While a direct cause-effect relationship has not been established between obesity and incontinence, weight reduction or decrease in BMI may be beneficial for treatment of incontinence. Kim et al. (2007) investigated the distribution of subjects cured from urinary incontinence according to tertiles of changes in BMI, maximum walking speed, and adductor muscle strength, and found that a significantly higher proportion among those who were cured of incontinence episodes, demonstrated improvements in BMI and walking speeds. Therefore, decrease in BMI and increase in walking speed are desirable outcomes for the treatment of stress urinary incontinence (Kim, 2012) (Table 3).

Table 3. Cured of urine leakage according to body mass index (BMI), maximum walking speed, and adductor muscle strength tertiles. (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, with permission from the American Geriatrics Society)

Variable Changes Compared with Baseline		Cured of Urine Leakage n(%)	Cochran's Q value	*p*- value	Post-hoc †
3-month exercise (n=33)					
BMI	Decreased (D)	16 (48.5)	7.091	0.029	D,N>I
	No change (N)	13 (39.4)			
	Increased (I)	4 (12.1)			
Maximum walking speed	Increased	17 (51.5)	6.545	0.038	I>D
	No change	11 (33.3)			
	Decreased	5 (15.2)			
Adductor muscle strength	Increased	11 (33.3)	4.545	0.103	
	No change	6 (18.2)			
	Decreased	16 (48.5)			
1-Year Follow-up (n=20)					
BMI	Decreased	10 (50.0)	3.700	0.157	
	No change	3 (15.0)			
	Increased	7 (35.0)			
Maximum walking speed	Increased	10 (50.0)	6.100	0.047	I>D
	No change	8 (40.0)			
	Decreased	2 (10.0)			
Adductor muscle strength	Increased	9 (45.0)	3.100	0.212	
	No change	8 (40.0)			
	Decreased	3 (15.0)			

2.3. Other Treatments

Commonly, PFM exercises are recommended for people with stress urinary incontinence, and fitness exercises have been effective in reducing incontinence episodes in the obese. Several other incontinence treatments have been developed apart from PFM and fitness exercises, and they have been the focus of recent investigation in order to determine the efficacy and validity of these treatment methods.

The use of an educational or retraining program as an intervention was introduced by Jeffcoate and Francis in 1966. The therapy, known as bladder training or sometimes as bladder discipline or drill, consists of three components: patient education, scheduled voiding, and positive reinforcement. Patient education includes teaching patients about the bladder and how continence is normally maintained; scheduled voiding is a fixed or flexible time table for voiding aimed to increase the interval between voids; and positive reinforcement offers encouragement and support provided by a healthcare professional. Bladder training is often prescribed to those experiencing urge urinary incontinence, with uninhibited bladder contractions, as well as those with stress or mixed incontinence. The purpose of bladder training is to inhibit involuntary bladder contractions, increase the interval between voids, and/or induce unspecified psychological benefits. The mechanism of bladder training remains unclear: one hypothesis is that the capacity of the bladder increases by lengthening the interval between voids, which may lead to the reduction in urinary incontinence (Wallace et al., 2009). While research has shown that bladder training can reduce the number of incontinence episodes and the volume of urine loss, this treatment method seems to be more effective as a supplement to PFM exercises, than as a stand-alone treatment (Wyman et al., 1998).

Unlike bladder training, which is very difficult to implement in those with cognitive impairment, other forms of toileting assistance methods such as prompted voiding and timed voiding can be used for elderly people with cognitive impairments. Prompted voiding is used to teach elderly people who may or may not be cognitively impaired to initiate toileting through the requesting of help, or notifying the urge to void to caregivers, and in turn receiving positive reinforcement from the caregivers, a form of operant conditioning. This therapy also requires more mobility in the elderly by having caregivers assist them to the toilet instead of simply changing urinary pads after each incontinence episode. The distinction between prompted voiding and other toileting assistance interventions is that prompted voiding is not initiated and controlled by caregivers, but the individuals with urinary incontinence themselves. The disadvantages with prompted voiding are that it requires a significant amount of commitment and motivation from caregivers, and there are major resource implications which may make this therapy inconvenient. While there has been evidence suggesting that prompted voiding is more effective than no therapy, the evidence is quite weak and further validation is necessary (Eustice et al., 2000).

Timed voiding sometimes referred to as scheduled, routine, or regular toileting is a therapy where the intervals between voiding are fixed. This program is considered a passive toileting assistance program initiated by caregivers, and is often provided to elderly people in long-term residential care facilities with cognitive or motor impairments. In contrast to bladder training, the intervals between voids are not lengthened or shortened, and the aim of this method is to avoid incontinence episodes and not to improve bladder function. Timed voiding is different from prompted voiding in that the caregivers initiate and maintain the program without participation from the elderly patients or residents, and there are no positive reinforcements. However like prompted voiding, evidence of the efficacy of timed voiding toileting assistance programs is inconclusive, and the evidence is insufficient (Ostaszkiewicz et al., 2004). There are also limited investigations where toileting assistance interventions are combined with other forms of behavioral urinary incontinence treatments.

Biofeedback is a training technique aimed to reduce urinary incontinence. Biofeedback can be defined as "augmented, concurrent or terminal feedback of biological signals that enables a person to identify and modify a bodily function of which they are usually unaware" (Herderschee et al., 2011). Augmented feedback refers to any supplementary information given, such as verbal feedback on performance, which can be given during muscle contraction (concurrent) or after (terminal). Kegel first published a report of biofeedback for stress urinary incontinence, where he developed the perineometer (1948), which as previously described, is an instrument now regarded as a biofeedback devise. A perineometer measures the strength of PFM contractions in women using an intravaginal balloon attached to an external manometer. Biofeedback is not only limited to squeeze pressure. Other devices are also used to measure different biological signals such as electrical activity or movement with ultrasound. Whether or not biofeedback is essential for behavioral treatment of urinary incontinence remains uncertain. Several researchers have investigated the role of biofeedback on the treatment of incontinence. Burgio et al.,(1986) indicated that biofeedback is more effective than verbal feedback for teaching selective sphincter control, and only those who had biofeedback treatment demonstrated increases in sphincter strength with training. These results however, were obtained from a very small sample size. Burns et al.,(1993) conducted a randomized controlled trial to assess the efficacy of biofeedback and PFM exercise for the treatment of stress incontinence in older community-dwelling women showing that biofeedback and PFM exercise are effective for treating stress incontinence. Although there were no significant differences in treatment effects between PFM exercise and biofeedback, the results suggest that there is a possibility that biofeedback may be more effective for incontinence of moderate and severe frequency. Burgio et al., (2002) evaluated the effects of training with and without biofeedback for urge incontinence. Behavioral training with biofeedback yielded a mean 63.1% reduction and verbal feedback a mean 69.4% reduction in incontinence episodes. Biofeedback showed less improvement in urinary incontinence compared with verbal feedback alone. A recent randomized controlled trial conducted to evaluate the effectiveness of behavioral therapy for reducing persistent post-prostatectomy incontinence found that the combination of biofeedback with pelvic floor electrical stimulation did not result in greater effectiveness (Goode et al., 2011).

