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Review

Effect of non-surgical interventions on pain relief and symptom improvement in farmers with diseases of the musculoskeletal system or connective tissue: an exploratory systematic review based on randomized controlled trials

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Abstract

Objective: There are many observational and clinical studies on pain treatment in farmers; however, little is known about the effects of interventions based only on randomized controlled trials (RCTs) on diseases of the musculoskeletal system or connective tissue (D-MSCT). This review aimed to summarize evidence on the effects of non-surgical interventions for pain relief and symptom improvement in farmers with D-MSCT.
Materials and Methods: We searched seven databases, including MEDLINE, and three clinical trial registries, including the International Clinical Trials Registry Platform, from inception up to February 15, 2021, to identify studies that included at least one treatment group wherein nonsurgical interventions were applied. We focused on 1) pain relief and symptom improvement and 2) quality of life and improvement in physical fitness.
Results: Four studies (three on low back pain and one on knee osteoarthritis) met all the inclusion criteria. Overall, the risk of bias was high, and meta-analysis could not be performed due to heterogeneity. However, a participatory ergonomic approach, exercise centered on strength training with a transtheoretical model, and/or a combination of both could be included in effective educational programs, at least in the short term, to prevent and/or reduce exacerbation of D-MSCT in farmers. Based on internal and external validity, we could postulate a future research agenda and a conceptual education model to prevent D-MSCT in farmers.
Conclusion: Participatory ergonomic intervention, exercise centered on strength training, and/or a combination of both could be included for effective educational programs to prevent and reduce exacerbation of D-MSCT in farmers. High-quality RCTs with a less risk of bias will be implemented for many agricultural work types in various parts worldwide (especially developing countries and regions) during the COVID-19 pandemic.

Key words: farmer, randomized controlled trials, musculoskeletal system, connective tissue, pain

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Introduction

Most developed countries have faced the challenge of an aging population, which also affects the workforce balance[1]. The aging of agricultural workers and the shortage of successors have become serious problems, resulting in an increasing burden on those who are currently working[2]. Farming is a rural occupation with longstanding exposure to high levels of physical loading starting at a young age and continuing after regular retirement age and has a high occupational risk of accident[3]. In fact, the agricultural sector typically involves heavy lifting, frequent climbing, prolonged kneeling, squatting, and standing, all of which increase the odds of knee osteoarthritis (knee OA)[4]. Due to such daily exposure, the number of diseases of the musculoskeletal system or connective tissue (D-MSCT) is extremely high[5].

Furthermore, isolation, long work days, and climate change are some of the many pressures that make farming an occupation that is vulnerable to incurring mental health issues[6], and mental health can strongly impact a farmer's individual health[7, 8]. A systematic review (SR) reported that male farmers experienced an increased risk of suicide (pooled effect size [ES] = 1.47; 95% confidence interval 1.30–1.68) compared with that in the general population[9], and a subgroup analysis showed that ES especially varied according to geographic area, with a higher ES in Japan.

Long-term repetitive heavy loading results in an increased prevalence of work-related symptoms and diseases, i.e., D-MSCT[3–5, 10–19]. A recent SR provided comprehensive knowledge about farmers' injuries in general, but was not limited to D-MSCT, and the research design did not focus on randomized controlled trials (RCTs)[20]. There are many observational studies and clinical studies on farmers, however, little is known about the effects of interventions based only on RCTs of D-MSCT.

The objective of this review was to summarize the evidence of the effects of non-surgical interventions on pain relief and symptom improvement in farmers with D-MSCT.

Methods

This review was based on an updated guideline for reporting SRs, PRISMA 2020[21]. The study was registered as UMIN 000044080 of the University Hospital Medical Information Network-Clinical Trials Registry (UMIN-CTR) (refer to https://upload.umin.ac.jp/cgi-open-bin/ctr/ctr_view.cgi?recptno=R000050330). We conducted research in compliance with the protocol.

Searches

The following databases were searched from inception up to February 15, 2021: MEDLINE via PubMed, CINAHL, PsycINFO, Ichushi Web (in Japanese), and World Health Organization (WHO) Global Index Medicus. We also searched CENTRAL via the Cochrane Library, and Campbell Systematic Reviews (the Campbell Collaboration) for relevant studies up to February 15, 2021.

All searches were performed by a specific individual (hospital librarian: SS) who was qualified in medical information handling and who was proficient in the methodology of clinical trial searches.

Search strategies

The special search strategies included the elements and terms for MEDLINE, CINAHL, PsycINFO, Ichushi Web, WHO Global Index Medicus, and Cochrane database. Only keywords related to the intervention were used for the searches. The titles and abstracts of the identified published articles were reviewed to determine their relevance.

Registry checking

We searched the International Clinical Trials Registry Platform (ICTRP), Clinical Trials.gov, and the UMIN-CTR.

The ICTRP in the WHO Registry Network met specific criteria for content, quality and validity, accessibility, unique identification, technical capacity, and administration. Primary registries met the requirements of the International Committee of Medical Journal Editors. Clinical Trials.gov is a registry of federally and privately supported clinical trials conducted in the United States and worldwide. The UMIN-CTR registers clinical trials conducted in Japan and worldwide.

Manual searching and reference checking

We manually searched for abstracts published on D-MSCT in relevant journals in Japan, specifically, Japanese and English journals of the Japan Association of Rural Medicine. We checked the references of included studies for further relevant literature and excluded studies not written in English or Japanese.

Types of studies included

Studies were eligible if they were RCTs (including quasi-RCTs). The targeted study designs included both parallel and crossover studies.

Condition or domain studied

We focused on all studies on cure and rehabilitation effects in farmers with D-MSCT in accordance with the International Classification of Diseases-11 (ICD-11, Chapter 15). We also included "ME 84.2: low back pain (LBP)" as defined in ICD-11, Chapter 21, "Symptoms, signs, or clinical findings, not elsewhere classified" as a target disease due to its high prevalence among farmers.

Participants/population

The participants included all types of professional farmers. However, the study was limited to farmers in cultivated agriculture and excluded livestock agriculture.

Interventions

Studies included at least one treatment group in which non-surgical interventions were applied. Additional interventions without surgery, such as exercise therapy (e.g., stretching, strength training, and underwater exercise) and physical therapy (e.g., thermal pad, bathing, and use of sauna), were included. However, interventions that used specific equipment, such as electrotherapy and ultrasound therapy, which cannot be performed by patients themselves, were excluded. We also included psychotherapy (e.g., behavior therapy, and cognitive therapy), lifestyle changes, and other alternative therapies. Basically, for the purpose of generalizability, an intervention was considered as "what participants can do on their own in their daily lives". If the control group also used medication, it did not matter whether or not it was used (i.e., as the same co-intervention).

