Effects of Low-Dose Therapist-Led Self-Exercise Education on the Management of Chronic Low Back Pain: Protocol for a Community-Based, Randomized, 6-Month Parallel-Group Study

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Abstract:

Introduction: Chronic low back pain (CLBP), defined as low back pain persisting for at least 3 months, leads to limitations in the activities of daily living and decreased quality of life. Individualized self-exercise education could be a preferable treatment option, especially in community-dwelling people with CLBP. Previous studies, however, did not directly compare the effects of therapist-led self-exercise education and material-only education, and there are only a few studies investigating the effects of low-dose (comprising a few sessions) self-exercise education on CLBP. We present a protocol of community-based, randomized study to evaluate the effects of low-dose (comprising a few sessions), therapist-led self-exercise education on CLBP.

Methods: Forty-eight participants with CLBP (men and women, aged 40-74 years) will be allocated to therapeutic self-exercise education programs, either a therapist-led group (2-week therapist's consultation and material use) or material-only group (material use only), in a randomized controlled trial. Pain intensity (NRS, numeric rating scale), pain disability (RDQ, Roland-Morris disability questionnaire), pain self-efficacy (PSEQ, pain self-efficacy questionnaire), and quality of life score (EQ-5D, European quality of life-5 dimensions) will be measured at baseline and at 4, 12, and 24 weeks. We will apply a repeated-measures design with mixed-effect models to estimate group differences from the baseline.

Ethics/Trial registration number: The protocol was approved by the Ethics Committees of the Osaka Center for Cancer and Cardiovascular Disease Prevention and Osaka University. The trial registration number is registered on the University Hospital Medical Information Network (UMIN000024537).

Keywords:

chronic low back pain, exercise therapy, self-management support, community-based trial

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Introduction

1.1 Background and rationale

Chronic low back pain (CLBP), defined as low back pain persisting for at least 3 months, leads to limitations in the activities of daily living and decreased quality of life (QoL)[1,2]. Although the cause of CLBP has not been well established, it may be induced in part by mechanical stress on joints and/or soft tissue and by psychosocial stress. Medium-quality evidence has supported that individualized exercise programs with psychological support (i.e., exercise therapy and cognitive behavioral therapy) improves pain intensity and functional loss among people with CLBP[3-7]. Several guidelines have also supported the use of non-pharmacologic therapy, such as exercise therapy, as first-line treatment[8]. Thus, individualized self-exercise education could be a preferable treatment option, especially for community-dwelling people with CLBP.

Previous studies did not compare between the effects of therapist-led self-exercise education (e.g. physical therapist; exercise therapist) and those of material-only education (e.g. book; leaflet). This is because of the group-based nature of education[9] or the inconsistency in the materials used[10,11]. In addition, the adequate dose of self-exercise education has remained unclear. The total amount of education for CLBP ranged from 2100 to 4320 minutes (e.g. only individual sessions: a total of 36 sessions, 120 minutes per session[12]; combined individual and group sessions: individual sessions, a total of 10 sessions, 30 minutes per session; and group sessions, 20 sessions, 90 minutes per session[13]. There are only a few studies investigating the effects of low-dose (comprising a few sessions) self-exercise education on CLBP[14,15].

1.2 Objectives

The purpose of this randomized controlled trial is to investigate the effects of low-dose therapist-led self-exercise education compared to material-only education among community-dwelling people with CLBP. This paper describes study design for the trial and presents the intervention procedures.

Methods

2.1 Trial design

A community-based, 6-month, parallel-group randomized, superiority study to compare the effects of low-dose therapist-led self-exercise education versus material-only self-exercise education in CLBP.

2.2 Study setting

A flow diagram is shown in Fig. 1 and a study synopsis is shown in Supplementary file 1. We will systematically recruit participants from a community (Ikawa, located in the northwest of Japan) via an annual cardiovascular risk survey namely the Circulatory Risk in Communities Survey (CIRCS). Details of the CIRCS protocol have been described in elsewhere[16].

