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Effect of Online Physical Therapy on Workplace Accident-related Outcomes in Caregivers: Study Protocol of a Randomized Controlled Trial

Shuto Higuchi,[1,2] Kouhei Funatsu,[2] Keishi Nawata,[2] Satoshi Kuhara,[2]

Yoshihisa Fujino[3] and Satoru Saeki[1]

[1]Department of Rehabilitation Medicine, University of Occupational and Environmental Health, Kitakyushu, Japan

[2]Department of Rehabilitation Center, University of Occupational and Environmental Health, Kitakyushu, Japan

[3]Department of Environmental Epidemiology, Institute of Industrial Ecological Sciences, University of Occupational and Environmental Health, Kitakyushu, Japan

Corresponding author:

Shuto Higuchi

Department of Rehabilitation Medicine, University Hospital of Occupational and Environmental Health, 1-1 Iseigaoka, Yahatanishi-ku Kitakyushu-shi, Fukuoka 807-0804, Japan

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Phone number: +81-93-603-1611

Fax number: +81-93-603-6691

E-mail: shuto.higu@gmail.com

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Keywords: Caregivers, Online Physical Therapy, Low Back Pain, Falls

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ABSTRACT

Introduction: It is estimated that there will be a shortage of approximately 0.55 million nursing care workers in Japan by 2025. Most nursing care workers are often women, and it is known that the number of occupational accidents caused by falls and low back pain (LBP) during work has increased by more than 20% since 2015. Although physical therapy has been shown to be effective in preventing falls and back pain in community-dwelling older adults, there are no randomized controlled trials examining whether online individual physical therapy can prevent falls and low back pain in health care workers to date.

Methods and analysis

A total of 120 caregivers aged ≥20 years will be randomly assigned to the online Individual Therapy Group (ITG) or the Usual Group (UG), after obtaining informed consent. A follow-up will be conducted post 12 months, and the results at 3, 6, and 12 months will be compared. The primary endpoint is the Oswestry Disability Index (ODI). ITG participants will receive expert advice on LBP and musculoskeletal problems from a physiotherapist via online interview and email as often as they wish over a 6-month period; UG participants will have access only to brochures on LBP and fall prevention. Due to the nature of the study, blinding of participants and interventionists is not possible, but outcomes will be assessed by a web-based questionnaire to prevent detection bias.

The null hypothesis is that there is no clinically important difference in the primary outcome between the two treatment groups; a reduction in ODI score of 20% or more will be considered clinically meaningful.

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Ethics and dissemination: The Ethics Committee of the Japanese Society of Occupational Medicine approved the protocol of this study. The results of this study will be disseminated through peer-reviewed journals and conference presentations.

Strengths and limitations of this study

Strengths:

・Recruitment of participants from multiple sites

・Difficulty of introducing researcher bias in the evaluation of outcomes

Limitation:

・Only cooperative participants were included, which reduces generalizability

・Lack of blinding of participants and interveners, which does not exclude the possibility of bias

INTRODUCTION

Japan is experiencing a change in its demographic make-up and is undergoing population aging. Senior citizens over 65 years of age will account for 30% of the entire Japanese population by 2025.[1] In 2018, there was a shortage of 0.10 million caregivers, and the number of nursing care workers needed by 2025 is estimated to be 0.55 million.[1,2] Furthermore, working population will decrease by approximately 10

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million by 2040,[3] and securing labor force is an urgent need. For this reason, in recent years, Japan has been actively promoting the participation of female workers in the society to secure the working population, and the percentage of female workers has increased by an average of 0.24% per year from 1985 to date. On the other hand, due to the increase in the number of female workers, the number of fatalities and injuries due to falls and LBP at work has been increasing, resulting in their absence from the work place for >4 days; this has become a big issue. In particular, it has become clear that nursing care workers in social welfare facilities are composed of middle-aged and older women, who are more likely to suffer these fatalities and injuries, and a survey by the Ministry of Health, Labor and Welfare reported that the number of these workers has increased by more than 20% from 2015 to date.[4] Such a situation will lead to a decrease in the labor force of nursing care workers in social welfare facilities, which may lower productivity and the quality of nursing care; thus, it is evident that immediate action is needed.[5]

Many studies have reported the factors involved in falls among workers. Studies focusing on internal factors have revealed that, in addition to being female and over 45 years old, balance ability and lower limb muscle weakness are risk factors for falls.[6–8] Internal factors resulting in falls and LBP is a familiar area for physical therapists, and a systematic review of community-dwelling elderlies patients found that physical therapist-assisted exercise therapy could prevent falls and LBP.[9,10] Recently, it has been shown that individual exercise instructions by physical therapists for workers improved their physical functions.[11] However, it is not clear whether the interventions of physical therapists for workers

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ultimately contribute to occupational injury-related outcomes and occupational injury prevention. Therefore, the purpose of this study is to examine whether the individual guidance of physical therapists to nursing staff working in social welfare facilities affects the outcomes related to occupational accidents.

METHODS AND ANALYSIS

Check list

The protocol for this study was drafted as per the check-list from the Standard Protocol Items for Clinical Trials (SPIRIT).[12]

Patient and public involvement

There was no involvement of the general public or patients in the development of this study.

Study setting

The study was a multicenter, randomized controlled trial that compared a study group that received only a training session and pamphlet on low back pain with a control group that received individualized management by a physical therapist online. Participating institutions and candidates were recruited on the website of the Development of Rehabilitation Medicine, University of Occupational and Environmental

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Health (UOEH), Japan. In addition, flyers were distributed to social welfare facilities in Kitakyushu City, Fukuoka Prefecture, through people related to the social welfare facilities.

Eligibility criteria

Members of the research group will assess the eligibility of potential institutions and candidates (aged ≥20 years) who wish to participate in the study. The inclusion and exclusion criteria are presented in Box 1. All participants who meet the eligibility criteria will be provided with detailed documents about the study; consent will be obtained through a signed informed consent form.