PFM exercise is the most common conservative treatment of urinary incontinence. The correct execution of these exercises is an essential factor for the improvement of incontinence, as improper PFM contractions may reduce the force of urethral contraction (Bump, 1991). Therefore, there have been attempts to make it easier for women to train their PFMs. One method that has been developed is using a set of graded weighted vaginal cones (Peattie et al., 1988). The vaginal cone is placed in the vagina so that the PFMs must contract in order to prevent the cone from slipping out. Research has shown that cones were better than no active treatment; however, there is not enough evidence to show that adding cones to PFM exercise is more effective than cones or PFM exercise alone (Herbison and Dean, 2002).

Pelvic floor electrical stimulation has been suggested as an effective and safe therapy for treatment of stress urinary incontinence (Sand et al., 1995). Electrical stimulation consists of brief electrical impulses administered via needle or surface electrodes and is used to inhibit detrusor overactivity or to cause contraction of PFMs, providing passive exercise. A randomized controlled trial found that the addition of pelvic floor electrical stimulation to an extensive PFM exercise program did not significantly reduce the frequency of episodes, but pelvic floor stimulation group had significantly better patient self-perception of outcomes and satisfaction with progress (Goode et al., 2003).

Table 4. Cured of urine leakage after the 3-month exercise between the intervention and control groups. (Kim, H.; Yoshida, H. & Suzuki, T. (2011a). The effects of multidimensional exercise treatment on community-dwelling elderly Japanese women with stress, urge, and mixed urinary incontinence: A randomized controlled trial. *International Journal of Nursing Studies, 48,* 1165-1172, with permission from Elsevier)

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/sec)	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/sec)	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	40.0[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 strenghth; 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 from generalized estimating equation. Cochran'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
(scheffes post-hoc=stess>urge, mixed urinary incontinence)

Previous research has not shown convincing evidence that biofeedback, electrical stimulation, and vaginal cones together with PFM exercise have significant effects on improving urinary incontinence compared with PFM exercise alone. Furthermore, several problems arise with the use of electrical stimulation and vaginal cones. Electrical stimulation, while offering passive exercise of the PFMs, is not as effective as voluntary contraction of the muscles, and most patients have low tolerance for electrical stimulation. Many women have also reported that electrical stimulation as well as vaginal cones was difficult to use (Bo et al., 1999).

Despite the aforementioned limitations of pelvic floor electrical stimulation and vaginal cones, these methods of treatment may be helpful for elderly people who have difficulty with voluntary contraction of the PFMs whether from weakness or decline in cognitive and motor function. Elderly people who cannot identify and isolate their PFMs can benefit greatly from pelvic floor electrical stimulation and vaginal cones without having to resort to more invasive treatments with greater risks.

One recent trial suggested that PFM and fitness exercises are beneficial for all three types of urinary incontinence after a training period of three months; however, the mechanisms of these positive effects have not been made clear. This study did find that the effects of combined PFM and fitness exercises are maintained more in those with stress incontinence compared to those with urge or mixed incontinence (Kim et al., 2011a) (Table 4).

Among the different combinations of treatments previously described, the combination of PFM exercises with a fitness exercise program is recommended. By repeating PFM exercises with fitness exercises aimed to reduce abdominal fat, improvements in cure rates of urinary incontinence can be expected (Figure 5).

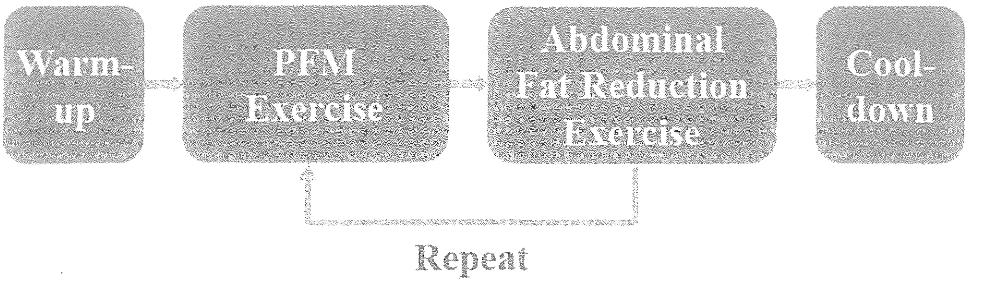

Figure 5. Recommended flow of combined PFM and abdominal fat reduction exercise.

Performing both PFM and fitness exercises may lead to greater physical function in elderly adults with urinary incontinence, which in turn may lead to a more active social lifestyle, increasing their quality of life. In fact, Kim et al. (2007), who investigated the effects of a combined PFM and fitness exercise intervention on cure rates of stress urinary incontinence as well as correlations between functional fitness measures and cure rates of incontinence, found that 54% of women who completed a 3 month PFM and fitness exercise class were cured of urine leakage (Table 5).

Moreover, as depicted in Tables 3 and 5, the PFM and fitness exercise program increased maximum walking speed in community-dwelling elderly women. Not only is this increase in walking speed an indicator of improved function, maximum walking speed may be correlated with being cured from urine leakage. Kim et al. (2007) suggested that an increase of 10.0% or more in walking speed may lead to improvements in urinary incontinence, and increased walking speeds can be maintained for at least one year after an exercise program (Table 3).

Table 5. Comparison of functional fitness and incontinence variables between the intervention and control groups after the 3-month exercise program. (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, with permission from the American Geriatrics Society)

Variable	Group	Baseline	3-Month Exercise	Analysis of Variance (Group ×Time)	*P*-Value
Body Weight, kg, mean±SD	I	52.2 ± 9.2	50.8 ± 9.2	*F*(1, 63)=9.1	0.004
	C	53.1 ± 9.4	52.9 ± 9.1		
BMI, kg/m², mean±SD	I	24.5 ± 4.2	23.8 ± 4.0	*F*(1, 63)=5.9	0.019
	C	24.2 ± 3.8	24.1 ± 3.6		
Usual walking speed, m/s, mean±SD	I	1.1 ± 0.3	1.1 ± 0.2	*F*(1, 63)=1.0	0.312
	C	1.1 ± 0.2	1.1 ± 0.3		
Maximum walking speed, m/s, mean±SD	I	1.6 ± 0.4	1.7 ± 0.4	*F*(1, 63)=4.7	0.035
	C	1.7 ± 0.3	1.6 ± 0.3		
Grip strength, kg, mean±SD	I	17.5 ± 4.3	18.2 ± 4.0	*F*(1, 63)=0.1	0.729
	C	18.5 ± 4.8	18.9 ± 4.8		
Adductor muscle strength, Nm, mean±SD					
Seated	I	48.6 ± 14.4	59.4 ± 14.7	*F*(1, 63)=13.4	0.001
	C	50.2 ± 12	51.5 ± 13.1		
Supine	I	42.3 ± 14.6	49.2 ± 17.3	*F*(1, 63)=10.8	0.002
	C	39.8 ± 10.1	40.7 ± 11.2		
Frequency score of urine leakage, point,	I	3.4 ± 1.3	1.5 ± 1.8	*F* (1,63)=6.0	0.018
mean±SD	C	3 ± 1.4	2.4 ± 1.4		
Cured of urine leakage (%)	I	0	54.5	Z=3.863	<0.001
	C	0	9.4		

SD = standard deviation; I = intervention group; C = control group.

2.4.3. PFM and Thermal Therapy

Recently, abdominal and lower back heating have been introduced as treatments for urinary incontinence (Kim, 2012). Heating may have positive effects on renal function by suppressing renal sympathetic nerve activity, promoting bladder voiding, and increasing frequency of urination (Tsai and Chen, 1993).