Comparator(s)/control

As a control, pre-planned stratified analyses were (a) trials that compared non-surgical interventions with no treatment or waiting list controls and (b) trials that compared observational therapies with other intervention(s).

Main outcomes

Although the therapeutic effects of D-MSCT are diverse, we focused on the following two aspects: (1) pain relief and improvement of symptoms and (2) quality of life and improvement of physical fitness. The former included subjective pain, symptoms, number of medications, analgesic and/or nonsteroidal anti-inflammatory drug consumption, and improved quality of life. The latter included muscle strength, stiffness and tender joints, balance, gait speed, aerobic capacity, mobility, and whole or partial function. Cure and rehabilitation effects were defined as primary outcome measures. We did not examine any secondary outcomes.

Data extraction (selection and coding)

For final selection of studies for review, all criteria were applied independently by two authors (SH and JK) to the full text of articles that had passed the first eligibility screening. Disagreements and uncertainties were resolved by discussion with another author (HO or HK). Studies were selected when (i) the design was an RCT or quasi-RCT and (ii) one of the interventions was a form of observational therapy. Protocols without results were excluded, and only completed studies were included. Trials that were excluded were presented with reasons for exclusion.

Risk of bias (quality) assessment

To ensure that variation was not caused by systematic errors in the study design or execution, two review authors (SH and JK) independently assessed the quality of articles. A full quality appraisal of these papers was made using Cochrane's criteria list for the methodological quality assessment (an arranged version)[22]. Disagreements and uncertainties were resolved by discussion with another author (HO or HK).

Each item was codified as "yes" (y), "no" (n), "do not know or unclear" (?), or "not applicable" (n/a). Some items were not applicable depending on the study design. An ''n/a'' appraisal was excluded from the calculation for quality assessment. We calculated the percentage of present description on all 11-check items for the quality assessment of articles. Then, based on the percentage of risk of poor methodology and/or bias, each item was assigned to the following categories: good description (80–100%), poor description (50–79%), or very poor description (0–49%). Inter-rater reliability was calculated on a dichotomous scale using percentage agreement and Cohen's kappa coefficient (k).

Strategy for data synthesis (including analysis of subgroups or subsets)

At the protocol stage, the planned analysis was as follows: "the results of each RCT are expressed, when possible, as relative risk with corresponding 95% confidence intervals for dichotomous data and as standardized or weighted mean differences with 95% confidence intervals for continuous data. But heterogeneous results of studies that meet the inclusion criteria are not combined. In agriculture, for example, since fruit tree cultivation, rice cultivation, bloom (flower) cultivation, etc. are obviously different types of work style, we plan to perform subgroup analysis for each work type".

However, we could not perform meta-analysis and subgroup analysis due to the heterogeneity of all outcome measurements and intervention methods.

Results

Study selection and characteristics (conclusions on each study)

Abstracts from potentially relevant articles identified in the literature search were assessed, and 14 papers were selected for further evaluation (checked for relevant literature) (Figure 1, Table 1). Four studies[23–26] met all inclusion criteria (Table 2), and 10 publications were excluded because they did not meet the eligibility criteria (Table 3). English was the language of all eligible publications.

Based on the ICD-11, we identified an ICD-11 disease targeted in each of the four eligible articles. One study[23] targeted "FA01: knee OA", classified under "D-MSCT", and three studies[24–26] targeted "ME 84.2: LBP", classified under "Symptoms, signs, or clinical findings, not elsewhere classified".

Isaramali *et al.*[23] investigated the effects of participatory ergonomic management in non-weight-bearing exercise (PEM-NWE), PEM in progressive resistance exercise (PRE), and standard treatment on self-care and functional ability in aged farmers with knee OA. Compared to the standard treatment, the mean scores for self-care and functional ability in both PEM-NWE and PEM-PRE were significantly

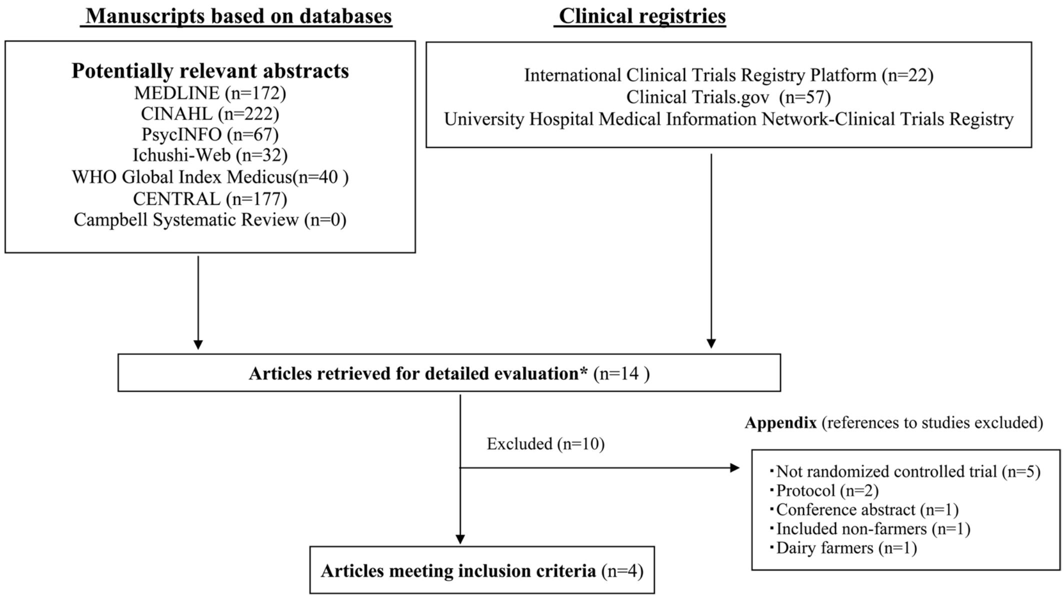

Figure 1 Flowchart of the trial process.
*Reduplication.

increased. However, no significant difference was found between the PEM-NWE and PEM-PRE. These results demonstrated that integrating education about ergonomic management comprised improved working conditions and muscle-strengthening exercises positively affected self-care and functional ability of aged farmers with knee OA within 2 months.

Thanawat *et al.*[24] evaluated the effects of an intervention program based on the transtheoretical model (TTM) of behavioral change on back muscle endurance, physical function, and pain in rice farmers with LBP. Measurement of back muscle endurance, physical function, and severity of pain significantly improved in the TTM group when compared with that in the non-TTM group.

