




# Feasibility of Imported Self-Management Program for Elderly People with Chronic Pain: A Single-Arm Confirmatory Trial

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## ABSTRACT

**Introduction:** Multidisciplinary pain management programs incorporating a cognitive-behavioral therapy (CBT) approach have been reported to be helpful for elderly people with chronic pain. However, it is unclear whether the same program for elderly people with chronic pain would translate to different cultures. This study investigated whether a multidisciplinary program based on that of Nicholas et al. (Pain 154(6):824–835, 2013) in Australia would be effective for elderly people with chronic pain in Japan.

**Methods:** Twenty-seven community-dwelling elderly people with chronic pain were enrolled

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to confirm changes (effect size  $d = 0.5$ ) in pain disability, which were previously reported by Nicholas et al. The multidisciplinary program consisted of eight sessions (2 sessions a week for 4 weeks). Pain disability was assessed using the Pain Disability Assessment Scale (PDAS) as the primary outcome at the baseline, the beginning and the end of the program, and the 1- and 3-month (final) follow-up. We also assessed the pain severity, catastrophizing, pain self-efficacy, and physical function with the Timed Up and Go test (TUG) and the two-step test as secondary outcomes.

**Results:** PDAS, pain catastrophizing, and pain self-efficacy were significantly improved immediately after the program compared with baseline, and these effects were maintained at 3-month follow-up. The effect size ( $d$ ) for the PDAS score was a medium size (0.54) from baseline to 3-month follow-up. Those who showed improvements in TUG immediately after the program tended to report improved psychometric measures at 3-month follow-up.

**Conclusion:** These results suggest that the Japanese multidisciplinary program has a similar effect on pain disability as that reported by Nicholas et al. This finding has important implications for the development of pain services in community-dwelling elderly Japanese.

**Keywords:** Chronic pain; Elderly people; Self-management program

## Key Summary Points

### Why carry out this study?

Multidisciplinary programs in conjunction with a cognitive behavioral therapy approach have been reported to be a useful strategy for elderly people with chronic pain.

However, it is unclear whether the same program for elderly people with chronic pain would work in different cultures.

We aimed to ascertain whether the multidisciplinary program imported from another country was feasible for community-dwelling elderly people with chronic pain in Japan.

### What was learned from the study?

We found that the imported multidisciplinary program was effective across cultures in improving pain disability for elderly Japanese with chronic pain.

This finding has important implications for the development of pain services in community-dwelling elderly Japanese.

## INTRODUCTION

Japan is facing the advent of a “super-aged” society sooner and more rapidly than any other country in the world [1]. As a general health issue, chronic non-cancer pain is a common problem and is often associated with impairment of physical and psychological health in older people worldwide [2]. Nakai et al. reported that 42.7% of community-dwelling older adults had chronic pain, and chronic pain was associated with frailty and pre-frailty [3]. Hirase et al. reported that 60.4% of community-dwelling older adults with frailty had chronic pain, and chronic pain was associated with negative emotional and cognitive aspects of pain, as well

as a decline in activities of daily living (ADL) and lower physical activity levels [4].

In recent years, there has been growing evidence that multidisciplinary pain management programs teaching self-management strategies using a cognitive behavioral therapy (CBT) approach are effective for helping people with chronic pain amongst younger and middle-aged generations as well as elderly people [5–9]. A randomized controlled trial by Nicholas et al. [5] reported a number of clinically significant improvements following their treatment program with elderly patients, including improvement in usual pain, disability, depression, and fear-avoidance beliefs. Importantly, these improvements were maintained over a 1-year follow-up period [6]. However, such CBT-based programs are rarely utilized by health professionals in Japan, and none have been reported with elderly patients in this country.

In 2017, we learned about the usefulness of the multidisciplinary program for elderly people with chronic pain in Australia, and hypothesized that the program would lead to similar results with elderly people with pain in Japan. Despite several reports showing the utility of multidisciplinary programs in younger patients with chronic pain in Japan [10–12], it was unclear whether multidisciplinary programs teaching self-management strategies were feasible for elderly people with chronic pain, because of cultural factors [13].

Therefore, in this study, we aimed to ascertain whether a multidisciplinary pain management program based on that described by Nicholas et al. [5] was feasible for community-dwelling elderly people with chronic pain in Japan, using a confirmatory case series.

## METHODS

### Ethics

This study was approved by the Nagoya-Gakuin University Board of Ethics (No. 2017-5). After being informed of the purpose and protocol of the study, participants provided written informed consent before taking part in the study. All procedures performed in studies

involving human participants were in accordance with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

### Sample Size Estimation and Outcome

As this was a confirmatory study, the sample size was estimated by the assumption of changes (effect size  $d = 0.5$ ) in pain disability as reported by Nicholas et al. [5]. We set the improvement in pain disability as the primary outcome because it is an important focus in the treatment of chronic pain [14]. Secondary outcomes included pain intensity, pain interference, pain catastrophizing, pain self-efficacy, physical function, and adverse events.

Based on this report, at least 27 subjects were required to detect this assumption with effect size (0.5),  $\alpha$  (0.05), and a power  $\beta$  (0.8) in the prior analysis. In this study, we adopted a per-protocol (PP) analysis because a PP analysis measures the treatment effect only for patients who comply with the protocol [15]. In accordance with a PP model analysis, participants were recruited until 27 subjects had completed a 3 month-follow-up.