2.3 Eligibility criteria

Inclusion criteria:

i) People with CLBP, defined as low back pain that had been recognized in the previous 4 weeks and had persisted beyond 3 months with/without buttock pain;
ii) People aged between 40 and 74 years old;
iii) People who gave informed consent to participate in the study;

Exclusion criteria:

i) People with suspected specific low back pain, such as intervertebral disc herniation, spinal compression fracture, and rheumatoid arthritis;
ii) People with neurological deficits;
iii) People not meeting the schedule;
iv) People with a scheduled move or long-term trip within a year;
v) People with difficulty in Japanese language;
vi) People with obvious cognitive impairment for answering the questionnaires;
vii) People with any difficulty to express own consent;
viii) Other people who are regarded as ineligible by a public health or orthopedic doctor;

2.4 Participant timeline

The timeline is shown in Table 1. Study enrolment and allocation will take place 2 weeks before the initial intervention. All possible participants will attend an orientation session to conduct eligibility screening and provide informed consent, and they will receive the allocation result before the beginning of intervention. All participants allocated in the therapist-led group will attend at least two individual sessions, one during the first visit and the second 2 weeks after the initial intervention, and they will be able to attend two more additional individual sessions at 4 and 12 weeks after. All participants, including the therapist-led and the material-only groups, will receive the same educational materials: a textbook at baseline and a DVD (digital versatile disc) at 4 weeks after the initial intervention. They will self-administer follow-up questionnaires at 4, 12, and 24 weeks after the initial intervention. We will provide the same individual sessions with the material-only group 24 weeks after the initial intervention and inform of that procedure in advance. This is intended as help to maintain their motivation to reply to the questionnaires.

2.5 Assessment

2.5.1 Baseline variables

For eligible participants, we will administer baseline assessments. The baseline assessments are pain intensity (NRS, numeric rating scale), pain disability (RDQ, Roland-