Box 1 Inclusion and exclusion criteria used in the randomized controlled trial

Inclusion criteria

1. Age: 20 years and older, but less than 60 years of age at the start of the study
2. Sex: Any sex possible

Exclusion criteria

1. Persons with severe visual impairment (disability level 1–6) or hearing impairment (Grade 2–6 disability level *Those with normal hearing level on one side are included in this category)
2. Those who have a history of spinal disease (surgery)
3. Those who have already received rehabilitation treatment and guidance by physical therapists, etc.
4. Those who wish to retire within one year at the start of the study, or those who are likely to retire during the intervention period or are likely to reach
5. Those who have been advised against participating in the study by their physicians due to medical reasons
6. Those who did not provide consent to participate in the study

Discontinuation criteria

1. Criteria for discontinuation: Those who wish to discontinue participation in the study and request for opting out.
2. Those who have health reasons that make it difficult to participate in the LBP and fall prevention program

Interventions

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Individual Therapy Groups (ITG): A group online training session on fall and low back pain prevention by physical therapists will be held once during the study period. The training session will be held during the first month of the study. The content of the workshop will be related to the prevention of physical weakness, falls, LBP, lifestyle-related diseases, and depression. Depending on the results of the baseline (T1) assessment, the physical therapist will provide individualized guidance online according to the various exercise guidelines. During the intervention period, participants will be provided with professional advice by the physiotherapist as required; this can take place individually online. During the first 6 months after attending the online seminar, the participants may receive exercise instructions at least once a week from a physical therapist only through online seminar interviews, video materials, or via e-mail.

Usual Group (UG): A group online workshop on fall and back pain prevention by a physical therapist will be conducted once during the study period. The workshop content will include prevention of physical weakness, falls, back pain, lifestyle-related diseases, and depression. After the workshop, pamphlets on the prevention of fall and back pain will be distributed. Subsequently, group online training sessions will be held once every 3 months.

Outcomes

We chose subjective patient-reported outcomes for all outcomes because we believe that they are free from evaluation bias of the physical therapy interventionists and allow for appropriate effect judgments. The effect of the intervention will be assessed after 3, 6, and 12 months.

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Baseline data

After registration of study participants, data such as sex, educational background, employment status, work experience as an employee, type of facility, overtime hours per week, workplace accident-related injury or experience in the previous year, and site of injury will be collected through questionnaires.

Primary outcome

The primary outcome measure of this study is the Oswestry Disability Index (ODI). The primary time point is at 6 months.

Oswestry Disability Index

The ODI is used to measure outcomes of occupation-related disabilities. The Japanese version of ODI has been validated and is the most widely used back pain assessment method in the world. It is characterized by the inclusion of items related to social life.[13,14] Primary outcomes will be assessed at baseline (T1), 3 months post-intervention (T2), 6 months post-intervention (T3), and 1 year post-intervention (T4).

Secondary outcome

Secondary outcomes are measured by participants' self-administered subjective ratings and self-reports. The list of measures of secondary outcomes is shown in Box 2. Participants will be asked to fill out questionnaires on fear of falling and decreased productivity. They will also be asked to self-report the

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number of days absent from work due to bac pain and falls. These assessments will be tabulated at each follow-up visit.

Box 2 Outcome measures

Measurements are recorded at 3 months, 6 months, and 12 months

Primary outcome measure

1. ODI at 6 months

Secondary outcome measures

1. FES-I
2. HPQ
3. Absenteeism

*See text definition

ODI, Oswestry Disability Index; FES-I, International Falls Evaluation Scale; HPQ; WHO Health and Work Performance Questionnaire.

International Falls Evaluation Scale

The International Falls Evaluation Scale (FES-I) will be used as an outcome measure for occupation-related disability, and a Japanese version of the FES-I has been developed to verify its reliability and validity.[15] The questionnaire consists of two items: fear of falling and falls self-efficacy. Those who have a fear of falling tend to be more eligible for hospitalization due to falls than those who are not, which is consistent with the purpose of this study.[16]

WHO Health and Work Performance Questionnaire

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The WHO Health and Work Performance Questionnaire (HPQ) will be used to investigate the impact of the intervention on the presenteeism of the workers; the reliability and validity of the Japanese version of the HPQ have been validated.[17,18]

Absenteeism

In this study, absenteeism due to falls was defined as frequency of absenteeism of 4 or more days due to falls. In addition, absenteeism due to LBP was defined as absenteeism of 4 or more days due to back pain. In addition, the frequency of occurrence and the total number of 4 or more days will be recorded as occupation-related injuries, including falls and LBP, and will be monitored during the follow-up period from the start point of the intervention.

Participant timeline

The timelines for enrolment, assessment, and intervention of this study are shown in Table 1. A flow diagram of the study is shown in Figure 1.

Table 1 Schedule of enrolment, interventions, and assessments

	Study period				
	Enrolment	Allocation	Post allocation		
Time point			3 months	6 months	12 months
Enrolment:					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
Interventions:					
[Individual therapy group]		◆		◆	
[Usual group]		◆	◆	◆	

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Assessments:				
Baseline data	X			
ODI, FES-I, HPQ	X	X	X	X
Absenteeism		X	X	X

*See text definition of absenteeism in this trial.

Sample size

The sample size was calculated using G*Power 3.1. In this study, the ODI after 6 months of intervention was the primary endpoint, and the alpha and beta levels were set at 0.05 and 0.2, respectively. Based on previous studies examining the effects of individual physical therapy on workers,[11] the effect size of individual physical therapy on physical function was estimated to be approximately 0.5. In addition, the dropout rate during the study period is often estimated to be 20%, but since the participants of this study were health care workers, we anticipated the follow-up to be easier than that of a study on outpatients. Therefore, we estimated the dropout rate to be 10% and set the number of study participants required for this study to be 60 in each group.

Allocation

Sequence generation and concealment

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After the baseline measurements were completed, the participants were assigned to either the ITG or the UG using a computer random number function in R by a third party who was not involved in this study. In addition, blocking was used to minimize bias in the sample sizes of the two groups.

Stratification

The participants randomly assigned to the ITG or UG were stratified by sex to examine the effect size for each sex in subsequent subgroup analysis.

Implementation of randomization

The order of allocation will be made by a physical therapist affiliated with the UOEH, who is not involved in the study. After obtaining informed consent from the participants, the physical therapist will distribute individual interventions or pamphlets according to the treatment allocation.

Blinding

The evaluation in this survey will be done through a questionnaire. The participants can freely choose whether to respond on paper or via the digital questionnaire. The number of incidences of back pain and falls, as well as the number of work days lost due to back pain and falls, will be reported by the participants and their facility administrators. Due to the nature of the study, it is difficult to blind the participants to the physical therapist conducting the intervention.

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Data collection methods

The questionnaires used in this study, from the baseline assessment to one year after participation in the study, can be completed by the participants either on paper or using a Google form. Participants who have not responded for more than one week will be listed, contacted, and encouraged to respond. The number of incidences of back pain and falls, and the number of days of absence related to back pain and falls will be self-reported by study participants and fact-checked with facility administrators, and absence rates will be tabulated as outcomes.

