



Original Article

# Physical therapist-delivered acceptance and commitment therapy and exercise for older outpatients with knee osteoarthritis: a pilot randomized controlled trial

YASUHIRO NAGASAWA, RPT, MS<sup>1, 2)\*</sup>, AI SHIBATA, PhD<sup>3)</sup>, HANAKO FUKAMACHI, PhD<sup>4)</sup>, KAORI ISHII, PhD<sup>5)</sup>, KOICHIRO OKA, PhD<sup>5)</sup>

<sup>1)</sup> Department of Rehabilitation, Hasegawa Hospital: 85 Yachimatani, Yachimata, Chiba 289-1103, Japan

<sup>2)</sup> Graduate School of Sport Sciences, Waseda University, Japan

<sup>3)</sup> Faculty of Health and Sports Sciences, University of Tsukuba, Japan

<sup>4)</sup> Sport Sciences Laboratory, Japan Sport Association, Japan

<sup>5)</sup> Faculty of Sport Sciences, Waseda University, Japan

**Abstract.** [Purpose] In this pilot study, we investigated the effectiveness of physical therapist-delivered acceptance and commitment therapy in older outpatients with knee osteoarthritis and chronic pain. [Participants and Methods] This single-center, open-label, parallel-group pilot randomized controlled trial included 30 patients assigned to the physical therapist-delivered acceptance and commitment therapy group (n=15) and the usual care physical therapy-only group (n=15). Both treatments were administered once a week for 8 weeks. Evaluation was performed 4 weeks before intervention, pre-intervention, post-intervention, and 4 weeks after intervention. The primary outcome was diagnosis of a physical disability, and secondary outcomes included psychological inflexibility, pain intensity, anxiety, depression, physical function, and objectively measured physical activity. [Results] Physical therapist-delivered acceptance and commitment therapy had a limited effect on physical disability, although we observed a favorable tendency. With regard to secondary outcomes, physical therapist-delivered acceptance and commitment therapy did not show significant effects. Notably, 15 patients withdrew from this study and 6 were diagnosed with coronavirus disease. [Conclusion] Physical therapist-delivered acceptance and commitment therapy did not appear to show significant effects in the present study. It is necessary to correct these issues in this study, and future studies are warranted to investigate the effects of this therapy.

**Key words:** Physical therapist-delivered acceptance and commitment therapy, Older outpatients, Knee osteoarthritis

(This article was submitted Jul. 24, 2022, and was accepted Sep. 14, 2022)

## INTRODUCTION

Knee osteoarthritis (KOA) is a major public health problem in rapidly aging Japanese societies. Japanese epidemiological studies of those aged 60 years or older revealed that the prevalence of radiographic KOA and knee pain was 61.9% and 32.8%, respectively<sup>1)</sup>. Joint space narrowing and osteophytosis are pathological features seen in the knee joint of older adults<sup>2)</sup>. These pathological features are often accompanied by pain catastrophizing and central sensitization, leading to increased chronic pain and physical dysfunction<sup>3)</sup>. In addition, KOA is deleteriously associated with the risk of physical

\*Corresponding author. Yasuhiro Nagasawa (E-mail: [nagasawaid@toki.waseda.jp](mailto:nagasawaid@toki.waseda.jp))

(Supplementary materials: refer to PMC <https://www.ncbi.nlm.nih.gov/pmc/journals/2193/>)

©2022 The Society of Physical Therapy Science. Published by IPEC Inc.



This is an open-access article distributed under the terms of the Creative Commons Attribution Non-Commercial No Derivatives (by-nc-nd) License. (CC-BY-NC-ND 4.0: <https://creativecommons.org/licenses/by-nc-nd/4.0/>)

disability, increased healthcare costs, and long-term care<sup>4</sup>). Therefore, it is important to improve the physical disability while managing chronic pain, psychological factors, and physical dysfunction associated with degeneration in patients with KOA.

Older patients with KOA often receive exercise therapy from a physical therapist to improve their physical disabilities. However, only a few systematic reviews have examined the long-term effects of exercise therapy<sup>5</sup>). One possible reason for this result may be low exercise adherence due to the fear of increased pain following exercise therapy in these patients<sup>6</sup>). Previous studies have found that maladaptive pain coping strategies, such as catastrophizing, praying, resting, and excessive medication behavior, are associated with low exercise adherence<sup>7, 8</sup>). Therefore, older patients with KOA need an intervention to improve maladaptive pain coping strategies in combination with exercise therapy, thereby promoting their exercise adherence.