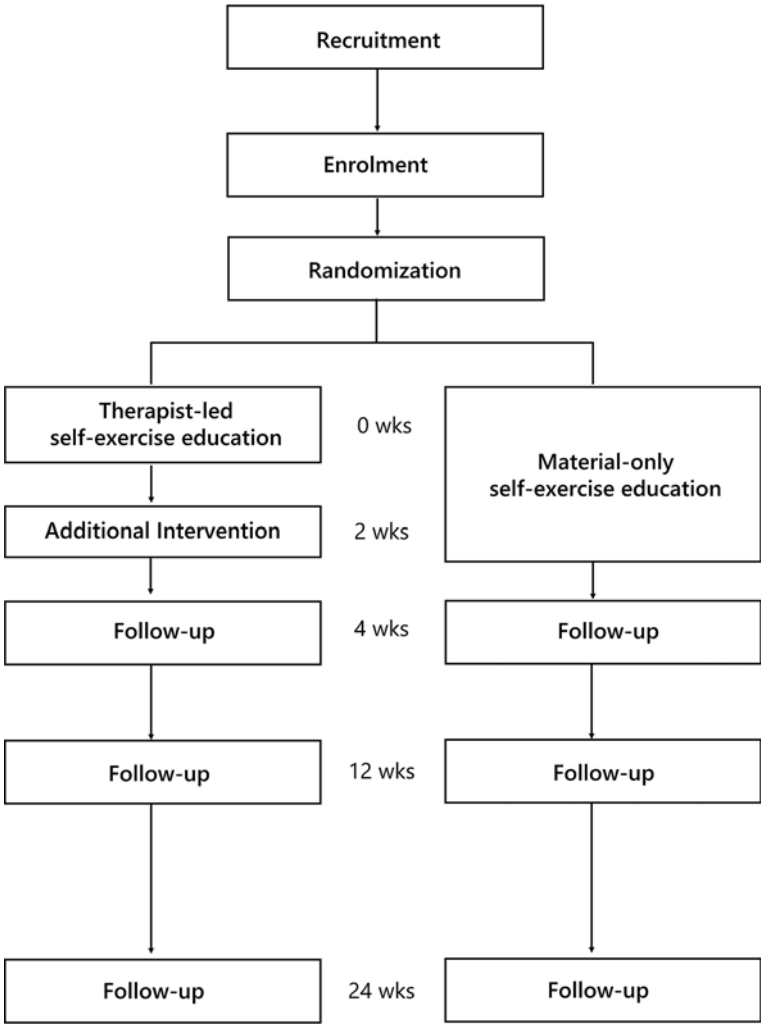


Figure 1. Study diagram.
Flow chart illustrating recruitment, enrolment, allocation, and follow-up.

Table 1. Study Schedule.

	Study period					
	Enrolment & Allocation	Initial intervention	Additional intervention	Follow-up period		
Time-point	−2 wks	0	2 wks	4 wks	12 wks	24 wks
Enrolment						
Eligibility screen	X					
Informed consent	X					
Allocation		X				
Self-exercise education						
Therapist-led		X	X			
Material-only		X (send)				
Assessments						
Baseline variables	X					
Outcome variables	X			X	X	X
Follow-up variables				X	X	X

Morris disability questionnaire)[17,18], pain self-efficacy (PSEQ, pain self-efficacy questionnaire)[19,20], QoL score (EQ-5D, European quality of life-5 dimensions)[21,22], and psychological factors assessment (STarT Back, subgroups for targeted treatment back screening tool)[23-25]. The STarT Back stratifies people with low back pain into three subgroups: low risk, medium risk, and high risk[23]. We will also refer to other basic information from the survey such as age, sex,

body height, body weight, current job, depressive symptoms ("in the past 4 weeks, little interest or pleasure in doing things" and "feeling down, depressed, or hopeless"), pain duration, pain frequency, current pain consultation use, and current pain medication use.

2.5.2 Outcome variables

The primary outcome measure is pain intensity (NRS). The secondary outcomes are pain disability (RDQ), pain self-efficacy (PSEQ) and QoL score (EQ-5D). Both NRS and RDQ have been recommended for use as outcome measures according to the IMMPACT (initiative on methods, measurement, and pain assessment in clinical trials) recommendation[26].

2.5.3 Follow-up variables

At 4, 12, and 24 weeks after the initial intervention, all outcome measures, as well as several additional evaluations, will be performed. The additional evaluations include frequency of self-exercise, global improvement, and satisfaction with intervention. Those questions and options are 1) "In the past 4 weeks, how often did you do stretching and/or exercises for low back pain?": "4 times or more per week", "1-3 times per week", "1-3 times per month", "less than 1 time per month"; 2) "Compared to the beginning of this educational program, how much is your low back pain at present?": "extremely improved", "improved", "neutral", "worse", and "extremely worse"; and 3) "How satisfied are you with this educational program at present?": "extremely satisfied", "satisfied", "neutral", "unsatisfied", and "extremely unsatisfied".

2.6 Sample size

A pilot study revealed that mean and standard deviation of the NRS score among the same population with CLBP were 4.8 ± 1.5. In general, at least a 1.0-point reduction, but no more than a 2.0-point reduction, was regarded as a moderate effect[4,8]. Thus, we planned to detect a true difference of a 1.5-point (approximately 30%) reduction between groups. We also planned a 1:3 repeated-measures design, which led to a reduction in sample size[27]. Considering a dropout rate of 15%, we estimated 24 participants per group will be necessary to achieve a study power of 0.80 and a significance level of 0.05. This sample size also allows the detection of a true difference in the RDQ of 2.0 points by using the mean and standard deviation (5.0 ± 3.4) for the same population with CLBP. For people with a low RDQ score, such as community-dwelling people, the minimally important change ranged from a 1.5-to-2.0-point reduction[28,29].

