

Original research

Self-administered Acupressure for Knee Osteoarthritis in Middle-aged and Older Adults: A Pilot Randomized Controlled Trial

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Abstract

Objective

To test the acceptability and feasibility of self-administered acupressure as an intervention for improving knee pain among middle-aged and older adults with osteoarthritis of the knee (KOA).

Methods

In this pilot randomized controlled trial, 35 participants with KOA were randomized to self-administered acupressure (n = 17, two self-administered acupressure training sessions and self-practice for 6 weeks) or knee health education (n = 18, two health education sessions about KOA management and self-care for 6 weeks). Current pain intensity (primary outcome) was measured using a numeric rating scale (NRS) at baseline and weeks 1, 2, 4, and 6 (post-intervention). Secondary outcome measures included worst and least pain intensity; the Western Ontario and McMaster Universities Osteoarthritis index, range of motion of the knee joints, and the Short Form-Six Dimension for health-related quality of life.

Results

Participants in both groups attended all training sessions. In the self-administered acupressure group, all subjects mastered the acupressure technique and passed the consistency check. Both groups showed a decreasing trend in current knee pain intensity by NRS at post-intervention. A medium between-group effect size (0.40) was found, but the between-group difference was not significant. The other secondary outcome measures were also comparable between both groups at post-intervention (all $P > 0.05$).

Conclusions

A 2-session self-administered acupressure training was acceptable and feasible among participants with KOA. A preliminary beneficial effect of self-administered acupressure for relieving pain in KOA was observed. Further trials with larger sample sizes and longer follow-up periods are warranted.

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Key Words

Self-administered acupressure, osteoarthritis of the knee, knee pain, intervention.

INTRODUCTION

Osteoarthritis is one of the most disabling diseases among the elderly in developed countries.¹ It most commonly affects the joints in the knees. Among patients with osteoarthritis of the knee (KOA), chronic pain is a common complaint and also the major reason for patients to receive medical care.² The pain is often accompanied by decreased mobility and impaired health-related quality of life,³ resulting in high healthcare expenditures.⁴

Acupressure is used in complementary and alternative therapies for pain management among women in labour,^{5,6} neck pain,⁷ dysmenorrhea,⁸ and symptom management in end-stage patients.⁹ Acupressure, a variant of acupuncture, involves rubbing, kneading, or percussion of the acupoints, soft tissues and joints of the body, with the hands. It can decrease muscle tension, increase blood and lymphatic circulations, and stimulate the nervous system.¹⁰ Compared with acupuncture, acupressure is non-invasive and can be administered by the patients, themselves.¹¹ Therefore, it serves as a low-cost, convenient, and safe modality for pain management.

In the context of KOA, the beneficial pain relief effect of acupuncture is supported.¹² Acupoint injection has also been shown to be effective in treating KOA.¹³ However, very few studies have evaluated the effects of self-administered acupressure in relieving the pain of KOA. A quasi-experimental study demonstrated greater improvement in pain among KOA female patients who received self-administered acupressure training than those who attended for exercise class, or the control group.¹⁴ Yet, causality cannot be inferred owing to the study design. A randomized controlled trial (RCT) was conducted among 31 women with KOA, and a significant difference in pain relief was not demonstrated in the acupressure group versus the control group.¹⁵ Of note, high attrition rate (47%) was found in the acupressure group and there was no skills assessment or monitoring for the self-practice throughout the intervention period. Another RCT was conducted

in 150 elderly with KOA, with results indicating that acupressure, though superior to usual care, did not differ in pain relief compared to sham acupressure.¹⁶ However, the study was limited by the acupressure protocol, which was developed primarily for reducing cancer-related fatigue of cancer survivors. A previous review summarized 8 acupoints commonly adopted by practitioners for treating KOA,¹⁷ only one of which was covered in Li et al.'s study.¹⁶ In addition, the most prevalent muscles with myofascial trigger points (i.e., small contraction knots located in the muscle tissue causing pain that may be relieved through massage) in KOA patients have been found to be located in the quadriceps vastus medialis and lateralis.^{18 19} It is worth noting that none of the acupoints in Li et al.'s protocol was located in the aforementioned muscles. Thus, there is a need for more rigorous RCTs to evaluate the effects of a clinically relevant acupressure protocol for KOA.