Drop prevention

To ensure that the participants assigned to each group comply with the research protocol, the ITG will receive follow-up e-mails from the physical therapist in charge at least once a week during the study period, and the frequency and duration of interventions and the content of exercise instruction will be recorded each time.

Data management

Data will be entered and coded in duplicate by two third-parties who are not involved in the study to prevent erroneous data entry. The completed database will be stored at the Department of Rehabilitation Medicine, University of Occupational and Environmental Health.

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Statistical methods

Bias in baseline characteristics of study participants assigned to the two groups will be adjusted for as covariates as needed. Two-way analysis of variance will be used to compare groups at 6 months post-intervention for the primary endpoint. Intention-to-treat (ITT) and per-protocol analyses will be used of between-group differences. If there is a significant difference in the primary endpoint between the two groups at 6 months post-intervention, the groups will be compared at 3 months, 6 months, and 1-year post-intervention for the primary and secondary endpoints. In addition, a subgroup analysis will be conducted between males and females to determine the differences in the magnitude of treatment impact by sex.

Any missing values for follow-up outcomes during the study period will be supplemented with multiple substitutions.

Data monitoring and auditions

This is not applicable to the study since it is not an invasive intervention study.

Harm

It is expected that muscle pain will occur after performing the fall and back pain prevention exercises that are included in the course content. However, these risks are clearly outweighed by their benefits.

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ETHICS AND DISSEMINATION

Research ethics approval

Approval was obtained from the Research Ethics Committee of the University of Occupational and Environmental Health. (Approved on 25 NOV 2021, reception number R3-058).

Protocol amendments

After approval by the Ethics Committee, the progress and results of the research at the end of each year are reported to the University Ethics Committee. If during the research, the expected risk is judged higher than the expected benefit, or in case sufficient results cannot be obtained, the research will be terminated, and if sufficient results are obtained, the research will be terminated even during the research period.

Consent or assent

The significance, purpose, and methods of this study, as well as the possible disadvantages and risks that the participants may face will be explained in writing and orally, and the participants will be asked to sign a consent form.

Confidentiality

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No biological samples will be collected in this study, but the data obtained will be kept in a locked vault in the Department of Rehabilitation Medicine under the supervision of the principal investigator. The data obtained in this study will be stored for 5 years after the completion of the study or 3 years from the date of reporting the study results, whichever is later, and then all data will be disposed after confirming anonymization.

Data sharing

The summary of this study will be registered in the public database of the Japan Registry of Clinical Trials (JRCT).

Ancillary and post–trial care

Emergency contact information for this research will be made available to the participants so that they can ask questions at any time during and after the research, and the principal investigators and research staff will have a system in place to respond appropriately.

Dissemination policy

Although this study does not provide any medical benefits to the research participants, such as their health status, the results of this study will be disclosed to the participants if they wish.

AUTHORS' CONTRIBUTIONS

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Shuto Higuch, Kouhei Funatsu, Keishi Nawata, Satoshi Kuhara, Yoshihisa Fujino, and Satoru Saeki were involved in major parts of the study design, and Shuto Higuch was the principal investigator. The manuscript was prepared by Shuto Higuch, and all members actively participated and contributed to the writing of the manuscript; Kouhei Funatsu, Keishi Nawata, and Yoshihisa Fujino were responsible for the preparation of figures and tables and statistical analysis. All authors reviewed the text and approved the final manuscript.

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COMPETING INTERESTS

None declared

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FIGURE LEGENDS

Figure 1 Flow chart of the trial. Individual therapy group (ITG) and usual group (UG)

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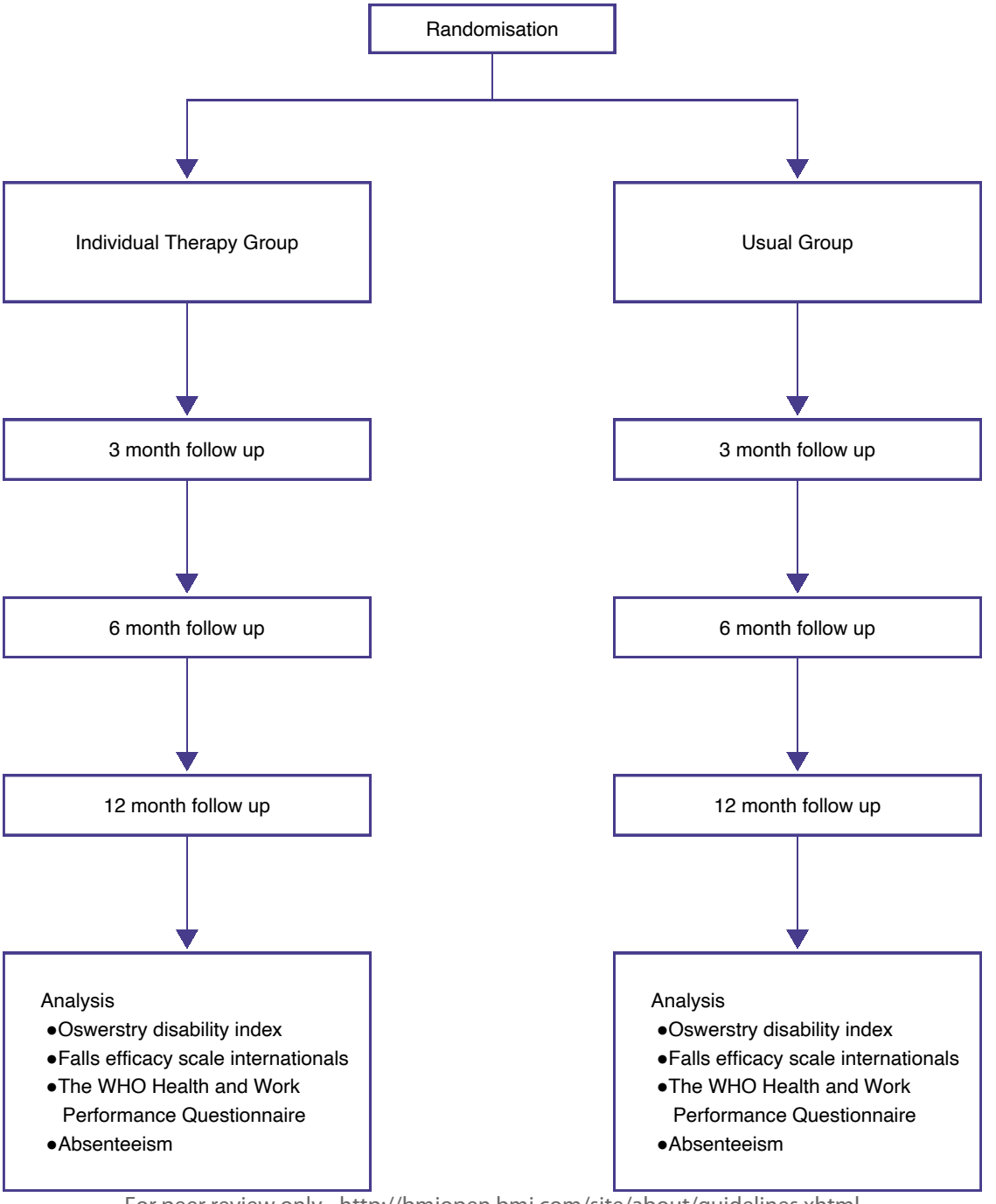

