



Brief self-exercise education for adults with chronic knee pain: A randomized controlled trial

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ABSTRACT

Objectives: Effective brief instructions for self-management of chronic knee pain are needed.

Methods: Forty-six participants with chronic knee pain were randomly allocated into two programmes: material-based education alone or brief self-exercise education (brief-See), which comprised a 100-minute instruction for self-exercise combined with compact pain education. Total function (KOOS₄, 4-subscale average of knee injury and osteoarthritis outcome score), pain intensity (NRS, numeric rating scale), self-efficacy (PSEQ, pain self-efficacy questionnaire), and health-related quality of life (EQ-5D, European quality of life-5 dimensions) were evaluated at baseline and 4 and 12 weeks after the initial intervention. A generalized mixed linear model estimated average group differences in changes from baseline and 95% confidence intervals (95% CIs) using intention-to-treat principle.

Results: Compared to material-based education alone, the brief-See provided significant additional improvements of 9.4% (95% CI: 2.3 to 16.4) on the KOOS₄ and 5.4 points (0.3 to 10.4) on the PSEQ at 12 weeks but did not on the NRS and EQ-5D. Adherence and satisfaction were favourable in the brief-See without any notable adverse event.

Conclusions: Adding the brief-See to material-based education could be more acceptable and restore total function and self-efficacy, which could contribute to the self-management of chronic knee pain in primary care.

KEYWORDS: Brief therapy; chronic knee pain; pain management; preventive medicine; public health

Introduction

Chronic knee pain, lasting for more than 3 months, is associated with future disability and reduced quality of life [1, 2]. Current clinical guidelines recommend supporting self-management among individuals with chronic knee pain [3–5], but this evidence shows only slight benefits on self-management skills, function, and symptoms, indicating low clinical importance [6]. Information provision and exercise are the most common types of interventions for knee pain, but most studies have assessed these interventions independently [7]. For effective self-management support, combining similar elements shared with exercise therapy and cognitive behavioural therapy interventions may be desirable. Furthermore, it would be useful if the interventions were as short as possible, such as brief interventions for mild to moderate alcohol problems [8].

Although there are many studies of education programmes with exercise to enhance self-management, the total contact time generally required has ranged from 720 minutes (60 minutes per session, twice a week, for 6 weeks) to 2160 minutes (45 minutes per session, three times a week, for 16 weeks) [7]. These required times, however, have become barriers to implementation in the community health-care and primary care. It is important from a practical perspective to identify additional effects of individualized education compared to material-based education alone because of the differences in required resources and cost.

In this community-based pragmatic trial, we assessed the additional effects of time-restricted self-management education using self-exercises on chronic knee pain compared to material-based education alone.

Materials and methods

Participants and setting

This trial was a community-based, randomized, 12-week parallel-group trial (Figure 1) and an ancillary study of the Circulatory Risk in Communities Study (CIRCS). The details of the CIRCS have been described elsewhere [9, 10]. As a result of systematic recruitment via an annual cardiovascular risk survey, 276 adults with chronic knee pain were identified. Of those, 49 participants applied to this trial, and, finally, 46 eligible adults with chronic knee pain participated in the study (Figure 1). The inclusion criteria were as follows: (1) had knee pain in the previous 4 weeks that had persisted for longer than 3 months, (2) were aged 40–79 years, and (3) attended an orientation session. The exclusion criteria were (1) with suspected inflammatory causes and/or referred pain from the hip or back (e.g. rheumatoid arthritis, intervertebral disc herniation, and spinal stenosis), (2) with a history of knee operation (e.g. total knee replacement and high tibial osteotomy) or had scheduled an operation during the study period, (3) with extremely mild knee pain (undetectable pain using outcome measures), (4) with a scheduled move or long-term trip during the study period, (5) with any difficulties comprehending the Japanese language and/or responding to the questionnaires (e.g. obvious cognitive impairment), (6) with any difficulty obtaining informed consent to participate in the study, or (7) who were deemed ineligible by a public health or orthopaedic doctor. Verbally informed consent was obtained from all subjects involved in the study. This study protocol was approved by the Ethics Committees of the Nippon Medical School (29–23), and the trial registration number is UMIN000035225.