We conducted a pilot RCT which aimed to: i) test the acceptability and feasibility of training patients with KOA to self-administer acupressure for pain relief, and ii) evaluate the preliminary effects of self-administered acupressure on improving knee pain, stiffness, physical function, range of motion (ROM), and health-related quality of life, compared with knee health education. This exploratory pilot study will inform the feasibility of design and sample size calculation for future trials.

METHODS

Study design

This pilot RCT evaluated the effects of self-administered acupressure for the treatment of KOA pain. A total of 35 participants with KOA were randomized at 1:1 ratio to self-administered

acupressure or the health education group, according to a randomization list with a random block size of 4 or 6 generated by an independent randomizer. Group allocation was enclosed in sealed and sequentially numbered opaque envelopes. The study was reviewed and approved by the institutional review board of the university. The study was designed and reported following the Consolidated Standards of Reporting Trials (CONSORT) and Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA) guidelines.^{20 21}

Participants

Community-living participants were recruited through advertisements at the university clinic of the Hong Kong Polytechnic University and social network media such as Facebook and WhatsApp. Participants were Chinese individuals aged 50 – 70 years, with self-rated knee pain of ≥ 3 and ≤ 7 on a 11-point numeric rating scale for at least 3 months, and diagnosed with KOA based on the clinical criteria developed by Altman et al.²² Details of inclusion and exclusion criteria are listed in Table 1. Interested individuals were contacted and screened by a research assistant (RA) for eligibility. Written informed consent was obtained from all participants.

Table 1. Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
<p>(1) A self-rated knee pain as ≥ 3 and ≤ 7 on a 11-point numeric rating scale for at least 3 months</p> <p><i>Rationale: Acupressure is most effective for mild-to-moderate pain intensity.¹⁵</i></p> <p>(2) A diagnosis of KOA based on fulfilment of any 3 of the clinical criteria developed by Altman et al.²² (i.e., morning stiffness ≤ 30 minutes, crepitus on active joint)</p>	<p>(1) Medical diagnoses or conditions that preclude individuals from active participation (bleeding disorders, alcohol, or drug abuse)</p> <p>(2) Cognitive impairment preventing informed consent or understanding of instructions (scored < 22 in the Hong Kong Montreal Cognitive Assessment)</p>

<p>motion, bone tenderness, bone enlargement, and no palpable joint warmth)</p> <p><i>Rationale: The criteria was found to be 89% sensitive and 88% specific for diagnosing KOA.²²</i></p> <p>(3) Ethnic Chinese</p> <p>(4) Aged 50–70 years</p> <p>(5) Able to provide informed consent</p> <p>(6) Ability of comprehend Chinese</p>	<p>(3) Participation in other interventional KOA research studies</p> <p>(4) Skin lesions or infections at the treatment sites</p> <p>(5) A body mass index over 25</p> <p><i>Rationale: A body mass index > 25 defines obesity in Asians.</i></p> <p>(6) Knee pain related to other conditions (cancer, fracture, rheumatoid arthritis, and rheumatism)</p> <p>(7) Previous foot injury or trauma</p> <p>(8) Use of steroid for knee pain</p> <p>(9) Pregnant or contemplating pregnancy</p> <p>(10) Received or self-administered acupressure in the past 6 months</p>
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Intervention

Self-administered acupressure group

Participants in the intervention group received two weekly 90-minute self-administered acupressure training sessions, delivered by a registered Chinese Medicine practitioner with at least 5 years of clinical experience in acupuncture and acupressure, in a group size of 4–6. The acupressure protocol, named WARM (acronym for: Warm-up, Acupressure, Rubbing the knee-cap, Moving the knee), was based on traditional Chinese medicine meridian theory with reference from the literature^{14 15 17} and modified by the investigators with expertise in acupuncture (LL and WFY). It included a total of eight acupressure points (Appendix 1). To ensure consistency, participants were asked to demonstrate the acupressure technique at the end of training and were assessed by the practitioner. Participants were told to perform acupressure for 15–20 minutes on their painful knee(s) twice a day: once in the morning (i.e., within 1 hour after waking) and once

at night (i.e., within 1 hour after dinner) for 6 weeks. Each participant received a written self-administered acupressure protocol and a log book for recording their daily acupressure practice at home.

Knee health education group

Participants in this group attended two weekly 90-minute health education sessions related to KOA management delivered by a registered nurse. A total of six self-care strategies were recommended, such as minimizing weight bearing at the knee joints and avoiding prolonged standing or walking.²³ A written summary of the health education content and a progress log for recording use of self-care strategies were distributed.