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Figure 1 Flow chart of the trial. Individual therapy group(ITG) and usual group(UG)

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

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Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	17
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	#3	Date and version identifier	N/A
Funding	#4	Sources and types of financial, material, and other support	18
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	17,18

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Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	N/A
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4,5,6
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	5,6
Objectives	#7	Specific objectives or hypotheses	5,6
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	12,13
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	14

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Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7,8
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	7(Box 1), 16
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	14
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	7(Box 1)
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9,10,11
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	11,12
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	12
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	6,7
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be	12,13

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		provided in a separate document that is unavailable to those who enrol participants or assign interventions	
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	12,13
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	12,13
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	13
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	13
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	14
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	14
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	14
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	15

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Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	15
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	15
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	16
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	16
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	15
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	16
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	16
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	16
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	16

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Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	16,17
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	N/A
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	17
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	17
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	17
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

Notes:

- 11b: 7(Box 1), 16 The SPIRIT Explanation and Elaboration paper is distributed under the terms of the Creative Commons Attribution License CC-BY-NC. This checklist was completed on 25. February 2022 using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai

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Effect of Online Physical Therapy on Workplace Accident-Related Outcomes in Nursing Care Worker : Study Protocol of a Multicenter Randomized Controlled Trial

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Effect of Online Physical Therapy on Workplace Accident-related Outcomes in Nursing Care Worker: Study Protocol of a Multicenter Randomized Controlled Trial

Shuto Higuchi,[1,2] Kouhei Funatsu,[2] Keishi Nawata,[2] Satoshi Kuhara,[2]

Yoshihisa Fujino[3] and Satoru Saeki[1]

[1]Department of Rehabilitation Medicine, University of Occupational and Environmental Health, Kitakyushu, Japan

[2]Department of Rehabilitation Center, University of Occupational and Environmental Health, Kitakyushu, Japan

[3]Department of Environmental Epidemiology, Institute of Industrial Ecological Sciences, University of Occupational and Environmental Health, Kitakyushu, Japan

Corresponding author:

Shuto Higuchi

Department of Rehabilitation Medicine, University Hospital of Occupational and Environmental Health, 1-1 Iseigaoka, Yahatanishi-ku Kitakyushu-shi, Fukuoka 807-8556, Japan

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Phone number: +81-93-603-1611

Fax number: +81-93-603-6691

E-mail: shuto.higu@gmail.com

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ABSTRACT

Introduction: According to 2017 data, social welfare facilities have more occupational accidents than other industries, and in particular, the number of occupational accidents resulting in four or more days of absence from work due to Low Back Pain(LBP) or falls has increased and is considered problematic. Although physiotherapy has been shown to be effective in preventing LBP and falls in older adults living in the community, no randomized controlled trials have examined whether individual online physiotherapy can prevent LBP and falls in nursing care workers.

Methods and analysis：120 nursing care workers aged 20 years or older will be randomly assigned to the online individualized therapy group (ITG) or the usual group (UG) after obtaining informed consent. Nursing care workers will identify as those performing caregiving duties in social welfare facilities and will be followed up after 12 months to compare results at 3, 6, and 12 months. The primary endpoint will be the Oswestry Disability Index (ODI); ITG participants will receive professional advice on LBP and musculoskeletal problems from a physiotherapist via online interview and e-mail as often as they wish over a 6-month period; UG participants will only have access to brochures and video feeds related to LBP and fall prevention. Due to the nature of the study, blinding participants and interventionists is not possible, but outcomes will be assessed via a web-based questionnaire to prevent detection bias. The null hypothesis is that there is no clinically important

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difference in the primary outcome between the two treatment groups and that a decrease in ODI score of at least 20% is clinically meaningful.

Ethics and dissemination: The Ethics Committee of the Japanese Society of Occupational Medicine approved the protocol of this study. The results of this study will be disseminated through peer-reviewed journals and conference presentations.

Strengths and limitations of this study

Strengths:

・Recruitment of participants from multiple sites

・Difficulty in introducing researcher bias in the evaluation of outcomes

Limitations:

・Only cooperative participants were included, which reduces generalizability

・Lack of blinding of participants and interveners, which does not exclude the possibility of bias

INTRODUCTION

Japan's population is aging as the birth rate declines and life expectancy increases; it is estimated that by 2025, those aged 65 and over will account for 30% of Japan's total population, and the working-age

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population will decrease by 10 million people by 2040. [1] As of 2016, there will be a shortage of 0.55 million nursing care workers working in social welfare facilities, [2] and securing the caregiver workforce is an urgent issue. [1,2] Data from 2017 shows that social welfare facilities in Japan have more occupational accidents than other industries, and the percentage of occupational accidents requiring four or more days of absence from work among all industries is increasing every year. This has become a major problem that has spurred a shortage of human resources for nursing care workers. [3] Back injuries and falls are particularly common in occupational accidents, accounting for nearly half of all cases, and mostly occurring in social welfare facilities. [3] While LBP and falls have been shown to be events that generally increase in frequency with age, [4] in nursing care workers, whose. Because nursing care worker work is characterized by physically taxing assistance to people and work in places with poor footing, a wide range of generations, from those in their 20s to those near retirement age, have experienced 4 days of lost work. This situation could lead to a decrease in the workforce of the nursing care worker in social welfare facilities, which could reduce productivity and the quality of care and thus requires countermeasures. Several studies have reported on factors related to LBP and falls among workers. A study examining the causes of LBP among nursing care workers working in social welfare facilities in Japan found that poor posture on the job was one of the problems. [5] Studies focusing on factors that cause workers to fall on the job have found that in addition to being female and over the age of 45, poor balance and lower extremity muscle strength are risk factors for falls. [6-8] The internal factors that contribute to falls and

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LBP are familiar territory for physical therapists, and systematic reviews of community-dwelling elderly patients have shown that exercise therapy by physical therapists can prevent falls and LBP. [9,10] In recent years, individualized exercise instruction by physical therapists to workers has been shown to improve physical function, [11] but it is not clear whether physical therapist interventions for workers ultimately contribute to work-related outcomes and work-related injury prevention. Therefore, the purpose of this study is to examine whether individual instruction by physical therapists to nursing care workers working in social welfare facilities has an impact on outcomes related to occupational accidents.

