9 ± 8.8	50.9 ± 8.9	$F = 5.78$	0.018
	C	53.9 ± 8.2	53.9 ± 8.2	53.9 ± 8.1		
BMI (kg/m^2)	I	23.7 ± 3.4	23.5 ± 3.0	23.2 ± 3.1	$F = 11.49$	0.001
	C	24.1 ± 2.9	24.0 ± 2.7	24.4 ± 3.4		
WC (cm)	I	78.8 ± 10.3	77.8 ± 9.7	77.7 ± 9.9	$F = 4.06$	0.041
	C	79.3 ± 10.4	79.2 ± 10.5	78.9 ± 9.6		
UWS (m/s)	I	1.2 ± 0.2	1.2 ± 0.2	1.2 ± 0.2	$F = 2.79$	0.099
	C	1.1 ± 0.3	1.1 ± 0.3	1.1 ± 0.2		
MWS(m/s)	I	1.7 ± 0.4	1.8 ± 0.4	1.8 ± 0.4	$F = 5.10$	0.027
	C	1.7 ± 0.4	1.6 ± 0.3	1.6 ± 0.4		
GS (kg)	I	19.0 ± 4.7	20.7 ± 5.0	19.8 ± 5.7	$F = 0.37$	0.547
	C	19.0 ± 4.2	20.2 ± 3.5	19.5 ± 3.8		
AMS (kg)	I	20.5 ± 7.1	24.1 ± 7.7	24.3 ± 7.9	$F = 11.00$	0.001
	C	21.2 ± 4.8	22.1 ± 4.8	21.8 ± 4.9		
ULS (point)	I	5.0 ± 1.0	3.0 ± 2.0	3.6 ± 2.2	$F = 7.64$	0.007
	C	5.1 ± 1.0	4.4 ± 1.6	4.8 ± 1.6		
Cure of urine leakage	I	0.0	44.1	39.3	21.96	<0.001
	C	0.0	1.6	1.6		
Cure of urine leakage in intervention group	Stress	0.0	63.2[d]	66.7[e]	15.77	<0.001
	Urge	0.0	35.0[d]	26.1[e]	7.49	0.032
	Mixed	0.0	40.1[d]	30.0[e]	9.56	0.016

[a] Data are presented as mean and standard deviation.. WC = waist circumference; UWS = usual walking speed; MWS = maximum walking speed; GS = Grip strength; AMS = adductor muscle strength; ULS = urine leakage score.
[b] G = group, I = intervention group, C = control group.
[c] ANOVA = analysis of variance, T = time. Chi-square and p values are from generalized estimating equation. Conhran's Q-value.
[d] Kruskal–Wallis test: chi-square = 1.99, $p = 0.391$.
[e] Kruskal–Wallis test: chi-square = 10.28, $p = 0.008$. (Scheffe's *post hoc* = stress > urge, mixed urinary incontinence).

randomization due to hip fracture ($n = 1$), moving ($n = 1$), knee pain ($n = 1$), spouse care ($n = 1$), death ($n = 1$), hospitalization ($n = 1$), and decreased motivation ($n = 1$) (Fig. 1). The exercise frequency during the 7-month follow-up period was reported to be every day in 35.7% of the subjects, two to three times a week in 42.9%, and once or less per week in 21.4%. The mean exercise time was 29.3 min, and the mean number of contractions of the PFM was 52 times a day during the 7-month follow-up period.

3.2. Functional fitness and urinary incontinence

The comparison of the effects of the treatment on selected variables between the intervention and control group are summarized in Table 2. A repeated measures ANOVA and generalized estimating equation revealed significant increases in adductor muscle strength ($F = 11.00$, $p = 0.001$) and maximum walking speed ($F = 5.10$, $p = 0.027$) after the 3-month exercise and at the 7-month follow-up in the intervention group compared with the control group. Body weight ($F = 5.80$, $p = 0.018$), BMI ($F = 11.49$, $p = 0.001$), waist circumference ($F = 4.06$, $p = 0.041$), and the urine leakage score ($F = 7.64$, $p = 0.007$) decreased significantly in the intervention group, whereas no significant changes were seen in the control group. The women who reported no urine leakage episodes in their 1-week urinary diaries accounted for 44.1% of the intervention group and 1.6% of the control group after the 3-month exercise treatment, and 39.3% of the intervention group and 1.6% of the control group at the 7-month follow-up ($\chi^2 = 21.96$, $p < 0.001$). After the 3-month exercise, the cure rates of urine leakage increased significantly across the three subgroups of UI. At the 7-month follow-up, although slight decreases were observed in the cure rates of urine leakage related to urge and mixed UI, the cure rates of all three subtypes; stress (Q-value = 15.77, $p < 0.001$), urge (Q-value = 7.49, $p = 0.032$), and mixed (Q-value = 9.56, $p = 0.016$) UI were significantly maintained. However, the efficacy of the exercise treatment on stress UI was greater than the effects on urge or mixed UI after 7-month follow-up ($\chi^2 = 10.28$, $p = 0.008$; *post hoc* = stress > urge, mixed UI).