One previous study used a heat and steam generating sheet (HSGS), a thin, flexible filmed sheet that generates heat and steam immediately after unsealing, as a thermal treatment (Kim, 2011b). The sheet increases the temperature of the skin surface to 38 to 40℃ as it generates heat and steam for over 5 hours. This particular study showed that the HSGS combined with exercise yielded the highest incontinence cure rates compared with exercise or the HSGS alone. The HSGS also seems to have beneficial effects for different urinary incontinence types. Research reveals higher cure rates in those with stress urinary incontinence with the combination of both exercise and HSGS; however, there is strong evidence that the HSGS can be used as a supplementary treatment method in order to enhance the effects of behavioral therapy on those with stress, as well as urge and mixed urinary incontinence (Kim et al., 2011b) (Table 6).

Table 6. Cure rate of urinary incontinence according to urinary incontinence type and intervention group. (Kim, H.; Yoshida, H. & Suzuki, T. (2011b). Effects of exercise treatment with or without heat and steam generating sheet on urine loss in community-dwelling Japanese elderly women with urinary incontinence. *Geriatrics and Gerontology International, 11,* 452-459, with permission from the Japan Geriatrics Society)

Type of UI	Ex+HSGS n=37	Ex n=35	HSGS n=37	GE n=34	χ^2 value	P-value*
Stress UI, %(n)	61.5(8)	53.8(7)	25.0(3)	9.1(1)	8.94	0.03
Urge UI, %(n)	50.0(7)	16.7(2)	13.3(2)	0.0(0)	12.88	0.005
Mixed UI, %(n)	40.0(4)	30.0(3)	30.0(3)	0.0(0)	3.02	0.389
Total cure rate	51.4(19)	34.3(12)	21.6(1)	2.9(1)	21.89	<0.001

UI=urinary incontinence; Ex=exercise group; HSGS=heat and steam generating sheet group; GE=general education group.

* Kruskal-Wallis test.

3. Predictor Variables

Several characteristics that may influence treatment outcomes have been examined, including age, gender, urine loss frequency and amount, incontinence type, duration of urinary incontinence, chronic conditions, medications, and functional fitness as well as compliance to the prescribed exercise therapy. Compliance to exercise is the key factor to long-term success (Lagro-Janssen & van Weel., 1998; McDowell et al., 1999), BMI reduction also has positive influences on urge, mixed and stress UI treatment (Kim et al., 2011a) (Table 7), and weight loss may be an effective treatment in obese women (Subak et al., 2005, 2009).

Behavioral treatments are effective in reducing urinary incontinence episodes; however, in some cases, the treatments described in this chapter may be insufficient. When the behavioral methods do not successfully reduce incontinence episodes in the elderly, other medical treatments such as surgery and pharmacological therapies may be necessary to alleviate the symptoms of urinary incontinence.

Table 7. Adjusted odds ratios for cure of urine leakage after intervention and the 7-month follow-up. (Kim, H.; Yoshida, H. & Suzuki, T. (2011a). The effects of multidimensional exercise treatment on community-dwelling elderly Japanese women with stress, urge, and mixed urinary incontinence: A randomized controlled trial. *International Journal of Nursing Studies, 48*, 1165-1172, with permission from Elsevier)

	After 3-month exercise			After 7-month follow-up		
	Adjusted			Adjusted		
Variable	OR *	95%CI	*p* Value	OR *	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

Conclusion

Urinary incontinence is highly prevalent in the elderly population and associated with morbidity and poor outcomes. Many factors contribute to the development of urinary incontinence in the elderly including sex, chronic disease, obesity, low sphincter muscle strength, lifestyle (smoking, alcohol, sedentariness), impaired mobility, and aging itself, some of which are preventable and/or modifiable. The benefits of behavioral treatments such as PFM and weight or BMI reduction exercises are that they are safe with few risks and no side effects. These therapies are often recommended as first line treatments for elderly people with urinary incontinence.

Evidence reveals that PFM training and fitness exercise targeted at reducing modifiable risk factors are effective strategies for treating urinary incontinence in elderly people, regardless of urinary incontinence type.

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Effectiveness of exercise with or without thermal therapy for community-dwelling elderly Japanese women with non-specific knee pain: A randomized controlled trial

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ABSTRACT

Knee pain is a common health problem in the elderly population, for which non-invasive treatments are recommended as a first line treatment in the management of knee pain. A randomized controlled trial was conducted to determine the effects of exercise with or without thermal therapy in community-dwelling elderly women with chronic knee pain. Women over 75 years of age with knee pain ($n = 150$) were randomly assigned into four groups; exercise (Ex) and heat/steam generating sheet (HSGS) ($n = 38$), Ex ($n = 37$), HSGS ($n = 38$), or health education (HE) ($n = 37$). The Ex group attended a 60-min comprehensive training program twice a week for 3-months. The HSGS group placed two sheets on the knee for five hours per day. Functional fitness, visual analog scale (VAS), and Japanese knee osteoarthritis measure (JKOM) were assessed at baseline and post-intervention. The results showed VAS improvements in the Ex + HSGS and HSGS groups. Total JKOM score, muscle strength, and functional mobility significantly improved in the Ex + HSGS group compared with the HE group. The odds ratio (OR) for VAS and functional mobility improvement was more than eight times as great in the Ex + HSGS group (OR = 8.60, 95% confidence interval (CI) = 2.82–32.73) compared with the education group. Ex or HSGS alone were insufficient in enhancing functional fitness or improving pain and quality of life. The combined effects of both Ex and heat therapy seems to have an added benefit of decreasing pain, improving physical function and increasing quality of life. Trial Registration Number: JMA-IIA00110.

1. Introduction

Knee pain is one of the most common knee problems experienced by elderly people (Hadler, 1992), and chronic knee pain has been associated with mobility limitations, and future dependence in activities of daily living (Davis, Ettinger, Neuhaus, & Mallon, 1991; Nishiwaki, Michikawa, Yamada, Eto, & Takebayashi, 2011). Risk factors including obesity, weakness of the knee extensor muscles, extreme physical activity levels (i.e. over-exercising, total sedentariness), and chronic diseases for knee pain are well documented (Jinks, Jordan, Blagojevic, & Croft, 2008; Lamb et al., 2000). The risk of developing knee pain is influenced by the presence of multiple risk factors (Dekker, Tola, Aufdemkampe, & Winckers, 1993; Jinks et al., 2008; Lamb et al., 2000; O'Reilly, Jones, Muir, & Doherty, 1998), and eliminating these risk factors may reduce symptoms and disability associated with knee pain. Some factors, such as age and sex are fixed and unchangeable, but others including obesity, muscle weakness, over-exercising, as well as sedentariness, can be modified with non-pharmacologic therapies (Doi et al., 2008; Fransen & McConnell, 2008).

Several previous investigations have focused on treatments for radiographic osteoarthritis (OA). However, Hadler suggested that knee pain, not OA, is the malady, as a greater percentage of elderly people suffer from knee pain than knee OA. It has been suggested that symptoms of knee OA, i.e. pain, can exacerbate or regress regardless of radiographic progression (Hadler, 1992). Many studies have suggested that exercise should be one of the mainstays of treatment (Ettinger et al., 1997; Fransen & McConnell, 2008; Minns Lowe, Barker, Dewey, & Sackley, 2007) for knee OA. The recommendations for exercise are based on several randomized controlled trials showing that both aerobic and resistance exercises improve physical fitness and can reduce pain symptoms in elderly people with chronic knee pain caused by OA (Deyle et al., 2000; Ettinger et al., 1997; Kovar et al., 1992; Roddy et al., 2005).