METHODS AND ANALYSIS

Checklist

The protocol for this study was drafted as per the check-list from the Standard Protocol Items for Clinical Trials (SPIRIT).[12]

Patient and public involvement

There was no involvement of the general public or patients in the development of this study.

Study setting

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This is a multicenter, randomized, controlled trial comparing a study group that received only pamphlet distribution and video delivery on LBP and falls with a control group that received individualized management by a physical therapist online. Participating facilities and candidates were recruited through the website of the Department of Rehabilitation Medicine and Development of Rehabilitation Medicine, School of Occupational and Environmental Medicine. In addition, flyers were distributed to social welfare facilities in Kitakyushu City, Fukuoka Prefecture, through interested parties.

Eligibility criteria

Members of the study group will assess the eligibility of the institution and the candidate (20 years of age or older) to participate in the study. Eligibility and exclusion criteria are presented in Box 1. All participants who meet the eligibility criteria will be provided with detailed information about the study. The minimum eligibility criteria for participants in this study are nursing care workers working in social welfare facilities, and consent will be obtained through a signed informed consent form.

Box 1 Inclusion and exclusion criteria used in the randomized controlled trial

Inclusion criteria

1. Age: 20 years and older, but less than 60 years of age at the start of the study
2. Sex: Any sex possible

Exclusion criteria

1. Persons with severe visual impairment (disability level 1–6) or hearing impairment (Grade 2–6 disability level *Those with a normal hearing level on one side are included in this category)
2. Those who have a history of spinal disease (surgery)
3. Those who have already received rehabilitation treatment and guidance by physical therapists, etc.
4. Those who wish to retire within one year at the start of the study, or those who are likely to retire during the intervention period or are likely to reach
5. Those who have been advised against participating in the study by their physicians due to medical reasons

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6. Those who did not provide consent to participate in the study

Discontinuation criteria

1. Criteria for discontinuation: Those who wish to discontinue participation in the study and request to opt out.
2. Those who have health reasons that make it difficult to participate in the LBP and fall prevention program

Interventions

Individual Therapy Groups (ITG)：Online training by physical therapists on LBP and fall prevention will be offered on the study start date. The training session will be pre-recorded and delivered to participants via chat or email on the study start date, with verification through the facility administrator that they have completed the viewing. The training session will last approximately one hour and will be related to the prevention of physical fitness, falls, LBP, lifestyle-related diseases, and depression. After the course, pamphlets on falls and LBP prevention will be distributed. The content of the pamphlet consists mainly of muscle strengthening and stretching for the trunk and lower extremities. Depending on the results of the baseline (T1) assessment, the physical therapist will provide individualized online instruction according to the exercise guidelines. During the intervention period, the patient will be required to perform the exercises and stretches following the instructions of an online physical therapist at least once a week. The type and frequency of exercises and stretches will be tailored to each participant due to the highly individualized nature of the program. Participants will have unrestricted access to their assigned physical therapist via online meetings, video streaming, or chat and email for 6 months after attending the online seminar.

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Usual Group (UG): An online seminar on LBP and fall prevention will be offered by a physical therapist. The delivery method and content are the same as for the ITG. The pamphlet distributed after the workshop is also the same as the one distributed at the ITG. Next, once a week, 3-5 exercises and stretches related to LBP and fall prevention will be selected and simultaneously delivered to participants via chat or email by a physical therapist not involved in the study; this process will continue for up to 6 months after taking the online seminar, but participants will not be able to seek advice from the physical therapist.

Outcomes

We chose subjective patient-reported outcomes for all outcomes because we believe that they are free from evaluation bias of the physical therapy interventionists and allow for appropriate effect judgments. The effect of the intervention will be assessed after 3, 6, and 12 months.

Baseline data

After registration of study participants, data such as sex, educational background, employment status, work experience as an employee, type of facility, overtime hours per week, workplace accident-related injury or experience in the previous year, and site of injury will be collected through questionnaires.

Primary outcome

The primary outcome measure of this study is the Oswestry Disability Index (ODI). The primary time point is at 6 months.

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Oswestry Disability Index

The ODI is used to measure outcomes of occupation-related disabilities. The Japanese version of ODI has been validated and is the most widely used LBP assessment method in the world. It is characterized by the inclusion of items related to social life.[13,14] Primary outcomes will be assessed at baseline (T1), 3 months post-intervention (T2), 6 months post-intervention (T3), and 1 year post-intervention (T4).

Secondary outcome

Secondary outcomes are measured by participants self-administered subjective ratings and self-reports. The list of measures of secondary outcomes is shown in Box 2. Participants will be asked to fill out questionnaires on fear of falling and decreased productivity. They will also be asked to self-report the number of days absent from work due to LBP and falls. These assessments will be tabulated at each follow-up visit.

Box 2 Outcome measures

Measurements are recorded at 3 months, 6 months, and 12 months

Primary outcome measure

1. ODI at 6 months

Secondary outcome measures

1. FES-I
2. HPQ
3. Absenteeism

*See text definition

ODI, Oswestry Disability Index; FES-I, International Falls Evaluation Scale; HPQ; WHO Health and Work Performance Questionnaire.

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International Falls Evaluation Scale

The International Falls Evaluation Scale (FES-I) will be used as an outcome measure for occupation-related disability, and a Japanese version of the FES-I has been developed to verify its reliability and validity.[15] The questionnaire consists of two items: fear of falling and falls self-efficacy. Those who have a fear of falling tend to be more eligible for hospitalization due to falls than those who are not, which is consistent with the purpose of this study.[16]

WHO Health and Work Performance Questionnaire

The WHO Health and Work Performance Questionnaire (HPQ) will be used to investigate the impact of the intervention on the presenteeism of the workers; the reliability and validity of the Japanese version of the HPQ have been validated.[17,18]

Absenteeism

In this study, absenteeism due to falls was defined as the frequency of absenteeism of 4 or more days due to falls. In addition, absenteeism due to LBP was defined as absenteeism of 4 or more days due to LBP. In addition, the frequency of occurrence and the total number of 4 or more days will be recorded as occupation-related injuries, including falls and LBP, and will be monitored during the follow-up period from the start point of the intervention.