Participants of both groups received follow-up phone call twice per week throughout the 6 weeks, to remind them of the self-practice/self-care, and to ask about any adverse events. Participants were advised to keep their routine medical care for KOA, including medications and physician visits. Any change in the use of pain medications during the intervention and evaluation periods were recorded. As compensation, participants in the health education group received the same acupressure training as the intervention group after the final outcome measurement time point at week 6, while those in the intervention group were given the same health education sessions as the health education group after week 6.

Data collection

The primary outcome (current pain intensity) was measured at baseline and weeks 1, 2, 4, and 6. Secondary outcomes (worst and least pain intensity, pain during various activities, physical

function, and stiffness, range of motion, health-related quality of life) were assessed at different time points until post-intervention (week 6). Figure 1 shows the data collection time points. The outcome assessors were blinded to the group assignment of the participants. Participants were required to submit their completed acupuncture log/progress log at week 6.

Current pain intensity by numeric rating scale (NRS)

Current pain intensity of the most symptomatic knee was assessed using the NRS for pain. The NRS is a single-item scale that measures pain intensity on 11 points from 0 (no pain) to 10 (worst possible pain), with higher scores indicating greater pain intensity. The NRS has excellent test-retest reliability (intraclass correlation coefficient [ICC] = 0.95).²⁴ Research has also supported the validity of the NRS through strong and significant correlations with other pain assessment measures²⁵ and demonstrated the responsiveness of the NRS to treatments aimed at relieving pain.²⁶ The minimum detectable change of the NRS was 1.33,²⁴ whereas a clinically important difference was a decrease by approximately two points or a reduction of approximately 30%.²⁷

Worst and least pain intensity by NRS

Intensity of the worst and least pain of the most symptomatic knee in the preceding week were assessed with the same 11-point NRS at baseline and weeks 1, 2, 4, and 6.

Western Ontario and McMaster University Osteoarthritis Index (WOMAC)

The WOMAC is a 24-item questionnaire that was used to measure pain during various activities, physical function, and stiffness of the most symptomatic knee at baseline and weeks 2, 4, and 6.²⁸ The individual item scale ranges from 0 to 4 (none, mild, moderate, severe, and extreme,

respectively), and the scores of each subscale are summed and converted according to the user manual. Higher scores represent worse pain, physical function, and stiffness. A change in more than 12% of baseline scores is regarded as minimal clinically important difference for the WOMAC.²⁹ The Chinese version of the WOMAC has been shown to have good test-retest reliability (intraclass correlation coefficients for the subscales from 0.76 to 0.85), internal consistency (Cronbach's alpha from 0.84 to 0.96),³⁰ and discriminant validity between healthy individuals and KOA patients.

Range of motion (ROM)

The ROM was measured in degrees using a goniometer³¹ for both knees at baseline and week 6. Participants were told to lay down and actively flex and extend their knee joints until they reached their limit. The assessor provided support against the pull of gravity, but no support for the completion of the joint actions. Degrees of full available knee extension to full available knee flexion were assessed. The total ROM was calculated by degree of flexion plus extension. A trained RA will be responsible for ROM measurement to standardize methods of testing in order to enhance reliability.³²

The Short Form-Six Dimension (SF-6D)

The SF-6D is derived from Short Form-36 health survey to measure health-related quality of life at baseline and week 6.³³ The six dimensions covered are: functional limitations, role limitations, social functioning, pain, mental health, and vitality. Higher scores indicate better quality of life.

The Chinese version of the SF-6D has been validated and demonstrated moderate reliability (ICC = 0.787).³⁴

The Credibility of Treatment Rating Scale (CTRS)

The CTRS which consists of four items measured with a 6-point Likert scale, was used at baseline to assess participants' "confidence in the treatment to alleviate your complaint," "perceived logic of the treatment," "confidence in recommending the treatment to your friends who have similar complaints," and "likelihood that the treatment would alleviate your other complaints." A higher score suggested greater confidence. This scale has been commonly used for assessing patients' beliefs about the treatment in acupuncture trials.³⁵

Evaluation Questionnaire

The investigator-designed Evaluation Questionnaire was administered to the self-administered acupuncture group to evaluate the participants' feedback on the acupuncture intervention after completing the training course. The questionnaire included a 10-point single item scale (ranging from 1 to 10) to assess the participants' acceptability of self-administered acupuncture. Open-end questions were also included to collect qualitative feedback regarding the strengths of the training and suggestions for any improvement.