Acceptance and commitment therapy (ACT) is attracting a lot of attention as a third-generation cognitive behavioral therapy that emphasizes the acceptance of pain. It attempts to increase valued action in the presence of pain and other negative thoughts<sup>9</sup>). Furthermore, ACT therapeutic theory targets psychological inflexibility which consists of six pathological conditions; “experiential avoidance”, “cognitive fusion”, “lack of values clarity”, “unworkable action”, “dominance of the conceptualized past and feared future”, and “attachment to the conceptualized self”<sup>10</sup>). Specific interventions improve six pathological conditions through techniques such as metaphors, mindfulness-related exercise, and exposure-based methods<sup>9</sup>). In particular, experiential avoidance and cognitive fusion have been reported to affect the selection of maladaptive pain coping strategies and are associated with physical disability in patients with chronic pain<sup>11</sup>). Therefore, the combination of exercise therapy and ACT in clinical practice is expected to allow patients to continue self-exercise and prevent physical disability without selecting maladaptive pain-coping strategies. In fact, the combination of physical therapist-delivered ACT with exercise therapy for patients with low back pain in the UK has been reported to be effective in improving physical disability and quality of life<sup>12</sup>).

However, no previous studies have examined the effect of the combined intervention of physical therapist-delivered ACT with exercise therapy in older patients with KOA. In addition, most of the previous studies were psychologist-delivered ACT interventions, and there were few previous studies on physiotherapist-delivered basis<sup>13</sup>). According to a survey conducted in 63 facilities under the Japanese National Hospital Organization, the percentage of clinical psychologists in medical institutions was at a low of 34.9%<sup>14</sup>). Therefore, it is important that physical therapists who mainly rehabilitate patients with chronic pain perform ACT. Furthermore, each ACT session often requires 60–90 min and based on research, many interventions are group sessions<sup>13</sup>). However, it is difficult to adapt such an intervention time and style in clinical practice, where outpatient rehabilitation is generally provided to patients on an individual basis within a limited time. It is necessary to develop a program that physical therapists can provide in clinical practice and examine its effects. Therefore, we developed the physical therapist-delivered acceptance and commitment therapy (PACT) that physical therapists can in outpatient rehabilitation based on ACT therapeutic theory. The purpose of this study was to examine the effect of physical therapist-delivered ACT in older outpatients diagnosed with KOA and chronic knee pain.

## PARTICIPANTS AND METHODS

This study was a single-center, open-label, parallel group pilot randomized controlled trial comparing the combination of exercise therapy and PACT versus usual care exercise therapy only (UC) in older patients diagnosed with KOA and chronic knee pain. This study was approved by the Human Research Ethics Committee of Waseda University (No. 2019-250). All the participants provided written informed consent. The study was registered in the University Hospital Medical Information Network Clinical Trials Registry (UMIN000038591) on November 15, 2019. This study complied with the Consolidated Standards of Reporting Trials 2010 guidelines and its extension to randomized pilot and feasibility trials<sup>15</sup>).

Participants were recruited from among the patients attending outpatient rehabilitation at Hasegawa Hospital, Chiba, Japan, between December 2019 and September 2021. The sample size was based on a previously reported pilot study in which the physical therapist performed cognitive-behavior therapy for patients with KOA<sup>16</sup>). In addition, the corresponding author and principal investigator determined the sample size considering feasibility and dropouts in this study. The recruitment was posted as an advertisement in the waiting room with information about the study, and the physical therapist informed the eligible patients about the opportunity to participate in the study. Inclusion criteria were adults aged 65 years or older, diagnosis of KOA, presence of persistent knee pain for 3 months or longer, and average pain during the previous week >30 on a 100 mm pain visual analog scale (PVAS). The exclusion criteria were difficulty answering the questionnaire due to cognitive decline, knee surgery within 3 months, knee surgery scheduled for 3 months, and CBT experience within 3 months. After checking the criteria, eligible participants were block-randomized into the PACT or UC groups using computer-generated random numbers. A random number sequence was generated by an investigator who was blinded to the participant’s condition, and the intervener did not know the sequence until the grouping was decided.

