表 5　リサーチクエスチョンの例 1：術前牽引は必要か

第 7 章　大腿骨転子部骨折(いわゆる外側骨折)の治療
7.1　入院から手術までの管理と治療
リサーチクエスチョン：術前牽引は必要か
【推奨】術前の牽引をルーチンに行うことは推奨しない．(Grade I)
【解説】早期手術を前提とした場合，術前牽引が有効であるという文献はない．ただし，待機手術や特殊な骨折型において術前牽引が有効である可能性は否定できない．
【サイエンティフィックステートメント】術前に画一的に牽引(介達牽引，直達牽引ともに)することは，手術および予後に対して有効とはいえないとする高いレベルのエビデンスがある(エビデンス level I a，level I b)．

表 6　リサーチクエスチョンの例 2：入院中のリハビリテーションの内容は

第 9 章　大腿骨頚部/転子部骨折のリハビリテーション
リサーチクエスチョン：入院中のリハビリテーションの内容は
【解説】高齢患者に対しては，術前から，上肢機能訓練や健側下肢機能訓練，また患肢足関節機能訓練を行うことが有用であり，呼吸理学療法，口腔内ケアも行う必要がある．
術後には翌日から座位をとらせ，早期から起立・歩行を目指して下肢筋力強化訓練を開始する．歩行訓練は平行棒，歩行器，松葉杖，T 杖歩行と進めることが多い．特別なリハビリテーションメニュー(患者教育，強力な筋力訓練，歩行指導など)も試みられ，それぞれの報告では有効性が認められている．しかし systematic review ではその研究デザインやアウトカム設定に問題があると指摘され，一定の結論に至っていないので，特に勧められるリハビリテーションメニューはない．

表 7　リサーチクエスチョンの例 3：退院後のリハビリテーションは有効か

第 9 章　大腿骨頚部/転子部骨折のリハビリテーション
リサーチクエスチョン：退院後のリハビリテーションは有効か
【推奨】退院後のリハビリテーションの継続は有効である．(Grade B)
【サイエンティフィックステートメント】術後最低 6 か月程度は，リハビリテーションによる機能回復が期待できるとする高いレベルのエビデンスがある(エビデンス level I b，level II)．

表 6，**表 7** はそれぞれ入院中のリハビリテーション，退院後のリハビリテーションについての「リサーチクエスチョン」とその「推奨」または「解説」である．入院中のリハビリテーションについては，特別なリハビリテーションメニューの有効性に関する高いレベルでのエビデンスが存在しないため[8]，「推奨」ではなく「解説」のみの記載となった．退院後のリハビリテーションについては，退院後 6 か月程度はリハビリテーションによる機能回復が期待できるとする高いレベルのエビデンスがあるため[9]，その継続を「推奨」した．

ガイドラインの利用方法

診療を行う上で疑問があれば，まず該当する各章の「リサーチクエスチョン」と，その「解答」にあたる「推奨」を探す．その中で，疑問点があれば，「推奨」に至った経緯である「サイエンティフィックステートメント」を参考にする．また，すべてのエビデンスに和文の構造化抄録が付記されているので，その研究デザイン，対象，統計手法，結果，結論を知ることができる．

本ガイドラインは南江堂から発刊されており，書店での購入が可能である．また，その全文を，財団法人日本医療機能評価機構の医療情報サービスのサイト「Minds」(http://minds.jcqhc.or.jp/)でも参照できる．さらに，学会員限定であるが，日本整形外科学会のサイト(http://www.joa.or.jp/)にも掲載されている．

今後の課題

ガイドライン作成にあたって，多くの問題点が指摘された．まず本ガイドラインは主として手術

治療が対象であるが，手術治療を介入としたRCTは困難であり，またエビデンスの数が少ない点が挙げられる．日本人でのエビデンスはさらに少なく，日本の文献(日本語のみでなく英文を含めた日本で行われた研究結果)はできるだけ採用するようにしたが，適切にランダム化がなされたRCTはごくわずかであった．したがって，エビデンスが日本の現状と一致しない場合が多くみられ，今後わが国での質の高い臨床研究を実施・蓄積することが極めて重要であることが再認識された．

また，RCTのような高いエビデンスレベルを有する論文でも，対象者の病型や病態が様々なことがある．さらに論文の研究デザインがRCTでも，「リサーチクエスチョン」の内容に関しては必ずしもRCTの内容に沿っていない場合があり，その際のエビデンスレベル決定が問題となった．

前述のように，臨床的な疑問(リサーチクエスチョン)を解決するために用いることができる論文は必ずしも多くなく，時には存在しないこともあるため，ガイドラインの「推奨」が広範かつ絶対的なものと理解されるのは危険である．しかしながら，実際にはガイドラインが医療紛争に利用されることが危惧されている．もともと診療ガイドラインがカバーできるのは，患者全体のせいぜい60〜95%であると言われ[10]，ガイドラインは一定の指針を示すものではあるが，誰もがやらなければならないスタンダードではないことが広く理解される必要がある．

おわりに

診療ガイドラインには新しいエビデンスの集積に応じた改訂が常に必要である．現在，本ガイドラインは発刊から4年を経て，改訂作業が進行中である．

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■連載予定

1．高血圧治療ガイドライン(JSH2009)
2．大腿骨頚部/転子部骨折診療ガイドライン
3．頸椎症性脊髄症診療ガイドライン
4．NICUにおける呼吸理学療法ガイドライン
5．リハビリテーション医療における安全管理・推進のためのガイドライン
6．介護予防ガイドライン

閉経後女性の運動機能に対するマイタケビタミンD_2サプリメントの効果

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要　旨

閉経後の中高年女性に対して，ビタミンDを強化したマイタケ（種苗登録申請中：一正蒲鉾株式会社開発菌株）を配合したサプリメントの服用を6ヵ月間行い，その有効性について臨床研究を実施した。「ビタミンD+カルシウム」サプリメントを連日6ヵ月間服用した併用群において，「カルシウム単独」サプリメント群に比べて運動機能評価での改善効果が一部に認められ，併用群でより改善傾向があることから，症例の追加により本サプリメントの効果が統計学的に明らかになる可能性が考えられる。

はじめに

人口の高齢化のなかで介護予防対策として高齢者の骨折予防は重要な課題である。骨粗鬆症は閉経前後から骨量減少が加速して，特に高齢女性において骨脆弱性を生じた結果，軽微な外力で骨折を発症する原因となっている[1)]。加齢による骨量低下を抑制するための十分なカルシウムとビタミンDの摂取は，骨折リスクを低下させ，ADL，QOLを維持するための栄養的サポートとなる。

近年，ビタミンDの臨床研究が多く報告され，骨代謝の改善効果とともに筋力の増強や転倒予防の効果など，広い範囲でその有効性が示されている[2)]。

ビタミンDは魚類や野菜など食品に幅広く含まれているが，日本人女性においてはその不足が指摘されている栄養素の一つである。本研究ではマイタケに含まれているビタミンD_2に着目して閉経後女性の骨代謝および運動機能に対するビタミンD_2の経口摂取の効果を検討した。