Sample size and Data analysis

Previous literature have recommend a sample size of at least 12 per group in a pilot RCT would be reasonable enough to provide sufficient methodological experience and estimation of effect size to conduct subsequent fully powered studies.³⁶ Taking into account a dropout rate of 30%, 18 subjects per group were needed. We planned to include a total sample of 36 subjects, with 18 in each group.

Analysis was performed using an intention-to-treat approach with SPSS version 25.0 (IBM Corp., Armonk, NY, USA). Participants' baseline characteristics were examined for potential between-group difference using the chi-squared tests and t-tests for categorical and continuous data, respectively. The normality of the distribution in each group was tested using the Shapiro-Wilk test. The between-group differences in primary outcome (current pain, as measured by the NRS) and other secondary outcomes over time were compared using the linear mixed effects model by examining the group by time point interaction effect. Mixed effects model can accommodate missing data and does not require imputation of missing observations; providing a natural way to deal with missing values or dropouts.³⁷ Bonferroni correction was used to adjust multiple time-points in comparison with conservative thresholds of $P < 0.0125$ and $P < 0.017$ in NRS (four time-points) and WOMAC (three time-points), respectively. Mean differences were divided by the pooled standard deviation to calculate the within-group and between-group effect sizes.

RESULTS

The study flow diagram is shown in Figure 2. Between June 2017 and September 2017, 167 people were assessed for eligibility. Screening resulted in a randomized sample of 35. Of those, 17

participants were randomized to the self-administered acupressure intervention group, and 18 to the knee health education group. Although the target sample size was 36, we had to stop the subject recruitment after recruiting 35 subjects due to limited resources. Of note, the final sample size was larger than the planned minimal sample size (n = 12 in each group) due to a low dropout rate. Participants aged 62.14 years on average (standard deviation = 5.9), with majority being female (77.1%). The duration of knee pain was 51.44 months (standard deviation = 64.6) and 2 (5.7%) participants were using medications for knee pain (paracetamol 665mg/day), whereas 11 (31.4%) participants were using medications for other chronic illnesses (Table 2). There were no significant differences in baseline characteristics or perceived credibility/expectancy towards the treatment between the two groups. In the self-administered acupressure group, 2 participants dropped out after receiving the intervention due to loss of contact. No patient in the knee health education group withdrew from the study.

Table 2. Baseline characteristics of the sample

Variable, mean ± standard deviation	All participants (n = 35)	Self-administered acupressure (n = 17)	Knee Health Education (n = 18)	P-value t-test/ chi-squared test
Age, years	62.14 ± 5.93	64.41 ± 6.15	62.83 ± 5.81	0.49
Female gender, n (%)	27 (77.10)	14 (82.35)	13 (72.22)	0.48
Education level, n (%)				0.85
Secondary or below	20 (57.10)	10 (58.82)	10 (55.56)	
Above secondary	15 (42.90)	7 (41.18)	8 (44.44)	
Marital status, n (%)				0.11
Single	5 (14.30)	1 (5.88)	4 (22.22)	
Married	28 (80.00)	16 (94.12)	12 (66.67)	
Divorced/widowed	2 (5.70)	0 (0)	2 (11.11)	
Employment status, n (%)				0.36
Employed	13 (37.10)	5 (29.41)	8 (44.44)	
Unemployed/retired/housewife	22 (62.90)	12 (66.67)	10 (55.56)	
Income, HK\$, n (%)				0.23
Below \$25,000	24 (68.60)	10 (58.82)	14 (77.78)	