In the intervention, the PACT group performed PACT and exercise therapy, while the UC group performed only exercise therapy. The frequency was once a week for 8 weeks in both groups. Exercise therapy in both groups was performed in the rehabilitation room by three physical therapists. The therapy comprised 30 min of strength training for the quadriceps, hamstrings, and gluteal muscles. The careers of the three physical therapists who performed exercise therapy were 3, 6 and 14 years, respectively. PACT intervention was performed 30 min after exercise therapy. Interventions were provided

individually to the patients in the rehabilitation room. The intervention was conducted by a physical therapist who received training on ACT and an intervention lecture from a clinical psychologist with rich ACT experience for 6 h in 3 days. The textbook was developed based on the advice of a psychologist. In addition, the intervention was simulated by a staff member at the study facility before the start of the study. PACT aimed to accept pain and improve maladaptive pain coping strategies based on ACT therapeutic theory. The first session focused on how to proceed with all the sessions and the PACT. From the second session onward, the program was conducted based on the psychological flexibility of the ACT treatment process. In addition, confirmation of homework and/or review of the previous session was conducted prior to each session. The PACT program is shown in Supplementary Table 1.

The measurement visit was conducted 4 weeks before intervention, pre-intervention, post-intervention, and 4 weeks after the intervention. The observation period was set as a 4-week period before the intervention to determine the efficacy of PACT and intergroup bias. The primary outcome was the presence of a physical disability. The secondary outcomes included psychological inflexibility, pain intensity, anxiety, depression, physical function, and objectively measured physical activity. Sociodemographic and pain-related variables were recorded only at assessment, 4 weeks before intervention. The Japanese Knee Osteoarthritis Measure (JKOM)<sup>17)</sup>, consists of 25 items that include pain intensity or stiffness during the past few days (8 items), daily life conditions during the past few days (10 items), general activities during the past month (5 items), and general health conditions during the past month (2 items). Each item is rated on a scale from 1 to 5, where a higher score indicates a higher level of physical disability. The physical disability score was calculated by summing all items except for pain intensity. Psychological inflexibility was investigated using the Japanese version of the Psychological Inflexibility in Pain Scale (PIPS-J)<sup>18)</sup>. The Psychological Inflexibility in Pain Scale was developed to measure psychological inflexibility in relation to chronic pain<sup>19)</sup>. This scale was used to evaluate the pathological condition of ACT. It consists of 12 items; 8 items concerning avoidance behaviors comprise a subscale for pain avoidance, while 4 items comprise a subscale for cognitive fusion. All items were rated on a 7-point Likert-type scale from 1 (never true) to 7 (always true). The total score was calculated by summing the responses for each of the 12 items, with higher scores indicating higher psychological inflexibility. The investigation of pain intensity was performed using PVAS<sup>20)</sup>. Anxiety and depression were investigated using the Japanese version of the Hospital Anxiety and Depression Scale (HADS-J)<sup>21)</sup>. This scale is a 14 item self-reported questionnaire that consists of two 7 item subscales, one targeting anxiety symptoms and the other targeting depression symptoms. Each item is rated on a scale from 0 to 3, where a higher score indicates a higher level of anxiety and depression. The clinical cutoff values were 0–7 for normal, 8–10 for borderline abnormal, and 11–21 for abnormal. Physical function was evaluated using the Five-times sit-to-stand test (FTSS)<sup>22)</sup>. The FTSS was performed standing up from a sitting position and sitting down from there, five times as quickly as possible without using the hands. FTSS was measured using a 45-cm tall chair. The time was recorded by physical therapists using a stopwatch. The measurement was performed twice, and measurements with a shorter time were included in the analysis. Objectively measured physical activity and sedentary behavior were measured using a tri-axial accelerometer (Active style Pro HJA 350-IT; Omron Healthcare Co. Ltd., Kyoto, Japan). Participants were asked to wear a triaxial accelerometer on their left hip during waking hours for 7 consecutive days. The intensity of activity by metabolic equivalents (METs), measured by this accelerometer, has been reported to correlate with METs calculated by indirect calorimetry<sup>23)</sup>. Data were recorded in a 60-sec epoch. Non-wear time was defined at least in continuous 60-min of no activity (0.9 or less METs), with an allowance of up to 2 minutes of observations for some limited movement ( $\leq 1.0$  METs) within these periods. Day wearing for 10 hours or more was defined as valid. Participants were included in the analyses if there were four valid days that included at least one weekend. The daily average time spent in sedentary behavior (SB;  $\leq 1.5$  METs), engaged in light-intensity physical activity (LPA;  $>1.5$  to  $<3.0$  METs), and moderate-to-vigorous-intensity physical activity (MVPA;  $\geq 3.0$  METs) were calculated. The analysis used the percentage of each average time divided by wearing time. Sociodemographic and pain-related variables included age, gender (male/female), body mass index (BMI), education level (high school or further education, lower secondary school or less), material status, household size, rehabilitation outpatient period, duration of pain, and radiographic severity of KOA. These variables were investigated using a self-reported questionnaire, except for radiographic severity of KOA. The radiographic severity confirmed the Kellgren–Lawrence grading (KL-grading) from the doctor’s medical record.