### Participants

The recruitment of participants was performed by announcing the program in a local public newsletter in Seto-city, Aichi, Japan. The newsletter was published 6 weeks before the program. The inclusion criteria were as follows: (1) aged 65 years or older, (2) having pain for longer than 3 months, (4) able to attend the 180-min sessions at the public hall in Seto-city twice weekly for 4 weeks, (5) native Japanese speaker, and (6) clearance by attending doctors for participation in light exercise and stretch program. Exclusion criteria were as follows: (1) diagnosed ongoing malignancies, (2) presence of dementia or active major mental disorder, (3) required care by others for daily living, and (4) further medical or surgical treatment for pain condition planned.

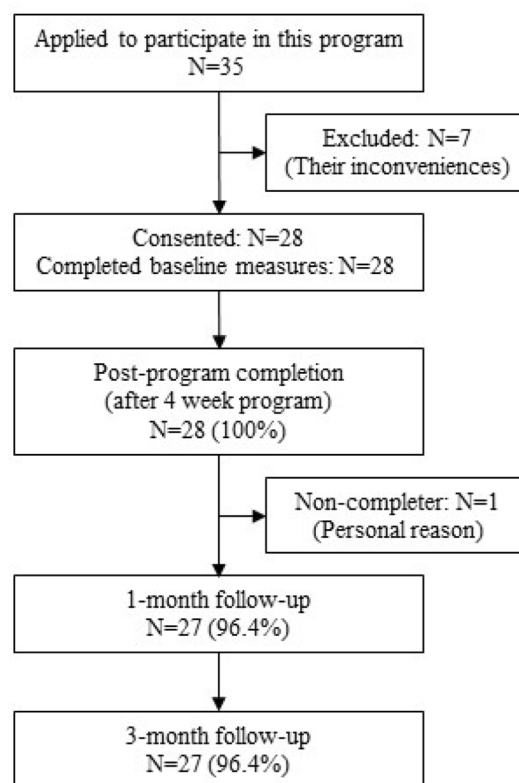
Because of limited resources, the number of participants was restricted to 10 in each

program. Four programs were conducted from September 2018 to February 2020. Although 35 individuals applied to participate in the program, seven did not participate because of attendance difficulties. Twenty-eight participants completed the 4-week program: nine in the first program, seven in the second program, three in the third program, and nine in the fourth program. One participant in the first program was lost to follow-up for personal reasons (Fig. 1).

### Measures

#### Self-Report Measures

The same set of questionnaires was completed by all participants a month prior to attending the program (baseline), at the beginning and the end of the program (first and last day), and at the 1- and 3-month follow-ups. The follow-up measures were performed where the program was conducted. Questionnaires included (1) the



**Fig. 1** Study participant flow chart

short form of the Brief Pain Inventory (BPI) [16], (2) Pain Disability Assessment Scale (PDAS) [17], (3) six-item short form of the Pain Catastrophizing Scale (PCS-6) [18], and (4) the two-item short form of the Pain Self-Efficacy Questionnaire (PSEQ-2) [19]. All questionnaires provided were Japanese translations of the originals [20].

When patient-report outcomes are assessed, according to the Consensus-Based Standards for the Selection of Health Measurement Instruments (COSMIN), each questionnaire needs to be confirmed as a unidimensional scale. Internal consistency is the degree of the interrelatedness among items, assuming the questionnaire to be unidimensional. Cronbach's alpha is often used as a measure of internal consistency, and a value  $> 0.7$  is considered to be adequate [21]. We calculated these values for each questionnaire.

**BPI [16]** The BPI was originally developed for cancer patients, but it has been used in samples with various clinical conditions. The BPI rapidly assesses the severity of pain and its impact on functioning in daily life. The pain items are composed of (1) worst pain in last 24 h, (2) least pain in last 24 h, (3) pain on average, and (4) current pain. A numerical rating scale (NRS) was used to measure pain intensity at each assessment, where 0 indicates "no pain" and 10 "the greatest pain possible." The BPI pain score is calculated as the mean of the four scores. The second set of items assess the degree of pain interference in daily activities. The items include relationships with others, enjoyment of life, mood, and sleep, as well as walking, general activity, and working. Cronbach's  $\alpha$  was 0.88 for the total score. Scores for the mean BPI-interference range from 0 to 10, with higher scores indicating higher levels of interference.

**PDAS [17]** The PDAS is a 20-item tool that assesses the degree of impact of pain-related disability on a person's lifestyle during the past week. Cronbach's  $\alpha$  was 0.91 for the total score. Scores for the total PDAS range from 0 to 60, with higher scores indicating higher levels of pain-related disability.

**PCS** Pain catastrophizing has been conceived as an exaggerated negative "mental set" brought to bear during actual or anticipated pain experience [22]. The original PCS consists of 13 items, and subjects rate how frequently they have catastrophizing thoughts about pain, with higher scores (0–52 points) indicating a greater degree of catastrophizing. A six-item (items 4, 5, 6, 10, 11, and 13) short form of the PCS (PCS-6) was developed in order to facilitate quick screening and to reduce participant burden. In addition, the six-item short form of the PCS was found to be comparable to the original PCS for assessing pain catastrophizing in patients with musculoskeletal pain [18]. Cronbach's  $\alpha$  was 0.91 for the total score of the PCS-6. Scores for the total PCS-6 range from 0 to 24, with higher scores indicating higher levels of catastrophizing thought.