Baseline and Follow-up Variables.

All pain-related outcomes and follow-up measures were self-administered and submitted by mail (follow-up period: 4 ± 1 weeks and 12 ± 1 weeks). The support staff, who were different from the intervention therapists, telephoned the participants once as a reminder if necessary. We measured pain-related outcomes, including total function (KOOS₄, 4-subscale average of knee injury and osteoarthritis outcome score) [11–13], pain intensity (NRS, numeric rating scale), self-efficacy (PSEQ, pain self-efficacy questionnaire) [14, 15], and health-related quality of life (EQ-5D, European quality of life-5 dimensions) [16, 17]. At the follow-up period, we assessed frequency of self-exercise per week (less than 1 day; 1 day; 2 to 3 days; 4 to 5 days; and 6 days or more), use of textbook (never; read through; and read and use it), global improvement (very much better; better; a little better; no change; a little worse; worse; and very much worse), and satisfaction with the programme (very much satisfied; satisfied; a little satisfied; neutral; a little unsatisfied; unsatisfied; and very much unsatisfied). To assess global ratings of improvement and satisfaction, a 7-point Likert scale is recommended according to the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) [18]. In addition, we obtained the baseline data regarding age, sex, body mass index, depressive symptoms, current job, pain duration, pain frequency, medical consultation use for pain (current), pain medication use (current), medical consultation use for pain (ever), intra-articular injection use (ever), receiving any exercise therapy instructions (ever), frequency of exercise use for pain, and psychological factors (generic STarT Back, subgroups for targeted treatment back screening tool) [19–21].

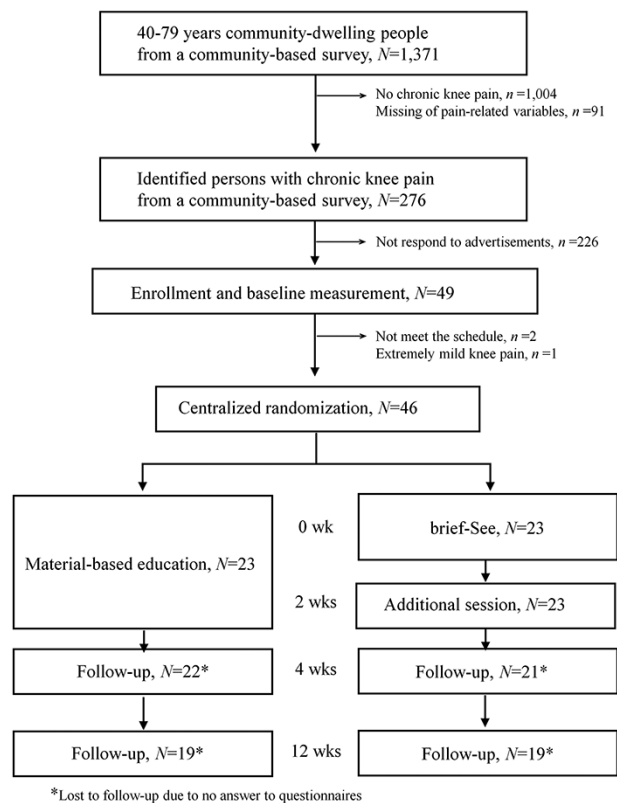


Figure 1. Flow diagram of the present study.

*Lost to follow-up due to no answer to questionnaires.

The item of receiving exercise therapy instruction (ever) was asked by ‘Have you ever been instructed how to stretch or exercise for pain by actually moving your body (including group exercise)?’, which means that the providers could be everybody who provide exercise therapy, such as physical therapists, doctors, health coaches, and judo therapists.

Allocation

The eligible participants were allocated into either the brief-See or the material-based education alone conditions. We stratified patients in terms of age (65 years or older; younger), sex (female; male), pain intensity (NRS, 7 or higher; lower), and the STarT Back subgroup (0 to 1 points; 2 points or greater) and randomly allocated the patients with minimization. To achieve allocation concealment, the allocation staff was not involved in the baseline assessment or intervention.