2.7 Recruitment

We will screen for CLBP during the survey. The definition of CLBP is pain that had been recognized in the previous 4 weeks and had persisted beyond 3 months[30]. For people with CLBP, we will send an advertisement of the self-exercise education program and inform all participants that they should attend the briefing session before the beginning of the program.

2.8 Allocation

2.8.1 Sequence generation

Eligible participants who give consent and fulfill the inclusion criteria will be randomly assigned to one of two groups in a 1:1 ratio: therapist-led group (therapist and material use) or material-led group (material use only). We will use a stratified randomization in terms of age (65 years or older/lower), sex (female/male), pain intensity (NRS, 7 or greater/lower), and the STarT Back subgroup (low risk/medium or high risk).

2.8.2 Allocation

The allocation sequence will be performed by the randomization staff who will not be involved in the intervention and baseline assessment. The results of the allocation will be informed to the intervention therapists before the initial intervention.

2.8.3 Blinding (masking)

Neither the participants nor the staff can be blinded to allocation because of the nature of the intervention. Self-administered questionnaires will be applied for all assessment measures, which will be submitted by mail or will be collect by visiting the responders. The responder staff will ensure that no missing values are present and that the participants' doubts while answering the questionnaires are answered. These investigators will be different from the intervention staff. The main data analyst, however, will also be part of the intervention staff.

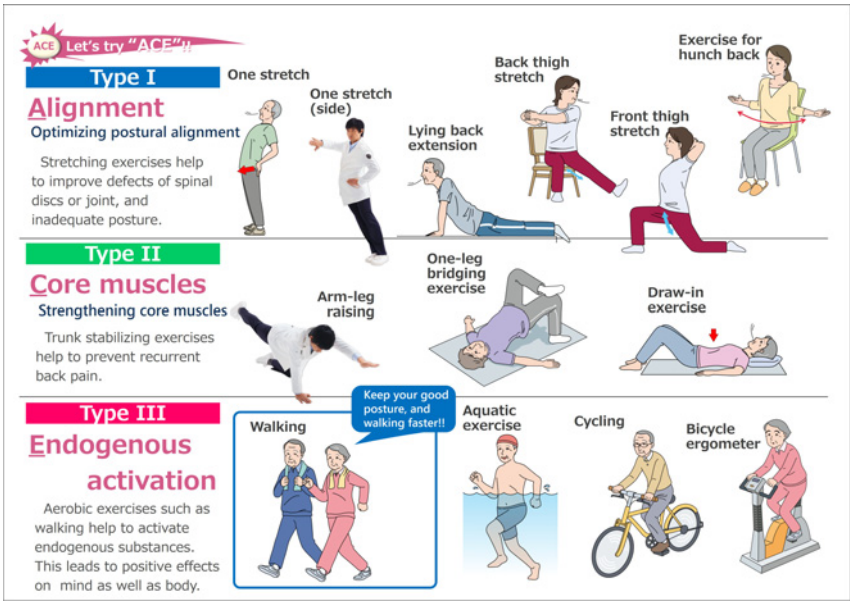
2.9 Data management

All data will be entered electronically. The original database will be stored at the data center (the Osaka Center for Cancer and Cardiovascular Disease Prevention), and the original questionnaires will be stored at the Ikawa town office. Basic information from the CIRCS survey will be merged at the data center. Each allocation and analysis dataset will be created at the data center by masking and replacing identification numbers. The decoding table will be stored at the data center.