**PSEQ** Self-efficacy beliefs in people with chronic pain have been assessed by the strength of a patient's beliefs in their ability to accomplish various activities despite pain [23]. The original PSEQ is an established 10-item measure of pain self-efficacy that is widely used in clinical and research settings. The two-item short form PSEQ (PSEQ-2, using items 5 and 9 in the original PSEQ) appears to be a robust brief measure of pain self-efficacy in people experiencing chronic pain [19]. Cronbach's  $\alpha$  was 0.82 for the total PSEQ-2 score. Scores for the total PSEQ-2 range from 0 to 12, with higher scores indicating higher levels of self-efficacy despite pain.

#### **Physical Function Measures**

Physical function was assessed at the beginning and the end of the program. Physical functional measures included (1) Timed Up and Go test (TUG) [24], (2) two-step test [25], (3) handgrip strength [26], and (4) one-leg standing time (OLST) with eyes open [27].

**TUG** TUG measures the time it takes a subject to stand up from a chair, walk a distance of 3 m, turn and walk back to the chair, and sit down [24]. All subjects performed two trials, and the better time was used. TUG was originally established as an objective measure of physical

function in the elderly population. It is also used to assess the risk of falls in older adults [28].

**Two-Step Test** The two-step test involves the subject starting from a standing posture and moving two steps forward with maximum stride, with caution not to lose balance. If the subject succeeds in holding the final standing position longer than 3 s without any additional steps, the trial is considered completed. The distance is then standardized by dividing it by the subject's height. The test is performed twice, and the better result is recorded. The value of the two-step test is strongly correlated with maximum walking speed [25], and is well known to be associated with locomotor disabilities among Japanese elderly [29].

**Handgrip Strength** Handgrip strength was measured bilaterally in a standing position using a Smedley III hand dynamometer. Both sides were tested, and the better value was adopted. Handgrip strength is commonly used as an indicator of overall body strength [26], and it has been shown to be inversely associated with survival [30].

**OLST** The one-leg standing with eyes open test was tried twice using the preferred leg. We measured the time it took between when the patient started to raise the leg until placing it back down on the floor, and the better time of two trials was adopted [27]. OLST can predict fall risk, especially for the elderly who cannot stand over 10 s on a single leg [31], and OLST has demonstrated a negative linear relationship with the risk of hip fracture [32].

#### **Multidisciplinary Pain Management Program**

The multidisciplinary program in this study was derived from the CBT-based pain management program described by Nicholas et al. [5]. The participants completed a 3-h session (13:30 to 16:30 pm) on a twice-weekly basis for 4 weeks (total time: 24 h). The contents of the sessions are outlined in Table 1. Attention was drawn to specific chapters according to the topics of the day. The orthopedist (T.I.) who studied the multidisciplinary program directed by Professor

Nicholas in Australia was responsible for all lecture and discussion sessions. The subject matter of these sessions is briefly described below.

**Models of Chronic Pain** This covered the definition of “chronic pain,” and differences between acute pain and chronic pain. Although acute pain is normally attenuated along with healing of tissue insults, chronic pain may continue even if tissue insults are repaired. Moreover, psychological problems (e.g. depression and anxiety) are a frequent complication that significantly changes the prognosis and course of chronic pain [33]. Chronic pain can also reduce ADL and quality of life, and may become a burden not only on the patient but also on family members and others involved [34].

**Red Flag Signs** Pain is fundamentally an alarm system that has evolved to protect us from injury. The alarm symptoms may include compression fractures, malignant tumors, serious infections, or other primary diseases [35]. For example, although vertebral fracture is one of prevalent causes of lower back pain (LBP) among elderly people, it may be overlooked [36]. Most often pain at night or at rest is also considered a red flag for various underlying pathologies [37]. Thus a careful examination is required at least once for pain lasting over 3 months.

#### **Self-Management Strategies Taught Using a CBT Approach for Chronic Pain**

The most empirically supported methods for teaching chronic pain self-management are based on CBT principles that target changes in both cognition and behaviors [38]. A typical treatment protocol for CBT will involve methods aimed directly at assessing the thoughts associated with pain, the extent of avoidance of unpleasant thoughts and painful experiences, and the consequences of these [38]. Participants learned the CBT model (i.e. relationship between thoughts, emotion, behavior, and physical sensation), and were expected to practice the self-management skills taught between sessions. These included activity pacing, goal

**Table 1** Summary of the self-management program

	<b>Tuesday</b>	<b>Thursday</b>
Week 1	Welcome (introductions) Assessment of physical function Introduce models of chronic pain/ <b>Caution to red flags sign</b> Discuss goals of pain self-management Introduce relax/stretchers Goal setting Homework assignments	Practice relax/stretchers <b>Introduce desensitization (meditation)</b> Discuss self-management strategy for chronic pain based on CBT approach Introduce functional exercises Homework assignments
Week 2	Weekend review (of achievements) Practice stretches/desensitization (meditation) Discuss pacing and tolerance Practice functional exercise Homework assignments	Practice stretches/desensitization (meditation) <b>Discuss role of thoughts and thought management for pain management</b> Practice functional exercise Homework assignments
Week 3	Weekend review (of achievements) Practice stretches/desensitization (meditation) Discuss <b>central sensitization</b> and chronic pain mechanism Practice functional exercise Homework assignments	Practice stretches/desensitization (meditation) Discuss dealing with flare-ups Practice functional exercise Homework assignments
Week 4	Weekend review (of achievements) Practice stretches/desensitization (meditation) Discuss the use of medication for chronic pain management and <b>placebo</b> Practice functional exercise Group work and presentation: plan maintenance of treatment gains	Practice stretches/desensitization (meditation)/functional exercise Home planning for 3 months Assessment of physical function and questionnaire Graduation

Bold indicates items that differ from Nicolas et al. (2013)

setting, and daily relaxation and exercise sessions [39].