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These previous studies were conducted on populations with wide age ranges, including middle-aged adults, from 40 to 50 years old (Hay et al., 2006; Hurley et al., 2007; O'Reilly, Muir, & Doherty, 1999; Thomas et al., 2002), and very few trials, if any, have studied the effects of exercise on non-specific knee pain focusing on community-dwelling elderly people over the age of 75. Other methods of treatments besides exercise can be used to treat pain. One such treatment method, topical heat therapy, has been reported to be effective and safe in the treatment of low back (Nadler et al., 2002), knee (Giombini, Di Cesare, Di Cesare, Ripani, & Maffulli, 2011; Mazzuca, Page, Meldrum, Brandt, & Petty-Saphon, 2004; Seto, Ikeda, Hisaoka, & Kurosawa, 2008; Yildirim, Filiz Ulusoy, & Bodur, 2010) and wrist pain (Michlovitz, Hun, Erasala, Hengehold, & Weingand, 2004). A recently developed HSGS has been suggested as an effective method for alleviating pain and improving stiffness and gait impairment in patients with knee OA (Oda et al., 2006; Seto et al., 2008). While several studies have confirmed the separate effects of thermal therapy and exercise treatment on symptoms of knee OA and physical function, the combined effects of both heat and exercise on non-specific knee pain and lower-extremity function is unknown in the elderly population.

We hypothesize that the combination of both heat therapy and exercise will be more beneficial for reducing knee pain and improving function. The purpose of this study was to determine the combined and separate effects of heat therapy and exercise on knee pain relief, physical function, and quality of life (QOL) in community-dwelling elderly women with chronic knee pain.

2. Methods

2.1. Subjects

The baseline survey was conducted in October 2010, on a sample of 859 women who were randomly selected from the Basic Resident Register of women aged 75 and older residing in the Itabashi ward of Tokyo as of April 1, 2010. Three hundred and two (35.2%) who reported knee pain in the baseline survey were classified as potential participants.

The inclusion criteria were: (1) age $\geq$ 75 years; (2) have knee pain at baseline; and (3) no missing baseline knee pain and functional fitness data. The exclusion criteria included: (1) severely impaired mobility (e.g. unable to walk without assistance from another person); (2) physician enforced restriction of exercise (e.g. post-knee surgery or chronic disease); (3) known dermal allergy to heat; and (4) unstable cardiac conditions such as ventricular dysrhythmias, pulmonary edema, or other musculoskeletal conditions. One hundred fifty women (150/302, 49.7%) were included in this trial, and 152 women were excluded based on the exclusion criteria.

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

2.2. Randomization

Randomization was performed after the baseline assessment, and any variable such as name, age, address, and telephone number that identified personal information was not included in the randomization process. The assigned identification numbers of 150 participants were divided into four groups based on computer-generated random numbers. The groups were randomly assigned to one of the four interventions: Ex ($n = 37$), HSGS ($n = 38$), Ex + HSGS ($n = 38$), or HE ($n = 37$). There was no attempt to equalize the size of the groups based on their characteristics or to recruit subjects with specific characteristics. The co-investigators were blind to the randomization procedure and group allocations, and data collection was conducted by separate physical therapy staff members who were also blind to the allocation of interventions.

2.3. Data collection

2.3.1. Interview survey

A face to face interview survey was conducted to assess the following variables: presence of knee pain, degree of knee pain, JKOM, history of falls, fear of falling, urinary incontinence, and chronic medical conditions. Knee pain was assessed by the question "Do you have knee pain?" A person who responded "yes" was defined as having knee pain, and the degree of pain was evaluated as light, medium, or severe. As the focus was on knee pain based on the subjective response to the questionnaire, there were no definite clinical diagnostic measures or X-ray assessments to define knee pain. Since the origin of the pain could not be determined, the term 'non-specific' knee pain was used.

2.3.2. Anthropometric and physical function measurements

Height and body weight measurements were converted to BMI (kg/m^2). Bone mineral density (BMD) of the distal radius and ulna of the non-dominant forearm was measured by the dual-energy X-ray absorptiometry (DEXA) method using a DTX-200 osteometer (Osteometer MediTech, Inc., USA) (Kelly, Crane, & Baran, 1994). Grip strength was measured using a hand-held Smedley type dynamometer. Usual walking speed was measured on a flat walking path of 11 m, with markers at the 3 m and 8 m points. A stopwatch was used to measure the time taken to walk 5 m between the markers, and the faster time of two trials was recorded. Stride length was measured using a WalkWay device (WalkWay MW-1000, Anima Co., Tokyo, Japan). The participants walked on the WalkWay at their normal pace for 3 m, with a 1.5 m approach before reaching the starting edge of the Walkway to ensure the participants were walking at their normal pace (Shimada et al., 2010). To measure one leg standing time with eyes open, participants were asked to stand on their preferred foot, with one foot lifted off the ground, while gazing at a point set at eye level 1 m away until they placed the other foot down. The longer of two trials was recorded. The timed up & go (TUG) was used to measure physical mobility, balance, gait speed, and functional ability. TUG was measured in seconds, as the time taken for the subject to stand up from a chair, walk a distance of 3 m to a cone, walk around the cone (turn), walk back to the chair, and sit down again. The trial was repeated, and the faster time was recorded. Participants were allowed to use assistive walking devices during the physical function measurements if they expressed strong concerns of walking without a device, or if there was any danger of falling.

2.3.3. Outcome measures

The primary outcome variable of this trial was the change in degree of pain as measured by the VAS. Secondary outcome measures included changes in functional mobility, muscle strength, and JKOM total score and the subscales of the JKOM. The subscales within the JKOM measure included: pain and stiffness in the knees, which included questions regarding knee function; condition in daily life, where participants were asked about difficulties performing daily routine activities; general activities; and health conditions. These assessments were conducted at baseline and after the 3-month intervention. All data were collected at the TMIG in Tokyo, Japan.

2.4. Intervention

2.4.1. Exercise

The Ex group attended a group-based 60-min exercise class focusing on strengthening of the muscles around the knee such as the quadriceps and hamstrings, as well as the tibialis anterior, gastrocnemius and soleus. The classes were held at the TMIG health promotion center, twice a week for 3-months. Each exercise session consisted of a five minute warm-up, 30 min of strengthening exercise, followed by 20 min of balance and gait training, and 5 min of cool-down. The strengthening exercises were performed in a progressive sequence from the seated to standing positions. For each type of exercise, participants were instructed to complete up to eight repetitions of the movements. When the exercises were properly executed without significant fatigue or loss of proper execution, the resistance was increased. The progressive resistance was provided through the use of the Thera-bands and ankle-weights, and each individual's ability to increase resistance was assessed by the principal investigator, along with the exercise instructor and assistant trainers who supervised the group classes. The intensity was maintained at approximately 12–14 on the Borg rate of perceived exertion (RPE) scale (Borg, 1982). Participants exercised together within their intervention groups, and those who attended at least 15 or more sessions out of the 24 exercise sessions (60%) were considered to have completed the trial.

2.4.1.1. Muscle strength training.

Chair exercise. The chair-seated exercises were used in the early stages of the program as they provided a secure and stable position without putting any pressure on the knee joint. Repetitions of toe raises, heel raises, knee lifts, knee extensions and others, were performed while seated on a chair. While standing upright behind the chair and holding the back of the chair for stability; hip flexions, lateral leg raises, and repetitions of other exercises were performed.