Before treatment, the urine leakage score was similar between the groups (Fig. 2). However, the urine leakage score significantly decreased after the 3-month exercise treatment and at the 7-month follow-up in the intervention group compared with the control group ($F = 7.22$, $p = 0.009$) (A). The effect of the treatment across the intervention period was assessed for each subgroup of UI (B). At baseline, the urine leakage scores were similar across the three subgroups, although the mixed UI subgroup had a slightly higher score. A repeated measures ANOVA also showed significant subgroup by time interaction ($F = 5.13$, $p = 0.008$). The stress subgroup showed a significant decline in urine leakage score after the 3-month exercise treatment and the 7-month follow-up ($F = 8.23$, $p < 0.001$). The urge ($F = 3.46$, $p = 0.034$) and mixed ($F = 4.10$, $p = 0.019$) subgroups each also showed significant declines in urine leakage scores after the 3-month exercise, although slight reverse patterns of increase were observed at the 7-month follow-up, these changes were not significant.

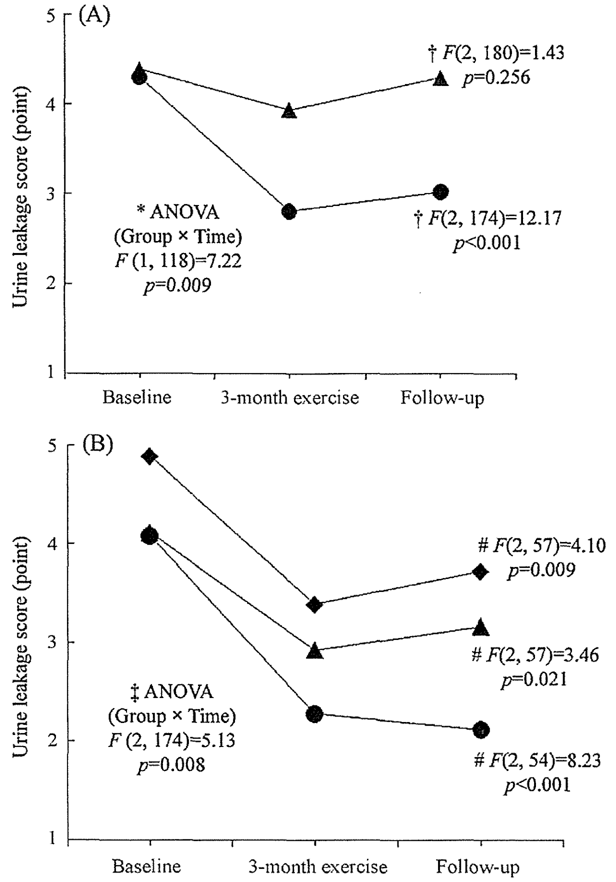

Fig. 2. Changes in the mean urine leakage score on a 5-point scale based on self-reported urinary diaries at the baseline, after 3-months exercise, and at the 7-month follow-up. (A) (●) intervention group; (▲) control group. (*) A comparison of urine leakage scores between the intervention and control groups ($F = 7.22$, $p = 0.009$. (†) A comparison of urine leakage scores at the baseline (b), after 3-months exercise (p), and at the 7-month follow-up (f) within group: intervention group ($F = 12.17$, $p < 0.001$; Scheffe's *post hoc* = b >p, f); control group ($F = 1.43$, $p = 0.256$). (B) (●) Stress incontinence; (▲) urge incontinence; (◆) mixed incontinence. (‡) A comparison of urine leakage scores among stress, urge, and mixed urinary incontinence in the intervention group. # A comparison of urine leakage scores at the baseline (b), after 3-months exercise (p), and at the 7-month follow-up (f) within group: stress incontinence ($F = 8.23$, $p < 0.001$; Scheffe's *post hoc* = b > p, f); urge incontinence ($F = 3.46$, $p = 0.021$; Scheffe's *post hoc* = b > p, f); mixed incontinence ($F = 4.10$, $p = 0.009$; Scheffe's *post-hoc* = b > p, f).

3.3. Predictor variables

As shown in Table 3, the amount of urine leakage (OR = 0.69, 95%CI = 0.39–0.98), compliance to the exercise treatment (OR = 1.03, 95%CI = 1.01–1.16), and BMI reduction (OR = 0.67, 95%CI = 0.48–0.89) were significantly associated with being cured of urine leakage after the 3-month exercise. The cure of urine leakage at the 7-month follow-up was significantly associated with compliance (OR = 1.13, 95%CI = 1.02–1.29) and BMI reduction (OR = 0.78, 95%CI = 0.60–0.96).