**Pacing and Tolerance** Activity pacing comprises two parts: (1) conserving energy for valued activities, and (2) setting graduated activity quotas to increase the ability to perform

activities (tolerance) and reduce disability despite the presence of pain [40].

**Goal Setting** Goal setting is intended to provide the patient with the motivation to work towards achieving specific goals both during and following the program. Goals may include

improved health-related quality of life, improved emotional status, and a greater sense of self-efficacy [41]. The participants were asked “to make sure your goals are clear, reachable, and meaningful to you, each goal should meet the SMART criteria (i.e. specific, measurable, achievable, realistic, and time-limited)” [42]. The SMART framework is easy to teach, easy to remember, and has been employed successfully across multiple disciplines, including medical education [43]. The participants were also instructed that the goal should be divided into short- and long-term goals [44].

**Desensitization (Meditation)** The fear-avoidance model has been one of the most influential behavioral pain models for the past 40 years [45]. One clinical implication of the model is that reducing the threat value of a specific pain should diminish the disability related to that pain. Nicholas et al. studied whether an interoceptive exposure method aimed at reducing pain-avoidance behaviors would add benefit to standard CBT [46]. Although the results indicated that this add-on to CBT did not differ significantly from CBT alone, higher adherence in each group was associated with improvement on measures of pain, pain perception, disability, and depression [46]. Here, we encouraged the participants to think that “(1) the pain is just activity in your nerves, (2) this pain is not acting as a warning signal, and (3) it is just pain and isn’t harmful.”

**Role of Thoughts and Thought Management for Pain Management/Dealing with Flare-Ups** Because unhelpful ways of thinking, like catastrophic thoughts, have been associated with higher pain-related distress [22], it is important for patients to learn to identify such thoughts and to change them to more helpful ways of responding to their pain, especially flares in pain. Thus, the patients were asked to monitor their thoughts in reaction to flares in pain and to identify any that might be unhelpful and risk promoting more distress (e.g. “When will my pain decrease?”, “I can’t do anything”). Alternative, more helpful responses were discussed, and the patients were encouraged to generate these sorts of thoughts

whenever they noticed they were having unhelpful thoughts (e.g. “This pain will subside soon,” “I have had this level of pain before, and I know it will subside if I calm myself”). In addition, the patients were encouraged to remind themselves of more constructive thinking (e.g. “What can I do instead of just using more medication or depending on another person?”, “What was my goal that I was trying to achieve?”) [44].

**Central Sensitization and Chronic Pain Mechanism** Central sensitization is a condition of the nervous system that is associated with the development and maintenance of chronic pain. The neuroplastic processes may result in gain (sensitization) or loss (desensitization) of function in relation to the incoming nociceptive signals [47]. This discussion was intended to help the patients understand that more injury was not the only possible explanation for their chronic pain, and other, harmless mechanisms were probably involved.

**The Use of Medication for Chronic Pain Management and Placebo** Placebo effects are positive outcomes that are attributable to the psychosocial context and individual treatment expectations rather than the action of the medication or intervention. The mental events induced by placebo administration can activate analgesic mechanisms that are similar to those activated by drugs [48]. This discussion was intended to help patients understand that even without medication, their pain could be affected by these sorts of mechanisms.

Throughout the program, the nurse and the physical therapist promoted the integration of all session topics in the program. The nurse was responsible for promoting the psychological skills and the physical therapist for the activities/exercises. All participants were encouraged to perform the exercises and skills both during the treatment sessions and at home between sessions. Self-monitoring of homework was also encouraged, and evidence of attempts to practice the exercises and to apply the skills at home was reinforced with praise at each session. Specific skills taught included setting specific, functional (and realistic) goals that were

meaningful to the participant, activity pacing, arousal reduction using a combination of cognitive challenging and dispassionate exposure, dealing with flare-ups, and structured problem-solving. The program of exercise included stretching and strength training. The exercise program was designated as “high,” “moderate,” or “low” level depending on the physical functioning of each participant. For example, a participant whose TUG at baseline was less than 6.5 s in men or less than 7 s in women was assigned to a “high-level” program, and those with more than 6.5 (+2 SD) s in men and more than 7.0 (+2 SD) s in women were assigned to a “low-level” program, based on the report by Muramoto et al. [49]. Each exercise program included muscle strengthening, balance training, and aerobic exercises. For example, the muscle strengthening exercise program included knee extensor, knee flexor, hip abductor, ankle plantar flexors, and ankle dorsiflexors. Balance training included knee bends, one-leg stand, stepping, etc., for fall prevention [50]. Rubber resistance bands (THERABAND®) of different magnitudes were used during exercises according to the exercise level and individual capacity. The participants were regularly encouraged to consistently utilize pacing principles in their graded increase in physical activity. Any changes in medications were left to the participants to discuss with their attending doctors. Medication reduction was not a specific goal of the treatment, due to time constraints, and it was felt this was best left to the prescribing doctors.