Intervention programme

The brief-See, i.e. a 100-minute therapist-delivered preventive intervention for enhancing self-management, comprised the initial instruction (30 minutes) at 2 weeks after the baseline and subsequent sessions at 2 weeks (30 minutes), 4 weeks (20 minutes), and 8 weeks (20 minutes) after the initial instruction. The last two sessions were conducted at the participants’ request. For the initial instruction, the intervention therapists individually supported the selection of two to four self-exercises, followed by mastering these self-exercises and understanding the relationships (possible mechanisms)

between functional limitations and these self-exercises (selecting information individually). The intervention therapists used a pain-provocation test to confirm that the participants could identify subjective changes from before to after the self-exercise. In the subsequent sessions, the participants shared their progress, and the intervention therapist provided advice about the self-exercises and modifications of the self-exercise intensity and/or their combination (progress monitoring). These instructions were based on the original self-management textbook. The intervention staff had experience in treating musculoskeletal disorders and specialized exercise therapy skills (more than 10 years of experience). In contrast to the brief-See condition, the material-based education condition comprised provision of the same textbook alone. The textbook included the self-exercises for chronic knee pain consisted of four types of self-exercises: contracture improvement, up-right posture, tracking movement, and endogenous activation (CUTE) (Figure 2(a)) [22], the basic principles to improve pain, the basic process and causes of chronic knee pain, the vicious cycle of pain caused by fear-avoidance beliefs, and the introduction of a self-monitoring tool (Figure 2(b)). More detailed information on the CUTE concepts is described in the Supplementary Box.

Thus, the difference between the two groups was whether or not a therapist was involved. Relative to most of the traditional interventions with therapists [7, 23], it was not characterized by regular and continuous face-to-face support but by therapist-delivered low-frequency and short-time education for enhancing self-management.

Statistical analysis

The primary major outcome was KOOS₄ scores, followed by NRS scores, as both have been recommended for use as outcome measures [18]. Prior to starting the intervention, we planned to use a generalized linear mixed effects model allowing sample size reduction while maintaining efficiency and analysis with intention-to-treat principles [24]. We estimated 22 participants per group with a power level of 0.80, a significance level of 0.05, and 15% dropout. This sample size allowed us to detect true mean group differences of 8 points or greater on the KOOS₄ and 1.5 points (30% of 5 points) on the

NRS, considered a minimally clinically important difference [11, 12, 18]. We estimated the mean changes from the baseline and the group differences in KOOS₄, NRS, PSEQ, and EQ-5D scores, the frequency of self-exercise and use of materials, and global ratings of improvement and satisfaction. Regarding the baseline characteristics, we used a generalized linear effects model to evaluate the group differences. Interaction trends of the effects based on participant characteristics, such as age, sex, overweight, pain duration/intensity/frequency, pain medication use, exercise use for pain (ever), psychometric factors, and self-exercise frequency/textbook use at 4 weeks, were investigated for the outcomes with significant group differences as subanalyses (significance level: 0.10). The statistical software used was SAS Version 9.4 (SAS Institute Inc., Cary, NC).

Results

There were no significant group differences in basic characteristics (Table 1). The participants were approximately 70 years old and predominantly female. Approximately 40% of the participants were overweight, 10% were depressed, and most of them were homemakers and unemployed. The duration of pain was 1–15 years in most participants, and the mean duration was 5.3 years. Approximately 40% of the participants currently used medical consultation for pain, and approximately 40% exercised more than four times a week. The proportion of ever intra-articular injection user was approximately 15%, and ever physical therapy support user was only one participant in the material-based group (data not shown). The calculated overall averages (standard deviations) at baseline were 69.1 (13.6) for the KOOS₄, 4.9 (2.2) for the NRS, 42.3 (12.5) for the PSEQ, and 0.776 (0.172) for the EQ-5D scores. In the brief-See condition, all participants completed the initial essential sessions and those 2 weeks after. Response rates at 4 and 12 weeks were 94% and 83%, respectively. In additional analyses to compare the participants (*n* = 46) with non-participants (*n* = 230), the participants in the programme showed a greater likelihood of being female, a homemaker, and an ever exercise and medication user for pain and a lower frequency of being office worker and having a medium severity level of pain (see the Supplementary Table S1).