Ayanniyi *et al.*[25] investigated the effect of back care education on farmers with LBP. They reported that back care education caused a reduction in pain intensity and functional disability among farmers with chronic mechanical LBP within 8 weeks.

Nochit *et al.*[26] examined the effects of the newly developed working behavior modification program (WBMP) for LBP prevention behaviors and back muscle endurance among farmers. Nochit *et al.* reported that WBMP was effective in improving LBP prevention behaviors and back muscle endurance among farmers, with short-term changes apparent within 6 weeks and sustained over 9 weeks in a follow-up period.

Quality assessment

We evaluated 11 items from Cochrane's criteria list in more detail (Table 4). Inter-rater reliability metrics for quality assessment indicated substantial agreement for all 44 items (percentage agreement 68.2% and k=0.506). This assessment evaluated the quality of the main findings of the studies summarized in the written reports. In general, there was a remarkable lack of execution and/or description in randomization, concealment, blinding, and compliance. The items for which the description was lacking (very poor; <50%) in many studies were as follows: "Was the method of randomization adequate?" (25%), "Was the treatment allocation concealed?" (0%), "Was the patient blinded to the intervention?" (0%), "Was the care provider blinded to the intervention?" (0%), "Was the outcome assessor blinded to the intervention?" (25%), and "Was the compliance acceptable in all groups?" (0%).

Discussion

This study is the first SR based on RCTs of the effects of non-surgical interventions on pain relief and symptom improvement in farmers with D-MSCT. The study results revealed that a participatory ergonomic approach (intervention), exercise centered on strength training, and/or a combination of both could be an effective educational program, at least in the short term, to prevent and reduce the exacerbation of D-MSCT in farmers.

Suggested mechanisms of the interventions: internal validity

1) Participatory ergonomic approach and/or comprehensive approach for occupational risk prevention

All occupations have their own work patterns and, at

Table 1 The special search strategies

1. MEDLINE		
#1	"farmers"[MeSH Terms] OR "agriculture"[MeSH Terms] OR "agricultural workers diseases"[MeSH Terms] OR "farmer*"[Title/Abstract] OR "farm"[Title/Abstract] OR "farms"[Title/Abstract] OR "farmwork*"[Title/Abstract] OR "farming"[Title/Abstract] OR "agricultur*"[Title/Abstract] OR "rural"[Title]	n=284,545
#2	"musculoskeletal system"[MeSH Terms] OR "musculoskeletal diseases"[MeSH Terms] OR "musculoskeletal pain"[MeSH Terms] OR "connective tissue"[MeSH Terms] OR "connective tissue diseases"[MeSH Terms] OR "pain"[MeSH Terms] OR "pain"[Title] OR "musculoskeletal"[Title/Abstract]	n=2,777,329
#3	#1 and #2	n=6,094
#4	#3 NOT ("animals"[MeSH Terms] NOT "humans"[MeSH Terms])	n=3,233
#5	"randomized controlled trial"[Publication Type] OR "controlled clinical trial"[Publication Type] OR "randomized"[Title/Abstract] OR "randomised"[Title/Abstract] OR "placebo"[Title/Abstract] OR "clinical trials as topic"[MeSH Terms:noexp] OR "randomly"[Title/Abstract] OR "trial"[Title]	n=1,398,744
#6	#4 and #5	n=172
2. CINHAL		
#1	MH "Farmworkers" OR MH "Agriculture+" OR TI (farmer* or farmwork* or farm or farms or farming or agricultur* or rural) OR AB (farmer* or farmwork* or farm or farms or farming or agricultur*)	n=51,051
#2	MH "Musculoskeletal System+" OR MH "Musculoskeletal Diseases+" OR MH "Pain+" OR MH "Connective Tissue+" OR MH "Connective Tissue Diseases+" OR TI (pain* or musculoskeletal) OR AB (pain* or musculoskeletal)	n=760,887
#3	#1 and #2 : Limiters - Human	n=1,012
#4	(MH randomized controlled trials) OR (MH double-blind studies) OR (MH single-blind studies) OR (MH random assignment) OR (MH pretest-posttest design) OR (MH cluster sample) OR (TI (randomised OR randomized)) OR (AB random*) OR (TI trial) OR ((MH "sample size" AND AB (assigned OR allocated OR control)) OR (MH placebos) OR (PT randomized controlled trial) OR (AB (CONTROL W5 GROUP)) OR (MH (CROSSOVER DESIGN) OR MH (COMPARATIVE STUDIES)) OR (AB (CLUSTER W3 RCT))	n=832,855