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

Resistance band (Thera-Band) exercise. Resistance bands were used to strengthen the upper and lower body. Lower body exercises consisted of leg extensions, hip flexions, looped ankle presses, looped toe lifts, and more. Upper body exercises included double-arm pull backs holding the band horizontally in front of the chest, bicep curls, and others.

Balance training. The training was focused on the improvement of static and dynamic balancing ability. Exercises included standing on one leg, multidirectional weight shifts, tandem stand, tandem walk, side stepping on alternate legs, and other items.

2.4.2. HSGS group

The HSGS is a thin (89 mm × 173 mm), flexible sheet (Kao, Tokyo, Japan), that generates heat and steam via reaction of iron and atmospheric oxygen. When the sheet is placed on the skin, the temperature of the skin surface rises to around 40 °C within 30 min and it continues to generate heat and steam for over 5 h. The HSGS produces high heat flux and warms the skin more widely and deeply than the heat-generating sheet without steam (Oda et al., 2006). The participants in the HSGS group were asked to place the HSGS on the painful knee for 6 h a day immediately after waking up, and if they had pain in both knees they were asked to place the HSGS on the most painful knee. Two HSGS were applied to around the patella, and a thin supporter was worn over the two sheets. The participants recorded the time of day they placed and removed the sheet on a HSGS monitoring log, which were collected at TMIG classes every two weeks, and HSGS were provided for two weeks.

2.4.3. Ex + HSGS group

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

2.4.4. HE

Participants in the education group took a 60-min class once a month for 3-months, a total of three times. The classes focused on nutrition, cognitive function, and oral hygiene. Participants were asked to continue their usual life-style habits, and no specific instructions on physical activity or heat therapy were given.

2.5. Data analysis

Sample size was calculated for changes in the primary outcome variable of VAS. Setting the power at 0.80 and an alpha value of 0.05, the total sample size required was estimated to be 128 subjects (Cohen, 1992). When considering a potential attrition rate of 15% (Doi et al., 2008), 150 subjects were required.

Means and standard deviations were calculated for continuous variables, and a one-way analysis of variance (ANOVA) was performed to measure significant differences in baseline and post treatment values between the intervention groups, and the chi-square test was used for categorical variables. The normality of the distribution was examined by the Komogorov–Smirnov test for primary and secondary outcomes. A repeated-measures ANOVA (4 × 2) was performed on normally distributed variables including VAS, total JKOM score, stride, normal walking speed, grip strength and TUG, and the generalized linear model (GLM) was used to assess non-normal variables including JKOM subscale scores and one leg standing time, to find differences in pre- and post-intervention between groups. Paired *t*-tests were done on pre- and post-intervention measures to find changes within groups. Percent change was calculated for each JKOM measure using the following formula: % change = ((post-intervention value − baseline value)/baseline value) × 100). One-way ANOVAs were performed to determine significant differences in percent changes between the groups. The Scheffe post hoc method was used when significance was found. Multiple logistic regressions were performed to compare the effects of the four intervention groups on VAS, usual walking speed, and combined outcome variables after the 3-month intervention. All analyses were performed using SPSS 19.0 and SAS 9.2 version for Windows and $P < 0.05$ was considered statistically significant.

3. Results

The mean attendance rates during the 3-month intervention were 71.1% (range 57.9–84.2%) in the Ex + HSGS group, 82.9% (78.4–89.2%) in the Ex group, 88.2% (84.2–92.1%) in the HSGS group, and 81.1% (78.4–83.8%) in the HE group. The mean ± SD for the duration of HSGS use for the Ex + HSGS group was 6.49 ± 0.79 h/day, and 6.41 ± 0.59 h/day for the HSGS group ($P = 0.660$). Thirteen participants (Ex + HSGS = 5, Ex = 3, HSGS = 3, HE = 2) were unable to complete the study after randomization because of admission to nursing home ($n = 1$), lack of motivation ($n = 4$), hip fracture ($n = 1$), spouse care ($n = 3$), severe back pain ($n = 1$), and other unknown reasons ($n = 3$) (Fig. 1). These 13 subjects were excluded from all post-intervention analyses.

Table 1 shows the baseline comparisons in anthropometric values, physical fitness measures, and interview survey results

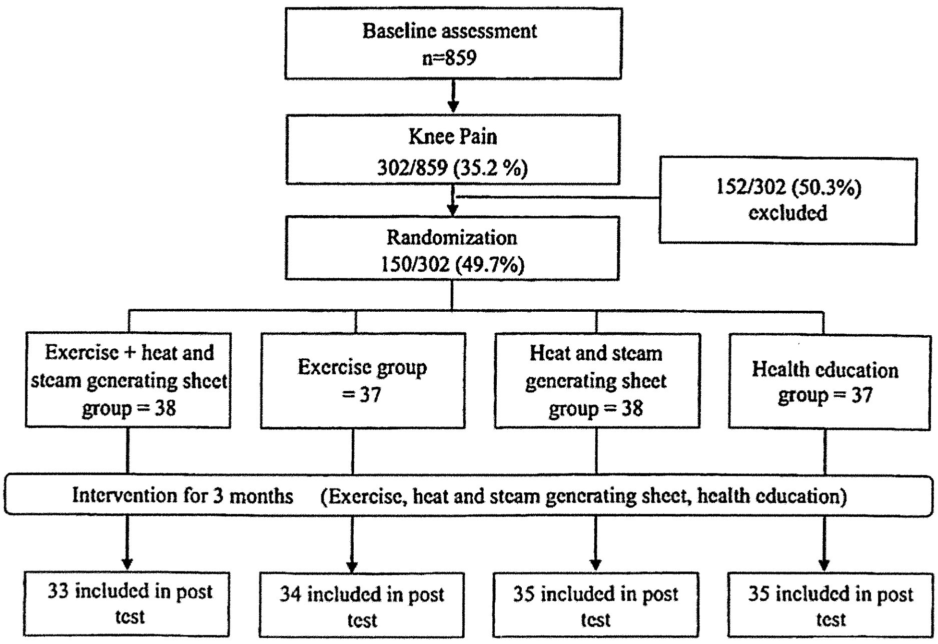

Fig. 1. Flow chart of participants in randomized controlled trial of Ex and HSGS for knee pain.

among the Ex + HSGS, Ex, HSGS, and HE groups. There were no significant differences between the groups in all variables including age, body weight, body mass index, BMD, TUG, degree of knee pain, and chronic medical conditions.

The repeated measure ANOVA showed significant improvements in VAS ($P = 0.006$) and total JKOM score ($P = 0.034$) in the Ex + HSGS group compared with the HE group (Table 2). TUG was significantly faster in the Ex + HSGS and Ex only groups, than in the HSGS or HE groups. The Ex + HSGS group also showed significantly greater changes in all other measures of mobility; usual walking speed ($P < 0.001$), and stride length ($P < 0.001$); as well as grip strength ($P = 0.001$). The GLM analysis showed no significant differences from baseline to post-intervention in the JKOM subscales of pain and stiffness of the knees, condition in daily life, general activities or health conditions, or in one leg standing time between any of the groups.

Fig. 2 shows the changes in VAS from pre- to post-intervention. Significant improvements were found in the Ex + HSGS group (39.4%, $P < 0.001$) and the HSGS group (26.9%, $P = 0.032$). The improvements were significantly greater in the Ex + HSGS and HSGS groups compared with the HE group.