I　方　法

地域在住の50歳以上の女性で，研究の趣旨，方法を口頭および文書で説明し，同意が得られた46名を対象にした。対象者の年代内訳は，50歳代：18名，60歳代：15名，70歳代：12名，80歳代：1名で，平均年齢は63.1±8.3歳である。この46名を無作為に2群に分け，①カルシウム単独群（以下「単独群」）と②カルシウム＋ビタミンD強化群（以下「併用群」）として，錠剤型のサプリメントを6ヵ月間連日経口にて服用を行った。②の併用群のビタミンD含有量は，マイタケ子実体にビタミンD強化処理を施した粉末（一正蒲鉾株式会社提供）により1日の摂取量が750IUとなるように調整した。

単独群21名（平均年齢62.3±8.8歳），併用群25名（平均年齢63.8±8.0歳）ともに，試験開始前に試験内容についての説明を行い，骨粗鬆症治療薬や骨代謝に影響を与える薬剤・サプリメントを現在服用していないこと，本試験が影響するような既往症や現病がないことを確認した後に，本

Key words：ビタミンD，運動機能，骨折予防

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表 1　検査項目と実施スケジュール

	初回時	1ヵ月後	6ヵ月後 終了時
身体測定（身長・体重・体脂肪率・体温）	○	体温のみ	○
問　診（Mini-JOQOL）	○		○
血液検査（肝機能・腎機能・25（OH）D）	○	○	○
尿検査（骨吸収マーカー）	○		○
運動機能検査（10m 全力歩行時間・膝伸展筋力・開眼片脚立位時間）	○		○
骨密度検査（腰椎・大腿骨頸部）	○		○

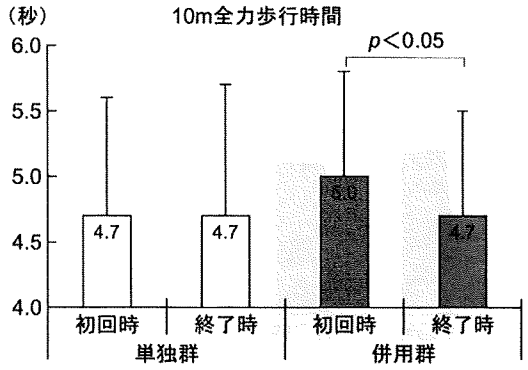

図 1-1　単独群・併用群の運動機能検査の変化

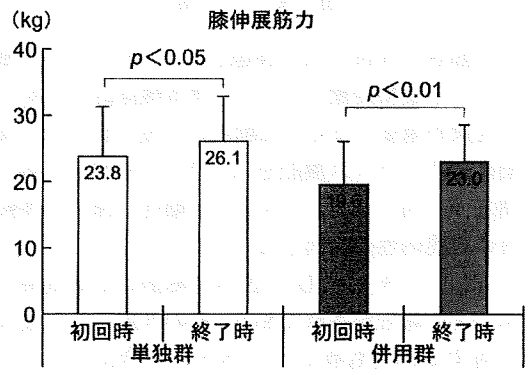

図 1-2　単独群・併用群の運動機能検査の変化

人の参加の意思に基づいて初回検査を 5 月に実施し，翌月の 6 月より介入試験を開始，同年 12 月に終了時検査を実施した。

実施した検査項目と実施スケジュールについては**表 1** に示す。なお，試験期間中は運動・食事・生活習慣などについて，可能なかぎりこれまでと変わらない生活を続けることとした。

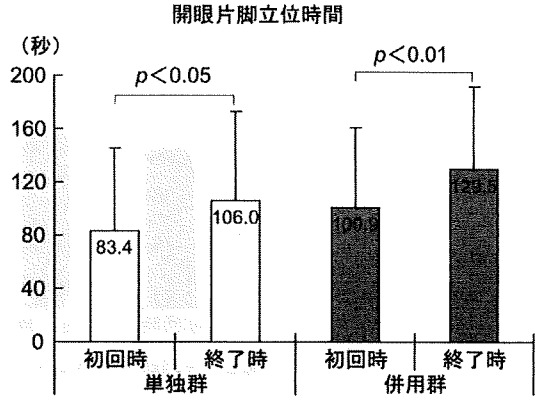

図 1-3　単独群・併用群の運動機能検査の変化

①身体測定：身長・体重・体脂肪率・体温

②問診：Mini-JOQOL

③血液検査：肝機能・腎機能・25(OH)D（D_2, D_3 を含む）

④尿検査：骨吸収マーカー

⑤運動機能検査：10m 全力歩行時間・膝伸展筋力・開眼片脚立位時間

⑥骨密度検査：腰椎・大腿骨頸部

得られたデータはすべて平均±標準偏差で示された。介入前後の差の検定は paired *t*-test を用いた。

II 結　　果

初回時と 6 ヵ月後の終了時の運動機能検査の結果を**図 1** に示す。

10m 全力歩行時間は単独群では変化がみられなかったものの，併用群では有意に改善していた（**図 1-1**）。また膝伸展筋力と開眼片脚立位時間で

表 2　単独群・併用群の骨密度検査ならびに問診（Mini-JOQOL）

		単独群		併用群	
		初回時	終了時	初回時	終了時
骨密度	腰椎（g/cm²）	0.830±0.167	0.843±0.159	0.856±0.110	0.863±0.109
	大腿骨頸部（g/cm²）	0.640±0.159	0.630±0.165	0.645±0.109	0.647±0.115
Mini-JOQOL（点）		58.7±4.2	59.6±4.7	56.4±5.8	57.2±4.8

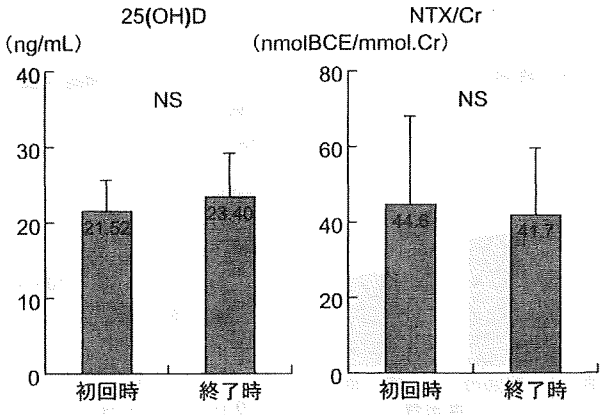

図 2　併用群の血液検査の変化

は，単独群・併用群ともに有意に改善したが，併用群ではその改善がより大きい傾向にあった（図 1-2，3）。

腰椎および大腿骨頸部骨密度ならびに Mini-JOQOL については，単独群・併用群ともに 6 ヵ月間で大きな変化はみられず，現状維持もしくは微増程度であった（表 2）。

骨代謝マーカーでは開始時の 25(OH)D は単独群：20.52±4.53（ng/mL），併用群：21.52±4.12（ng/mL）で，20ng/mL 以下が 41.3%，25ng/mL 以下が 84.8%であった。今回の介入前後の 25(OH)D レベルは単独群，併用群ともに有意な変化は認められなかった。一方，骨代謝マーカーである尿中 NTX/Cr は単独群で軽度増加傾向を認めたが，併用群で低下傾向が認められた（図 2）。

その他の血液検査所見では肝機能，腎機能を含めた一般血液生化学に変動はなく（表 3），研究期間中有害事象は認められなかった。

III　考　　察

高齢者の骨折予防の課題として，低下した骨量に対する薬物治療とともに，身体機能低下に対する対策が重要である。加齢に伴う筋力低下は，移動能力やバランス機能を低下させ，転倒のリスク増加の一因となるとともに，活動性の減少が高齢者の骨脆弱性の原因となっている。