In statistical analysis,  $\chi^2$  tests, unpaired t-tests, and Mann–Whitney U-tests were first conducted to examine whether there would be significant differences in sociodemographic and pain-related variables at 4 weeks before intervention between the intervention and control groups. Second, a series of repeated measures of analysis of covariance (ANCOVA) between intervention groups (PACT and UC) as a treatment factor were conducted to examine whether there would be intergroup bias (interaction effect treatment-by-time) on each primary and secondary outcome between the two assessment time points (4 weeks before intervention and pre intervention). Covariates included sociodemographic and pain-related variables. When a significant interaction was found, pairwise comparison with Bonferroni correction was performed as a post-hoc test to investigate the simple main effect of treatment (intervention group) within each time point. There was no significant interaction between treatment and assessment time. The main effects of the treatment and assessment time were also assessed. Third, a series of repeated measures of ANCOVA, similar to the observation period, were conducted to examine whether there would be an intervention effect on primary and secondary outcome between three assessment time points (pre-intervention, post-intervention, and 4 weeks after intervention) or not. The covariates were sociodemographic and pain-related variables, and the outcomes were measured using pre-intervention data. When a significant interaction was found, pairwise comparisons

were performed in the intervention groups, and multiple comparisons were performed for each time point with Bonferroni correction to explore the simple main effect. If there was no significant interaction between treatment and assessment time, the main effect of treatment and assessment time was assessed. Missing data were replaced with the last measured data using an intention-to-treat principle. In addition, considering the small sample size in this analysis, the effect size was utilized. The eta-squared effect size was interpreted based on a previous study (small=0.01, medium=0.06, and large=0.14)<sup>24</sup>. Statistical significance was declared at  $p < 0.05$  in all analyses. Data were analyzed using IBM SPSS Statistics for Windows (version 25.0; IBM SPSS Japan, Armonk, NY, USA).

## RESULTS

Supplementary Fig. 1 shows a flowchart of the participants. Of the 35 recruited patients, 30 who met the inclusion criteria participated. The primary reasons for participant exclusion were age  $< 65$  years ( $n=3$ ) and a decline in cognitive function ( $n=2$ ). The mean age of all 30 participants was  $74.2 \pm 6.9$  years. Twenty-seven (93.3%) were women, while 16 (53.3%) were overweight according to the standard interpretation of BMI. In addition, 22 (73.3%) participants were high school graduates, 27 (90.0%) were married, and had the mean household size of  $2.2 \pm 1.27$ . Furthermore, the mean duration of pain was  $46.0 \pm 52.4$  months and the rehabilitation outpatient period was  $9.3 \pm 9.1$  months. Most patients had a KL-grade  $\geq 2$  (86.6%), with pathological changes in the knee joint. Table 1 shows the sociodemographic and pain-related variables and other study outcomes at 4 weeks before the intervention in both groups. There were no significant differences between the intervention groups in any of these variables.

Eight (53.3%) patients in the PACT group completed the study. The number of dropouts were one at pre-intervention, five during the intervention, and one at post-intervention. The reasons for dropout were concerns about coronavirus disease 2019 (COVID-19) ( $n=2$ ), exacerbation of complications ( $n=3$ ), and orthopedic surgeons' decision to end rehabilitation ( $n=2$ ). In contrast, seven patients (43.7%) in the UC group completed the study. The reasons for dropout were concern about COVID-19 infection ( $n=4$ ), orthopedic surgeons' decision to end rehabilitation ( $n=1$ ), and dissatisfaction with the study ( $n=3$ ). Supplementary Table 2 shows the characteristics of completed and dropouts. There were no significant differences in the sociodemographic and pain-related variables and assessment of 4 weeks before the intervention between completers and dropouts in either group.