There was a significant improvement in the Ex + HSGS group (14.2%, $P < 0.001$) for TUG from pre- to post-intervention (Fig. 3). Improvements in TUG were also observed in the Ex

Table 1
Selected baseline variables of participants by study group.

Variables[a]	Category	$M \pm SD$				F-Value[†]	P-Value
		Ex + HSGS group $n = 38$	Ex group $n = 37$	HSGS group $n = 38$	Education group $n = 37$		
Age (yr)		80.50 ± 2.41	80.86 ± 2.30	80.29 ± 2.96	80.54 ± 2.70	0.311	0.817
Height (cm)		149.42 ± 6.50	147.70 ± 4.90	149.17 ± 5.87	146.78 ± 4.78	1.888	0.134
Body weight (kg)		51.82 ± 7.89	51.73 ± 8.01	51.46 ± 7.31	50.72 ± 6.25	0.168	0.918
Body fat (%)		32.16 ± 3.69	32.86 ± 4.15	31.58 ± 4.68	32.47 ± 4.10	0.625	0.600
Body mass index (kg/m^2)		23.16 ± 2.78	23.67 ± 3.20	23.12 ± 2.91	23.59 ± 3.09	0.341	0.796
BMD (g/cm^2)		0.29 ± 0.06	0.30 ± 0.07	0.29 ± 0.06	0.30 ± 0.06	0.159	0.924
Calf girth (cm)		33.61 ± 2.72	33.66 ± 3.13	33.88 ± 2.93	33.73 ± 2.45	0.063	0.979
Grip strength (kg)		20.70 ± 4.43	19.75 ± 3.71	20.51 ± 4.74	19.81 ± 3.69	0.493	0.688
Usual walking speed (m/s)		1.11 ± 0.24	1.13 ± 0.23	1.11 ± 0.21	1.14 ± 0.27	0.192	0.902
Stride length (cm)		105.84 ± 15.53	103.92 ± 11.37	106.26 ± 16.39	98.64 ± 18.25	1.564	0.202
TUG (s)		8.67 ± 4.01	7.54 ± 1.91	7.80 ± 2.27	8.30 ± 3.63	1.012	0.389
One leg standing time (s)		26.55 ± 23.37	27.05 ± 22.66	31.76 ± 23.58	32.00 ± 24.47	0.586	0.625
Degree of knee pain	Light	55.3	59.5	50.0	48.6	2.066	0.914
	Medium	34.2	27.0	34.2	40.5		
	Severe	10.5	13.5	15.8	10.8		
Falls	Yes	23.7	24.3	21.1	10.8	2.734	0.435
Fear of falling	Yes	92.1	83.8	78.9	83.8	2.622	0.454
Urinary incontinence	Yes	47.4	35.1	39.5	43.2	1.267	0.737
Chronic medical conditions (%)							
Stroke	Yes	5.3	10.8	7.9	5.4	1.118	0.773
Heart disease	Yes	21.1	29.7	31.6	24.3	1.363	0.714
Diabetes	Yes	15.8	5.4	15.8	8.1	3.179	0.365
Osteoporosis	Yes	44.7	45.9	44.7	43.2	0.055	0.997

[a] Data are presented as M (mean) and SD (standard deviation) for continuous variables, and percentage for categorical variables.
[†] One-way ANOVA for continuous variables and chi-square test for categorical variables.

Table 2
Comparison of physical function and JKOM between groups before and after the 3-month intervention.

Variables	Group	M±SD Baseline	M±SD After intervention	P value[#]	Post hoc analysis[†]
JKOM					
VAS (mm)	Ex+HSGS	36.28±20.89	19.64±16.42	0.006[a]	Ex+HSGS>HE
	Ex	39.60±24.14	33.77±21.91		
	HSGS	45.68±19.99	34.06±24.54		
	HE	32.76±19.78	37.86±22.58		
Total score (point)	Ex+HSGS	44.74±9.74	41.29±9.10	0.034[a]	Ex+HSGS>HE
	Ex	45.38±11.59	42.72±11.55		
	HSGS	46.94±13.68	44.29±11.72		
	HE	45.82±12.80	48.24±13.80		
Subscale 1: pain and stiffness in the knees (point)	Ex+HSGS	16.74±5.52	13.96±4.24	0.121[b]	
	Ex	15.40±4.72	14.00±3.89		
	HSGS	16.25±5.09	15.41±5.19		
	HE	16.94±5.67	17.42±5.93		
Subscale 2: condition in daily life (point)	Ex+HSGS	16.33±4.50	15.11±4.18	0.370[b]	
	Ex	17.03±4.90	15.93±5.15		
	HSGS	17.34±5.64	16.56±5.08		
	HE	18.52±6.83	18.94±7.06		
Subscale 3: general activities (point)	Ex+HSGS	7.19±1.52	7.59±2.08	0.327[b]	
	Ex	7.93±2.32	7.93±2.66		
	HSGS	8.44±3.04	8.19±2.66		
	HE	9.30±4.25	8.94±3.03		
Subscale 4: health conditions (point)	Ex+HSGS	4.11±1.28	3.78±1.22	0.603[b]	
	Ex	4.07±1.36	3.60±1.25		
	HSGS	4.31±1.65	4.09±1.57		
	HE	4.30±1.63	4.45±1.52		
Physical function measures					
TUG (s)	Ex+HSGS	8.47±4.19	7.00±3.00	0.004[a]	Ex+HSGS, Ex>HSGS, HE
	Ex	7.51±1.96	6.21±1.22		
	HSGS	7.51±2.11	7.28±2.06		
	HE	7.94±2.96	7.65±2.52		
Usual walking speed (m/s)	Ex+HSGS	1.14±0.22	1.36±0.21	<0.001[a]	Ex+HSGS>HE
	Ex	1.17±0.22	1.40±0.20		
	HSGS	1.13±0.20	1.23±0.19		
	HE	1.14±0.28	1.18±0.27		
Stride length (cm)	Ex+HSGS	105.84±15.53	114.76±14.21	<0.001[a]	Ex+HSGS>HE
	Ex	103.92±11.37	114.42±12.06		
	HSGS	106.26±16.39	105.86±16.50		
	HE	98.64±18.25	102.53±17.91		
Grip strength (kg)	Ex+HSGS	20.96±4.49	22.15±4.74	0.001[a]	Ex+HSGS>HE
	Ex	20.47±3.35	21.10±3.09		
	HSGS	20.97±4.87	20.00±4.67		
	HE	19.74±3.71	18.88±3.83		
One leg standing time with eyes open (s)	Ex+HSGS	32.86±24.06	33.46±22.88	0.807[b]	
	Ex	27.42±23.67	27.74±24.17		
	HSGS	33.21±23.35	27.67±22.29		
	HE	31.89±24.88	28.09±22.19		

[#] a = P value was calculated using ANOVA; b = P value calculated by generalized linear model.
[†] Scheffe post hoc method.

only group (13.2%, $P = 0.001$); however no significant changes were observed in the HSGS (1.9%) and HE groups (2.8%). Significant improvements were observed in the Ex + HSGS group (7.1%, $P = 0.032$) for total JKOM score from pre- to post-intervention (Fig. 3). The ANOVA results revealed that the Ex + HSGS group had significantly greater improvements compared with the HE group in total JKOM score (Fig. 3), although no superiority between the other intervention groups were observed.