近年，ビタミン D の投与が転倒の予防効果をもつとの報告がされており，その作用として筋肉に対する作用も有しているためと考えられている[3,4]。一方，日本人女性における血清 25(OH)D 値の測定によるビタミン D レベルの調査では日本人女性の半数以上がビタミン D の欠乏状態と報告されている[5]。

今回の調査ではマイタケのビタミン D_2 に注目し，その経口摂取が特に運動機能の変化にどのように影響するか観察したところ，ビタミン D を含む併用群では 10m 全力歩行時間，膝伸展筋力，開眼片脚立位時間のいずれも有意な改善効果を

表3　単独群・併用群の血液検査の変化

平　均	単独群		併用群	
	初回時	終了時	初回時	終了時
RBC（$10^4/\mu$L）	420.8	429.2	430.4	441.2
WBC（/μL）	5299.0	5800.0	5178.0	5701.6
Hb（g/dL）	12.7	12.9	13.3	13.6
Ht（%）	37.9	38.1	39.3	39.6
Plt（$10^4/\mu$L）	20.7	23.6	19.1	22.6
GOT（IU/L）	21.3	23.0	20.0	22.0
GPT（IU/L）	18.7	18.9	15.4	17.5
LDH（IU/L）	194.2	193.2	192.3	190.4
ALP（IU/L）	239.6	244.7	244.2	241.4
γ-GTP（IU/L）	19.0	22.4	25.8	28.2
T-Bil（mg/dL）	0.7	0.8	0.7	0.7
BUN（mg/dL）	14.7	14.4	15.5	14.1
TP（g/dL）	6.9	7.1	7.0	7.1
Alb（g/dL）	4.2	4.2	4.2	4.2
T-cho（mg/dL）	217.7	219.6	206.7	212.6
Cr（mg/dL）	0.7	0.6	0.6	0.6
Ca（mg/dL）	9.4	9.5	9.6	9.7
25(OH)D（ng/mL）	20.5	21.8	21.5	23.4
NTX/Cr（nmolBCE/mmol.Cr）	44.7	46.4	44.6	41.7

認め，一方，カルシウム単独群では 10m 全力歩行時間では変化はなかったものの，膝伸展筋力，開眼片脚立位時間で弱いながら有意な改善を示していた。

運動機能検査ではしばしば被験者の検査方法への慣れや研究事業の参加による意識の変化でコントロール群においても軽度改善傾向を示すことを経験する。しかし今回の研究においては単独群に比べて併用群ではすべての運動機能指標で一貫した改善が認められ，統計上も高い有意性をもった変化であり，ビタミン D がサプリメントとして運動機能改善効果を高める可能性を示唆する結果となった。

骨密度については 6 ヵ月間と比較的短い期間のため一定の傾向は観察されなかったが，骨吸収マーカーである尿中 NTX は併用群で低下傾向を示しており，骨代謝回転の改善効果があると考えられた。特に開始時の値が 50nmolBCE/mmol.Cr 以上のグループのみ調べると 25%の低下が認められ，ビタミン D 不足を補うことで骨吸収亢進を抑制するものと考えられた。

今回用いたビタミン D_2 のサプリメントは，新しい試みとしてマイタケに紫外線照射してビタミン D を増強している。単独群，併用群ともに参加した全被験者において肝機能，腎機能等の異常変化は認められず，その他全般的な安全性について問題のないサプリメントであると考えられる。

ビタミン D のなかで D_2（ergocalciferol）の potency は D_3（cholecalciferol）に比べて低いことが指摘されている[6]。また D_2 および D_3 を含んだビタミン D の RCT のメタ解析では，700～800IU のビタミン D が高齢者の骨折を予防することが報告されている[7]。一方，2006 年に報告された WHI の clinical trial では，カルシウムとビタミン D_3 の併用が腎結石のリスクを高めていることが報告され，活性の強い D_3 についてはカルシウム摂取とともに過剰な摂取も注意すべきことと考

えられる[8]。最近の D_2 に関する RCT では D_2 の投与が転倒ハイリスク高齢者の転倒を減少させているとの報告が出されている[9]。以上のことから，ビタミン D の効果発現および有害事象のリスクについては個々の血液中のビタミン D レベルや，カルシウム摂取量にも影響を受けるため，サプリメントとしては比較的安全性の高い D_2 を用いることは考慮すべきであると思われる。今回の研究において血中の 25(OH)D レベルの有意な上昇は認められなかったが，D_2 投与による 25(OH)D レベルの変化についての研究報告はこれまでも乏しく，D_3 の補充効果に比べて 25(OH)D レベルの上昇作用は劣ると考えられることから，今後さらに投与量の増加など検討が必要である。

近年，介護予防の視点から運動器不安定症という疾患概念が登場し，高齢者においては加齢→活動性低下→筋萎縮，骨量低下→転倒・骨折という構図で廃用が高齢者の ADL を低下させている。本研究の結果から，骨代謝と身体機能への栄養学的同時アプローチという試みにおいて有効である可能性を示唆する結果が得られた。高齢者の QOL 維持に栄養学的サポートの必要性，需要度は今後高まることが予想され，さらに臨床研究の積み重ねによって効果と安全性についての確かなエビデンスが求められる。

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Effects of a Vitamin D_2 Supplement on Physical Function in Postmenopausal Women; A Prospective Randomized Controlled Study

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Key words: Vitamin D, Locomotor function, Fracture prevention

Background : Fracture prevention in elderly is important issue in aging society. A recent systematic review of vitamin D supplementation demonstrated that it reduced the risk of fall in elderly. We conducted a randomized controlled trial to evaluate the effect of vitamin D_2 powder from Maitake mushroom with calcium on bone mineral density and locomotor function in community-dwelling postmenopausal women.

Methods : Forty six postmenopausal women (aged 63.1±8.3) were randomly divided into two groups with age, A; calcium alone group (300mg milk calcium tablet), B; calcium+vitamin D_2 combination group (300mg milk calcium+750IU ergocalciferol tablet). Participants in both group were received one of these supplements for 6 months. Main outcome measures were bone mineral density (BMD) and motor function tests.

Results : Serum 25(OH)D concentration is 20.52±4.53 (ng/mL) in control group, 21.52±4.12 (ng/mL) in combination group at beginning. After 6 months administration of supplement, slightly increasing of 25(OH)D level were observed in combination group. No significant changes were observed in BMD in femoral neck and lumbar spine, but motor function test of combination group showed significant improvements in 10m walking speed by 6% ($p<0.01$), compared with control group. The other tests such as muscle power of knee extension and one leg standing time were improved in both groups after six months treatment.

Conclusion : Vitamin D_2 ergocalciferol supplementation for 6 months improved motor function in postmenopausal women. It may induce the protective effect against falling and fracture in elderly. Further studies are required to clarify the effects of this supplementation.