**Table 1.** Participant sociodemographic and health-related variables and 4-weeks before intervention data

		PACT (n=15)	UC (n=15)
Age (years)		$73.3 \pm 7.0$	$75.1 \pm 6.9$
Gender (female, n)		14	13
BMI (kg/m <sup>2</sup> )		$24.5 \pm 3.5$	$25.9 \pm 3.1$
Education level (n)	Junior high school	3	5
	High school	10	10
	Junior college	2	0
Marital status (married, n)		13	14
Household size (n)		$2.0 \pm 1.1$	$2.3 \pm 1.3$
Duration pain (month)		$64.1 \pm 64.5$	$27.9 \pm 28.9$
Rehabilitation outpatient period (month)		$9.2 \pm 9.1$	$9.4 \pm 9.2$
KL-grading		$2.1 \pm 0.5$	$2.2 \pm 0.8$
Physical disability		$36.6 \pm 14.1$	$30.9 \pm 12.7$
Psychological inflexibility	Pain avoidance	$27.2 \pm 11.4$	$28.3 \pm 11.9$
	Cognitive fusion	$16.6 \pm 3.9$	$16.7 \pm 4.0$
Pain intensity		$46.6 \pm 18.3$	$51.4 \pm 17.9$
Anxiety		$4.93 \pm 3.3$	$3.0 \pm 2.1$
Depression		$4.93 \pm 2.3$	$4.4 \pm 2.3$
Physical function (sec)		$10.1 \pm 2.4$	$11.2 \pm 2.3$
Physical activity (%)	SB	$52.2 \pm 13.6$	$60.7 \pm 12.9$
	LPA	$42.6 \pm 9.1$	$35.3 \pm 12.5$
	MVPA	$6.2 \pm 5.4$	$6.0 \pm 6.3$

PACT: physical therapist-delivered acceptance and commitment therapy; UC: usual care; BMI: body mass index; KL-grading: Kellgren–Lawrence grading; SB: sedentary behavior; LPA: light-intensity physical activity; MVPA: moderate-to-vigorous intensity physical activity.

The differences in primary and secondary outcomes between PACT and UC during the observational period are presented in Supplementary Table 3. There was no significant interaction in any outcome between intervention group and time. There was no main effect. Differences in the primary and secondary outcomes between PACT and UC at pre-intervention, post-intervention, and 4 weeks after intervention are presented in Table 2. There was a tendency for a significant interaction in physical disability scores between the intervention group and time ( $F=2.80$ ,  $p=0.09$ ,  $\eta^2=0.13$ ). The main effect was not treatment ( $F=2.79$ ,  $p=0.11$ ) and assessment time ( $F=0.27$ ,  $p=0.69$ ). In a post-hoc test, the physical disability scores in the PACT group significantly decreased from pre-intervention to post-intervention ( $p=0.01$ , 95% CI: 1.03–7.36), from post-intervention to 4 weeks after intervention ( $p=0.02$ , 95% CI: 0.17–1.82), and from pre-intervention to 4 weeks after intervention ( $p=0.01$ , 95% CI: 2.49–7.90). However, there were no significant differences in physical disability scores among the three time periods in the UC group. In addition, the physical disability score was not significantly different between the two groups post-intervention. However, the PACT group at 4 weeks after intervention was significantly lower than that in the UC group ( $p=0.04$ , 95% CI: -8.75 to -0.15). For the secondary outcomes, there was a significant difference in LPA between the intervention group and time ( $F=4.85$ ,  $p=0.01$ ,  $\eta^2=0.21$ ). The main effect was treatment ( $F=6.28$ ,  $p=0.02$ ) and assessment time ( $F=3.51$ ,  $p=0.04$ ). Pairwise comparisons showed that LPA in the PACT group was higher than that in the UC group post-intervention ( $p=0.01$ , 95% CI: 1.13–10.34) and 4 weeks after intervention ( $p=0.03$ , 95% CI: 0.52–9.15). However, both the PACT and UC groups showed no significant differences in LPA at three time points. There was a trend for a significant interaction in the SB between the intervention group and time ( $F=3.04$ ,  $p=0.06$ ). The main effect was only in the treatment ( $F=4.55$ ,  $p=0.04$ ). In the post-hoc test, pair-wise comparison showed that SB in the PACT group was lower than that in the UC group only post-intervention ( $p=0.01$ , 95% CI: -6.50 to -0.83). However, there were no significant differences in SB at three time points between the PACT and UC groups. For other secondary outcomes, there were no significant interactions between the intervention group and time. A significant main effect of assessment time was also found for pain intensity ( $F=5.39$ ,  $p=0.01$ ) and depression ( $F=3.49$ ,  $p=0.04$ ). However, multiple comparisons showed no significant differences in either variable at three time points.

## DISCUSSION

The purpose of this pilot study was to investigate the effect of PACT in older outpatients with KOA and chronic knee pain. The present study expands on previous studies by focusing specifically on KOA and conducting a physical therapy. The results of this study for primary outcome showed that the effect of combined ACT with exercise therapy on physical disability was limited, even though a favorable tendency and medium effect size were observed among patients with KOA in outpatient rehabilitation. Regarding secondary outcomes, such a combined approach of physical therapist-based ACT and exercise therapy did not have enough impact on improving psychological inflexibility. In addition, there were no apparent changes in LPA over time in either group, although the LPA immediately and 4 weeks after intervention in the PACT group was higher than that in the UC group. A major concern in this study was the negative influence of the coronavirus disease 2019 (COVID-19) pandemic, as the sample size decreased more than expected. Thus, future studies should be conducted in more stable environments.