2.10 Statistical methods

We will use a generalized linear mixed-effects model, which has advantages in handling individual variances and missing values, for analyzing changes in NRS, RDQ, PSEQ, and EQ-5D over time. A model will be constructed on the basis of group (therapist-led group and material-only group), time (baseline, 4, 12, and 24 weeks after the initial intervention), and group-by-time interaction. This model will estimate least square group mean changes at all measurement points from baseline. Based on intention-to-treat principles,

a



b

Choosing exercises	Exercise dose
1) Let's start with the exercises of Type I and III. 'One stretch' and 'faster walking in good posture' are easy to continue, and these exercises help your exercises be more effective.	[Type I] Trying to do exercise at time of pre-, post-, and inter-activities you may feel low back pain. [Type III] Trying to reach a total of 8000 steps per day, or about 20 minutes per day.
2) We recommend you to choose exercise of Type II after well used to exercise of Type I, although start with exercise of Type II if you have spondylolisthesis, scoliosis, or kyphosis.	[Type II] Trying to reach a total of 3 minutes per day. You can choose whichever exercise you like.

Figure 2. Basic concept of self-exercise education for management of chronic low back pain: the ACE concept.
The ACE concept consists of three types of exercise: type I (Alignment), optimizing postural alignment; type II (Core muscles), strengthening deep muscles; and type III (Endogenous activation), activating endogenous substances: a) exercise variations; b) basic choosing strategy.

we will analyze according to original allocation without any consideration about the level of attendance. The main interest of this analysis is a group-by-time interaction effect on the changes at 4, 12, and 24 weeks from baseline in NRS, RDQ, PSEQ, and EQ-5D. The statistical software used will be the SAS Version 9.4 (SAS Institute Inc., Cary, NC), and the level of significance will be set at alpha level 0.05.

Interventions

The aim of the intervention is to foster self-exercise skills thorough self-exercise education using the following materials and individual sessions.

3.1 Educational materials

We will provide a textbook and DVD for all participants at the intervention period. The textbook and DVD we will use are the ready-made Japanese textbook of "Tatta San Byo Kara Hajimeru Yotsu Taiso (Let's Begin with Just 3-Second Exercise for Low Back Pain)" (ISBN, 9784148272437) and the DVD of "San Byo Kara Hajimeru Yotsu Taiso (Let's Begin with Three-Second Exercise for Low Back Pain)" (Product Code, NSDS-21747), published by "Nippon Hoso Kyokai (National Media Association)". These materials are composed of 13 therapeutic self-exercises: one-stretch (standing trunk extension), standing trunk lateral flexion, lying back extension, back thigh stretch, front thigh stretch, exercise for hunch back, arm-leg raising, one-leg bridging exercise, abdominal draw-in exercise, walking with good posture, aquatic exercise, cycling, and bicycle ergometer. Additionally, eight short columns were also included for better understanding of CLBP: prevalence and major causes of CLBP; posture and mechanical stress on intervertebral disc; fear avoidance model; preferable timing for self-exercise in one's daily life; basic information about a sprained lower back, spinal canal stenosis, and ischialgia; and the ACE concept.

3.2 Individual sessions for therapist-led group

The therapist-led group will perform the initial intervention with an exercise therapist at 2 weeks after baseline. The following sessions will be conducted at 2, 4, and 12 weeks after the initial intervention. The last two sessions will be conducted according to the participants' request. The initial and second sessions may last up to 30 minutes, and the last two sessions may last up to 20 minutes. The total intervention time will be between 60 and 100 minutes. At the initial intervention, the exercise therapist may provide information about individualized self-exercise (which exercise should be selected), individually advise on how to correctly perform these self-exercises, and inform the participants of the relationship between their daily disabilities and abilities and the recommended exercises (possible mechanisms). At the second session and all additional sessions, the participants share their progress with the therapists, who in turn provide additional advice such as improving their exercise form, changing the exercise combination, and encouraging to continue the self-exercises. Two exercise therapists (a physical therapist and a doctor) provide all the sessions. Both therapists have experience in treating musculoskeletal disorders and specialized exercise therapy skills (more than 10 years' experience).