4. Discussion

While the ratio of participation by the random population was very low, a baseline of 957 people is an

Table 3
Adjusted OR for cure of urine leakage after intervention and the 7-month follow-up.

Variable	After 3-month exercise			After 7-month follow-up		
	Adjusted OR[a]	95%CI	*p* Value	Adjusted OR[a]	95%CI	*p* Value
Amount of urine leakage	0.69	0.39–0.98	0.049	0.78	0.26–1.88	0.600
Frequency of urine leakage	1.16	0.24–5.79	0.856	1.63	0.73–4.01	0.248
Compliance to exercise	1.03	1.01–1.16	0.048	1.13	1.02–1.29	0.031
Decreased of BMI	0.67	0.48–0.89	0.011	0.78	0.60–0.96	0.028
Increased of walking speed	0.97	0.91–1.04	0.414	0.99	0.94–1.06	0.913
Period of urine leakage	1.01	0.91–1.13	0.919	1.01	0.91–1.14	0.913

[a] Dependent variable; cure of urinary incontinence: 1 = cured, 0 = urine leakage. Independent variables: (a) Amount of urine leakage: large amount, 1 = requiring change of undergarments or soaked outerwear, small amount, 0 = wet undergarments. (b) Frequency of urine leakage: high frequency 1 = every day, low frequency, 0 = less than once every two days. (c) Compliance to exercise: full compliance, 1 = more than 60.0% attendance, partial compliance, 0 = less than 59.9% attendance. OR = odds ratio; CI = confidence interval.

acceptable sample size for analysis of UI in the community-dwelling elderly. Analysis of the efficacy of a 3-month exercise treatment for UI, demonstrated that exercise treatment was equally effective in reducing stress, urge, and mixed UI; although the cure rates of urine leakage were maintained until the 7-month follow-up for all the three types of UI, the efficacy of the treatment was greater for stress UI than urge or mixed UI in the intervention group. However, the changes of UI cure rate were not significant in the control group. These results suggest that improvements in primary outcomes may be observed in an intervention group but such improvements may not be expected in a control group.

PFM exercise is known to be an effective treatment for stress UI (Bo et al., 1990; McDowell et al., 1999; Kim et al., 2007). However, a previous study reported that the mean number of incontinent episodes per day decreased not only stress but also urge and mixed UI, so PFM exercises are equally effective against all three urodynamic conditions, and no urodynamic test is necessary before behavioral treatment (Nygaard et al., 1996). Another study showed that behavioral training achieved comparable improvements in urge UI (Burgio et al., 2002). These previous studies had no control or follow-up data. Recently, one study suggested that decrease in BMI and increase in walking speed may contribute to the decline in stress UI episodes, but they did not examine urge or mixed UI (Kim et al., 2007). In this study no significant relationship between hand grip strength and cure of urinary incontinence was shown. A significant relationship was seen between adductor muscle strength, maximum walking speed and cure of urinary incontinence.

After the 3-month intervention and 7-month follow-up, UI was defined as cured if no urine loss episodes were present in the 1-week urinary diary. Our trial confirmed that exercise treatment involving PFM training and fitness exercises can achieve a 63.2% cure rate in stress UI, a 35.0% in urge UI, and a 40.0% in mixed UI within the intervention group after 3-months of exercise. This exercise treatment had immediate effects in women with UI regardless of their urodynamic diagnosis, and the effects are comparable to those of the previous study. The efficacy of the exercise treatment was greater for stress UI than urge or mixed UI, and although the cure rates of urge and mixed UI showed slight decreasing trends after the 7-month follow up, the decreases were statistically not significant. Our data suggests that exercise treatment is more effective for stress UI than urge or mixed UI, and also raises the possibility that for both urge and mixed UI, a combined behavioral and drug therapy (Burgio et al., 2000) may be more effective than exercise treatment alone. However, this study does not provide an explanation for the slight reversal in the effectiveness of the treatment on urge and mixed UI after the follow up.

Many studies have indicated that BMI (Bump et al., 1992; Brown et al., 1999; Richter et al., 2010) and waist circumference (Krause et al., 2010) are a risk factor for UI, and decrease in BMI may contribute to the decline in stress UI episodes (Kim et al., 2007). Presumably, a decrease in BMI causes a decrease in abdominal-wall weight, decreasing intra-abdominal pressure and intra-vesicular pressure, which may have led to the improvement of stress UI. In this analysis, BMI reduction was significantly associated with the total cure rates of urge, mixed as well as stress UI, but the data does not explore the mechanism of how decreases in BMI improves urge and mixed UI. Also, previous studies have emphasized that compliance to exercise is the key factor to long-term success (Lagro-Janssen, 1998; McDowell et al., 1999). In this study, compliance to the multidimensional exercise treatment was the most significant and consistent predictor of efficacy post-intervention and follow-up. Our findings also support the idea that high compliance and BMI reduction have positive influences on urge, mixed and stress UI treatment. However, the current results were obtained based on a small sample size. The relationships need to be further researched in a population study which would contain a larger number of subjects and for a longer follow-up period.