**Table 2.** Comparison of study outcomes between PACT and UC from pre-to 4-weeks after intervention

	PACT			UC		
	Pre intervention	Post intervention	4-weeks after intervention	Pre intervention	Post intervention	4-weeks after intervention
Physical disability	35.8 ± 17.6 <sup>†</sup>	31.6 ± 14.6 <sup>†</sup>	30.6 ± 14.4 <sup>†</sup>	27.8 ± 11.9 <sup>†</sup>	26.7 ± 11.2 <sup>†</sup>	27.1 ± 11.1 <sup>†</sup>
Psychological inflexibility						
Pain avoidance	27.5 ± 9.6	26.2 ± 8.7	24.4 ± 9.6	28.3 ± 11.4	26.9 ± 11.4	26.7 ± 12.0
Cognitive fusion	17.0 ± 4.3	14.9 ± 3.9	14.9 ± 3.5	16.2 ± 3.5	16.6 ± 4.1	17.0 ± 3.5
Pain intensity	41.3 ± 18.1	36.0 ± 20.2	35.7 ± 19.2	41.1 ± 16.6	39.0 ± 16.3	38.6 ± 17.9
Anxiety	4.2 ± 2.9	4.1 ± 2.5	3.7 ± 2.4	3.6 ± 1.8	3.6 ± 1.8	3.4 ± 2.0
Depression	5.4 ± 2.7	5.1 ± 2.8	4.5 ± 2.9	4.5 ± 2.3	3.9 ± 2.4	4.0 ± 2.5
Physical function (sec)	9.5 ± 2.6	9.2 ± 2.4	8.8 ± 2.4	10.6 ± 2.4	10.4 ± 1.8	10.1 ± 1.7
Physical activity (%)						
SB	52.3 ± 10.8	50.6 ± 9.9	50.9 ± 9.1	57.8 ± 13.8	56.1 ± 14.1	55.2 ± 19.4
LPA	43.3 ± 8.7*	45.4 ± 8.1*	44.9 ± 8.2*	37.3 ± 11.4*	36.2 ± 11.0*	36.0 ± 10.9*
MVPA	4.7 ± 2.9	5.0 ± 2.6	5.2 ± 2.7	4.7 ± 4.1	5.5 ± 4.1	5.8 ± 4.8

\*Significant interaction between treatment and assessment time ( $p<0.05$ ).

<sup>†</sup>Significant interaction between treatment and assessment time ( $p<0.1$ ).

PACT: physical therapist-delivered acceptance and commitment therapy; UC: usual care; SB: sedentary behavior; LPA: light-intensity physical activity; MVPA: moderate-to-vigorous intensity physical activity.

In this study, improvement in psychological inflexibility was the focus of ACT-based interventions. Thus, it was hypothesized that physical disability could be improved by enhancing psychological flexibility. However, there were no apparent changes in psychological inflexibility items, including pain avoidance and cognitive fusion, in the PACT group, whereas physical disability had the potential for improvement. Although the underlying mechanism is unknown, extra 30 min intervention with a physical therapist may have had some positive effects on physical disability. In addition, one of the possible reasons why the PACT did not have enough impact on improving psychological inflexibility may be the insufficient skill and experience of the physical therapist conducting the ACT intervention. Nielsen et al.<sup>25)</sup> suggest that physical therapists lack intervention skills in negative thoughts about pain. In addition, there was no intervention effect on psychological inflexibility in a previous study in which PACT was performed on patients with low back pain<sup>12)</sup>. This previous study also suggested the need for an intervention support system for physical therapists and private rooms where patients could focus on intervention. In this study, the intervener attended a 6 h 3 days lecture, simulated intervention before starting the study, and used a textbook during the ACT intervention. No additional support from the clinical psychologist or private room was provided during the intervention period. Based on the findings of previous studies and the present study, it may be necessary to reconsider intervention support and facilities for ACT skill shortages in the future study.

In terms of LPA and SB, the patients in the PACT group were more physically active and less sedentary than those in the UC group at both 4 weeks before intervention and pre-intervention. Although all analyses examining the intervention effect were adjusted for pre-intervention data, this factor may have caused intergroup differences in SB and LPA. Physical disability may also have affected the LPA results. The JKOM items include difficulties such as standing up, changing clothes, walking, stairs, light housework, and shopping<sup>17)</sup>. These activities had a favorable tendency in the PACT group, which may have affected the significant differences between the groups.