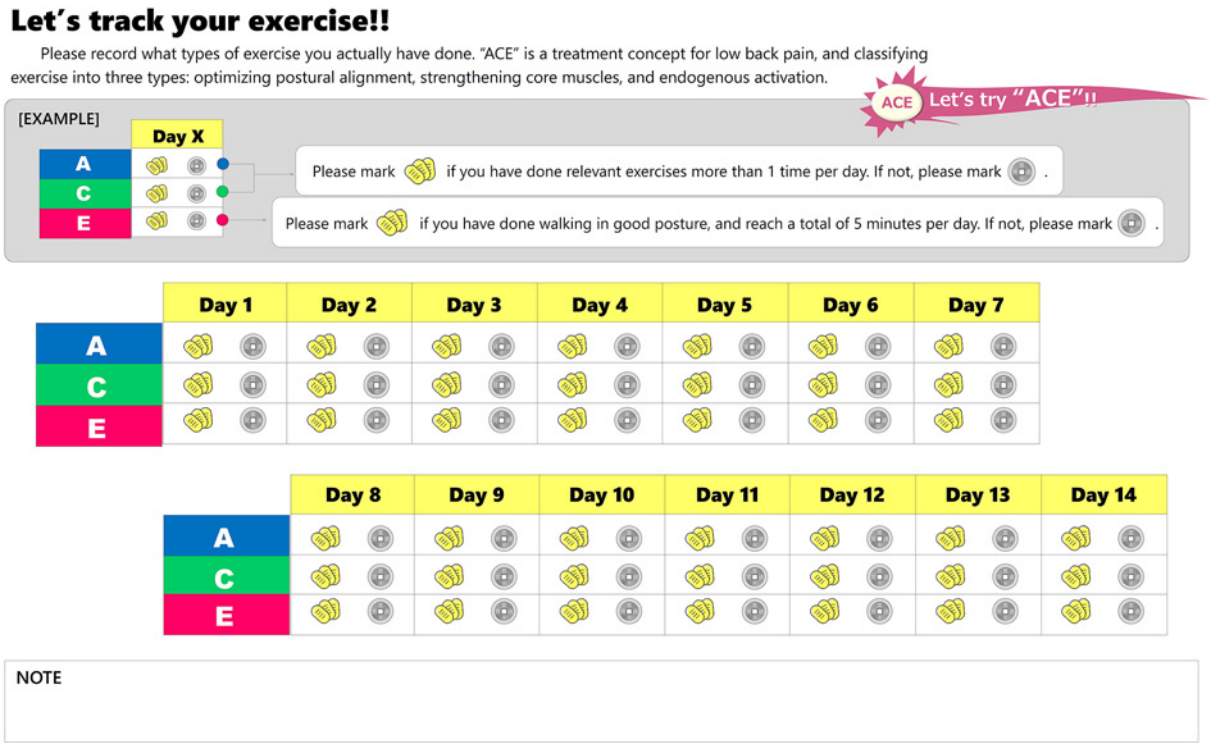


Figure 3. Self-monitoring tool for the participants.
A self-monitoring tool will be applied only in the therapist-led group. Participants will be asked to mark the daily progress until the next 2-week visit.

3.3 The ACE concept

The ACE concept (alignment, core muscles, and endogenous activation concept), which was proposed by Matsudaira[31,32], is a basic concept of exercise therapy for CLBP (Fig. 2a). The ACE concept consists of three types of exercise: type I (Alignment), optimizing postural alignment; type II (Core muscles), strengthening deep muscles; and type III (Endogenous activation), activating endogenous substances. All types of exercises will be combined; type II exercise is basically applied following type I and III exercises. In case of participants with suspected lumbar spondylolisthesis and/or posterior kyphosis, type II exercise is preferentially selected. On the other hand, in case of strong resistance to exercise, type III exercise with good posture is preferentially selected (Fig. 2b). For more detailed information on the each type of exercise, see the Supplementary file 2.

3.4 Behavior monitoring

Behavior monitoring may help to share participants' achievements, and to maintain exercise frequency. The monitoring tool to be used is shown in Fig. 3. This tool will be applied only in the therapist-led group. We will instruct participants to mark the daily progress until the next 2-week visit.