### Statistical Analysis

All continuous variables were expressed as median (range) or mean (standard deviation [SD]). The normality of the distribution for each measurement was evaluated using the Shapiro–Wilk test for continuous variables. Pain disability (PDAS score) was the primary outcome, and the baseline scores were compared with the 3-month follow-up using the paired *t* test. Cohen’s *d* was used to evaluate the magnitude of the effect size, calculated by standardized mean difference, with *d* ranges of 0.2–0.5 = small effect, 0.5–0.8 = medium effect, and

*d* > 0.8 = large effect [51]. One-way repeated-measures analysis of variance (ANOVA), followed by Bonferroni post hoc comparisons to control for possible type I errors, was also used to compare the differences in scores of questionnaires across each assessment. The physical function at the beginning and immediately after the program was compared using matched pair Wilcoxon or Student *t* test, depending on the distribution of the data.

To examine the association between changes in pain disability, psychological or motor functioning during the 4-week program, and changes in outcomes from baseline to final follow-up, correlation coefficients between changes in functional parameters and patient-reported outcomes during the program and changes in psychosomatic function between baseline and final follow-up were analyzed using Spearman’s test. All statistical analyses were performed using Excel BellCurve® (Social Survey Research Information Co., Ltd.). Differences were considered statistically significant at a level of  $p < 0.05$ .

## RESULTS

The demographic characteristics of the participants are described in Table 2. Women comprised 81.5% of the total participants. More than 50% of the participants had pain in the back or lower back.

The primary outcome, pain disability (PDAS score), among participants was significantly improved at the 3-month follow-up after the program (mean ± SD;  $12.3 \pm 9.0$ ) compared to the baseline ( $18.4 \pm 13.2$ ), with a medium effect ( $d = 0.55$ ,  $p < 0.01$ ). Also, of the self-report secondary outcomes, all (mean score of BPI-interference, total scores of PCS-6 and PSEQ-2) except participants’ pain severity significantly improved immediately after the program compared to baseline, and these effects were maintained over 3 months (Fig. 2). Although mean pain severity was not significantly improved immediately after the program, there was a significant improvement at the 3-month follow-up relative to baseline (Fig. 3).



**Table 2** Participant characteristics at baseline

Variable	Total sample ( $n = 27$ )
Gender (male/female)	5/22
Age (years)	73.5 (5.7)
Height (cm)	155.1 (7.8)
Weight (kg)	55.3 (11.1)
BMI ( $\text{kg}/\text{m}^2$ )	23.0 (4.1)
Painful area % (no.)	
Neck–head	14.8 (4)
Upper extremities <sup>a</sup>	22.2 (6)
Lower extremities <sup>b</sup>	33.3 (9)
Back to lower back <sup>c</sup>	55.6 (15)
Pain length term (months)	107.4 (145.8)
Pain severity (0–10)	
Worst	5.2 (2.5)
Least	2.4 (1.9)
Average	4.0 (2.0)
Current	3.7 (2.7)
BPI-interference (0–70)	23.8 (14.2)
PDAS (0–60)	18.4 (13.2)
PCS-6 (0–24)	13.5 (6.6)
PSEQ-2 (0–12)	6.8 (2.6)

Value: mean (SD)

*BPI* Brief Pain Inventory, *PDAS* Pain Disability Assessment Scale, *PCS* Pain Catastrophizing Scale 6-item version, *PSEQ-2* Pain Self-Efficacy Questionnaire 2-item version

<sup>a</sup> Upper extremities indicates from shoulder to hand, and pain diseases include adhesive capsulitis and osteoarthritis of hand

<sup>b</sup> Lower extremities indicates from hips to foot, and pain diseases include lumbar spinal canal stenosis and osteoarthritis of the hip, knee and ankle

<sup>c</sup> Pain diseases of back to lower back include degenerative spondylosis, spondylolisthesis, degenerative scoliosis, and spinal canal stenosis