No effect in either group was observed in the secondary outcomes, including pain intensity, anxiety, depression, and physical function. It is understandable that PACT was not effective in relieving pain intensity because the treatment purpose of ACT is pain acceptance and increased value-based action<sup>9)</sup>. The anxiety and depression levels in both groups were within normal range at baseline data, so it may not have seen any significant changes. Therefore, future studies should consider whether to target interventions based on baseline scores. The results of physical function may be due to the lower amount of exercise therapy conducted in the intervention in both groups. Most previous studies reported that the frequency and duration of exercise to observe effectiveness on physical function among KOA patients were at least 2–3 times a week for 20–30 minutes a day<sup>5)</sup>. The World Health Organization (WHO) recommends strength training and balance training for at least 3 days a week to improve physical function in older people<sup>26)</sup>. However, this study consisted of a weekly 30 min stretch and strength training. Therefore, it will be necessary to revise the program in future studies, such as the frequency of exercise therapy and the introduction of self-exercise.

The present study had several limitations. First, the results may not apply to the general older population with KOA and knee pain because this study was performed in only one facility and most of the participants were women. Second, the grouping randomization was not blinded or stratified. Therefore, measurements and interventions may have been biased. Third, the number of dropouts in this study was half the total number. As a countermeasure, the intention-to-treat principle was applied to correct for the missing values, but the results were not fully reflected. Half of the dropouts had been affected by the COVID-19 pandemic. During this period, the government requested activity restrictions and patient behavior was greatly limited. Therefore, it is necessary to address these problems and investigate the effects of PACT in a more stable environment.

In conclusion, PACT did not seem to have a sufficient impact on physical disability as the primary or secondary outcomes, even though the PACT showed a possibility of physical disability improvement. The quality and amount of physical therapy-based ACT intervention may need to be modified to observe its apparent effectiveness on both psychological inflexibility and physical disability. In addition, the present study was heavily influenced by COVID-19. Therefore, it is necessary to modify the interventions and investigate the effects of PACT in future studies.

### *Funding and Conflict of interest*

The authors declare no conflict of interest.

## REFERENCES

- 1) Muraki S, Oka H, Akune T, et al.: Prevalence of radiographic knee osteoarthritis and its association with knee pain in the elderly of Japanese population-based cohorts: the ROAD study. *Osteoarthritis Cartilage*, 2009, 17: 1137–1143. [[Medline](#)] [[CrossRef](#)]
- 2) Guccione AA, Felson DT, Anderson JJ, et al.: The effects of specific medical conditions on the functional limitations of elders in the Framingham Study. *Am J Public Health*, 1994, 84: 351–358. [[Medline](#)] [[CrossRef](#)]
- 3) Wideman TH, Finan PH, Edwards RR, et al.: Increased sensitivity to physical activity among individuals with knee osteoarthritis: relation to pain outcomes, psychological factors, and responses to quantitative sensory testing. *Pain*, 2014, 155: 703–711. [[Medline](#)] [[CrossRef](#)]
- 4) Hunter DJ, Schofield D, Callander E: The individual and socioeconomic impact of osteoarthritis. *Nat Rev Rheumatol*, 2014, 10: 437–441. [[Medline](#)] [[CrossRef](#)]
- 5) Fransen M, McConnell S, Harmer AR, et al.: Exercise for osteoarthritis of the knee: a Cochrane systematic review. *Br J Sports Med*, 2015, 49: 1554–1557. [[Medline](#)] [[CrossRef](#)]