Ethics and Dissemination

4.1 Research ethics approval

This randomized controlled study was approved by the Ethics Committees of the Osaka Center for Cancer and Cardiovascular Disease Prevention and Osaka University and registered on the University Hospital Medical Information Network (UMIN000024537).

4.2 Protocol amendments

When revising the protocol, the investigators should require a permission of the Ethics Committees of the Osaka Center for Cancer and Cardiovascular Disease Prevention and Osaka University.

4.3 Consent

All potential participants should attend the briefing session before the beginning of the program in order to obtain an explanation about the research project. Community nurses will obtain oral informed consent. We will record the date of consent, the explanation given, the briefer's name, and the consent details. Details of the explanation are provided in the Supplementary file 3.

4.4 Declaration of interests

None.

4.5 Access to data

All the investigators involved in this study will be provided access to the analysis datasets.

Conflicts of Interest: The authors declare that there are no relevant conflicts of interest.

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Author Contributions: HJ wrote and prepared the manuscript. HJ, AK, KM, HO, HK, MK, and HI conceived of and initiated the study and AK, MK, MHT, TO, EH, HI, KY, and TO helped with community-based implementation. MK, AK, HK, MHT, and HI provided professional comments on intervention design. HO and HI provided statistical expertise in randomized controlled trial design. HI, MK, and TO are grant holders. All authors contributed to refinement of the study protocol and approved the final manuscript.

References

1. Shah RC, Buchman AS, Boyle PA, et al. Musculoskeletal pain is associated with incident mobility disability in community-dwelling elders. J Gerontol A Biol Sci Med Sci. 2011;66(1):82-8.
2. Woo J, Leung J, Lau E. Prevalence and correlates of musculoskeletal pain in Chinese elderly and the impact on 4-year physical function and quality of life. Public Health. 2009;123(8):549-56.
3. Babatunde OO, Jordan JL, Van der Windt DA, et al. Effective treatment options for musculoskeletal pain in primary care: a systematic overview of current evidence. PLoS One. 2017;12(6):e 0178621.
4. Chou R, Huffman LH. Nonpharmacologic therapies for acute and chronic low back pain: a review of the evidence for an American Pain Society/American College of Physicians clinical practice guideline. Ann Intern Med. 2007;147(7):492-504.
5. Liddle SD, Gracey JH, Baxter GD. Advice for the management of low back pain: a systematic review of randomised controlled trials. Man Ther. 2007;12(4):310-27.
6. Hayden JA, van Tulder MW, Tomlinson G. Systematic review: strategies for using exercise therapy to improve outcomes in chronic low back pain. Ann Intern Med. 2005;142(9):776-85.
7. Hayden JA, van Tulder MW, Malmivaara AV, et al. Meta-analysis: exercise therapy for nonspecific low back pain. Ann Intern Med. 2005;142(9):765-75.
8. Qaseem A, Wilt TJ, McLean RM, et al. Noninvasive treatments for acute, subacute, and chronic low back pain: a clinical practice guideline from the American College of Physicians. Ann Intern Med. 2017;166(7):514-30.
9. Albaladejo C, Kovacs FM, Royuela A, et al. Spanish back pain research network. the efficacy of a short education program and a short physiotherapy program for treating low back pain in primary care: a cluster randomized trial. Spine. 2010;35(5):483-96.
10. Sherman KJ, Cherkin DC, Erro J, et al. Comparing yoga, exercise, and a self-care book for chronic low back pain: a randomized, controlled trial. Ann Intern Med. 2005;143(12):849-56.
11. Sherman KJ, Cherkin DC, Wellman RD, et al. A randomized trial comparing yoga, stretching, and a self-care book for chronic low back pain. Arch Intern Med. 2011;171(22):2019-26.
12. Dufour N, Thamsborg G, Oefeldt A, et al. Treatment of chronic low back pain: a randomized, clinical trial comparing group-based multidisciplinary biopsychosocial rehabilitation and intensive individual therapist-assisted back muscle strengthening exercises. Spine. 2010;35(5):469-76.
13. van der Roer N, van Tulder M, Barendse J, et al. Intensive group training protocol versus guideline physiotherapy for patients with chronic low back pain: a randomised controlled trial. Eur Spine J. 2008;17(9):1193-200.
14. Toomey E, Currie-Murphy L, Matthews J, et al. The effectiveness of physiotherapist-delivered group education and exercise interventions to promote self-management for people with osteoarthritis and chronic low back pain: a rapid review part I. Man Ther. 2015; 20(2):265-86.
15. Toomey E, Currie-Murphy L, Matthews J, et al. Implementation fidelity of physiotherapist-delivered grouped education and exercise interventions to promote self-management in people with osteoarthritis and chronic low back pain: a rapid review part II. Man Ther. 2015;20(2):287-94.
16. Yamagishi K, Muraki I, Kubota Y, et al. The circulatory risk in communities study (circs): a long-term epidemiological study for lifestyle-related disease among japanese men and women living in communities. J Epidemiol. 2019;29(3):83-91.
17. Roland M, Morris R. A study of the natural history of back pain: part I: development of a reliable and sensitive measure of disability in low-back pain. Spine. 1983;8(2):141-4.
18. Nakamura M, Miyamoto K, Shimizu K. Validation of the Japanese version of the Roland-Morris Disability Questionnaire for Japanese patients with lumbar spinal diseases. Spine. 2003;28(20):2414-8.
19. Nicholas MK. The pain self-efficacy questionnaire: taking pain