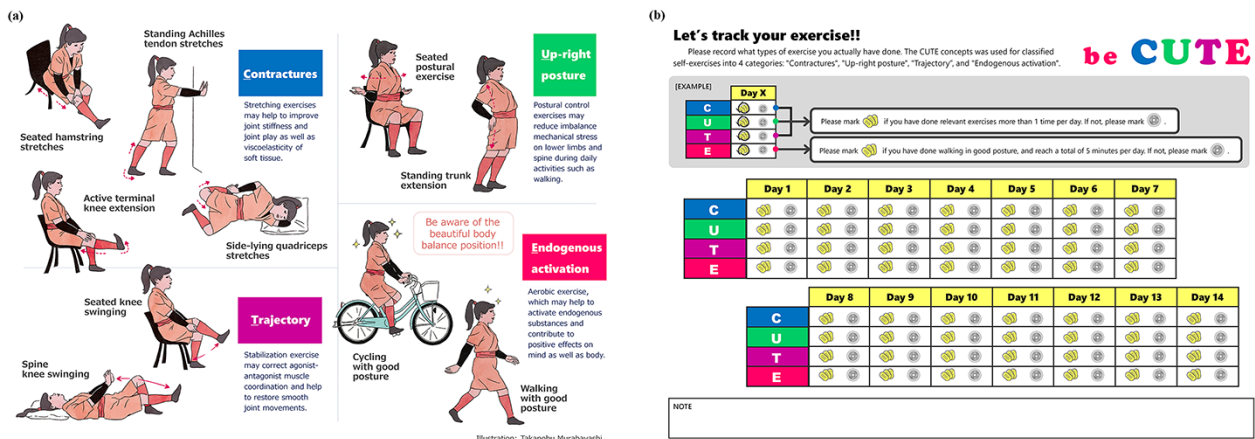


Figure 2. The CUTE concept of self-exercise and self-monitoring tools for the management of chronic knee pain. (a) The CUTE concepts were used to classify self-exercises into four categories: 'Contractures', 'Up-right posture', 'Trajectory', and 'Endogenous activation'. (b) Self-monitoring tool for the initial 2 weeks.

Table 1. Characteristics of participants at baseline.

	Material-based	Brief-see	<i>p</i> -value
Number of participants	23	23	
Age, year	69, 65–75	69, 65–75	.918
40 to 64 years, %	5 (12)	5 (12)	1.000
Male, %	2 (9)	3 (13)	.645
Body mass index, kg/m ²	23.9, 21.8–25.6	23.8, 20.7–26.1	.959
Overweight (≥ 25 kg/m ²), %	9 (39)	9 (39)	1.000
Depressive symptom, %	2 (9)	3 (13)	.645
Job, %			
No job	7 (30)	6 (26)	.750
Homemaker	9 (39)	9 (39)	1.000
Farmer	4 (17)	3 (13)	.690
Other office worker	3 (13)	5 (22)	.448
Pain duration, %			
3 months to 1 year	4 (17)	6 (26)	.486
1 to 5 years	8 (35)	10 (43)	.556
5 to 15 years	9 (39)	5 (22)	.209
15 years or longer	2 (9)	2 (9)	1.000
Pain frequency, %			
Less than 1 day per week	4 (17)	8 (35)	.187
1 to 3 days per week	8 (35)	7 (30)	.760
4 days or more per week	11 (48)	8 (35)	.380
Medical consultation use for pain (current), %	8 (35)	8 (35)	1.000
Pain medication use (current) ^a , %	9 (39)	10 (44)	.771
Medical consultation use for pain (ever), %	20 (87)	18 (78)	.556
Intra-articular injection use (ever), %	3 (13)	4 (17)	.690
Received any exercise therapy instructions (ever), %	15 (65)	13 (57)	.448
Exercise frequency for pain, %			
Less than 1 day per week	5 (22)	8 (35)	.337
1 to 3 days per week	8 (35)	6 (26)	.532
4 days or more per week	10 (44)	9 (39)	.771
Psychometric factors (generic STarT Back)			
Total points	1.0, 0–2	1.0, 0–2	1.000
Risk severity, %			
0 to 1 points	20 (87)	19 (83)	.690
2 to 3 points	3 (13)	2 (9)	.645
4 points or greater	0 (0)	2 (9)	.155
Total function (KOOS ₄)			
Total points	68, 58–80	71, 62–81	.463
Pain intensity (NRS)			
Rating points	4.9, 4–6	4.9, 3–6	1.000
Severity, %			
Mild (0 to 3)	5 (22)	8 (35)	.337
Medium (4 to 6)	14 (61)	10 (44)	.247
Severe (7 to 10)	4 (17)	5 (22)	.718
Self-efficacy (PSEQ)	42.2, 35–57	42.5, 36–52	.926
Health-related QoL (EQ-5D)			
QoL score	0.760, 0.685–0.895	0.792, 0.759–0.895	.530