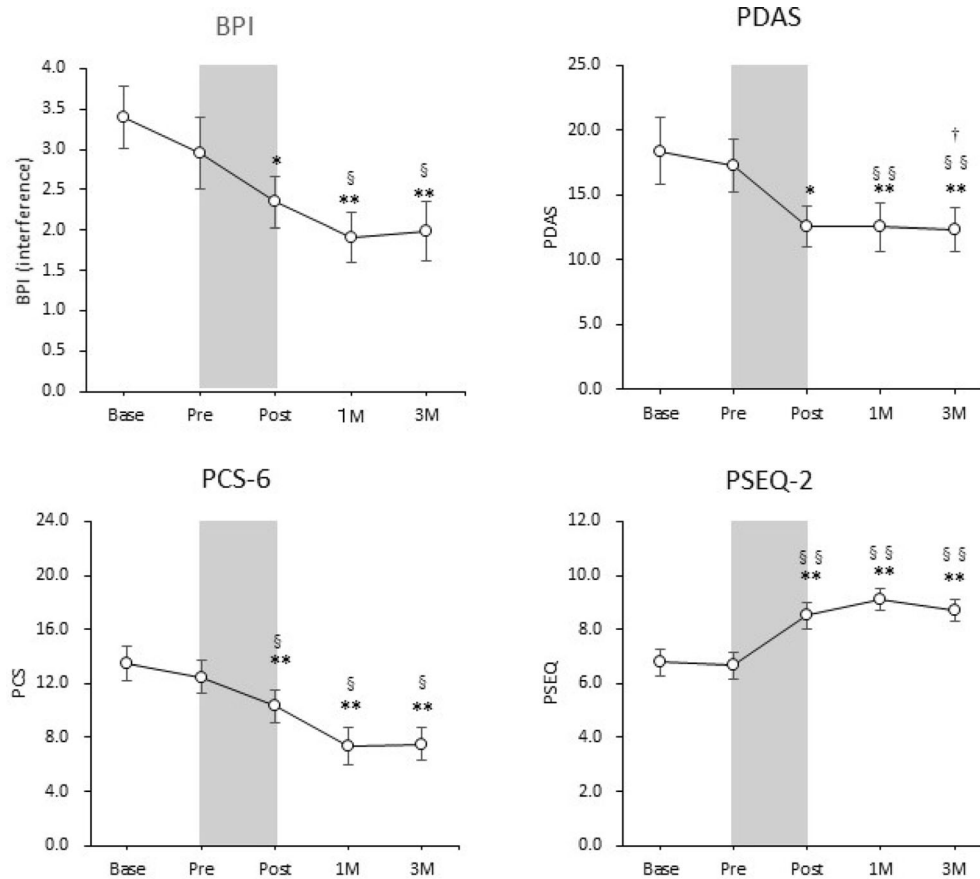
Of the physical function measures, TUG, two-step test, and handgrip strength were

significantly improved immediately after the program compared with baseline measures. OLST did not show a significant change from before to after the program (Table 3).

Improvements in the TUG during the 4-week program correlated with the improvements in total scores of BPI-interference, PCS-6, and PSEQ-2 between baseline and final follow-up (Table 4). There was no significant (just) correlation between improvements in the TUG during the 4-week program and improvements in the PDAS score between baseline and final follow-up (Pearson's  $r = 0.375$ ,  $p = 0.054$ ). In contrast, changes in self-reported function during the 4-week program did not correlate with any changes in those between baseline and final follow-up (Table 4). No adverse events relevant to the program were reported during the programs and follow-up periods. In addition, none of the participants added new analgesic agents or other therapies during the program and follow-up periods.

## DISCUSSION

This study investigated the effect of a CBT-based multidisciplinary pain management program based on the program reported by Nicholas et al. [5] in a sample of elderly Japanese people with chronic pain. The results showed that pain disability, interference of pain in daily activities, pain catastrophizing, and pain self-efficacy amongst the participants improved immediately after the program, and these improvements were maintained over the 3-month follow-up. No adverse events were reported during the program or follow-up periods. Although the current study did not have a control group, a recent report indicates that randomized controlled trials reflect clinical practice when comparing similar populations [52]. According to results from an RCT by Nicholas et al., the effect size ( $d$ ) of improvement in pain disability at the end of the program and at 1-month and 6-month follow-ups was 0.57, 0.60, and 0.48 respectively, which was a medium effect [6]. In the current study, the improvement in pain disability post-program was similar at the 1-month and 3-month follow-



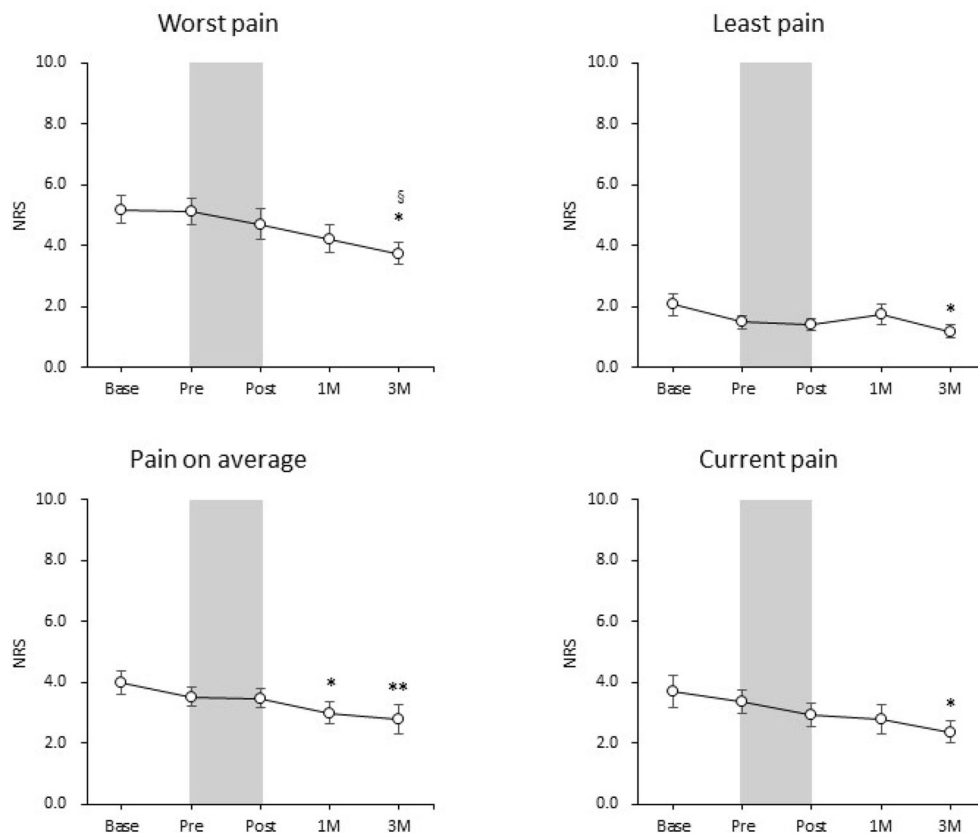
**Fig. 2** Changes in scores of each questionnaire. \*, \*\*, vs. Base:  $p < 0.05, 0.01$ ; §, §§, vs. Pre:  $p < 0.05, 0.01$ ; †, vs. Post:  $p < 0.05$ . *BPI* Brief Pain Inventory (term of interference), *PDAS* Pain Disability Assessment Scale, *PCS-6* Pain Catastrophizing Scale 6-item version, *PSEQ-2* Pain Self-Efficacy Questionnaire 2-item version, *Base*