into account. Eur J Pain. 2007;11(2):153-63.
20. Adachi T, Nakae A, Maruo T, et al. Validation of the Japanese version of the Pain Self-Efficacy Questionnaire in Japanese patients with chronic pain. Pain Med. 2014;15(8):1405-17.
21. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Qual Life Res. 2011;20(10):1727-36.
22. Ikeda S, Shiroiwa T, Igarashi A, et al. [Developing a Japanese version of the EQ-5D-5L value set]. J Natl Inst Public Health. 2015; 64(1):47-55. Japanese.
23. Hill JC, Dunn KM, Lewis M, et al. A primary care back pain screening tool: identifying patient subgroups for initial treatment. Arthritis Rheum. 2008;59(5):632-41.
24. Beneciuk JM, Robinson ME, George SZ. Subgrouping for patients with low back pain: a multidimensional approach incorporating cluster analysis and the STarT back screening tool. J Pain. 2015; 16(1):19-30.
25. Matsudaira K, Oka H, Kikuchi N, et al. Psychometric properties of the Japanese version of the STarT back tool in patients with low back pain. PLoS One. 2016;11(3):e0152019.
26. Dworkin RH, Turk DC, Farrar JT, et al. Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. Pain. 2005;113(1-2):9-19.
27. Tango T. On the repeated measures designs and sample sizes for randomized controlled trials. Biostatistics. 2016;17(2):334-49.
28. Stratford PW, Binkley JM, Riddle DL, et al. Sensitivity to change of the Roland-Morris Back Pain Questionnaire: part I. Phys Ther. 1998;78(11):1186-96.
29. Roland M, Fairbank J. The Roland-Morris Disability Questionnaire and the Oswestry Disability Questionnaire. Spine. 2000;25 (24):3115-24.
30. Merskey H, Bogduk N. Classification of chronic pain. 2nd ed. Seattle: IASP Press; 1994.
31. Matsudaira K, Kawamata K, Yoshimoto T, et al. [New concept exercises for control of back pain]. Jpn Soc Phys Ther Occup Health. 2016;43(3):109-12. Japanese.
32. Jinnouchi H, Matsudaira K. [Therapeutic Exercise for chronic low back pain]. Jpn J Clin Anesth. 2018;39(3):343-53. Japanese.