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Physiotherapy Program through Home Visits for Community-Dwelling Elderly Japanese Women with Mild Knee Pain

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Knee pain is extremely common among the elderly, particularly women. Hence, there is an urgent need for applicable community-based intervention models for halting the progression of knee pain and related disabilities in elderly women. We aimed to assess the efficacy of home-visit physiotherapy as a new intervention model. This non-randomized 5-month-long controlled trial enrolled elderly community-dwelling women (aged 60-83 years) with mild knee pain. The intervention consisted of two home visits by a physiotherapist, with instructions on routinely performing muscle-strengthening exercises at home and implementing simple environmental modifications when necessary. Outcome measures were assessed at baseline and 5 months later. The primary outcomes were measured as the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and a newly devised *seiza*-style sitting score. People in Japan, especially elderly women, are accustomed to *seiza*-style sitting that involves kneeling on one's lower legs while resting the buttocks on the heels. The secondary outcomes included quadriceps isometric strength, knee alignment in the frontal and sagittal planes, and passive knee extension range. Forty-two subjects (20 in the intervention group and 22 in the control group) completed the study. At baseline, characteristics and the primary outcomes did not significantly differ between the 2 groups. At 5 months, the primary outcomes improved significantly in the intervention group. Estimated differences in the change from baseline for each outcome between the 2 groups were computed, adjusting for outcome variables imbalanced at baseline. Even after the adjustment, the home-visit physiotherapy regimen provides favorable improvement in the *seiza*-style sitting score. ——— Knee pain; community; physiotherapy; Japanese elderly women; *seiza*-style sitting.

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Epidemiological studies conducted worldwide have reported knee pain as a common condition in the elderly (O'Reilly et al. 1998; Brooks 2006). A literature review by Peat et al. (2001) revealed that during a 1-year period, 25% of people over 55 years of age experience a persistent episode of knee pain. The prevalence of knee pain increases with age, and the tendency is stronger in women than men. The onset of new knee pain in community-dwelling adults over 50 years of age is accompanied by a substantial decline in physical function within a 3-year period (Jinks et al. 2007). In the same timeframe, only a quarter of the adults who have knee pain will experience resolution of the pain. However, their general health and physical function status will not return to the same levels they experienced prior to the onset. Further, a majority of the adults who continue to experience knee pain are women.

Therefore, we require a new early intervention model for halting and reversing the progression of knee pain at the population level. Jinks et al. (2008) reported that almost a quarter of the adults with mild to moderate knee pain will develop severe or disabling knee pain within a 3-year period. This implies that healthcare fails to prevent progression

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of knee pain at the population level. Knee pain is a principal feature of knee osteoarthritis (OA), and it is usually diagnosed by X-rays. Further, only a minority of elderly subjects suffering from knee pain consult their doctor about their knee pain (Peat et al. 2001; Mitchell et al. 2006). Consequently, knee OA has remained undiagnosed in a majority of elderly patients with knee pain, due to which they were unable to receive structured treatment by healthcare professionals (Jordan et al. 2004).

The severity of knee pain in elderly patients is strongly associated with restricted mobility outside the home (Wilkie et al. 2007). This restricted mobility can easily lead to a reduction in physical function. Thus, knee pain in elderly subjects is a growing public health concern in the rapidly aging Japanese society.

Apart from genetic factors, environmental factors may also contribute to the increased prevalence of knee pain in elderly Japanese women in rural areas (Aoyagi et al. 1999). In Japan, people are accustomed to sitting *seiza*-style at home. *Seiza*-style sitting involves kneeling on one's lower legs while resting the buttocks on the heels. Japanese people regard *seiza* as the polite way of sitting, and Japanese natives commonly adopt this sitting position in daily life. Older women from the rural population in Japan tend to form the majority of the population accustomed to sitting in the *seiza* style at home.

There is evidence indicating that exercise improves physical function and reduces pain in patients with knee OA (Jamtvedt et al. 2008). Therapeutic exercise is the most common type of hospital-based physiotherapy treatment. Several evidence-based clinical practice guidelines have recommended exercise as therapy for managing patients with OA (Philadelphia Panel 2001; Ottawa Panel 2005). If the beneficiaries of physiotherapy can be extended to subjects apart from those who receive treatment at hospital visits, we would target the elderly female population with mild knee pain. In this context, physiotherapy is considered the process of instructing individually planned exercise to patients to assist the improvement of physical function and the alleviation of pain. The home-visit approach will enable rapid intervention in the case of patients with functional limitations and mobility restrictions. The purpose of this study was to determine whether home-visit physiotherapy treatment could meet the significant needs of community-dwelling elderly women with mild knee pain.

Methods

Study Design and Subjects

This study was performed as a component of a community-based *hiza*-care (knee care) program in Agano city, Niigata Prefecture, northern Japan. This program was designed by the authors of the current study. In collaboration with relevant healthcare institutions of the city and district healthcare staff, we conducted the experimental program in 2006 and 2007. The study protocol was approved by the ethics committee of the Niigata University of Health and Welfare. Written informed consents were obtained from all the subjects who participated in the study.

This study employed a non-randomized controlled design. Residents of Agano city were invited to participate in the study through city newsletters, posters, and direct invitations issued by public health nurses. Sixty-five women, aged 60 years and older, with knee pain and without history of leg surgery were enrolled in the baseline assessment. We interviewed the subjects to assess their knee conditions and physical function, which was also determined by measurement.

The target population of this study comprised elderly women. We used the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) with the Likert scaling format LK3.1 for Japanese patients (Bellamy 2002) as one of the primary outcome measures and a screening tool to determine eligibility to participate in the study. If the WOMAC pain thresholds were lowered in the eligibility criteria, this may result in the inclusion of subjects with only mild knee pain with activity (Goggins et al. 2005). Since the WOMAC total score (range, 0-98) is likely to be more appropriate than the WOMAC pain score (range, 0-20) to represent the conditions with knee pain, elderly women with WOMAC total scores of less than 20 were considered as having mild knee pain. A total of 55 elderly women with mild knee pain (25 in the intervention group and 30 in the waiting-list control group) were included in the 5-month-long controlled trial (Fig. 1). We grouped the participants from 2 districts into 1 group and the participants from the other 2 districts into another group to avoid the free flow of information regarding the contents of intervention among members within the same district.

To ensure consistency in home-visit physiotherapy across visits and patients, the 2 sessions of treatment received by all the subjects in the intervention group were administered by the same physiotherapist. This physiotherapist has a working experience of 10 years and is one of the authors of the present paper. In this paper, we define physiotherapy as a healthcare approach concerned with human function and movement by applying carefully planned physical exercise. At the baseline level, subjects from the control group were asked to remain in the study, and they were informed that after the completion of the second assessment, they would receive home-visit physiotherapy treatment for their knee pain. During the study period, the subjects were not provided with any specific information regarding the contents of the home visit.

The second assessment was performed 5 months from the baseline assessment. We analyzed the effects of the intervention on the outcome measures by comparing the changes from the baseline in each group and the change values between the 2 groups.