#5	#3 and #4	n=222
3. PsycINFO		
#1	(DE "Agricultural Workers" OR DE "Migrant Farm Workers") OR DE "Agriculture" OR TI (farmer* or farmwork* or farm or farms or farming or agricultur* or rural) OR AB (farmer* or farmwork* or farm or farms or farming or agricultur*)	n=29,266
#2	DE "Musculoskeletal System" OR DE "Arm (Anatomy)" OR DE "Bones" OR DE "Feet (Anatomy)" OR DE "Hand (Anatomy)" OR DE "Hips" OR DE "Jaw" OR DE "Joints (Anatomy)" OR DE "Leg (Anatomy)" OR DE "Muscles" OR DE "Spinal Column" OR DE "Tendons" OR DE "Musculoskeletal Disorders" OR DE "Bone Disorders" OR DE "Bruxism" OR DE "Joint Disorders" OR DE "Muscular Disorders"	n=30,879
#3	DE "Connective Tissues" OR DE "Body Fat" OR DE "Bones" OR DE "Joint Disorders" OR DE "Arthritis" OR DE "Rheumatic Fever"	n=7,039
#4	DE "Pain" OR DE "Acute Pain" OR DE "Aphagia" OR DE "Back Pain" OR DE "Chronic Pain" OR DE "Headache" OR DE "Myofascial Pain" OR DE "Neuralgia" OR DE "Neuropathic Pain" OR DE "Somatoform Pain Disorder"	n=61,834
#5	TI (pain* or musculoskeletal) OR AB (pain* or musculoskeletal)	n=115,480
#6	#2 or #3 or #4 or #5	n=152,187
#7	#1 and #6	n=521
#8	DE "Treatment Effectiveness Evaluation" OR DE "Clinical Trials" OR DE "Mental Health Program Evaluation" OR DE "Placebo" OR TI placebo* OR AB placebo* OR AB randomly OR TX randomi* OR TI trial OR AB trial OR TX ((singl* OR doubl* OR trebl* OR tripl*) N3 (blind* OR mask* OR dummy)) OR TI (control* N3 (trial* OR study OR studies OR group*)) OR AB (control* N3 (trial* OR study OR studies OR group*)) OR TI factorial* OR AB factorial* OR TI allocat* OR AB allocat* OR TI assign* OR AB assign* OR TI volunteer* OR AB volunteer* OR TI (crossover* OR "cross over*") OR AB (crossover* OR "cross over*") OR TX (quasi N5 (experimental OR random*))	n=541,547
#9	#7 and #8	n=67
4. Ichushi Web		
#1	農業従事者 /TH or 農業 /TH or 農民病 /TH or 農家 /TA or 農民 /TA or 農業 /TA or 農作業 /TA or 農村 /TA or 農園 /TA or 農地 /TA or 農場 /TA or agriculture/TA or agricultural/TA or farmer/TA or farmers/TA or rural/TA	n=22,085
#2	筋骨格系 /TH or 筋骨格系疾患 /TH or 筋骨格系疼痛 /TH or 結合組織 /TH or 結合組織疾患 /TH or 疼痛 /TH or 筋骨格 /TA or 運動器 /TA or 関節 /TA or 結合組織 /TA or 痛み /TA or 疼痛 /TA	n=1,522,616
#3	#1 and #2	n=931
#4	#3 and (CK= ヒト)	n=735
#5	ランダム化比較試験 /RD or 準ランダム化比較試験 /RD or random/TA or ランダム /TA or 無作為 /TA or 盲検 /TA or 臨床試験 /TH or 試験 /TA or RCT/TA or trial/TA or 研究デザイン /TH or 臨床研究 /TA	n=333,185
#6	#4 and #5	n=32
5. WHO Global Index Medicus		
#1	(mh:("Farmers" OR "Agriculture") OR (tw:(farmer* OR agricultur*))) AND (mh:("Musculoskeletal System" OR "Musculoskeletal Diseases" OR "Musculoskeletal Pain" OR "Connective Tissue" OR "Connective Tissue Diseases" OR "Pain") OR (tw:(musculoskeletal))) AND mh:("Humans")	n=40
6. CENTRAL		
#1	(farmer* or farm or farms or farmwork* or farminig or agricultur*):ti,ab,kw OR (rural):ti	n=5,174
#2	MeSH descriptor: [Farmers] explode all trees	n=15
#3	MeSH descriptor: [Agriculture] explode all trees	n=180
#4	MeSH descriptor: [Agricultural Workers' Diseases] explode all trees	n=41
#5	#1 or #2 or #3 or #4	n=5,236
#6	(pain* or musculoskeletal):ti OR (pain* or musculoskeletal):ab	n=171,645
#7	MeSH descriptor: [Musculoskeletal System] explode all trees	n=33,465
#8	MeSH descriptor: [Musculoskeletal Diseases] explode all trees	n=41,312
#9	MeSH descriptor: [Musculoskeletal Pain] explode all trees	n=987
#10	MeSH descriptor: [Connective Tissue] explode all trees	n=7,635
#11	MeSH descriptor: [Connective Tissue Diseases] explode all trees	n=9,678
#12	MeSH descriptor: [Pain] explode all trees	n=49,844
#13	#6 or #7 or #8 or #9 or #10 or #11 or #12	n=229,657
#14	#5 and #13 (in Trials)	n=177
7. Campbell Systematic Reviews		
#1	(farmer OR farmers OR agriculture OR agricultural OR farm OR farms OR farming OR rural) AND (musculoskeletal OR connective OR pain)	n=0
8. ICTRP		
Standard Search	farmer* AND musculoskeletal OR farmer* AND connective OR farmer* AND pain OR agricultur* AND musculoskeletal OR agricultur* AND connective OR agricultur* AND pain	n=22
9. Clinical Trials. gov		
Advanced Search	Condition or disease: musculoskeletal OR connective OR pain Other terms: farmer OR farmers OR "farm workers" OR agriculture OR agricultural	n=57
10. UMIN-CTR		
フリーワード検索	農家 OR 農業	n=9