^aPain medication included prescription and non-prescription drugs. Numbers (proportions) for categorical variables, and averages with lower-upper quartiles for continuous variables; Statistical significance was set at *p*-value < .05. STarT Back, subgroups for targeted treatment back screening tool; KOOS₄, 4-subscale average score of knee injury and osteoarthritis outcome score; NRS, numeric rating scale; PSEQ, pain self-efficacy questionnaire; QoL, quality of life; EQ-5D, European quality of life-5 dimensions; brief-See, brief self-exercise education; depressive symptom, defined as answering 'yes' to either 'In the past 4 weeks, little interest or pleasure in doing things?' or 'feeling down, depressed, or hopeless?'; pain medication use, defined as 'At present, do you use any medication or vaccine (except for chiropractic uses)?'.

Individuals in the brief-See condition showed significant changes from baseline on the KOOS₄, NRS, PSEQ, and EQ-5D (Table 2): for the KOOS₄, 6.1% (95% CI: 1.2 to 11.1) at 4 weeks and 9.7% (4.7 to 14.8) at 12 weeks; for the NRS, -1.8 points (-3.0 to -0.6) at 12 weeks; for the PSEQ, 4.8 points (1.3 to 8.3) at 4 weeks and 5.7 points (2.1 to 9.3) at 12 weeks; and for the EQ-5D, 0.076 points (0.018 to 0.134) at 4 weeks and 0.069 points (0.010 to 0.129) at 12 weeks. These changes did not occur with those in the material-based education alone condition. Significant additional improvements of the brief-See were observed on the KOOS₄ and PSEQ: for the KOOS₄,

9.4% (2.3 to 16.4) at 12 weeks; for the PSEQ, 5.4 points (0.3 to 10.4) at 12 weeks. Self-exercise and textbook use were significantly more frequent in those in the brief-See condition at 4 weeks (Table 3): regarding self-exercise for 4 days or more per week, 50% in the material-based education and 81% in the brief-See condition (increased by 31%); regarding reading and using the textbook, 41% in the material-based education and 95% in the brief-See condition (increased by 54%). Regarding pain improvement and satisfaction, global subjective ratings of the brief-See were significantly greater than those of the material-based education alone: subjective

Table 2. Mean changes from baseline and group differences in pain-related outcomes estimated by using a generalized mixed linear model.