The multiple logistics regression showed that significant effects on changes in VAS were observed in the HSGS group (OR = 7.06, 95% CI = 2.37–23.25) and the Ex + HSGS group (OR = 9.88, 95% CI = 3.09–36.88); whereas significance was seen in the Ex + HSGS (OR = 3.73, 95% CI = 1.16–11.99) group on changes in TUG. Only the Ex + HSGS intervention had a significant effect on changes in the combination of VAS and TUG (OR = 8.60, 95% CI = 2.82–32.73), while the separate HSGS and Ex interventions did not have a significant effect (Table 3).

4. Discussion

The data suggest that heat therapy combined with exercise showed beneficial effects on elderly Japanese women with chronic knee pain, as hypothesized. The combination group observed knee pain reductions of 39.6%, as well as increases in functional mobility as measured by TUG (14.2%). The participants in the Ex group did not show significant improvements in knee pain or JKOM, while the HSGS group showed significant alleviation of knee pain, but not JKOM or functional mobility.

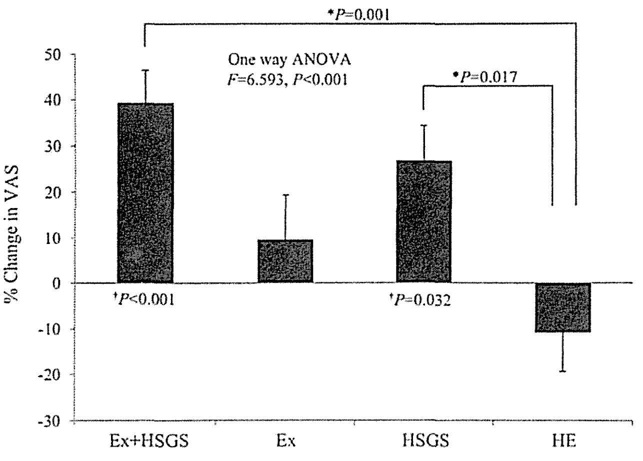

Fig. 2. Percent changes in VAS between study groups. †P-value for within-group analyses. *P-value for between-group analyses.

One previous study reported that exercise treatment can have an 8–27% reduction in knee pain and a 10–39% improvement in function (Deyle et al., 2000). Exercise alone in the current study successfully improved functional mobility, but only reduced knee pain by 9.5%, as measured by VAS. However, exercise combined with the HSGS sheet produced a 39.4% reduction in knee pain and a 14.2% improvement in TUG, a measure of functional mobility, both which are comparable values to those found in previous studies. The improvements observed in the Ex + HSGS group are clinically relevant as several published works have suggested that changes ranging from 12% to 25% may be considered clinically important and could represent meaningful changes in patients with lower-extremity knee pain (Angst, Aeschlimann, & Stucki, 2001; Barr et al., 1994).

Several studies have presented positive results of exercise treatments on knee pain and physical function in elderly adults with knee OA (Deyle et al., 2000; Ettinger et al., 1997; Kovar et al., 1992; Roddy et al., 2005). There has been evidence that exercise can also decrease knee pain through various proposed mechanisms including improved knee cartilage glycosaminoglycan content with increased exercise (Fransen & McConnell, 2008; Roos & Dahlberg, 2005; Tse, Wan, & Ho, 2011); nevertheless, the Ex group only showed a slight, non-significant decrease in stiffness and pain as seen in Table 2. As for non-specific knee pain, the results of this study suggest that exercise alone may be insufficient in relieving pain in community-dwelling elderly people. Recently Woollard et al. (2011) reported that there were no changes in the pain and stiffness subscales of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) in the 17 participants who underwent physical therapy programs similar to the program provided in the current study. However, in comparing the results of the current study with the study by Woollard et al., it is important to note that their study population included those with radiographically diagnosed knee OA, not non-specific knee pain; they compared pain levels from baseline to 1-year follow up, and did not report pain levels immediately after the 6-week physical therapy program; and had a very small sample size of 17 people. Nevertheless, both our study and the study by Woollard et al. showed little overall change in pain levels in elderly participants after similar exercise programs. Perhaps the inconsistent evidence of whether exercise can relieve knee pain is due to the differences in exercise dosage (frequency, intensity, and duration), as mentioned by (Fransen & McConnell, 2008). Further research investigating the effects of various exercise dosages on knee pain is required.

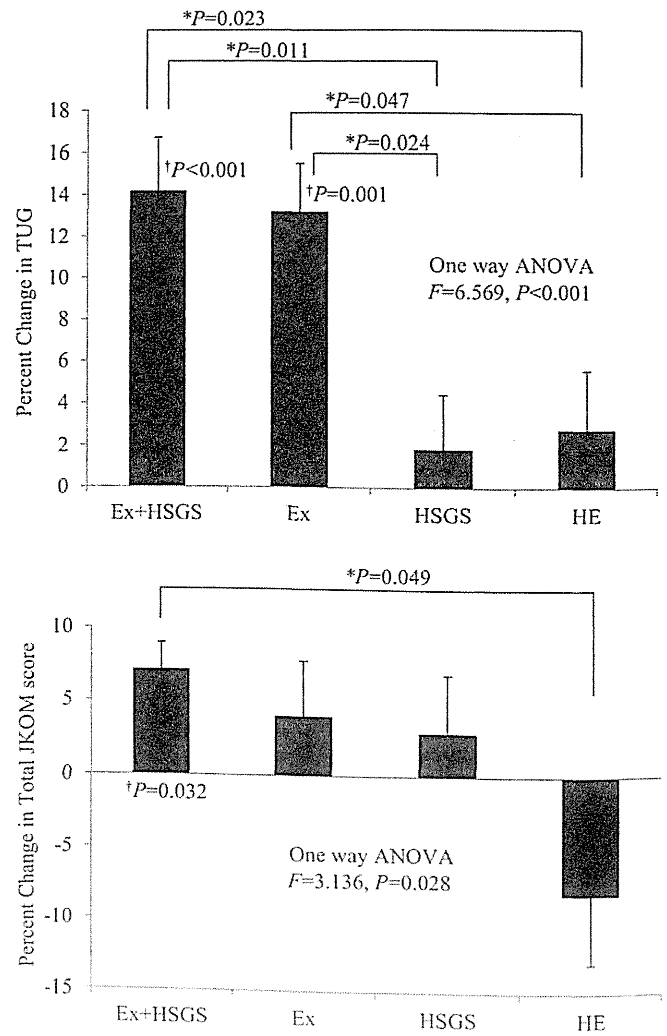

Fig. 3. Percent changes in TUG and JKOM total score. †P-value for within-group analyses. *P-value for between-group analyses.

The use of HSGS seems to promote significantly greater pain reductions than exercise alone. Our data shows that significant reductions in pain, as measured by VAS, were observed in the Ex + HSGS and HSGS groups. The results support previous findings that have reported the pain-relieving effects of heat

Table 3
Adjusted ORs with 95% CIs for changes in single and combined variables of VAS and TUG according to study group.

Dependent variable[a]	Adjusted ORs (95% CI)		
	HSGS	Ex	Ex + HSGS
Change in VAS	7.06 (2.37–23.25)	2.82 (0.98–8.50)	9.88 (3.09–36.88)
Change in TUG	0.79 (0.31–2.04)	2.57 (0.87–7.51)	3.73 (1.16–11.99)
Change in VAS and TUG	2.78 (0.92–8.37)	3.12 (0.95–10.26)	8.60 (2.82–32.73)

Reference: HE.
[a] 1 = improve, 0 = no change or decrease.