\$25,000 or above	11 (31.40)	7 (41.18)	4 (22.22)	
Body mass index, kg/m ²	22.35 ± 1.76	22.66 ± 1.33	22.06 ± 2.09	0.32
Knee pain duration, months	51.44 ± 64.59	51.35 ± 46.91	51.53 ± 79.21	0.99
Current use of medications for knee pain, n (%)	2 (5.71)	1 (5.88)	1 (5.56)	0.97
Current use of medication for other chronic illness, n (%)	11 (31.40)	7 (41.18)	4 (22.22)	0.23
Treatment received for knee osteoarthritis management, n (%)				
Western medicine	7 (20.00)	2 (11.76)	5 (27.78)	0.24
Physiotherapy	6 (17.10)	3 (17.65)	3 (16.67)	0.94
Chinese medicine (internal use)	1 (2.90)	0 (0)	1 (5.56)	0.32
Chinese medicine (external use)	7 (20.00)	2 (11.76)	5 (27.78)	0.24
Acupuncture	1 (2.90)	0 (0)	1 (5.56)	0.32
Supplements	8 (22.90)	3 (17.65)	5 (27.78)	0.48
Others	4 (11.40)	1 (5.88)	3 (16.67)	0.32
Credibility/expectancy towards the intervention ^a				
How confident do you feel that this treatment can alleviate your complaint?	4.66 ± 0.839	4.71 ± 0.85	4.61 ± 0.85	0.74
How confident would you be recommending this treatment to a friend who suffered from a similar problem?	4.71 ± 1.073	4.59 ± 1.06	4.83 ± 1.10	0.51
How logical does this treatment seem to you?	4.77 ± 0.88	4.88 ± 0.93	4.67 ± 0.84	0.48
How successful do you think this treatment would be in alleviating other complaints?	4.29 ± 0.89	4.47 ± 0.80	4.11 ± 0.96	0.24

^aLikert scale = 1 (not at all logical/useful/confident) to 9 (very logical/useful/confident)

Acceptability and feasibility

All participants attended all sessions according to their group assignment. In the self-administered acupressure group, their rating on degree of willingness to attend similar training courses in the future was 9.2 out of 10. The strengths of the training were identified as enhancing knowledge about acupressure and improving knee pain and flexibility. Participants' suggestions for improvement included coverage of more acupressure points, more time for hands-on practice, and more contact time with the practitioner. For the 15 participants in the self-administered acupressure group who had returned their acupressure log, the duration of self-practice at home was 31.9 minutes/day on average, and 13 of them (72.2%) performed acupressure at least once daily during

the 6-week intervention period. In the knee health education group, the participants' compliance in the use of self-care strategies throughout the 6-week study course is shown in Appendix 2.

Primary outcome

The differences in the current pain scores as measured by the NRS of the self-administered acupressure group and knee health education group across study time-points were compared using the mixed-effects model (Table 2). Both groups showed a decrease trend in current knee pain intensity by NRS from baseline (self-administered acupressure group: mean = 4.53, standard error [SE] = 0.36; health education group: mean = 4.83, SE = 0.35) to week 6 (self-administered acupressure group: mean = 2.23, SE = 0.37; health education group: mean = 2.83, SE = 0.35). Although the observed mean pain scores were lower in the self-administered acupressure group than in the knee health education group at week 2 (effect size = 0.23), week 4 (effect size = 0.23), and week 6 (effect size = 0.40), no significant between-group difference was observed at all study time points after Bonferroni corrections (all $P > 0.05$).

Secondary outcomes

The mean worst pain scores as measured by the NRS within the preceding 1 week of the intervention and health education group at week 6 were 3.72 (SE = 0.43) and 4.11 (SE = 0.41), respectively. A small between-group effect size of 0.22 was demonstrated (Table 2). There were no significant differences between the two groups in worst pain and least pain intensity measured by NRS across the study time points. In addition, at week 6, no significant between-group difference was found in WOMAC scores in pain, stiffness, and functional limitations; the ROM; or the SF-6D scores after Bonferroni corrections (all $P > 0.05$).

Adverse events

In this study, 7 participants in the self-administered acupressure group reported having adverse events, including pain at the acupoints (n = 3), worsening of knee pain (n = 2), prick pain sensation on legs (n = 1), and bruise at the acupoints (n = 1). However, all the reported adverse events were mild and spontaneously resolved.

Post-hoc power analysis

The post-hoc power analysis revealed that the power of the present sample size in determining the difference in current pain, as measured by the NRS at week 6, was 22.3%. The effect size estimated in the present study suggested that a sample size of 77 in each group was needed to detect between-group differences in the current pain score at week 6, with a power level of 80%.