This study has several limitations. First, the assessments of UI type and urine leakage episodes were self-reported. This could have led to a reporting bias, as subjects with UI may have underreported their symptoms, but a urinary diary is a reliable method for assessing episodes of urine leakage (Wyman et al., 1988; Locher et al., 2001). Thus, this study provided data that was reliable for objective assessment of the behavioral treatment on urinary incontinence. Second, PFM strength, which is likely to have increased through the PFM exercises, was not measured. Therefore, whether the cure rate of urine leakage is correlated with the increase in PFM strength or functional fitness, or the decrease in BMI or abdominal fat could not be explored.

The results suggest that a multidimensional exercise intervention may be equally effective for treatment of stress, urge, and mixed UI. BMI reduction as well as compliance to the prescribed exercise regimen was a significant and consistent predictor of the effectiveness of the behavioral therapy. Thus, multidimensional exercise treatments should be considered for elderly women as part of a strategy for improving functional capacity and UI. Health care for UI patients should undertake a team approach where physical therapists, doctors and nurses work together. Nurses should not only objectively assess the urinary diaries collected, they will play a very important role for the prevention of UI and maintenance of cured UI cases by instructing changes in daily lifestyle among the elderly.

Acknowledgements

H. Kim: study concept and design, subject recruitment, developed the exercise treatment, analysis and interpretation of data, and preparation of manuscript. Y. Hideyo: assisted in the subject recruitment, supervised the survey, and interpretation of data. S. Takao: statistical design and interpretation of data, and revision of manuscript.

This research was supported in part by a Research Grant from the Ministry of Health and Welfare of Japan and a Grant-in-Aid for Scientific Research B from the Japan Society for the Promotion of Science (19300236) and was supported by the Sanitary Products Research Foundation of the KAO Corporation.

Ethical approval: The study protocol was approved by the Clinical Research Ethics Committee of Tokyo Metropolitan Institute of Gerontology. The procedures were fully explained to all participants, and written informed consent was obtained.

Conflict of interest: The authors have no financial or any other kind of personal conflicts with this manuscript.

Sponsor's role: Neither sponsors had any role in the design and conduct of the study, subject recruitment, collection, management, analysis, and interpretation of data or preparation of the manuscript.

References

Auwad, W., Steggles, P., Bombieri, L., Waterfield, M., Wilkin, T., Freeman, R., 2008. Moderate weight loss in obese women with urinary incontinence: a prospective longitudinal study. International Urogynecology Journal and Pelvic Floor Dysfunction 19, 1251–1259.

Avery, K., Donovan, J., Peters, T.J., Shaw, C., Gotoh, M., Abrams, P., 2004. A brief and robust measure for evaluating the symptoms and impact of urinary incontinence. Neurourology and Urodynamics 23, 322–330.

Bo, K., Hagen, R.H., Kvarstein, B., Jorgensen, J., Larsen, S., 1990. Pelvic floor muscle exercise for the treatment of female stress urinary incontinence: III effects of two different degrees of pelvic floor muscle exercises. Neurourology and Urodynamics 9, 489–502.

Bo, K., Talseth, T., Holme, I., 1999. Single blind, randomized controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment in management of genuine stress incontinence in women. British Medical Journal 318, 487–493.

Brown, J.S., Grady, D., Ouslander, J.G., Herzog, A.R., Varner, R.E., Posner, S.F., 1999. Prevalence of urinary incontinence and associated risk factors in postmenopausal women. Obstetrics and Gynecology 94, 66–70.

Bump, R.C., Sugerman, H.J., Fantl, J.A., McClish, D.K., 1992. Obesity and lower urinary tract function in women: effect of surgically induced weight loss. American Journal of Obstetrics and Gynecology 167, 392–399.

Burgio, K.L., Goode, P.S., Locher, J.L., Umlauf, M.G., Roth, D.L., Richter, H.E., Varner, R.E., Lloyd, L.K., 2002. Behavioral training with and without biofeedback in the treatment of urge incontinence in older women: a randomized controlled trial. The Journal of the American Medical Association 288, 2293–2299.

Burgio, K.L., Locher, J.L., Goode, P.S., 2000. Multidimensional behavioral and drug therapy for urge incontinence in older women. Journal of the American Geriatrics Society 48, 370–374.

Cammu, H., Van Nylen, M., 1995. Pelvic floor muscle exercises: 5 years later. Urology 45, 113–117.