Outcome	Time point	Estimates from within-group analysis						Superiority of brief-See		
		Material-based			Brief-see			Change from the baseline		
		Point-average value	Mean	p-value	Point-average value	Mean	p-value	Mean	p-value	p-value
Total function (KOOS4, higher is better)	Baseline	67.6 [62.0, 73.2]	-	-	70.5 [65.0, 76.1]	-	-	-	-	-
	4 weeks	69.6 [62.8, 76.3]	2.0 [-2.9, 6.9]	.412	76.7 [69.9, 83.5]	6.1 [1.2, 11.1]	.017	4.1 [-2.8, 11.1]	.238	
	12 weeks	67.9 [61.1, 74.8]	0.4 [-4.6, 5.4]	.896	80.3 [73.4, 87.1]	9.7 [4.7, 14.8]	<.001	9.4 [2.3, 16.4]	.011	
Pain intensity (NRS, lower is better)	Baseline	4.9 [4.0, 5.8]	-	-	5.0 [4.0, 5.8]	-	-	-	-	-
	4 weeks	4.8 [3.7, 5.8]	-0.1 [-1.3, 1.1]	.854	4.4 [3.4, 5.4]	-0.5 [-1.6, 0.7]	.430	-0.4 [-2.0, 1.3]	.667	
	12 weeks	4.6 [3.5, 5.7]	-0.3 [-1.5, 0.9]	.661	3.1 [2.0, 4.2]	-1.8 [-3.0, -0.6]	.005	-1.5 [-3.2, 0.2]	.083	
Self-efficacy (PSEQ, higher is better)	Baseline	42.2 [37.2, 47.6]	-	-	42.5 [37.5, 47.5]	-	-	-	-	-
	4 weeks	42.3 [37.0, 47.6]	0.1 [-3.3, 3.6]	.944	47.3 [41.9, 52.7]	4.8 [1.3, 8.3]	.008	4.7 [-0.2, 9.6]	.062	
	12 weeks	42.5 [37.1, 47.9]	0.3 [-3.2, 3.9]	.854	48.2 [42.8, 53.7]	5.7 [2.1, 9.3]	0.002	5.4 [0.3, 10.4]	.039	
Health-related QoL (EQ-5D, higher is better)	Baseline	0.760 [0.695, 0.825]	-	-	0.792 [0.727, 0.858]	-	-	-	-	-
	4 weeks	0.807 [0.729, 0.885]	0.047 [-0.024, 0.104]	.105	0.868 [0.790, 0.947]	0.076 [0.018, 0.134]	.012	0.029 [-0.052, 0.111]	.480	
	12 weeks	0.745 [0.712, 0.874]	0.035 [-0.024, 0.094]	.244	0.862 [0.782, 0.941]	0.069 [0.010, 0.129]	.024	0.035 [-0.049, 0.118]	.413	

Estimates values and 95% confidence intervals [lower, upper] are presented. Statistical significance was set at *p*-value <.05. KOOS4, 4-subscale average score of knee injury and osteoarthritis outcome score; NRS, numeric rating scale; PSEQ, pain self-efficacy questionnaire; QoL, quality of life; EQ-5D, European quality of life-5 dimensions; brief-See, brief self-exercise education.

Table 3. Exercise frequency, textbook use, and global ratings of improvement and satisfaction.

		Follow-up period	
		4 weeks	12 weeks
Frequency of self-exercise 2 days or more per week, %	Material-based	68	77
	brief-See	95	91
	Superiority of brief-See	27 [4, 50]	13 [-10, 37]
	<i>p</i> -value	.021	.250
4 days or more per week, %	Material-based	50	46
	brief-See	81	49
	Superiority of brief-See	31 [1, 61]	3 [-29, 34]
	<i>p</i> -value	.041	.862
Use of materials (textbook) Read through or more, %	Material-based	77	83
	brief-See	100	100
	Superiority of brief-See	23 [5, 40]	17 [-2, 35]
	<i>p</i> -value	.013	.077
Read and use it, %	Material-based	41	42
	brief-See	95	100
	Superiority of brief-See	54 [31, 77]	59 [35, 83]
	<i>p</i> -value	<.001	<.001
Global rating of improvement for knee pain Slightly improved or more, %	Material-based	32	42
	brief-See	67	97
	Superiority of brief-See	35 [8, 62]	55 [26, 83]
	<i>p</i> -value	.012	<.001
Improved or more, %	Material-based	9	10
	brief-See	33	64
	Superiority of brief-See	24 [-1, 49]	54 [28, 80]
	<i>p</i> -value	.054	<.001
Global rating of satisfaction for the programme Slightly satisfied or more, %	Material-based	41	55
	brief-See	90	90
	Superiority of brief-See	50 [24, 75]	35 [8, 62]
	<i>p</i> -value	<.001	.011
Satisfied or more, %	Material-based	18	20
	brief-See	81	80
	Superiority of brief-See	63 [38, 88]	60 [33, 86]
	<i>p</i> -value	<.001	<.001