Table 3. Study outcomes across study time-points

Variables	Self-administered acupressure (n = 17)		Knee Health Education (n = 18)		Between- group effect size ^b	P- value ^c
	Mean ± SE	Within-group effect size ^a	Mean ± SE	Within-group effect size ^a		
<i>Primary outcome</i>						
NRS-Current pain ^d						
Baseline	4.53 ± 0.36		4.83 ± 0.35			
Week 1	3.77 ± 0.36	0.52	3.50 ± 0.35	0.91	-0.18	0.19
Week 2	3.29 ± 0.36	0.84	3.64 ± 0.35	0.81	0.23	0.93
Week 4	2.82 ± 0.36 [^]	1.16	3.17 ± 0.35	1.13	0.23	0.94
Week 6	2.23 ± 0.37	1.54	2.83 ± 0.35	1.36	0.40	0.54
<i>Secondary outcomes</i>						
NRS-Worst pain ^d						
Baseline	5.77 ± 0.42		6.17 ± 0.41			

Week 1	4.82 ± 0.42	0.54	5.06 ± 0.41	0.64	0.23	0.70
Week 2	4.77 ± 0.41	0.58	5.00 ± 0.41	0.67	0.14	0.76
Week 4	4.23 ± 0.42	0.89	4.22 ± 0.41	1.12	-0.01	0.47
Week 6	3.72 ± 0.43	1.17	4.11 ± 0.41	1.19	0.22	0.99
NRS-Least pain ^d						
Baseline	3.53 ± 0.42		3.33 ± 0.41 [^]			
Week 1	3.06 ± 0.42	0.27	3.22 ± 0.41	0.06	0.09	0.36
Week 2	2.35 ± 0.42	0.68	2.94 ± 0.41	0.23	0.33	0.10
Week 4	2.12 ± 0.42 [^]	0.81	2.29 ± 0.41	0.60	0.10	0.46
Week 6	1.96 ± 0.43 [^]	0.89	1.83 ± 0.41	0.86	-0.07	0.89
WOMAC-Pain ^e						
Baseline	9.06 ± 0.71		9.00 ± 0.69			
Week 2	7.12 ± 0.71	0.66	7.47 ± 0.70	0.519	0.12	0.64
Week 4	6.35 ± 0.71	0.92	6.14 ± 0.70	0.968	-0.07	0.87
Week 6	6.98 ± 0.74	0.70	6.44 ± 0.69	0.870	-0.18	0.65
WOMAC-Stiffness ^e						
Baseline	3.29 ± 0.43		2.67 ± 0.42			
Week 2	2.65 ± 0.43	0.37	2.03 ± 0.42 [^]	0.359	-0.35	0.98
Week 4	2.18 ± 0.43	0.64	1.92 ± 0.42 [^]	0.423	-0.15	0.44
Week 6	2.29 ± 0.44	0.56	2.33 ± 0.41	0.189	0.02	0.17
WOMAC-Functional limitations ^e						
Baseline	28.29 ± 2.64		27.67 ± 2.56			
Week 2	22.29 ± 2.64	0.54	23.53 ± 2.59	0.379	0.11	0.46
Week 4	19.94 ± 2.64	0.76	19.90 ± 2.59	0.711	-0.00	0.86
Week 6	20.59 ± 2.71	0.70	21.44 ± 2.56	0.572	0.08	0.68
Left knee ROM						
Baseline	125.30 ± 2.12		126.94 ± 2.06		0.19	
Week 6	124.43 ± 2.22	-0.10	125.79 ± 2.10	-0.130	0.15	0.92
Right knee ROM						
Baseline	122.24 ± 2.47		125.94 ± 2.40		0.36	
Week 6	122.15 ± 2.60 [^]	-0.01	125.96 ± 2.46	0.001	0.36	0.98
SF-6D scores						
Baseline	0.668 ± 0.029		0.695 ± 0.028			
Week 6	0.672 ± 0.029	0.03	0.744 ± 0.028	0.415	-0.61	0.36

Abbreviations: SE, standard error; NRS, Numeric Rating Scale; WOMAC, Western Ontario and McMaster University Osteoarthritis Index; ROM, range of motion; SF-6D, Short Form-Six Dimension

^aEffect size calculation was based on the difference of estimated mean and standard deviation comparing each time-point and baseline.

^bEffect size calculation was based on the between-group difference in total scores divided by pooled standard deviation.