baseline, *Pre/Post* pre-/post-program, *1M/3M* 1-month/3-month follow-up. Gray bars indicate a period of intervention

ups (0.54, 0.52, and 0.55, respectively), and also in the medium effect range. These findings suggest that the Japanese multidisciplinary program broadly replicated the results reported by Nicholas et al. [5] and can therefore be considered effective in helping elderly Japanese patients with chronic pain.

Pain behavior is influenced by social, cultural, and psychological factors. For example, it has been reported that Aborigines in Australia did not perceive back pain to be a health problem and consequently did not complain of symptoms, display pain behaviors, or seek treatment [53]. Japan has universal public healthcare: all Japanese citizens are able to have

health insurance provided by the state. The Japanese healthcare system does not necessarily distinguish between primary and secondary care, and there is no gatekeeper system [55]; thus people can access very convenient services at affordable prices almost anywhere in the country and receive treatment at a comparatively early stage of any illness [54]. It has been reported that Japan has the largest number of CT and MRI scanners per population; the number of CT scanners per population in Japan is approximately double that in Australia [54]. Frequent testing and visits to doctors have been found to provide little reassurance and instead increase feelings of worry and anxiety among



**Fig. 3** Changes in pain severity. \*, \*\*, vs. Base:  $p < 0.05, 0.01$ ; §, vs. Pre:  $p < 0.05$ . *NRS* numerical rating scale, *Base* baseline, *Pre/Post* pre-/post-program, *1M/3M* 1-month/3-month follow-up. Gray bars indicate a period of intervention

**Table 3** Mean and standard deviation (SD) of outcome variables of physical function

	Pre-program	Post-program	<i>p</i> value
TUG (s)	6.6 (5.9–7.4)	6.3 (5.6–6.6)	0.003
Two-step test	1.25 (1.13–1.41)	1.36 (1.24–1.54)	0.012
Handgrip strength (kg)			
Right	22.8 (7.16) <sup>a</sup>	25.56 (6.99) <sup>a</sup>	< 0.001
Left	20.91 (7.52) <sup>a</sup>	22.44 (6.80) <sup>a</sup>	0.026
OLST (s)			
Right	62 (12–120)	50 (16–120)	0.509
Left	71.1 (14.8–120)	54.6 (26.3–120)	0.349

Value: median (IQR)

*TUG* Timed Up and Go test, *OLST* one-leg standing time

<sup>a</sup> Mean (SD)

**Table 4** The relationship between the immediate effect of 1-month program and the long-term effect of 3 months later

	Long-term effect (3-month follow-up – baseline)					$\Delta$ BPI	$\Delta$ PDAS	$\Delta$ PCS	$\Delta$ PSEQ
	$\Delta$ Pain severity								
	Worst	Least	Average	Current					
Immediately effect (last day – 1st day)									
Physical function									
$\Delta$ TUG	0.352	0.079	0.201	0.248	0.547**	0.375	0.445*	-0.436*	
$\Delta$ Two-step test	-0.134	0.055	0.078	-0.163	-0.105	0.081	-0.174	0.178	
$\Delta$ Handgrip strength (better side)	-0.132	-0.366	-0.249	-0.132	0.012	0.253	0.091	-0.363	
$\Delta$ OLST (better side)	-0.132	-0.122	0.023	-0.148	-0.194	-0.184	-0.158	-0.048	
Psychosomatic function									
$\Delta$ BPI-interference	0.305	0.296	0.141	0.088	0.180	-0.143	-0.103	0.135	
$\Delta$ PDAS	0.212	0.504**	0.273	0.290	0.062	0.203	-0.088	-0.095	
$\Delta$ PCS-6	0.483*	-0.125	0.211	0.224	-0.089	-0.299	0.010	-0.112	
$\Delta$ PSEQ-2	-0.211	-0.029	-0.187	-0.069	0.144	-0.009	0.055	0.157	

Value: correlation coefficients, \*, \*\*:  $p < 0.05$ , 0.01

BPI Brief Pain Inventory, PDAS Pain Disability Assessment Scale, PCS Pain Catastrophizing Scale 6-item version, PSEQ Pain Self-Efficacy Questionnaire 2-item version, TUG Timed Up and Go test, OLST one-leg standing time

patients [55]. Nevertheless, psychological treatment of chronic pain in East and Southeast Asia lags behind that in North America and Europe [56].