ratings of improved or more were 10% with the material-based education and 64% with the brief-See at 12 weeks (54% increase); ratings of satisfied or more with the programme were 18% in the material-based education and 81% in the brief-See at 4 weeks (63% increase) and 20% in the material-based education and 80% in the brief-See at 12 weeks (60% increase). Additional subanalyses showed that shorter pain duration (less than 5 years) and textbook use at 4 weeks were significantly associated with greater improvements in KOOS₄ and PSEQ scores, and 4 days or more self-exercise frequency at 4 weeks was significantly associated with greater improvements in KOOS₄ scores (Supplementary Table S2). Across the entire follow-up period, no notable adverse events were observed.

Discussion

The present study developed a time-restricted self-management education programme using self-exercises and evaluated the effects of these instructions in community-dwelling people with chronic knee pain. Compared to material-based education alone, the brief-See demonstrated significant additional effects on total function and self-efficacy and boosted short-term self-exercise frequency, subjective

pain improvement, and satisfaction with the programme; although the effects were not significant for pain intensity and health-related quality of life improvements, there were significant trends towards better results observed in the brief-See condition.

Several previous studies have investigated the effects of self-management education with/without exercise compared to the provision of information alone, especially focusing on function and pain as primary outcomes. A recent Cochrane review synthesized four studies with a total of 1251 adults with chronic knee pain comparing self-management education with provision of information alone and showed no differences in outcomes in terms of function, pain, self-efficacy, and quality of life [6]. A randomized controlled trial of 120 middle-aged and older adults with non-severe osteoarthritis investigating the effects of the Stanford Arthritis Self-Management Program, which was composed of a 2.5-hour weekly group session for 6 weeks, did not show any additional differences in function, pain, or health-related quality of life compared to the effects of book provision alone [25]. Most of the relevant studies involved group education, but one study involving 107 older adults with mild hip/knee osteoarthritis with individualized nurse-led brief education, which was composed of a 30-minute home visit and a follow-up phone call in addition to the provision of information,

did not show any significant difference in function compared to the provision of information alone [26]. By comparison, several tailored self-management education programmes with therapeutic exercise (including consultation with a physiotherapist) favoured function and pain; however, those total contact times were longer, and there was no comparison to a condition with the provision of information alone. For example, the ESCAPE programme, which is composed of exercise, self-management skills, and pain coping strategy education involving 648–780 minutes for individuals with mild to severe chronic knee pain, showed significant improvements in function and pain compared to usual care [27]. However, compared to no intervention, two booster individualized sessions after the 12-week physical therapy programme did not show any difference in either function or pain [28]. The present study indicated that the therapist-delivered brief preventive intervention for enhancing self-management of chronic knee pain also improved function and self-efficacy in addition to the effects of providing material-based education. Such an intervention has shown similar effects on function and self-efficacy even in individuals with chronic low back pain [29].

Our study has several strengths and limitations. First, the brief-See education programme was low frequency and 100 minutes or less in duration, which will help to implement the programme in general primary care of a community. However, the effects of the intervention could not be simply compared with those of previous studies because of the different programs. Second, using population-based systematic recruitment allowed us to describe the adequate target population to apply the present results. Third, this study could detect the additional effects of individualized instructions compared to the effects of material-based education alone because the same materials were used in both groups. Fourth, our results may not be applicable to office workers because of the small number of participants in the present study. Finally, the participants and therapists were not blinded due to the nature of the intervention.

In conclusion, adding the brief-See to material-based education could be more acceptable to patients while restoring function and improving self-efficacy, which has the potential to contribute to the self-management of chronic knee pain in the community healthcare and primary care.

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Supplementary data

Supplementary data is available at *Modern Rheumatology* online.

Conflict of interest

None.

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CIRCS Investigators

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Author contributions

Conceptualization, H.J. and A.K.; Methodology, H.J., H.I., and H.O.; Intervention design, H.J., K.M., and H.K.; Project Administration, M.K., K.Y., and H.I.; Writing – Original Draft Preparation, H.J.; Writing – Review & Editing, all authors.

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