Intervention

The intervention group performed muscle-strengthening exercises with elastic resistance, following planning and specific instructions provided by the physiotherapist. The main purpose of the initial home visit was to instruct and train the subjects to perform the exercise at home. The physiotherapist spent an average of 1 hour for each of the initial home visits. Muscle-strengthening exercise for the legs was a core component of the training. Several exercises were prepared as the available choices of treatment for the subjects, such as active knee terminal range extension and resistive hip-knee extension by using elastic materials like Thera-Band® tubing (The Hygenic Corporation, Akron, Ohio, USA). The exercises were selected by the physiotherapist according to the subject's baseline assessment and on-site observation. A training schedule was individually planned

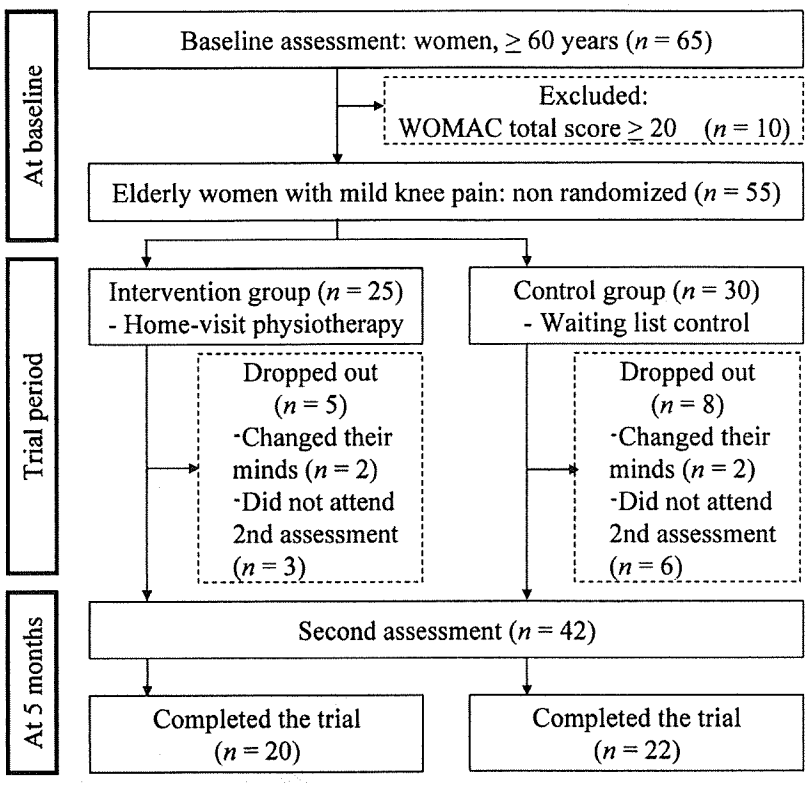

Fig. 1. Summary of study design.

after taking the baseline characteristics (e.g., amount of routine exercise) and the subject's opinion into consideration. The subjects progressively increased the number of repetitions per session according to their level of fatigue. We advised them to maintain the resistance within the limit so as not to worsen their knee pain during the training. At least 3 sessions per week with 1- to 2-day intervals between each session were recommended. Advanced exercise such as stepping up or stepping down was applied when the physiotherapist deemed it appropriate. All the exercise sessions took place unsupervised in the subject's home. All the subjects were asked to maintain an exercise log.

Simple modifications of the home with low-cost materials (e.g., non-slip mesh materials, floor marking tapes, and stools) were also implemented as additional measures to prevent accidental knee injuries. Primary prevention of knee pain by tackling knee injuries at home is important because previous knee injury has been reported to be the strongest risk factor for the onset of knee pain in adults (Jinks et al. 2008). The planned modifications were based on our experience and included modifications for fall prevention that could be instantly implemented in the home-visit intervention. Reducing potential hazards (such as false stepping, slipping, and performing difficult tasks such as climbing up or stepping down) might help in preventing falls and subsequent knee injuries. Therefore, we included a basic home evaluation in the initial home visit to determine if any of the planned modifications could be implemented.

Approximately 1 month following the initial home visit, we conducted a follow-up home visit for each subject to check the exercise log and provide further instructions. If appropriate, the intensity of elastic resistance training was increased by changing the type of elastic tubing (e.g., from heavy to extra heavy).

Expected effects and outcome measures

We expected the home visits to improve physical function and reduce knee pain. We devised a *seiza*-style sitting score determined by 2 items: difficulty while sitting *seiza*-style and difficulty in standing from this position. In the current study, we used the *seiza*-style sitting score along with WOMAC (pain, stiffness, and function subscales and total score) as the primary outcome measures to assess the effects of intervention on physical function and knee pain.

We used the *seiza*-style sitting score because the activities involved in *seiza*-style sitting are not included in the WOMAC. We applied the same scoring approach for the newly devised score as the WOMAC function subscale. The subjects were asked how much difficulty they perceived in sitting in the *seiza* position and in standing from this position. The 5-point Likert scale, which is scored from 0 to 4 (0 = none, 1 = mild, 2 = moderate, 3 = severe, and 4 = extreme), is rated. The *seiza*-style sitting score (range, 0-8) is determined by adding the responses for 2 items that form this score. Lower scores indicate better conditions.

The primary outcome measures were assessed through an interview by a trained interviewer (a public health nurse, a medical student, or a physiotherapy student). They conducted the interviews according to a structured approach. We provided them with guides including the official Japanese version of the WOMAC user guide.

During the assessments, the interviewer would read the questionnaire aloud, and the subject would indicate their response on an A3-sized copy of the questionnaire. Although some public health nurses were aware of the intervention status at the assessment session, other interviewers (the medical and physiotherapy students) were blinded to the status.

The secondary outcome measures included quadriceps muscle strength, knee alignment, and the range of passive knee extension. For evaluation of the secondary outcomes, all the evaluators were blinded to the intervention status of the study subjects. Quadriceps muscle strength is a predictor of knee OA (Slemenda et al. 1997), and it may be subjected to fluctuations depending upon the amount of pain experienced by the subject because pain may contribute to weakness of the quadriceps (Baker et al. 2004). Resistance training for elderly women with mild knee pain was expected to improve the quadriceps muscle strength, as reported in a previous study in which patients with knee OA underwent strength training (Lange et al. 2008).

We measured the strength of the quadriceps muscle when the subject was sitting on a chair. The distal lower leg of the subject was fixed at a 90° knee flexion position. Then, the sensor of the hand-held dynamometer MF-01 (ANIMA Corporation, Tokyo, Japan), the equipment used to measure isometric muscle strength, was placed on the anterior aspect of the subject's lower leg above the ankle. The sensor was attached to the end of a looped belt, the opposite end of which was fixed to the base of the chair. Then, isometric maximal contractions of the muscles used for knee extension were performed for the measurement trials. The maximal forces (N) were recorded, and the average of 2 trials was multiplied by the lever arm length (m) to calculate the torque (Nm). The lever arm length is defined as the distance between the lateral epicondyle of the femur and the center of the sensor.

Knee malalignment increases the risk of knee OA progression (Tanamas et al. 2009), and it mediates symptomatic outcome from exercise intervention in knee OA (Lim et al. 2008b). It is clinically important to distinguish people with varus malalignment from those with neutral alignment since higher varus deviation increases loading on the medial site of the tibiofemoral joint. Measurement of the intercondylar gap using a tape measure or calipers may be the simplest test for varus malalignment, although the correlation between the gap and self-reported physical function is very weak (Wood et al. 2008). Alternatively, in order to measure knee alignment with greater accuracy than the gap measurement and without the use of radiographs, we defined knee alignment as follows (Fig. 2): knee alignment in the frontal and sagittal planes is defined by the angle subtended by the line connecting the greater trochanter with the lateral epicondyle of the femur and the line connecting the lateral epicondyle of the femur with the lateral malleolus of the fibula. However, since a neutral alignment had not yet been determined for clinical use, we evaluated the change of this angle from the baseline level to 5 months. In the current study, in the frontal plane, deviation with higher varus from the baseline is shown as negative and deviation with higher valgus from the baseline level is shown as positive. Similarly, in the sagittal plane, deviation with greater flexion angle is shown as negative and deviation with greater extension angle is shown as positive.