Table 2 Brief summary of articles based on structured abstracts

Reference No.	23	24	25	26
Author	Isaramalai S *et al.*	Thanawat T	Ayanniyi O *et al.*	Nochit W *et al.*
Citation	Clin Interventions Aging 2018;13:101–8.	J Back Musculoskel Rehabil 2017;30:847–56.	J Exp Integr Med 2015;5:215–21	Pacific Rim Int J Nurs Res 2014;18(4):305–19
Title	Integrating participatory ergonomic management in non-weight-bearing exercise and progressive resistance exercise on self-care and functional ability in aged farmers with knee osteoarthritis: a clustered randomized controlled trial	Effects of an intervention based on the transtheoretical model on back muscle endurance, physical unction and pain in rice farmers with chronic low back pain.	Back care education on peasant farmers suffering from chronic mechanical low back pain	Effects of working behavior modification program on low back pain prevention behaviors and back muscle endurance among Thai farmers
Aim/ Objective	To investigate the effect of participatory ergonomic management in non-weight-bearing exercise (PEM-NWE), PEM in progressive resistance exercise (PRE), and standard treatment (ST) on self-care and functional ability in the aged farmers.	To evaluate the effects of an intervention program based on the Transtheoritical Model of behavioral change (TTM) on back muscle endurance, physical function and pain in rice farmers with chronic low back pain (LBP).	To determine the effect of back care education on farmers suffering from chronic mechanical low back pain (LBP).	To examine the effects of the newly developed Working Behavior Modification Program (WBMP) for low back pain prevention behaviors and back muscle endurance among farmers.
Setting/ Place	Three communities in southern Thailand.	Two districts hospitals in Uttaradit Province, Thailand.	Six identified villages in Ibrapa East Government Area of Oyo State, Nigeria and the primary and secondary health centers in this area.	One province in central Thailand.
Participants	Para rubber farmers aged >60 years who currently had symptomatic knee Osteoarthritis (OA), as determined by the clinical and radiographic criteria of the American College of Rheumatology and the Kellgren-Lawrence radiographic scale (<4).	Rice farmers aged between 30 to 50 years who had non-specific LBP symptoms on most days over at least 3 months, with or without having radiating pain in one or both legs, currently working in rice paddyfield with at least 2 crops harvested annually for longer than a year.	Farmers aged between 25 to 60 years who had chronic LBP at least 6 months. They must have mechanical LBP as determined through a pre-selection screening process using McKenzie approach.	Rice farmers who had mild low back pain (LBP) and indicating normal working ability and without sciatica pain. Their ages were: experimental group (mean=47.13 years; SD=7.14 years) and control group (mean=46.75 years; SD=6.77 years.).
Intervention	ST received usual care services, based on standard protocols, coupled with a 2-hour boosted educational session, whereas PEM-NWE and PEM-PRE received both center-based and home-based activities as follows. Center-based interventions were held at community centers. i) Twenty-minute job hazard analysis, ii) One-hour health education session: a 20-minute teaching and a 40-minute exercise demonstration on ergonomic management through participatory group discussion, and iii) Thirty-minute mutual goal setting. Home-based interventions were conducted every other week. Thirty-minute home visits were carried out for providing guidance and support. With regard to the procedures of both exercise programs, all participants were required to complete their own exercise programs at least 3 days per week for 8 weeks. Both exercise programs were designed to increase lower extremity muscle strength bilaterally around the hip and knee joints.The exercise sessions included at least three sets of ten repetitions of nine exercises. Each exercise started with dynamic movement through the full range of motion and continued to a 10-second hold static movement at the end of the range of movement. The repetitions and durations of exercises were self-prescribed by participants based on PEM. In the PRE group, intensity was based on participants' ability to execute a maximum of 10 repetitions (10 RM). Sandbags were used for the weight increments, starting from 50% of 10 RM in the first to second week, increasing to 75% of 10 RM in the third to fourth week, and reaching 100% of 10 RM in the fifth to eighth week. The load adjustment took place under the supervision of an experienced physical therapist to yield a gradual progression of training. Furthermore, a muscle-strengthening training booklet was given to each exercise group.	Two intervention were proposed to all participant in the two groups, health education and exercises. A number of health education sessions were administrated every 2 weeks in the matter of group discussion and practice. Topics of interest about LBP, e.g., causes and consequences, signs and symptoms, pain management, and proper physical exercise as well as postures for persons with LBP were presented. A booklet regarding those topics of interest was distributed and audiovisual materials were provided. Seven home-based exercise for individuals with LBP were recommended with the exercise prescription of 15–20 minutues per set, 1–2 sets per day and at least 3 days per week. They were derived from available evidence for the most efficient methods of producing the desired effects of increasing flexibility, mobility, and endurance of the back and surrounding structures. The exercises were progressed by increasing exercise sets or advancing to a more difficult program. For the TTM group, an 8-week intervention program including health education and exercise was administrered to all participants. However, strategies used for providing the intervention to the participants in each sub-group, i.e., the Pre-Contemplation (PC) group and the C group, the Preparation (P) group and the Action (A) group and the Maintenance (M) group, were different. Ten processes of change of the TTM were chosen and applied appropriately to each sub-group. For example, the processes change primarily used for the PC group were consciousness raising, dramatic relief and environmental reevaluation, whereas, the processes of change used for the P group consisted of self-reevaluation and reinforcement management.	Back care education seminars/trainings were scheduled as follows: (a) once a week in the first three weeks and (b) once in two weeks in the next four weeks. Back care education protocol utilized in this study consisted of principles from some previous studies. To ensure consistency in delivery of the back care education protocol to participants the material used was translated into Yoruba language for easy comprehension by participants. McKenzie extension protocol was incorporated into the back care education to manage LBP problems of the participants. The back care education outlines were set as follows: i) Anatomy of the back and biomechanical principle guiding the functions of the human spine. Injurious postures and activities that may hurt the back and how to avoid them; ii) Proper and safe lifting techniques for carrying loads; iii) Good postures that enhance the health of the back in different farming activities and other activities of daily living such as bathing, sitting, getting to and out of bed; iv) The following specific prophylactic instructions were taught and given to the participants orally and in writing; a) Avoid prolonged sitting, bending, stooping and squirting; b) Interrupt static posture every thirty minutes before developing any discomfort during work in the farm; c) Maintain lumbar lordosis (hollow in the low back) in sitting and other postures; d) Use supportive roll/cushion placed in the hollow of the back in sitting position at home; e) Avoid sitting on low chairs, stool and soft couch with deep seat; e) Use a firm, high chair with a good comfortable back support; f) Consciously control and maintain good upright posture when sitting on a seat without back rest or support; g) Avoid lifting heavy loads as much as possible: when you have to lift, carry only a moderate load. Before lifting or carry heavy load extend your back five times and after lifting or carrying the load extend your back three times, etc.	The WBMP was first developed by research based on the Protection Motivation Theory (PMT) aiming to enhance LBP prevention behaviors and back muscle endurance (BME) among the Thai farmers. The final program consisted of three sessions. Each session was sequentially organized into three major components: a) enhancing perceived severity and vulnerability of LBP by way of giving information about risk and impact of LBP; b) enhancing perceived self-efficacy of having proper working posture and SBE by giving information by following the handbook about proper working posture-SBE training and techniques for practice and presenting a live modeling done by farmers who had proper working posture; and c) eliminating the time barrier to SBE by providing short-time SBE practice.

Table 2 (continued)