Folstein, M.F., Folstein, S.E., McHugh, P.R., 1975. Mini-mental state: a practical method for grading the cognitive state of patients for the clinician. Journal of Psychiatric Research 12, 189–198.

Goode, P.S., Burgio, K.L., Locher, J.L., Roth, D.L., Umlauf, M.G., Richter, H.E., Varner, R.E., Lloyd, L.K., 2003. Effect of behavioral training with or without pelvic floor electrical stimulation on stress incontinence in women: a randomized controlled trial. The Journal of the American Medical Association 290, 345–352.

Gotoh, M., Homma, Y., Funahashi, Y., Matsukawa, Y., Kato, M., 2009. Psychometric validation of the Japanese version of the International Consultation on Incontinence Questionnaire-Short Form. International Journal of Urology 16, 303–306.

Kegel, A.H., 1948. Progressive resistance exercise in the functional restoration of the perineal muscles. American Journal of Obstetrics and Gynecology 56, 238–248.

Kegel, A.H., 1951. Physiologic therapy for urinary stress incontinence. The Journal of the American Medical Association 146, 915–917.

Kim, H., Suzuki, T., Yoshida, Y., Yoshida, H., 2007. Effectiveness of multidimensional exercises for the treatment of stress urinary incontinence in elderly community-dwelling Japanese women: a randomized, controlled, crossover trial. Journal of the American Geriatrics Society 55, 1932–1939.

Krause, M.P, Albert, S.M., Elsangedy, H.M., Krinski, K., Goss, F.L., daSilva, S.G., 2010. Urinary incontinence and waist circumference in older women. Age Ageing 39, 69–73.

Lagro-Janssen, T., Van Weel, C., 1998. Long-term effect of treatment of female incontinence in general practice. British Journal of General Practice 48, 1735–1738.

Locher, J.L., Goode, P.S., Roth, D.L., Worrell, R.L., Burgio, K.L., 2001. Reliability assessment of the bladder diary for urinary incontinence in older women. Journal of Gerontology: Medical Sciences 56A, M32–M35.

McDowell, B.J., Engberg, S., Sereika, S., Donovan, N., Jubeck, M.E., Weber, E., Engberg, R., 1999. Effectiveness of behavioral therapy to treat incontinence in homebound older adults. Journal of the American Geriatrics Society 47, 309–318.

Nygaard, I.E., Kreder, K.J., Lepic, M.M., Fountain, K.A., Rhomberg, A.T., 1996. Efficacy of pelvic floor muscle exercises in women with stress, urge, and mixed urinary incontinence. American Journal of Obstetrics and Gynecology 174, 120–125.

Richter, H.E., Kenton, K., Huang, L., Nygaard, I., Kraus, S., Whitcomb, E., Chai, T.C., Lemack, G., Sirls, L., Dandreo, K.J., Stoddard, A., 2010. The impact of obesity on urinary incontinence symptoms, severity, urodynamic characteristics and quality of life. The Journal of Urology 183, 622–628.

Subak, L.L, Whitcomb, E., Shen, H., Saxton, J., Vittinghoff, E., Brown, J.S., 2005. Weight loss: a novel and effective treatment for urinary incontinence. The Journal of Urology 174, 190–195.

Thom, D., 1998. Variation in estimates of urinary incontinence prevalence in the community: effects of differences in definition, population characteristics, and study type. Journal of the American Geriatrics Society 46, 473–480.

Wing, R.R, Creasman, J.M., West, D.S., Richter, H.E., Myers, D., Burgio, K.L., Franklin, F., Gorin, A.A., Vittinghoff, E., Macer, J., Kusek, J.W., Subak, L.L., 2010. Improving Urinary Incontinence in Overweight and Obese Women Through Modest Weight Loss. Obstetrics and Gynecology 116, 284–292.

Wyman, J.F., Choi, S.C., Harkins, S.W., Wilson, M.S., Fantl, J.A., 1988. The urinary diary in evaluation of incontinent women: a test-retest analysis. Obstetrics and Gynecology 71, 812–817.

Geriatr Gerontol Int 2011; **11:** *452–459*

ORIGINAL ARTICLE: EPIDEMIOLOGY, CLINICAL PRACTICE AND HEALTH

Effects of exercise treatment with or without heat and steam generating sheet on urine loss in community-dwelling Japanese elderly women with urinary incontinence

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Aim: To determine the effects of exercise treatment with or without heat and steam generating sheet (HSGS) on reducing urine loss in community-dwelling elderly women with urinary incontinence (UI).

Methods: One hundred and forty-seven community-dwelling women aged 70 years and older with stress, urge and mixed UI were randomly assigned to exercise + HSGS ($n = 37$), exercise only ($n = 37$), HSGS only ($n = 37$) or an education group ($n = 36$). Exercise + HSGS, and exercise groups received exercise training twice a week for 3 months. When the HSGS was placed on the lower back, the temperature of the skin surface rose to 38–40°C and it continued to generate heat and steam for over 5 h. The HSGS group used one sheet per day continuously for 3 months. Urine loss and fitness data were collected at baseline and after intervention.