We measured the knee alignments of subjects in the static standing position. Knee alignments in each subject were measured by 3 evaluators. The first evaluator stood in front of the subject and

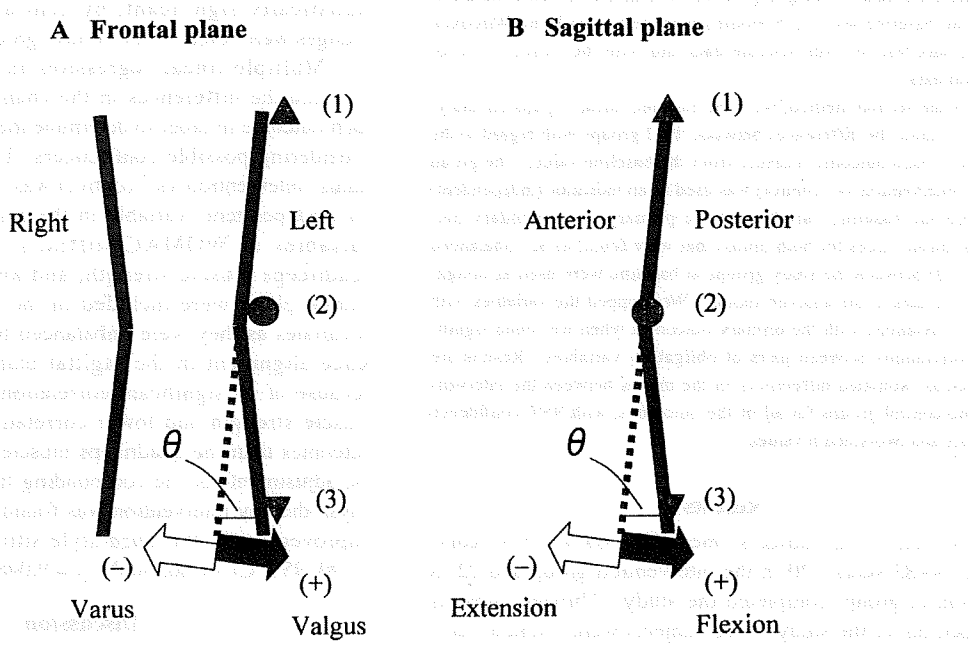

Fig. 2. Knee alignment.
Knee alignments were measured in a static standing position. Black and grey bold lines represent femurs and lower legs, respectively. The dotted lines are the longitudinally projected lines from the femurs. Knee alignment was quantified in this study by the degree (θ), which represents the deviation of the lower leg from the line projected from the upper femur. In the frontal plane, a positive value of θ indicates outside deviation (valgus change) whereas a negative value indicates inside deviation (varus change) of the lower leg. In the sagittal plane, θ expresses the degree of knee flexion.

simultaneously palpated the lateral aspects of the greater trochanter of both sides to determine the center points. The other 2 evaluators knelt at the right and left sides of the subject and palpated the other regions to determine the center points of the lateral epicondyle and the malleolus. First, they assessed the upper lines simultaneously; then, the lower lines were assessed using the same procedure. The evaluators measured the angle of inclination of each line using a Digital Level DL-155V (STS Corporation, Nagoya, Japan) in the frontal and sagittal planes. The angle of alignment in each plane was calculated using the angles of inclination of the upper and lower lines. We used a standard 35-cm metal. goniometer to measure the range of motion of the knee (in degrees to the nearest 1°) on passive knee extension in a supine position. We measured the extension range to determine whether the change in the alignment occurred with greater flexion or extension, which could be explained by change in the structural limitation of knee extension range (flexion contracture).

Statistical Analysis

SPSS version 12.0J for Windows (SPSS Japan Inc., Tokyo, Japan) was used for the analyses. Statistical significance was defined as $p < 0.05$. Data were analyzed in 2 ways. First, the primary outcomes were presented as the group median (the lowest and highest values), and the secondary outcomes were presented as the means ± standard deviations. Comparisons of the baseline characteristics between the intervention and control groups were conducted by the Student's *t*-test for numerical data and by the Fisher's exact test or the chi-square test for categorical data. Comparisons of outcome measures at the baseline between the 2 groups were performed by the Mann-Whitney *U* test for ordinal-scale data and by the Student's *t*-test for numerical data. Intra-group differences in the outcome measures from the baseline level to 5 months were tested with the Wilcoxon signed rank test for ordinal-scale data and with the paired *t*-test for numeral data.

In the second method, we used multiple linear regression analyses to estimate the differences between the 2 groups with regard to the change in each outcome measure from the baseline value. The group status (intervention vs. control) was used as an indicator (independent) variable and baseline variables of the primary and secondary outcomes (mean values for both limbs) that were found to be imbalanced ($p < 0.10$) between the study groups at baseline were used as obligatory covariates in the analytic model. We dropped the variables with lower correlations with the primary outcomes when we found significant correlations between pairs of obligatory variables. Results are reported as estimated differences in the means between the intervention and control groups for all of the outcomes, with 95% confidence intervals and two-sided *p* values.

Results

A total of 42 subjects (mean age 69.4 ± 5.9 years; range, 60-83 years), 20 in the intervention group and 22 in the control group, completed the study. Thirteen subjects dropped out of the study; these subjects were found to have weaker quadriceps and had experienced fewer falls in the previous year (data not shown). At the first home visit, the subjects in the intervention group were instructed to complete 2 sets of 3-10 repetitions each 2-3 times per week (if more than 2 different types of exercise were instructed, they were asked to repeat the exercises 4-6 times per week). Thus, the subjects were instructed to exercise at a mean frequency of 3.4 ± 1.6 (range, 2-6) times per week, and they exercised at a mean frequency of 4.3 ± 2.2 (range, 2-7) times per week. At the end of the initial home visits, the home was briefly scanned to identify the scope for environmental modifications. We modified the following 12 points in the homes of 9 subjects: installing a non-slip mesh material under the removal mat at the entrance threshold (7 points), using floor marking tapes on the step edges for increased visibility (2 points), and setting a stool by the platform to increase safety and ease in stepping up and down (3 points).

At the baseline assessment, characteristics of the subjects such as age, weight, height, body mass index, duration of knee pain, medication status, pain in other body part(s), and exercise habits did not significantly differ between the intervention and control groups (Table 1). There were no significant differences between the 2 groups in the primary outcomes at baseline (Table 2). In the secondary outcomes at baseline, the intervention group had weaker quadriceps and higher varus and flexion knee alignments than the control group. At the second assessment, WOMAC scores (pain, $p < 0.05$; stiffness, $p < 0.05$; function, $p < 0.05$; total, $p < 0.01$) and the *seiza*-style sitting score ($p < 0.01$) improved significantly in the intervention group, whilst the differences in those scores were not significant in the control group (Table 3 left). In the secondary outcomes, the differences from baseline in the intervention group were not statistically significant; by contrast, some significant changes were found in the control group.