- 6) Kanavaki AM, Rushton A, Efstathiou N, et al.: Barriers and facilitators of physical activity in knee and hip osteoarthritis: a systematic review of qualitative evidence. *BMJ Open*, 2017, 7: e017042. [[Medline](#)] [[CrossRef](#)]
- 7) Robinson ME, Riley JL 3rd, Myers CD, et al.: The Coping Strategies Questionnaire: a large sample, item level factor analysis. *Clin J Pain*, 1997, 13: 43–49. [[Medline](#)] [[CrossRef](#)]
- 8) Blyth FM, March LM, Nicholas MK, et al.: Self-management of chronic pain: a population-based study. *Pain*, 2005, 113: 285–292. [[Medline](#)] [[CrossRef](#)]
- 9) Feliu-Soler A, Montesinos F, Gutiérrez-Martínez O, et al.: Current status of acceptance and commitment therapy for chronic pain: a narrative review. *J Pain Res*, 2018, 11: 2145–2159. [[Medline](#)] [[CrossRef](#)]
- 10) Hayes SC, Luoma JB, Bond FW, et al.: Acceptance and commitment therapy: model, processes and outcomes. *Behav Res Ther*, 2006, 44: 1–25. [[Medline](#)] [[CrossRef](#)]
- 11) Wicksell RK, Renöfält J, Olsson GL, et al.: Avoidance and cognitive fusion—central components in pain related disability? Development and preliminary validation of the Psychological Inflexibility in Pain Scale (PIPS). *Eur J Pain*, 2008, 12: 491–500. [[Medline](#)] [[CrossRef](#)]
- 12) Godfrey E, Wileman V, Galea Holmes M, et al.: Physical Therapy Informed by Acceptance and Commitment Therapy (PACT) versus usual care physical therapy for adults with chronic low back pain: a randomized controlled trial. *J Pain*, 2020, 21: 71–81. [[Medline](#)] [[CrossRef](#)]
- 13) Hughes LS, Clark J, Colclough JA, et al.: Acceptance and Commitment Therapy (ACT) for chronic pain: a systematic review and meta-analyses. *Clin J Pain*, 2017, 33: 552–568. [[Medline](#)] [[CrossRef](#)]
- 14) Japanese Society of Certificated Clinical Psychologists. 2014 Needs survey results report for clinical psychologists in the medical field. [http://jscep.jp/suggestion/sug/pdf/iryou\\_20141202.pdf](http://jscep.jp/suggestion/sug/pdf/iryou_20141202.pdf) (Accessed Oct. 4, 2020)
- 15) Eldridge SM, Chan CL, Campbell MJ, et al. PAFS consensus group: CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *Pilot Feasibility Stud*, 2016, 2: 64. [[Medline](#)] [[CrossRef](#)]
- 16) Hunt MA, Keefe FJ, Bryant C, et al.: A physiotherapist-delivered, combined exercise and pain coping skills training intervention for individuals with knee osteoarthritis: a pilot study. *Knee*, 2013, 20: 106–112. [[Medline](#)] [[CrossRef](#)]
- 17) Akai M, Doi T, Fujino K, et al.: An outcome measure for Japanese people with knee osteoarthritis. *J Rheumatol*, 2005, 32: 1524–1532. [[Medline](#)]
- 18) Nagasawa Y, Shibata A, Fukamachi H, et al.: The Psychological Inflexibility in Pain Scale (PIPS): validity and reliability of the Japanese version for chronic low back pain and knee pain. *J Pain Res*, 2021, 14: 325–332. [[Medline](#)] [[CrossRef](#)]
- 19) Wicksell RK, Lekander M, Sorjonen K, et al.: The Psychological Inflexibility in Pain Scale (PIPS)—statistical properties and model fit of an instrument to assess change processes in pain related disability. *Eur J Pain*, 2010, 14: 771.e1–771.e14. [[Medline](#)] [[CrossRef](#)]
- 20) Gaston-Johansson F: Measurement of pain: the psychometric properties of the Pain-O-Meter, a simple, inexpensive pain assessment tool that could change health care practices. *J Pain Symptom Manage*, 1996, 12: 172–181. [[Medline](#)] [[CrossRef](#)]
- 21) Hatta H, Higashi A, Yashiro H, et al.: A validation of the hospital anxiety and depression scale. *Jpn Soc Psychosom Med*, 1998, 38: 309–315.
- 22) Whitney SL, Wrisley DM, Marchetti GF, et al.: Clinical measurement of sit-to-stand performance in people with balance disorders: validity of data for the Five-Times-Sit-to-Stand Test. *Phys Ther*, 2005, 85: 1034–1045. [[Medline](#)] [[CrossRef](#)]
- 23) Ohkawara K, Oshima Y, Hikiyama Y, et al.: Real-time estimation of daily physical activity intensity by a triaxial accelerometer and a gravity-removal classification algorithm. *Br J Nutr*, 2011, 105: 1681–1691. [[Medline](#)] [[CrossRef](#)]
- 24) Cohen J: *Statistical Power Analysis for the Behavioral Sciences*, 2nd ed. London: Routledge, 1988, pp 273–403.
- 25) Nielsen M, Keefe FJ, Bennell K, et al.: Physical therapist-delivered cognitive-behavioral therapy: a qualitative study of physical therapists' perceptions and experiences. *Phys Ther*, 2014, 94: 197–209. [[Medline](#)] [[CrossRef](#)]
- 26) World Health Organization: WHO guidelines on physical activity and sedentary behavior. <https://www.who.int/publications/i/item/9789240015128> (Accessed Nov. 25, 2020)