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Participant timeline

The timelines for enrolment, assessment, and intervention of this study are shown in Table 1. A flow diagram of the study is shown in Figure 1.

Table 1 Schedule of enrolment, interventions, and assessments

	Study period				
	Enrolment	Allocation	Post allocation		
Time point			3 months	6 months	12 months
Enrolment:					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
Interventions:					
[Individual therapy group]		◆		◆	
[Usual group]		◆	◆	◆	
Assessments:					
Baseline data	X				
ODI, FES-I, HPQ	X		X	X	X
Absenteeism			X	X	X

*See text definition of absenteeism in this trial.

Sample size

The sample size was calculated using G*Power 3.1. In this study, the primary endpoint was the ODI after 6 months of intervention, with alpha and beta levels set at 0.05 and 0.2, respectively. Based on previous studies examining the effects of individual physical therapy on workers [11], the effect size of the

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individual physical therapy on physical function was estimated to be approximately 0.5. ODI has been found to be associated with items included in the Short Physical Performance Battery (SPPB) It has been shown [19]. Although a dropout rate of 20% is often estimated over the course of a study, it was expected that the participants in this study would be easier to track than in studies involving outpatients because they were health care workers. Therefore, we estimated a dropout rate of 10% and set the number of study participants required for this study at 60 in each group.

Allocation

Sequence generation and concealment

After baseline measurements were completed, a third party not involved in the study assigned participants to either ITG or UG using a computer random number function in R.

Blocking

Anonymized patient information is subjected to block random assignment using R codes, with block sizes ranging from 2 to 6 for women and 2 to 4 for men, and measures are taken to ensure that the assignment order is not specified. The reason for the difference in block sizes for men and women is to minimize the bias in the number of men in the ITG and UG in the event that block sizes are not met, as it is expected that there are few male caregivers working in social welfare facilities. [20]

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Stratification

Subjects randomized to the ITG or UG were stratified by gender, and subsequent subgroup analyses examined effect sizes by gender. Several reports have revealed a higher prevalence and severity of LBP and poorer postoperative outcomes in women compared to men [21–24], and bias of gender in each group is likely to affect primary outcomes.

Implementation of randomization

The order of allocation will be made by a physical therapist affiliated with the UOEH, who is not involved in the study. After obtaining informed consent from the participants, the physical therapist will distribute individual interventions or pamphlets according to the treatment allocation.

Blinding

The evaluation in this survey will be done through a questionnaire. The participants can freely choose whether to respond on paper or via the digital questionnaire. The number of incidences of LBP and falls, as well as the number of workdays lost due to LBP and falls, will be reported by the participants and their facility administrators. Due to the nature of the study, it is difficult to blind the participants to the physical therapist conducting the intervention.

Data collection methods

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The questionnaires used in this study, from the baseline assessment to one year after participation in the study, can be completed by the participants either on paper or using a Google form. Participants who have not responded for more than one week will be listed, contacted, and encouraged to respond. The number of LBP and falls and the number of days of absence related to LBP and falls will be self-reported by study participants and fact-checked with facility administrators, while absence rates will be tabulated as outcomes.

Patient retention

Participants may contact the principal investigator directly or through the facility administrator at any time during the study period if they have questions or concerns about the study, thus preventing participants from dropping out due to dissatisfaction with the study content. Contact information for the principal investigator is provided in the study description. To ensure that participants assigned to each group are complying with the study protocol, the ITG will receive at least one follow-up e-mail per week from the assigned physical therapist throughout the study period, documenting the frequency and duration of interventions and exercise instruction as they occur.

Data management

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Data will be entered and coded in duplicate by two third parties who are not involved in the study to prevent erroneous data entry. The completed database will be stored at the Department of Rehabilitation Medicine, University of Occupational and Environmental Health.

Statistical methods

To deal with any bias in baseline characteristics of study participants assigned to the two groups, the policy was not to adjust for covariate adjustment, given the background that the study was conducted by strict randomization. For the primary endpoint, two-way analysis of variance will be used to compare groups at 6 months post-intervention. Intention-to-treat (ITT) and per-protocol analyses will be used for group differences. If there is a significant difference in the primary endpoint at 6 months post-intervention, the primary and secondary endpoints will be compared at 3 months, 6 months, and 1 year post-intervention. In addition, a subgroup analysis will be performed between males and females to identify differences in the magnitude of the treatment effect by sex. Any missing values for follow-up results during the study period will be supplemented by multiple assignment.

Data monitoring and auditions

This is not applicable to the study since it is not an invasive intervention study.

Harm

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It is expected that muscle pain will occur after performing the LBP and fall prevention exercises that are included in the course content. However, these risks are clearly outweighed by their benefits.

ETHICS AND DISSEMINATION

Research ethics approval

Approval was obtained from the Research Ethics Committee of the University of Occupational and Environmental Health. (Approved on 25 NOV 2021, reception number R3-058). Subsequently, the enrollment in the clinical trial was completed. https://jrct.niph.go.jp/search (jRCT1070210128).

Protocol amendments

After approval by the Ethics Committee, the progress and results of the research at the end of each year are reported to the University Ethics Committee. If during the research, the expected risk is judged higher than the expected benefit, or in case sufficient results cannot be obtained, the research will be terminated, and if sufficient results are obtained, the research will be terminated even during the research period.

Consent or assent

The significance, purpose, and methods of this study, as well as the possible disadvantages and risks that the participants may face will be explained in writing and orally, and the participants will be asked to sign

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a consent form. The contents of the consent form, as well as the study protocol, are published in the Japan registry of clinical trials. https://jrct.niph.go.jp/search (jRCT1070210128).

Confidentiality

No biological samples will be collected in this study, but the data obtained will be kept in a locked vault in the Department of Rehabilitation Medicine under the supervision of the principal investigator. The data obtained in this study will be stored for 5 years after the completion of the study or 3 years from the date of reporting the study results, whichever is later, and then all data will be disposed after confirming anonymization.