Multiple linear regression analyses were used to estimate the differences in the change from baseline for each outcome in order to determine the effect of intervention considering possible confounders (Table 3 right). Group status (intervention vs. control) was included as an indicator (independent) variable in the analyses. The baseline variables of WOMAC stiffness, *seiza*-style sitting, quadriceps muscle strength, and knee alignment in the frontal plane were included in the model as obligatory covariates as they were imbalanced between the 2 groups. Knee alignment in the sagittal plane was not included because of its significant correlation with the quadriceps muscle strength and lower correlation with the primary outcomes than the quadriceps muscle strength. Even after the adjustment for the confounding factors, the home-visit physiotherapy intervention was found to produce favorable improvement in the *seiza*-style sitting score (difference −0.90; 95% CI −1.80, −0.01; $p = 0.048$).

Discussion

Home-visit physiotherapy intervention in a community improved common activities of elderly women with mild knee pain in Japan. Disabilities in sitting *seiza*-style and in standing from this position were particular concerns of community-dwelling elderly Japanese women although their knee pain was not severe.

Table 1. Comparison of the baseline characteristics between intervention and control groups.

	Intervention (n = 20)	Control (n = 22)	p value*
Age, yr	70.0 ± 5.6	68.8 ± 6.2	0.540
Weight, kg	57.1 ± 8.1	54.3 ± 7.1	0.242
Height, cm	150.2 ± 5.1	150.4 ± 5.7	0.878
Body mass index, kg/m^2	25.3 ± 2.9	24.0 ± 2.8	0.152
Knee pain and relevant conditions			
Laterality of current knee pain			0.277
Unilateral (left)	4 (20.0)	9 (40.9)	
Unilateral (right)	5 (25.0)	7 (31.8)	
Bilateral	8 (40.0)	5 (22.7)	
Currently missing	3 (15.0)	1 (4.6)	
Duration of current knee pain			0.249
< 1 month	2 (10.0)	0 (0.0)	
1 to 11 months	3 (15.0)	3 (13.6)	
≥ 12 months	12 (60.0)	18 (81.8)	
Currently missing	3 (15.0)	1 (4.6)	
Use of analgesics for knee pain, yes	2 (10.0)	4 (18.2)	0.380
Use of outpatient services for knee pain, yes	4 (20.0)	5 (22.7)	0.565
Use of lower limb orthoses, yes	1 (5.0)	4 (18.2)	0.203
Difficulty walking, yes	9 (45.0)	6 (27.3)	0.191
Physical conditions except knee pain			
Current pain, yes	14 (70.0)	12 (54.2)	0.239
Use of analgesics, yes	3 (15.0)	2 (9.1)	0.453
Use of outpatient services, yes	10 (50.0)	9 (40.9)	0.390
Experience of the fall in the past one year, yes	7 (35.0)	3 (13.6)	0.104
Fall-associated fracture in the past, yes	2 (10.0)	5 (22.7)	0.247
Routine exercise habits, yes	12 (60.0)	14 (63.6)	0.530

Data are expressed as mean ± S.D. or number of respondents (%).
*Using Student's t-test, Fisher's exact test, or chi-square test.

Only the control group exhibited decline in the quadriceps muscle strength at 5 months. This could indicate the natural course in elderly women with knee pain because the strength of this muscle may fluctuate with the variable pain experienced by the subject throughout the trial period. Only a minority of the adults with knee pain can experience a resolution of pain and a return to the prior functional levels (Jinks et al. 2007). In comparison with the control group, the intervention group could preserve their quadriceps muscle strength and prevent progression to severe or disabling knee pain.

Our target group comprised elderly women with mild knee pain who cannot avail of hospital-based physiotherapy. Many studies have shown the favorable effects of exercise routine on knee pain for middle-aged and elderly patients (both men and women) with knee OA (O'Reilly et al. 1999; Patrella and Bartha 2000; Baker et al. 2001; Thomas et al. 2002; Oida et al. 2008; Doi et al. 2008). However, little information is available on the effects of exercise intervention to treat elderly women with knee pain at a population level. The researchers of a previous intervention study on community-dwelling subjects did not restrict their trial to patients with knee OA alone (Hay et al. 2006). Significant improvements in the WOMAC pain and function scores were observed in the physiotherapy intervention group of Hay et al., and the mean baseline WOMAC scores of the subjects in that study were more than 5 times the corresponding scores of the subjects in the present study. Since subjects with only mild knee pain participated in the current study, it might have been difficult to detect any improvement in those who started with lower WOMAC pain scores at the baseline than subjects enrolled in other studies. Despite the fact that there were no significant differences in the WOMAC scores in the multiple regression models, the significant improvement in performing common activities such as *seiza*-style sitting may imply that home-visit physiotherapy could meet their needs at the community level.

The home-visit intervention performed with a frequency of 2 times over a 5-month period in the present

Table 2. Baseline comparison of the outcome variables between intervention and control groups.

		Intervention (n = 20)	Control (n = 22)	p value*
Primary outcomes†				
WOMAC pain (0 - 20)		2.1 (0 - 8)	1.2 (0 - 4)	0.102
WOMAC stiffness (0 - 8)		1.1 (0 - 4)	0.4 (0 - 3)	0.058
WOMAC function (0 - 68)		4.0 (0 - 15)	3.5 (0 - 13)	0.639
WOMAC total (0 - 96)		9.5 (0 - 19)	5.2 (1 - 17)	0.210
Seiza-style sitting (0 - 8)		3.6 (0 - 8)	1.9 (0 - 7)	0.092
Secondary outcomes				
Quadriceps muscle strength, Nm				
Left		54.9 ± 20.4	66.1 ± 16.4	0.057
Right		57.3 ± 22.2	73.0 ± 19.4	0.019
Average		56.2 ± 20.5	69.6 ± 17.0	0.026
Knee alignment, degree				
Frontal plane‡	Left	−1.0 ± 2.9	1.6 ± 2.9	0.007
	Right	−2.4 ± 5.3	1.0 ± 3.0	0.016
	Average	−1.7 ± 3.3	1.3 ± 2.6	0.002
Sagittal plane§	Left	11.6 ± 3.8	8.5 ± 4.6	0.021
	Right	12.5 ± 3.3	9.6 ± 3.9	0.013
	Average	12.1 ± 3.0	9.0 ± 3.7	0.006
Knee extension range of motion‖, degree				
Left		−2.0 ± 3.6	−3.1 ± 3.7	0.319
Right		−1.7 ± 4.0	−2.3 ± 4.0	0.618
Average		−1.8 ± 3.4	−2.7 ± 3.4	0.408

Data are expressed as group median (range) for primary outcomes and mean ± S.D. for secondary outcomes.

WOMAC = Western Ontario and McMaster University Osteoarthritis Index.

*Using Mann-Whitney U test and Student's t-test.

†Higher scores indicate worse symptoms.

‡Higher values indicate more valgus-angulated alignment, and lower values indicate more varus-angulated alignment.

§Higher values indicate more flexion-angulated alignment, and lower values indicate more extension-angulated alignment.