Results: The intervention groups showed significant improvements in muscle strength and walking speed compared to the education group. Exercise and HSGS showed urine loss cure rates of 54.1%, exercise 34.3% and HSGS 21.6% after treatment; whereas, the education group (2.9%) showed no significant improvement (χ^2=21.89, $P < 0.001$). Combining the HSGS to the exercise intervention showed a 61.5% cure rate for stress UI, 50.0% urge UI and 40.0% mixed UI.

Conclusion: This data suggests that exercise treatment with HSGS is more effective for treating urine loss regardless of UI type. The HSGS can be used as a supplementary treatment method to enhance the effects of exercise on women with urge, mixed and stress UI. **Geriatr Gerontol Int 2011; 11: 452–459.**

Keywords: elderly women, fitness exercise, heat and steam generating sheet, pelvic floor muscle exercises, urinary incontinence.

Accepted for publication 6 March 2011.

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Introduction

Urinary incontinence (UI) is one of the most prevalent health problems among the elderly population. Several studies have assessed the association of UI with multiple factors, such as smoking, obesity, cognitive impairment,

 doi: 10.1111/j.1447-0594.2011.00705.x

nocturia and poor mobility.[1–3] Currently, a number of methods are used to treat or deal with UI including medication, surgery and behavior management. Behavioral therapy for UI is not a new topic, and several randomized control trials and systematic reviews have confirmed that pelvic floor muscle (PFM) training is an effective treatment for stress UI.[4,5] Even though many studies have validated the effectiveness of these behavioral therapies, reporting improvement rates from 17–84%,[6] such previous studies have focused exclusively on stress UI, and investigations on the effects of behavioral therapies on urge and mixed UI have been relatively limited.[7] Furthermore, several studies have suggested that abdominal and lower back heating may have positive effects on renal function such as renal sympathetic nerve activity suppression, promotion of bladder voiding and increasing frequency of urination.[8–10] Therefore, it can be speculated that heating methods will positively affect renal function.

The purpose of the current study was to investigate the effects of a 3-month exercise and/or heat and steam generating sheet (HSGS) intervention aimed to treat urine loss in community-dwelling women with UI.

Methods

The study population was randomly selected from the Basic Resident Register of 5935 women aged 70 years and older that resided in the Itabashi ward of Tokyo as of 1 April 2006. Information about the comprehensive health check-up was mailed to selected subjects. The recruitment survey was conducted in November 2006, where 957 women participated in baseline testing and 416 of them reported experience of urine loss over several times a year.

The inclusion criteria were: (i) suffering from urge, stress or mixed UI; (ii) being 70 years or older; and (iii) having urine loss episodes more than once a month. The exclusion criteria included: (i) an unclear UI type; (ii) having urine loss episodes less than once a month; (iii) impaired mental health (a Mini-Mental State Examination score of <24);[11,12] and (iv) unstable cardiac conditions such as ventricular dysrhythmias, pulmonary edema or other musculoskeletal conditions. One hundred and twenty-six (30.3%) potential subjects were excluded because they were classified into one or more of the exclusion criteria. The study protocol was approved by the Clinical Research Ethics Committee of Tokyo Metropolitan Institute of Gerontology (TMIG). The procedures were fully explained to all subjects and written informed consent was obtained (Fig. 1).

Randomization

After the baseline assessment, 147 participants (stress = 50, urge = 59 and mixed = 38) were randomly