Reference No.	23	24	25	26
Main and secondary outcomes	The Thai version of Self-Care Questionnaires (Thai SCQ), modified from Boonsrichan,18 comprises three phases of self-care (estimative, transitive, and productive). A total of 15 items were scored on the 5-point Likert scale, with a higher score indicating higher self-care. The modified Thai version of Western Ontario and McMaster Universities Osteoarthritis (WOMAC) comprises 24 self-report items with numeric rating scale categorized into pain (5 items), stiffness (2 items), and physical function (17 items). A higher score indicates a lower functional ability.	The first outcome was back muscle endurance which was evaluated by the modified Biering-Sorensen test. The endurance time was recorded in seconds from the point at which the participants assumed the horizontal popsition untile the upper body came out of contact with the stick. The second outcome was physical function based on Oswestry Disability Questionnaire (ODM) in Thai version. The third outcome was severity of low back pain based on the visual analogue scale (VAS).	The chronic pain questionnaire was used to determine the pain intensity and disability level of participants. It is a seven-item Guttman scale developed by Von Korff *et al.* [34]. Three items assess pain intensity and four items assess functional disability. This questionnaire was translated into Yoruba language by a linguist for easy comprehension by the participants and back translated to ensure consistency of the content and internal validity.	The Lower Back Pain Prevention Behaviors Questionnaire (LBP-PBQ) measures the frequency of behaviors that the respondent performs including proper working posture and SBE. Higher scores indicate more frequency to perform proper working posture and SBE. The Prone Double Straight-leg Raise Test (PDSRT) was used to test low BME.
Randomization	A random number sequence was generated by package integrated computing environment, R. Clusters. In the trial, an author (CK) prepared the allocation sequence list, and another author (KH) carried out the allocation through identification of home and working areas of the volunteers.	Two groups were randomized by location area, matching on age and gender.	The six villages were randomly divided into two groups of three villages per group. The two groups were randomly allocated to treatment groups under supervision of twelve research assistants who were randomly assigned to a different group every two weeks throughout the period of the study. This was done in order to ensure equality in supervision and in delivery of instruction and to minimize biases among research assistants to any group.	Two villages were randomly assigned as experimental and control groups and 40 participants were purposively selected into each group.
Blinding/ masking	Not described.	Not described.	Independent and blinded assessors who were not involved in the study carried out the pre- and post-treatment assessments of pain and disability status of the participants to minimize biases.	Not described.
Numbers randomized	PEM-PRE (n=30), PEM-NWE (n=33), and ST (n=45).	TTM group (n=62) and non-TTM group (n=64).	Back care education group (BG, n=126) and control group (CG, n=121).	Experimental group (n=40) and control group (n=40).
Recruitment	Aged para rubber farmers were recruited from three communities in southern Thailand.	Rice farmers were recruited from two sub-districts in Uttaradit Province, Thailand.	Farmers suffering from chronic LBP were recruited from six villages namely: Idiata, Olorunda, Olori, Alapa, Aderounmu, Igbo-olorin and from primary/secondary health centers nearest to the villages.	Participants were recruited in one province in central Thailand and engaged in rice farming, undertaken by hand. Multi-stage sampling was used to obtain participants in two villages and these were randomly selected. Both villages had similarities in terms of being areas where rice farming was done for at least 2 cycles per year.
Numbers analyzed	Full analysis set. PEM-PRE (n=25), PEM-NWE (n=25), and ST (n=25).	Intention-to-treat analysis. TTM group (n=62) and non-TTM group (n=64).	Per protocol set. BG (n=100) and CG (n=100).	Intention-to-treat analysis. Experimental group (n=40) and control group (n=40).
Outcome	At the end of the trial, GLMM analyses revealed statistically significant differences in self-care between groups in the mixed-effect model in which all time points were included (*P*,0.001; R2 GLMM(c) =0.59). Both PEM-NWE and PEM-PRE showed a significant difference in the total mean score of self-care (*P*,0.05). GLMM analyses revealed statistically significant differences in functional ability between groups in the mixed-effect model wherein all time points were included (*P*,0.001; R2 GLMM(c) =0.93). Both PEM-NWE and PEM-PRE showed a significant difference from the ST in the total mean score of functional ability (*P*,0.05).	The portions of participants' behavioral stage changed significantly ($P<0.05$) for the TTM group; more members of the TTM group (51.6%) achieved active stages of action and maintenance than those of the non-TTM group (20.3%). The mean difference in back muscle endurance between the TTM and non-TTM groups was 11 seconds (95% of confidence interval 0.7 to 21.3 seconds, $P<0.05$). The physical function and severity of pain variables indicated that they significantly improved in the TTM group when compared with the non-TTM group at weeks 20 and 32 ($P<0.05$).	The pre-treatment pain intensity of participants in BG was found to be significantly ($P<0.05$) higher than those of participants in the control group, while there was no significant difference in pre-treatment functional disability scores between the groups. At the end of 8 weeks of training the pain intensity and functional disability scores of the BG were significantly ($P<0.001$) lower than those of the CG.	Farmers who received the WBMP had higher mean scores of LBP prevention behaviors (F=9665.54, $P<0.001$) and BME (F=248.641, $P<0.001$) than the control group at 6 and 9 weeks.
Harm	Not described.	Not described.	Not described.	Not described.
Conclusion	Integrating the PEM in NWE and PRE based on the theory of self-care operations contributes to positive effects of self-care and functional ability for aged para rubber farmers with knee OA in 2 months. The program may be a beneficial intervention that could be used for improving health and work capability in aged workers with chronic health conditions, as previously mentioned in the literature.	TTR-based intervention can improve back muscle endurance as well as physical function and reduce pain in rice farmers with chronic LBP.	Back care education caused a reduction in pain intensity and functional disability among farmers with chronic mechanical LBP. It is recommended that back care education should be used to reduce back pain and disability among farmers.	The WBMP developed for this study is effective in improving LBP prevention behaviors and BME among Thai farmers with the short-term changes during six weeks, and the changes were sustained over the nine weeks of the follow-up period.
Trial registration	Thai Clinical Trial Registry (TCTR20160219001)	Not described.	Not described.	Not described.
Fund	The Higher Education Research Promotion and National Research University Project of Thailand, Office of the Higher Education Commission.	The Faculty of Associated Medical Sciences, Graduate School and Research and Training Center for Enhancing Quality of Life of Working-Aged People, Khon Kaen University, Thailand.	Not described.	The Thailand Nursing and Midwifery Council.

Abbreviations were added for each article.

Table 3 References to studies excluded in this review

No.	Author (year)	Title	Reason of exclusion
1	Baek S *et al.* (2020)	A mobile delivered self-exercise program for female farmers	Protocol
2	Terhorst Y *et al.* (2020)	Clinical and cost-effectiveness of a guided internet-based Acceptance and Commitment Therapy to improve chronic pain-related disability in green professions (PACT-A): study protocol of a pragmatic randomised controlled trial	Protocol
3	Balaguier R *et al.* (2017)	Effects of a worksite supervised adapted physical activity program on trunk muscle endurance, flexibility, and pain sensitivity among vineyard workers	Not randomized controlled trial
4	Ganesh S *et al.* (2016)	The effectiveness of rehabilitation on pain-free farming in agriculture workers with low back pain in India	Not randomized controlled trial
5	Thanawat T *et al.* (2005)	Effects of transtheoretical model-based intervention on physical function of rice farmers with chronic low back pain: a randomized controlled trial	Conference abstract
6	Phajan T *et al.* (2014)	Work-related musculoskeletal disorders among sugarcane farmers in north-eastern Thailand	Not randomized controlled trial
7	Yoo IG *et al.* (2011)	Neck and shoulder muscle activation in farm workers performing simulated orchard work with and without neck support	Not randomized controlled trial
8	Rana AKMM *et al.* (2008)	The impact of health education in managing self-reported arthritis-related illness among elderly persons in rural Bangladesh	Not randomized controlled trial
9	Ishida F *et al.* (2008)	Pain relief for patients with knee osteoarthritis: Outpatient guidance attempting to reexamine daily life including farm work	Included non-farmers
10	Perkiö-Mäkelä M (2001)	Exercise and ergonomics-focused group counseling among female farmers	Dairy farmers