^cP-value for group × time interaction of mean score using linear mixed-effects models

^dMeasured by the Numeric Rating Scale

^eMeasured by the Western Ontario and McMaster Universities Osteoarthritis Index

[^] **Shapiro-Wilk test was significant, indicating that the data were not normally distributed.**

DISCUSSION

This study is the first RCT, to our knowledge, to pilot and examine the potential effects of a specifically designed self-administered acupressure protocol for managing knee pain compared to a knee health education group. This pilot trial aimed at examining the acceptability and feasibility of training KOA participants to perform self-administered acupressure through two training sessions and estimating effect sizes for future fully powered studies. The intervention group participants demonstrated high acceptance towards the intervention, as evidenced by the high attendance, low dropout rate, and positive qualitative feedback. A decreasing trend was observed in current, least, and worst pain by NRS; and WOMAC scores for pain, stiffness, and functional limitations, as well as an increase in health-related quality of life, in both the self-administered acupressure and knee health education groups, from baseline to post-intervention. However, there were no statistical significance in post-intervention between-group differences due to the small sample size in this pilot trial. The findings regarding the effects of the intervention are inconclusive due to the pilot nature of the study.

Interestingly, improvement in knee pain was observed in both the self-administered acupressure and health education groups in the present study. We adopted Knee Health Education workshop as a comparison, instead of a waiting list control, because it can control for the contact time between the participants and the researchers which may contribute to a placebo effect to relieve pain. Based on log book, health education group participants complied with most of the recommended self-care management strategies. This may have contributed to the relief of the participants' pain in the knee health education group. A previous three-arm quasi-experimental study showed that KOA patients in both the isometric exercises and acupressure group reported improvement in pain but not the usual care control group, and acupressure acted better than the isometric exercises.¹⁴ A usual care group as the control in future studies may assist in

distinguishing the effects of acupressure, knee health education, and usual care on pain relief of KOA participants.

Although no statistically significant difference in pain was observed between the self-administered acupressure and knee health education group at the end of intervention, comparison of pain improvement in the self-administered acupressure group against the previous studies is worth exploration. Two previous studies examining effects of acupressure on knee pain also included WOMAC in pain measurement, with the change in scores from baseline to post-intervention being -0.63¹⁵ and -1.6,¹⁶ respectively, which are lower than that of our study (-2.08). To explain for such difference, methodology and protocol design may be the key factors. First, regarding methodology, Zhang et al.'s study lacked encouragement of self-practice and skill assessment (which may contribute to low adherence and high attrition),¹⁵ whereas our study tracked the participants' self-practice throughout the intervention period by follow-up phone calls and conducted skills assessment (which may result in good adherence and high retention). Second, unlike Li et al.'s protocol which was primarily designed by relieving fatigue of cancer patients,¹⁶ our protocol was designed specifically for KOA patients based on clinical expertise and established literature. This may explain the greater effect estimate reported in the present study. A full-scale RCT with a sample size large enough to provide adequate statistical power for examining the effectiveness of the intervention is needed. Also, a longer follow-up period is recommended to assess whether participants continue to perform acupressure and whether the effect remains.

Major strengths of the study include indications of acceptability, feasibility, and efficacy of the acupressure intervention and knee health education for improving pain, minimal adverse events, generation of estimates of effect sizes for future fully powered studies, and the enthusiasm about the study by participants of both groups.

There are also several limitations in our study, besides a small sample size due to its pilot nature. First, voluntary participation may lead to a higher expectancy and compliance to the acupressure, which might have inflated the effects observed. Second, the timeframe for our study was only 6 weeks, so whether the therapeutic effect would be maintained over a longer period could not be predicted. Further studies with a longer follow-up period is necessary. Third, although the self-administered acupressure technique is easy to master, and all participants passed the consistency check by the practitioner and were asked to record their practice in a log book, it is possible that some participants did not completely follow the instructions during their self-practice. Finally, the WARM protocol contains different components other than acupressure such as rubbing and moving the knees. Although acupressure is the major component (10 min out of 16 min treatment) of the WARM protocol, the specific effects of acupressure and other components were not examined in this study. Further study may investigate the specific therapeutic component of the WARM protocol.

In summary, a 6-week self-administered acupressure intervention is acceptable and feasible among KOA participants. Rigorous trials with larger sample sizes must be undertaken to evaluate the effectiveness of the intervention. Findings from this and future studies have the potential to influence clinical practice related to pain management of KOA by introducing self-administered acupressure.

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Declaration of conflicting interests

The authors declare that they have no competing interests.

Authors' contributions

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Preparing and reviewing the manuscript: DST Cheung, HY Chen, WF Yeung, and YS Ho

All authors read and approved the final manuscript.

Ethics approval

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