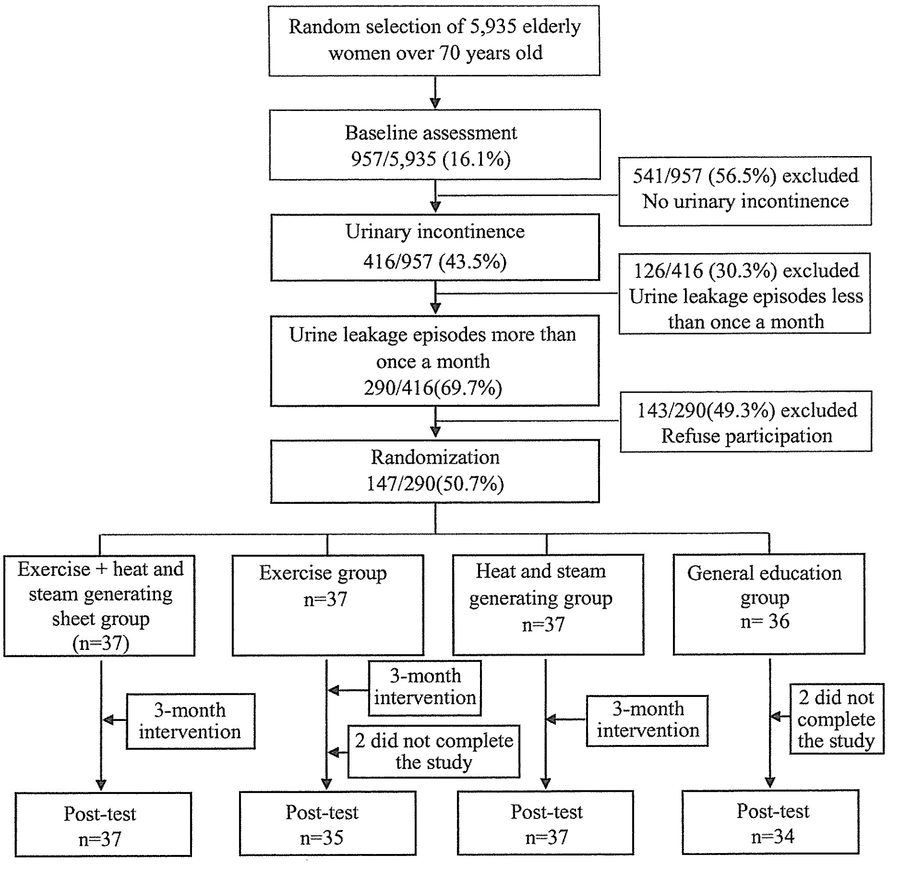

Figure 1 Flow chart of participant recruitment through the randomized controlled trial of exercise and/or heat and steam generating sheet trial.

assigned to the general education ($n = 36$), HSGS ($n = 37$), exercise ($n = 37$) or exercise + HSGS ($n = 37$) groups with an allocation ratio of 1:1 according to computer-generated random numbers. There was no attempt to equalize the size of the groups based on their characteristics or to recruit subjects with specific characteristics. The investigators were blind to the allocation of interventions.

Outcome measures

The primary outcome variable of this study was the cure of urine loss episodes, which was assessed by interview.[13] Complete cessation of urine loss episodes was defined as cured. The secondary outcomes were functional fitness and changes in frequency of urine loss episodes, which was assessed based on changes in a 5-point scale obtained in the interviews conducted pretreatment and after the 3-month intervention.

Interview survey

A face-to-face interview was conducted to assess temporary UI conditions based on the modified International Consultation on Incontinence Questionnaire (ICIQ).[14] The first question was "Have you experienced urine loss during the previous year?". If the participant responded "yes", we then asked the frequency, volume and circumstance of urine loss. The frequency of UI was assessed based on a 5-point scale by interview (1, every day; 2, once every 2 days; 3, once or twice per week; 4, once or more per month; 5, several times per year). Those whose response ranged 1–4 were classified as potential subjects. The same 5-point scale was presented to the participants after the 3-month intervention. The changes in the 5-point scale were converted to the following 6-point scale in order to assess improvements observed in urine loss frequency from baseline to after the 3-month intervention: 0 for no urine loss, 1 for several times per 3 months; 2 for one to three times per month, 3 for one to two times per week, 4 for once every 2 days, and 5 for every day.

Urinary incontinence type was assessed based on all answers to the following question: "When do you experience urine loss? 1, before reaching the toilet; 2, while coughing, sneezing or laughing; 3, while sleeping at night; 4, while physically active or exercising; 5, upon re-dressing after urinating; 6, for no apparent reason; 7, all the time; 8, while working with water, touching water or drinking cold water."[14] Participants were classified as having stress UI when urine loss was associated with increased abdominal pressure, as in responses 2 and/or 4. Participants were classified as having urge UI if they responded with 1 and/or 8. When characteristics of both stress and urge UI types were present, it was defined as mixed UI. Urine loss volume was assessed based on the answer to the question: "How much urine is leaked each time? 1, wets or dampens undergarment; 2, requires a change in undergarment; 3, soaks through to outer clothing; 4, runs down the leg(s) and onto the floor."

The subjects were asked about the onset age and duration of UI, frequency of daytime and nighttime voiding, and chronic medical conditions such as heart disease, diabetes, hypertension and osteoporosis.

Functional fitness test

Measurements of height and body weight were converted to body mass index (BMI, kg/m^2), and fitness test variables including grip strength, one-leg standing time with eyes open, usual and maximum walking speed, and seated adductor muscle strength were taken. The procedures for the fitness tests have been described in detail in a previous report.[15]

Intervention

Exercise group

The exercise group participants attended an exercise training session 2 times a week for 3 months at the TMIG health promotion classes. The following exercises were performed by the participants.

Stretching exercise

The participants performed 5–10 min of warm-up and stretching exercises, including shoulder rotation, waist rotation and others.