‖ Lower values indicate further limitations in the knee extension range.

study was less frequent than the home visits undertaken by other previous studies. For instance, in the study of O'Reilly et al. (1999), 4 home visits were performed during a 6-month period; the study of Baker et al. (2001) conducted 12 home visits during a 4-month period; and Thomas et al. (2002) conducted 4 home visits in the first 2 months (with follow-up visits at 6-month intervals for their 2-year-long study). However, exercise instructions provided on-site for home exercise training was a unique feature of the current study. A number of studies have furnished evidence that home exercise training for knee OA is effective. However, in most studies, the exercise instructions were delivered at sessions or demonstrations conducted at institutions. Simple and low-cost environmental modification was another unique advantage of home-visit physiotherapy, which we demonstrated in our present study. As reported by our subjects at baseline, around a quarter of elderly women with mild knee pain are likely to have experienced the fall in the past one year. This finding supported the necessity of including means to address risk factors for injuries related to falls in the home-visit program.

We demonstrated the practical use of knee alignment measurement without the use of radiographs. Varus or valgus changes should be interpreted considering the alignment change in the sagittal plane because the valgus angles in knee alignment increased with increased flexion contracture (Koshino et al. 2002). In the current study, the change in the intervention group is estimated to be more varus than that in the control group. The increase in flexion of knee alignment from the baseline to the assessment at 5 months in the control group might have influenced the result in the multiple regression model. Interestingly, the reduction of quadriceps muscle strength from the baseline to the assessment at 5 months in the control group could be

Table 3. Comparison of changes in outcome variables after 5-month trial.

		Second measurement		Change from baseline				
				Univariate analysis			Multivariate analysis	
		Intervention (n = 20)	Control (n = 22)	Intervention (n = 20)	Control (n = 22)	p value[§]	Difference (95%CI)	p value
Primary outcomes								
WOMAC pain (0 - 20)		0.9 (0 - 3)*	0.7 (0 - 3)	−0.9 (−8 - 2)	−0.4 (−3 - 3)	0.495	−0.03 (−1.43 - 1.37)	0.965
WOMAC stiffness (0 - 8)		0.5 (0 - 3)*	0.5 (0 - 3)	−0.5 (−3 - 1)	0.0 (−3 - 2)	0.080	−0.37 (−0.94 - 0.20)	0.200
WOMAC function (0 - 68)		2.8 (0 - 13)*	2.0 (0 - 14)	−1.8 (−11 - 8)	−0.8 (−12 - 10)	0.300	−0.05 (−3.28 - 3.17)	0.973
WOMAC total (0 - 96)		4.9 (0 - 15)†	3.2 (0 - 19)	−4.0 (−11 - 4)	−1.2 (−15 - 15)	0.235	−0.45 (−4.24 - 3.33)	0.810
Seiza-style sitting (0 - 8)		1.6 (0 - 4)†	1.1 (0 - 6)	−1.5 (−5 - 1)	−0.4 (−3 - 2)	0.026	−0.90 (−1.80 - −0.01)	0.048
Secondary outcomes								
Quadriceps muscle strength, Nm								
Left		60.8 ± 28.3	59.5 ± 15.9*	+5.9 ± 24.5	−6.6 ± 14.7	0.058	+7.1 (−7.7 - 21.8)	0.339
Right		63.2 ± 23.8	65.3 ± 17.9†	+5.8 ± 24.4	−7.7 ± 11.5	0.032	+10.3 (−2.8 - 23.3)	0.120
Average		62.0 ± 25.3	62.4 ± 15.8†	+5.8 ± 23.2	−7.1 ± 11.7	0.032	+8.7 (−4.2 - 21.5)	0.181
Knee alignment, degree								
Frontal plane	Left	−0.8 ± 3.4	3.2 ± 3.0*	+0.2 ± 2.2	+1.6 ± 3.4	0.119	−1.9 (−4.1 - 0.3)	0.088
	Right	−1.8 ± 4.4	2.4 ± 3.8*	+0.7 ± 3.0	+1.4 ± 2.7	0.451	−1.5 (−3.7 - 0.6)	0.164
	Average	−1.7 ± 3.3	1.3 ± 2.6†	+0.5 ± 1.7	+1.5 ± 2.5	0.122	−1.7 (−3.4 - −0.1)	0.039
Sagittal plane	Left	12.7 ± 3.9	14.3 ± 3.8‡	+1.0 ± 4.5	+5.9 ± 6.4	0.008	−4.9 (−9.3 - −0.5)	0.031
	Right	13.4 ± 4.8	10.6 ± 4.1	+0.9 ± 3.3	+1.0 ± 5.3	0.946	+0.4 (−3.1 - 3.8)	0.835
	Average	12.1 ± 3.0	9.0 ± 3.7†	+1.0 ± 2.7	+3.4 ± 5.1	0.058	−2.3 (−5.5 - 1.0)	0.163
Knee extension range of motion, degree								
Left		−0.9 ± 4.3	−2.0 ± 3.9	+1.1 ± 5.2	+1.1 ± 2.6	0.994	−0.2 (−3.1 - 2.7)	0.891
Right		−1.5 ± 5.9	−1.8 ± 4.7	+0.2 ± 5.0	+0.5 ± 4.8	0.841	−0.5 (−4.3 - 3.3)	0.794
Average		−1.2 ± 4.7	−1.9 ± 4.0	+0.6 ± 4.5	+0.8 ± 3.2	0.902	−0.3 (−3.3 - 2.6)	0.813

Data are expressed as group median (range) or mean ± S.D. except those for multivariate analyses. Multivariate analysis estimated the difference between the intervention and control groups with regard to the change in each outcome measure from the baseline value adjusted for the baseline data of WOMAC stiffness, *seiza*-style sitting, average quadriceps muscle strength, and average knee alignment in the frontal plane by using multiple linear regression analysis. If an estimate is negative, then the intervention leads to a more negative change in the outcome variable; if an estimate is positive, then the intervention leads to a more positive change in the outcome variable.

*$p < 0.05$, †$p < 0.01$, ‡$p < 0.001$ significant intra-group difference from the baseline level to 5 months tested by Wilcoxon signed rank test or paired t-test.

[§]Using Mann-Whitney U test or Student's t-test.

See Table 2 for the definition of each variable.

explained by the alignment changes, since greater varus deviation from neutral alignment is associated with increased quadriceps muscle strength (Lim et al. 2008a). To consider more variables as possible confounding factors, we should aim to conduct studies with larger sample size in the future.

Since the eligibility criteria reflected the target group for intervention, the criteria we used may have influenced the results of our study. At baseline, more than 60% of the subjects reported that they followed routine exercise habits. This pre-existing exercise routine may have influenced their compliance to the exercise instructions because the subjects in the intervention group performed the exercises more frequently than recommended. Another factor that negatively influenced the results of our study was the study design: the distinct weak point being the lack of a randomized or matched control design. Instead, for practical reasons, participants from 2 districts were placed in the intervention group and those from the other 2 districts were placed in the waiting-list control group. Although this study design is advantageous in that it prevented the free flow of information about the contents of intervention, it also posed as a disadvantage since the baseline measurements in the secondary outcomes differed between the intervention and control groups. However, the multivariate adjustment for some of the baseline outcomes could have reduced this negative influence to a certain extent.

In conclusion, home-visit physiotherapy treatment for assisting community-dwelling elderly Japanese women with mild knee pain could prevent the progression to severe and disabling knee pain and also improve specific physical functions. Further studies with a larger sample size span-

ning over more districts across multi-administrative areas are required to elucidate the effects of home-visit physiotherapy.

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