Although a systematic review showed that CBT-based pain management alone had small positive effects on pain disability and catastrophizing when compared with other therapies such as physical therapy and education [38], the effectiveness of this approach has not been demonstrated in Japan. However, a trial of a multidisciplinary CBT-based program for patients aged 20–80 years with chronic pain has just recently begun in Japan [10], and this should eventually help to answer this question. The present study has demonstrated that building on an existing and established program rather than trying to develop a new program from scratch may lead to faster accumulation of evidence and dissemination of the value of this approach.

In patients with chronic musculoskeletal pain disorders, an educational strategy addressing neurophysiology and neurobiology of pain is known to have a small positive effect on pain, disability, catastrophizing, and physical performance [57]. Our multidisciplinary program included the same lectures on neurophysiology and neurobiology of pain, but it went further by teaching patients specific pain self-management strategies and an activity upgrade program of exercises, as was done by Nicholas et al. [5]. On the other hand, our modified program included a lecture about caution regarding red flags which differed from the program described by Nicholas et al. [5]. Chronic pain is often regarded as a faulty alarm system (e.g. chronic primary pain [58]), and thus we applied an education approach to reassure subjects that continuing pain signals were not always indicative of harm. However, chronic pain also sometimes implies progressive tissue insults (e.g. osteoarthritis). As elderly people are

assumed to be biologically more vulnerable than young and middle-aged generations, it is important for them to keep in mind that pain sensation has a role in warning of possible tissue insults.

A recent review of physical activity and exercise for chronic pain reported some favorable effects in reduced pain severity and improved physical function, though these were mostly small to moderate [59]. Our exercise program was determined by individual levels of physical function, and the frequency and the length of exercise time were adjusted by participants themselves, based on advice from physical therapists. In addition, we had weekly reviews (of achievements) and feedback. It is known that interventions such as supervised or individualized exercise therapy and self-management techniques enhance exercise adherence [60].

Interestingly, we found that significant associations between improvements in pain disability (trend of significance), pain self-efficacy, and catastrophizing 3 months after the 4-week program and decreased time in TUG during the program. Since it was reported that time on TUG correlated with gait speed and ADL among elderly people [24], enhancement in physical performance among those with chronic pain may help to sustain sound mental health as well as physical capacity.

Self-efficacy has been characterized as a protective psychological resource in patients with persistent pain, and a resiliency factor associated with improved functional outcomes in adults with chronic pain [61, 62]. Importantly, self-efficacy is not a trait, and patients can increase their level of self-efficacy with programs like the one evaluated in the present study. Moreover, high levels of catastrophizing have been shown to be a risk factor for the development of long-term pain and for negative sequelae of pain such as heightened distress, worsening physical disability, and the amplification of pain sensitivity among patients with lower back pain (LBP) and joint pain [61]. As with self-efficacy, our pain self-management program demonstrated that catastrophizing can be reduced in elderly people with chronic pain with the methods employed.

Several limitations of this study need to be mentioned. First, there was no control group. Since we cannot know the natural course of the outcome, our results cannot be interpreted in comparison to a control group. Chronic pain is influenced by different physical, psychological, and social factors [63–65] known as “contextual factors” (CFs). CFs directly impact on the quality of the therapeutic outcomes, with positive CFs (i.e. placebo) reducing pain and negative CFs (i.e. nocebo) increasing pain [65]. As a multidisciplinary pain management program can be regarded as a positive CF for the participants, CFs may have effects on the therapeutic outcomes. However, as an effectiveness trial, our results are consistent with those of studies that have used control groups [5], thereby confirming its effectiveness. Second, our study excluded elderly people with dementia and high care needs for daily living. The number of elderly people who need nursing care is increasing, and 10.7% of those needing such services in Japan have dementia [1]. Patients with Alzheimer’s disease also suffer from chronic pain [66], but clearly, our findings cannot be generalized to this group. Third, this study did not evaluate physical function at 1- and 3-month follow-up. Thus, the sustainability of increased physical function is not clear. Fourth, women constituted approximately 80% of the participants in the current study. Previous research has shown gender differences in description and expression of pain, the use of coping strategies, and the benefit of different treatments [67, 68]. Therefore, the approach requires further testing with elderly male samples. Finally, this study did not investigate the long-term results beyond 3-month follow up. Therefore, the long-term effects of the imported program need to be evaluated in the future.

## CONCLUSION

This study investigated whether a multidisciplinary pain self-management program modified from that of Nicholas et al. [5] was effective for elderly people with chronic pain in Japan. We found that the program was effective in improving pain disability and achieved similar

results as those reported by Nicholas et al. This finding has important implications for the development of pain services in community-dwelling elderly Japanese.

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**Compliance with Ethics Guidelines.** This study was approved by the Nagoya-Gakuin University Board of Ethics (No. 2017-5). After being informed of the purpose and protocol of the study, participants provided written informed consent before undergoing the study. All procedures performed in studies involving human participants were in accordance with

the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

**Data Availability.** The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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