PFM exercises

The participants were informed that straining the abdomen increases abdominal pressure and exerts pressure on the PFM. The subjects were trained to exert force only on the PFM without excessively straining the abdomen. The exercise regimen was designed to strengthen the fast- and slow-twitch muscle fibers located on the pelvic floor. The participants were initially instructed to perform 10 fast contractions (3 s) with a 5-s rest and 10 sustained contractions (8–10 s) with a 10-s rest between the contractions. The PFM exercise was performed in the sitting, lying and standing positions with the legs apart, while emphasizing contraction of the PFM and relaxation of the other muscles.

Fitness exercises

Strength training of the thigh and abdominal muscles were performed between the PFM exercises. The exercises included chair exercises, weight-bearing exercises, ball exercises, and others.

HSGS group

The HSGS is a thin, flexible filmed sheet (120 mm × 204 mm; Kao, Tokyo, Japan), that generates heat and steam immediately after unsealing. When the sheet is placed on the body, the temperature of the skin surface rises to 38–40°C and it continues to generate heat and steam for over 5 h.[16] The participants gathered at TMIG classes every 2 weeks, where HSGS were provided for 2 weeks and the urinary diaries were collected. The participants in the HSGS group were asked to place the HSGS on their lower back once a day immediately after waking up. The participants recorded the time of day that they placed and removed the sheet in their urinary diary.

Exercise + HSGS group

The participants were instructed to perform a combination of the same intervention as the exercise group as well as the HSGS group.

General education group

General education classes were held (topics including cognitive function, osteoporosis and oral hygiene) once a month, a total of three times.

Urinary diary

A urinary diary was distributed to the participants in the exercise, HSGS and exercise + HSGS groups where they recorded times of urination (number of times during the day [waking up in the morning to sleeping at night] and number of times during the night [sleeping at night to waking up in the morning]), time of defecation, presence or absence of UI, time of loss, volume of loss and actions taken at the time of loss.[17] The urinary diaries were collected every 2 weeks and were monitored for any changes in UI for 3 months.

Data analysis

Means and standard deviations were calculated for continuous variables, and a one-way ANOVA was performed to measure significant differences in baseline values and urine loss score post-treatment between the intervention groups, and the χ^2-test was used for categorical variables. Scheffé's post-hoc method was performed when significance was found. A repeated-measures ANOVA (4 × 2) was performed to find differences in pre- and post-intervention functional fitness and urine loss score between groups, and paired student's *t*-tests were done on pre- and post-intervention measures to find changes within groups. A Kruskal–Wallis test was used to measure the difference in cure rates between the intervention groups. All analyses were performed using SPSS ver. 15.0 for Windows and $P < 0.05$ was considered statistically significant.

Results

Table 1 shows the baseline comparisons in anthropometric values, physical fitness measures and interview survey results among the exercise + HSGS, exercise, HSGS and general education groups. There were no significant differences between the groups in all variables including age, walking speed, adductor muscle strength, duration and onset age of urine loss, frequency of urine loss episodes, and chronic medical conditions.

In comparing the pre- and post-intervention changes in physical fitness between groups (Table 2), there was a significant group × time interaction in adductor muscle strength and usual walking speed, where the exercise + HSGS group was significantly greater than the other groups.

The within group analysis showed that grip strength ($P = 0.001$), one-leg standing time with eyes open ($P = 0.033$), adductor muscle strength ($P < 0.001$) and usual walking speed ($P = 0.020$) changed significantly in the exercise + HSGS group; grip strength and adductor muscle strength significantly improved and BMI decreased in the exercise group; and grip strength and adductor muscle strength significantly improved in the HSGS group (Table 2).

The cure rates of UI after the 3-month intervention were 51.4% in the exercise + HSGS group, 34.3% in the exercise group, 21.6% in the HSGS group and 2.9% in the general education group ($\chi^2 = 21.89$, $P < 0.001$). Analysis of stress UI cure rates revealed 61.5% in the exercise + HSGS group, 53.8% in the exercise group, 25.0% in the HSGS group and 9.1% in the general education group ($\chi^2 = 8.94$, $P = 0.030$). Urge UI had a 50.0% cure rate in the exercise + HSGS group, 16.7% in the exercise group, 13.3% in the HSGS group and 0.0% in the general education group ($\chi^2 = 12.88$, $P = 0.005$). No significant differences were observed in mixed UI cure rates (Table 3).

In comparing the pre- and post-intervention urine loss scores between the groups (Fig. 2), there was a significant group × time interaction in stress and urge UI, and the exercise + HSGS group showed a significantly larger decrease in urine loss score compared with the other three groups. At baseline, there were no significant differences in urine loss scores (based on the converted 6-point scale) between the stress, urge or mixed UI groups. However, there was a significant improvement in stress and urge urine loss scores (urine loss scores of participants who had stress and urge UI) after the 3-month intervention. The stress urine loss score post-intervention was significantly lower in the