Data sharing

De-identified individual participant data collected in this study that support the study results will be shared. These data will also be available for up to three years after publication. Access to the data will be granted only to those who intend to conduct research that also addresses topics related to this study. In addition, a pre-designed research plan must be presented, and analysis to achieve the objectives of the application approved as a research plan by the Ethics Committee will be permitted. For data access applications, permission to use the data must be requested from reha@mbox.med.uoeh-u.ac.jp. The applicant must execute a data access agreement. Information on submitting an application and data access can be obtained

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by visiting the following site and following the contact link. (https://www.uoeh-u.ac.jp/kouza/rihabiri/homepage/contact.html)

Ancillary and post-trial care

Emergency contact information for this research will be made available to the participants so that they can ask questions at any time during and after the research, and the principal investigators and research staff will have a system in place to respond appropriately.

Dissemination policy

We will disseminate our findings through publication in a peer-reviewed journal and conference presentation, and our study will support the development of international clinical practice guidelines.

AUTHORS' CONTRIBUTIONS

Shuto Higuch, Kouhei Funatsu, Keishi Nawata, Satoshi Kuhara, Yoshihisa Fujino, and Satoru Saeki were involved in major parts of the study design, and Shuto Higuch was the principal investigator. The manuscript was prepared by Shuto Higuch, and all members actively participated and contributed to the writing of the manuscript; Kouhei Funatsu, Keishi Nawata, and Yoshihisa Fujino were responsible for the preparation of figures and tables and statistical analysis. All authors reviewed the text and approved the final manuscript.

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COMPETING INTERESTS

None declared.

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FIGURE LEGENDS

Figure 1 Flow chart of the trial. Individual therapy group (ITG) and usual group (UG)

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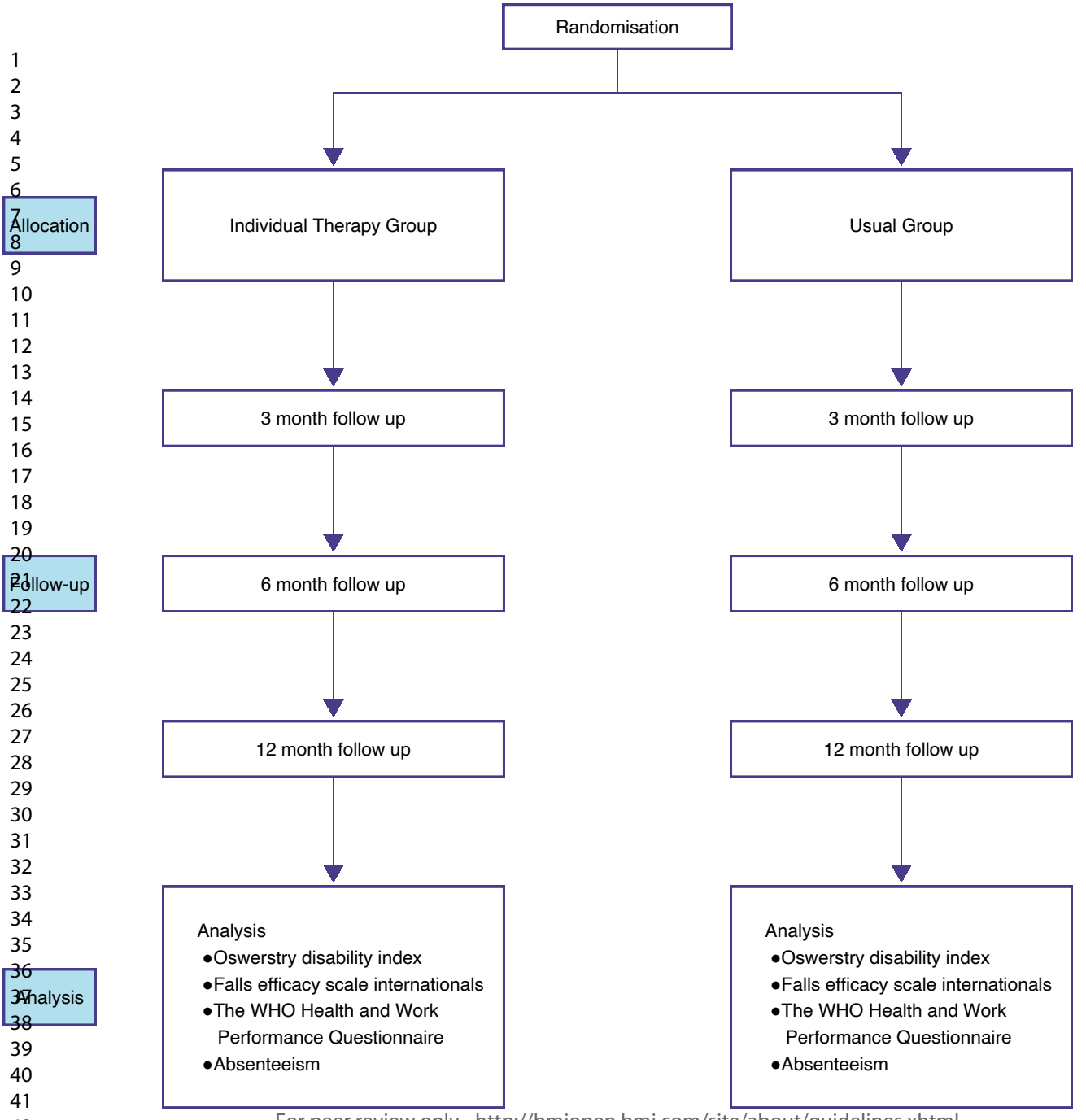

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Figure 1 Flow chart of the trial. Individual therapy group(ITG) and usual group(UG)

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		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	18
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	18
Protocol version	#3	Date and version identifier	18
Funding	#4	Sources and types of financial, material, and other support	20,21
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1,20

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Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	n/a
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	n/a
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	20
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5,6
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	6
Objectives	#7	Specific objectives or hypotheses	6
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	7
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will	7

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		perform the interventions (eg, surgeons, psychotherapists)	
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8,9
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	8
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	16
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	8
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9,10.11
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	12,13
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	13
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	7
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	14

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Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	14
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	14,15
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	15
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	19,20
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	15
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	16
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	16
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	16,17
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	16,17

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Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	16,17
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	n/a
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	18
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	17
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	17,18
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	18
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	18
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	18,19

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Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	21
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	19
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	19,20
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	20
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	19
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	18
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