Table 4 Evaluation of the quality of methodology for each article

No	Criteria list	Reference number				Present description**	
		23	24	25	26	no/4	rate (%)
1	Was the method of randomization adequate?	y	n	n	n	1	25%
2	Was the treatment allocation concealed?	n	n	n	n	0	0%
3	Were the groups similar at baseline regarding the most important prognostic indicators?	?	y	?	?	1	25%
4	Was the patient blinded to the intervention?	?	?	?	?	0	0%
5	Was the care provider blinded to the intervention?	?	?	?	?	0	0%
6	Was the outcome assessor blinded to the intervention?	?	?	y	?	1	25%
7	Were cointerventions avoided or similar?	y	y	y	y	4	100%
8	Was the compliance acceptable in all groups?	?	?	?	?	0	0%
9	Was the drop-out rate described and acceptable?	y	y	y	?	3	75%
10	Was the timing of the outcome assessment in all groups similar?	y	y	y	y	4	100%
11	Did the analysis include an intention-to-treat analysis?	y	y	?	y	3	75%
	Present description no/11	5	5	4	3	---	
	rate (%)	45%	45%	36%	27%		

Yes: y; no: n; do not know or unclear: ?; not applicable: n/a.

the same time, have their own risks of injury. Previous SRs showed that a participatory ergonomic approach could significantly affect musculoskeletal symptom relief and prevent muscle injury[27, 28]. The main concept of this approach is that self-care behavioral promotion requires strategies for enhancing ergonomic management and helps overcome barriers to behavioral changes. Although there were slight differences in each intervention among the four selected studies[23–26], each study also adopted this method and achieved a certain effect. This approach could help workers realize their risks and enhance their attitudes toward ergonomic measures through problem-solving approaches, as well as improve their self-care change behaviors.

One previous study developed the ergonomic checkpoint in agriculture using a three-dimensional static prediction program for typical agricultural work in Indonesia and clarified the risks associated with each operation[29]. This suggests that if evidence-based action-oriented education is accepted by farmers and practiced with high compliance, the risk of D-MSCT would surely be reduced.

This issue is not limited to farmers, but also applies to other workers. It is well known that caregivers in nursing homes have high prevalence rates of LBP because of physical work such as repeated manual lifting with anomalous posture while transferring patients[30–32]. A transfer technique intervention adapted to the care method has been found to be effective in reducing LBP[33]. This indicates that tailor-made guidance is needed for each task across many professions.

2) Exercise centered on strength training

It is accepted that physical exercise plays an important role in the treatment of patients with LBP[34–36]. Numerous exercises have been devised for LBP, including exercises that enhance flexibility, mobility, and endurance of the back while focusing on muscle strengthening are recommended[36–40]. Strength training is also a key component of conservative treatments that significantly improve functional ability and minimize pain in patients with knee OA[41, 42].

In general, high compliance and appropriate postures and procedures will certainly have a positive effect on reducing pain and improving physical function. The most important factor is whether participants will implement these practices. Agricultural work itself is already overloaded with physical labor, and aversion to an additional exercise (i.e., exercise for LBP) is considered a major barrier for farmers.

Therefore, it is necessary to approach exercise practices that are tailored to the readiness of participants[43]. Behavioral science-based TTM[44] was developed in 1997. One of our four studies[24] adopted TTM as an intervention to increase long-term compliance for participants and achieved positive results in reducing back pain and improving back muscle endurance and physical function. The effects of TTM in intervention studies for other diseases such as obesity[45, 46], type 2 diabetes mellitus[47], and hypertension[48] have been widely reported. Based on these findings, we propose that TTM is the most important strategy for successful intervention.

Actual education at agricultural sites during the COVID-19 pandemic: external validity

Based on internal validity, there are three key educational and enlightenment activities for farmers that prevent and alleviate D-MSCT (Figure 2). One is the participatory ergonomic approach, which is carried out by farmers with a

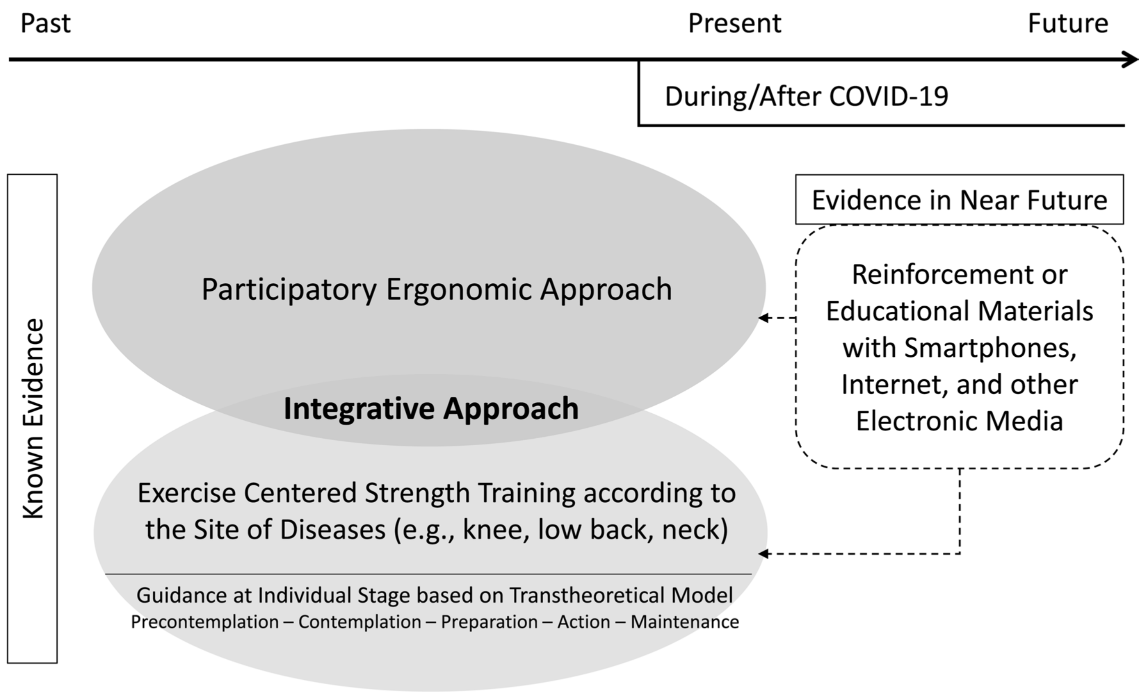

Figure 2 Conceptual model of the educational program for farmers. Method without use of special facilities or equipment.

thorough understanding of its purpose. The second is exercise practice based on TTM. The third is a combination of the two methods.