(Nadler et al., 2002; Seto et al., 2008). While our data could not confirm the mechanisms of HSGS use and exercise on knee pain, Seto et al. suggested that significant alleviation of pain of the knee can improve gait with the use of HSGS due to the increase in soft-tissue flexibility and decrease in pain from improved blood circulation (Seto et al., 2008). Consistent with such previous findings, even in the subjective JKOM subscales used in this study, the results did indeed show significant alleviation of knee pain and stiffness in the Ex + HSGS group. These results seem to suggest that perhaps the combination of exercise and thermal therapy have more beneficial effects on pain and stiffness of the knee than thermal therapy alone in this population.

The Ex + HSGS group improved significantly in measures of functional fitness compared with the HE group, especially in functional mobility measured by TUG. This test was originally developed to easily evaluate the risk of falls using balance and basic functional mobility (Podsiadlo & Richardson, 1991), and there have been recent studies that report the effectiveness of TUG for functional evaluation in knee OA patients (Adegoke, Babatunde, & Oyeyemi, 2012; Zeni, Axe, & Snyder-Mackler, 2010). One particular study (Kennedy, Stratford, Wessel, Gollish, & Penney, 2005), reported that the TUG test has excellent reliability for examining outcomes in persons with knee OA. The TUG test is a test measuring function, and previous studies have shown that knee extensor and flexor muscles training has beneficial effects on functional mobility including standing, walking, lifting, transferring loads and rising from a chair in individuals with rheumatoid arthritis (McMeeken, Stillman, Story, Kent, & Smith, 1999).

Comparably, in the present study, exercise focusing on strengthening the muscles surrounding the knee, combined with HSGS showed significant improvement in TUG in community-dwelling elderly people with non-specific knee pain. While the results of this study did not show that the combination of exercise and HSGS was more beneficial than exercise, our results along with previous studies confirm that exercise and the HSGS is effective in the treatment of not only knee pain, but functional mobility as part of a multifactorial treatment method.

The improvement in functional mobility seen with exercise and HSGS in participants with knee pain is an important finding. We believe the most effective treatment of knee pain involves improvement in not only pain itself, but in functional mobility as well. In our study, we found that the combination of exercise and HSGS had a significant effect on the combined improvements of pain (VAS) and TUG (OR = 8.60, 95% CI = 2.82–32.73; Table 3), suggesting that knee pain treatment using both exercise and heat therapy can have added beneficial effects on pain alleviation and functional mobility improvement compared with exercise or heat therapy alone.

This study has several limitations. First, the measures used to assess pain were based on subjective answers. However, the VAS and JKOM measures have been shown to be valid and reliable methods of assessing degree of knee pain (Akai et al., 2005; Carlsson, 1983). Hence, the validity of the results obtained in this study should not affect the interpretation of the results. Secondly, the data does not show the physiological mechanisms of how HSGS and exercise reduced knee pain. Third, this study did not investigate the long term effects of the exercise and HSGS. Whether or not the reductions in knee pain and improvements in walking ability affected daily physical activity levels in community-dwelling elderly women could not be determined. Fourth, some caution is needed in interpreting the results of this study as a non-thermal placebo group was not included, and the possibility that other non-thermal sensory stimuli may have affected the participants' perception of pain cannot be denied. Moreover, although the ideal study design to examine the pain-relieving effects of the interventions would have been to include a control group taking established forms of pain relief methods such as non-steroidal anti-inflammatory drugs, this could not be done in the current study. Finally, there were 13 dropouts in this study who were not included in the post-intervention analyses. However, these dropouts have very little effect on the primary outcome of this study, as there were no significant differences in baseline values between the dropouts and the participants. Future research should focus on the physiological changes induced by the combination of exercise and HSGS, long term effects, as well as the comparison of the introduced interventions with other common non-invasive forms of pain alleviation.

5. Conclusion

The combined exercise and heat therapy intervention resulted in improvements of knee pain and functional mobility that can be considered clinically important. While both exercise and heat therapy have beneficial effects on physical function and pain, respectively, the combination of both treatments may be beneficial as a wider range of improvements were observed in physical function, pain and QOL.

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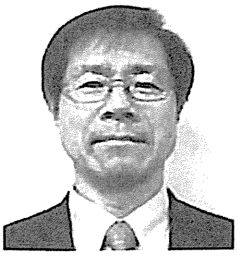
サルコペニアに対する運動・栄養による介入効果

Effects of exercise and nutrition supplementation for the prevention of sarcopenia



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◎骨格筋量の減少に伴う筋力の衰え，あるいは歩行機能の低下をさすサルコペニアを効率よく予防するためには，多様な危険因子のなかから可変的要因を見出し，その改善に焦点を当てた包括的支援が有効である．可変的要因として注目されているのは，骨格筋の不使用と栄養不良の改善である．運動・栄養による介入効果を検証するために，地域在住サルコペニア高齢者をRCTにより運動，栄養，運動＋栄養，教育の４群に分け，運動群には週２回，１回当り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，栄養群にはロイシン高配合の必須アミノ酸３ｇを１日２回補充する介入を３カ月間実施した．その結果，骨格筋量と通常歩行速度は，運動，栄養，運動＋栄養の３群で，下肢筋力は運動＋栄養群のみで有意な向上が観察された．この結果は，サルコペニア予防には運動にロイシン高配合の必須アミノ酸を補充する複合介入がより効果的であることを強く示唆する．

Key word：サルコペニア，RCT，包括的運動，必須アミノ酸補充

骨格筋量の減少に影響する要因は，加齢，慢性疾患，内分泌環境の変化，骨格筋の不使用，栄養不良などさまざまであるが，そのメカニズムの完全解明までには至ってない．骨格筋量の減少に伴う筋力あるいは身体機能の低下を予防するためには，さまざまな要因のなかから可変因子を見出し，その改善に焦点を当てた包括的な支援が有効である．可変因子として注目されているのは，“からだの不使用”と“栄養不良”である．

からだの不使用を解消する手法としては運動が勧められ，たとえ高齢者でも，progressive resistance strength trainingを行うと筋肉量や筋力の増大効果は期待できると多くの研究で指摘している[1,2]．一方，高齢者の筋量上昇に栄養補充が有効であるとの研究も多く報告されている[3]．なかでも，必須アミノ酸補充による筋蛋白質の合成促進効果が検証され，サルコペニア予防のための栄養補充としての有効性に関心が高まっている[4]．

サルコペニアに対する運動介入の効果と問題点

高齢者の筋量上昇や筋力向上には，レジスタンス運動が有効であると多くの研究で指摘している．先行研究49編の介入研究をmeta-analysisしたPetersonによると，介入後にlean body mass (LBM)は平均で1.1 kg(95%CI＝0.9-1.2 kg，$p<0.001$)増大効果を認め，レジスタンス運動の有効性を検証している[1]．一方，レジスタンス運動が筋力向上に及ぼす影響は部位によって異なり，leg press(32介入研究)で31.63 kg(95%CI＝27.59-35.67 kg，$p<0.001$)，chest press(36介入研究)で9.83 kg(95%CI＝8.42-11.24 kg，$p<0.001$)，knee extension(28介入研究)で12.08 kg(95%CI＝10.44-13.72 kg，$p<0.001$)といずれの部位においても有意な向上効果を認めた[5]．このように，レジスタンス運動指導によって筋肉量のみならず筋力増大効果は十分得られると期待される．しかし，ここで注意すべき点は先行研究で採用している運動の量である．上昇効果を検証している先行