However, even if the effectiveness of these activities can be grasped by the participant, there are major barriers to their implementation. Globally, only a small percentage of farmers work under large corporations; most farmers are sole proprietors (i.e., peasant farmers) and may not have the opportunity to receive comprehensive education on the prevention of D-MSCT. Even in Japan, which is a developed country, it is a fact that education for the prevention of D-MSCT is not sufficient for farmers[2]. It is essential for policy makers and government officials in each country and region to interpret this accurately and practice it through guidance staff, such as doctors, physiotherapists, and public health nurses.

As a result, COVID-19 has become a deadly foe for humans. Globally, as of 3:09 pm CEST, May 2, 2021, there have been 151,803,822 confirmed cases of COVID-19, including 3,186,538 deaths, reported by the WHO[49]. Therefore, it is becoming difficult to provide face-to-face, easy-to-understand, and polite explanations to farmers to prevent the spread of infection. We have already identified the latest research protocols[50, 51] that may provide new and pragmatic programs for farmers. As generations of farmers change, Internet and mobile-based interventions are frequently used worldwide. We hope that these two research protocols will yield positive results in future studies.

Conversely, the need for online instruction via the Internet or smartphones will certainly increase, but in countries and regions where such tools remain insufficient, other methods (i.e., education style) should be required to avoid COVID-19 infection. An important SR that examined geographical region, gender, commodity, and employment context in research on LBP in farmers reported that despite the predominance of an agricultural workforce in developing nations, 91% of included studies were conducted in a developed country[52]. This means that existing knowledge or current research using cutting-edge electronic devices is not necessarily universal.

Based on current evidence, we suggest that a conceptual model of an educational program for the prevention and mitigation of D-MSCT in farmers is possible without the use of special facilities or equipment.

Future research agenda for better work conditions of farmers

Table 5 shows the future research agenda for new studies. Overall, the evidence suggests that the risk of bias in previous studies was high. Cochrane's criteria list[22] is the most important tool related to the internal validity of trials. In the present SR, serious problems were noted with the conduct and reporting of the target studies. Our review especially detected omissions of the following descriptions: method used to generate randomization, concealment, blinding, and compliance. Descriptions of these items were lacking (very poor; <50%) in many studies.

All studies included in our SR were not registered in any clinical trial registry and were insufficient in descriptions based on RCT-specific checklists such as "CONSORT 2010"[53], "CONSORT 2010 statement: extension to cluster randomized trials"[54], and "CONSORT statement for randomized trials of nonpharmacologic treatments: a 2017 update and a CONSORT extension for nonpharmacological trial abstracts"[55]. In addition to these checklists, it is necessary to report studies in accordance with a checklist suitable for the study design, such as the "CONSORT 2010 statement: extension to randomized crossover trials"[56].

Furthermore, to prevent bias, more studies should be implemented for many agricultural work types in various parts worldwide (especially developing countries and regions) during the COVID-19 pandemic. Future cohort studies should be conducted to clarify the long-term effects of these interventions. A disadvantage of interventional studies, such as RCTs, is that the long-term effects cannot be confirmed. Therefore, it is necessary for effective intervention (education) methods to be utilized in the field and to be clarified by cohort studies.

Limitations

This review has several limitations that should be acknowledged. First, some selection criteria were common across SRs; however, bias remained due to differences in eligibility for participation, which were described in each

Table 5 Overall evidence and future research agenda for better work conditions of farmers

Overall evidence presently	Research agenda	
Overall, the risk of bias was high, but a participatory ergonomic approach, exercise centered on strength training, and/or the combination of both could be effective educational program, at least in the short term, for the prevention and reduced exacerbation of musculoskeletal system or connective tissue in farmers.	1	Implementation of RCT without risk of bias
	2	Satisfactory description and methodology including the CONSORT 2010, CONSORT crossover, and the CONSORT for nonpharmacological trials
	3	Implementation of RCTs in diverse regions
	4	Intervention effect by work type in agriculture
	5	Follow-up study of long-term effects

original article. Second, a weakness of this study is the possibility that important SRs were overlooked because the Population, Intervention, Comparison, Outcomes and Study setting criterion might not have been fully appropriate. In fact, although there are many RCTs that targeted the inhabitants of rural areas, they were excluded from this study because they were not specialized studies on farmers. Third, publication bias was a limitation due to the inadequate use of multiple databases for each SR. Although there were no linguistic restrictions in the eligibility criteria, we searched for studies with only English and Japanese keywords. Fourth, we could not perform meta-analysis and subgroup analysis because of the heterogeneity of all outcome measurements and intervention methods. Finally, although the use of ergonomic goods and devices that reduce the burden on the body can be expected to be effective, no target studies met the eligibility criteria for our study.

Conclusion

Participatory ergonomic intervention, exercise centered on strength training, and/or a combination of both could be an effective educational program, at least in the short term, for the prevention and reduction of exacerbation of D-MSCT in farmers.

It is expected that high-quality RCTs with less risk of bias will be implemented for many agricultural work systems in various parts worldwide (especially developing countries and regions) during the COVID-19 pandemic. Furthermore, it is of interest to conduct cohort studies to clarify the long-term effects of these interventions.

Author Contribution: All authors made a significant contribution to the work reported, whether in the conception, study design, execution, acquisition of data, analysis, and interpretation or in all of the following areas: drafting, revising, or critically reviewing the article; final approval of the version to be published; agreement on the journal to which the article has been submitted; and agreement on being accountable for all aspects of the work.

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Availability of data and materials: The study was registered as UMIN 000044080 by the UMIN-CTR (refer to https://upload.umin.ac.jp/cgi-open-bin/ctr/ctr_view.cgi?recptno=R000050330). The trial was registered with the International Prospective Register of Systematic Reviews (PROSPERO) trial on February 10, 2021, in advance, but for some reason, it was not posted on the homepage. Therefore, although the research was in the middle of implementation, we registered it with the UMIN-CTR.

The full protocol (UMIN-CTR has a limited amount and only a part of it is listed) and all data are available in the online cloud (https://drive.google.com/file/d/1qzxp0DnaH5jsT1UCuhbAJBc4O7rbJO0o/view?usp=sharing).

Ethics approval and consent to participate: Ethics approval was not applicable for this study because it is a secondary research based on thesis materials.

Conflict of interests: The authors have no competing interests to declare.

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