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Effect of Online Physical Therapy on Workplace Accident-related Outcomes in Nursing Care Worker: Study Protocol of a Multicenter Randomized Controlled Trial

Shuto Higuchi,[1,2*] Kouhei Funatsu,[2] Keishi Nawata,[2] Satoshi Kuhara,[2]
Yoshihisa Fujino[3] and Satoru Saeki[1]

[1]Department of Rehabilitation Medicine, University of Occupational and Environmental Health, Kitakyushu, Japan

[2]Department of Rehabilitation Center, University of Occupational and Environmental Health, Kitakyushu, Japan

[3]Department of Environmental Epidemiology, Institute of Industrial Ecological Sciences, University of Occupational and Environmental Health, Kitakyushu, Japan

***Corresponding author:**

Shuto Higuchi

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Department of Rehabilitation Medicine, University Hospital of Occupational and Environmental Health, 1-1 Iseigaoka, Yahatanishi-ku Kitakyushu-shi, Fukuoka 807-8556, Japan

Phone number: +81-93-603-1611

Fax number: +81-93-603-6691

E-mail: shuto.higu@gmail.com

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ABSTRACT

Introduction: According to the 2017 data, occupational accidents are more common in social welfare facilities compared to other industries; in particular, the number of occupational accidents resulting in four or more days of absence from work due to low back pain (LBP) or falls has increased and is considered problematic. Although physical therapy has been demonstrated to be effective in preventing LBP and falls in older adults living in the community, no randomized controlled trials have examined whether individual online physical therapy can prevent LBP and falls in nursing care workers (NCW).

Methods and analysis: A total of 120 NCW aged 20 years or older will be randomly assigned to an online individualized therapy group (ITG) or usual group (UG) after obtaining informed consent. We defined a NCW as a person who assists disabled and elderly persons with eating, bathing, and toileting activities in social welfare facilities. We will follow up the participants 12 months after the start of the intervention and compare the results at 3, 6, and 12 months. The primary endpoint will be the Oswestry Disability Index (ODI); ITG participants will receive professional advice on LBP and musculoskeletal problems from a physical therapist via online interview and e-mail as often as they wish over a 6-month period; UG participants will only have access to brochures and video feeds related to LBP and fall prevention. Owing

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to the nature of the study, blinding the participants and interventionists is not possible; however, the outcomes will be assessed via a web-based questionnaire to prevent detection bias. The null hypothesis is that there is no clinically important difference in the primary outcome between the two treatment groups and that a decrease in the ODI score of at least 20% is clinically meaningful.

Ethics and dissemination: The Ethics Committee of the Japanese Society of Occupational Medicine approved the protocol of this study. The results of this study will be disseminated through peer-reviewed journals and conference presentations.

Strengths and limitations of this study

Strengths:

・Recruitment of the participants from multiple sites

・Difficulty in introducing researcher bias in the evaluation of the outcomes

Limitations:

・Only cooperative participants will be included, which reduces generalizability

・Lack of blinding of the participants and interveners, which does not exclude the possibility of bias

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INTRODUCTION

Japan's population is aging owing to the decline in the birth rate and increase in life expectancy; it is estimated that by 2025, those aged 65 and over will account for 30% of Japan's total population, and the working-age population will decrease by 10 million people by 2040.[1] As of 2016, there will be a shortage of 0.55 million nursing care workers working (NCW) in social welfare facilities; [2] thus, securing the NCW workforce is an urgent issue.[1,2] Data from 2017 shows that social welfare facilities in Japan have more occupational accidents than other industries, and the percentage of occupational accidents requiring four or more days of absence from work among all industries is increasing every year. This has become a major problem resulting in a shortage of human resources for NCW.[3] Back injuries and falls are particularly common in occupational accidents, accounting for nearly half of the cases, and mostly occurring in social welfare facilities.[3] Low back pain (LBP) and falls have generally been shown to be events that increase in frequency with age; the same trend has been observed in the NCWs.[4] Particularly among workers in their 40s and older, occupational accidents have occurred owing to the physically burdensome assistance unique to NCWs and work in areas with poor footholds.[4] This situation may lead to a decrease in the workforce of NCWs at social welfare facilities, which could reduce productivity and the quality of care, thereby warranting countermeasures.

Several studies have reported on the factors associated with LBP and falls among workers. A study examining the causes of LBP among NCW in social welfare facilities in Japan found that human lifting

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movements and improper posture during bathing were some of the problems.[5] Inappropriate posture generally includes excessive forward bending and twisting movements of the lower back.[6] Studies focusing on the factors that cause workers to fall on the job have found that in addition to being female and over the age of 45, poor balance and lower extremity muscle strength are risk factors for falls.[7-9] The internal factors that contribute to falls and LBP are familiar territory for physical therapists, and systematic reviews of community-dwelling elderly patients have shown that exercise therapy by physical therapists can prevent falls and LBP.[10,11] In recent years, individualized exercise instruction by physical therapists to workers has been shown to improve physical function;[12] however, it is not clear whether physical therapist interventions for workers ultimately contribute to work-related outcomes and work-related injury prevention. Therefore, this study aimed to examine whether individual instruction by physical therapists to NCW in social welfare facilities has an impact on the outcomes related to occupational accidents.

METHODS AND ANALYSIS

Checklist

The protocol for this study was drafted as per the check-list from the Standard Protocol Items for Clinical Trials (SPIRIT).[13]

Patient and public involvement

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There was no involvement of the general public or patients in the development of this study.

Study setting

This is a multicenter, randomized, controlled trial comparing a study group that received only pamphlet distribution and video delivery on LBP and falls with a control group that received individualized management by a physical therapist online. Participating facilities and candidates were recruited through the website of the Department of Rehabilitation Medicine and Development of Rehabilitation Medicine, School of Occupational and Environmental Medicine. In addition, flyers were distributed to social welfare facilities in Kitakyushu City, Fukuoka Prefecture, through interested parties.

Eligibility criteria

Members of the study group will assess the eligibility of the institutions and candidates (20 years of age or older) for participation in the study. Eligibility and exclusion criteria are presented in Box 1. Eligibility for participation in the study is defined as NCW working in a social welfare facility and who provide assistance with eating, bathing, and toileting activities for disabled and elderly persons. All the participants who meet the eligibility criteria would be provided with detailed information regarding the study, and consent will be obtained via a signed informed consent form.

Box 1 Inclusion and exclusion criteria used in the randomized controlled trial

Inclusion criteria

1. Age: 20 years and older, but less than 60 years of age at the start of the study

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2. Sex: Any sex possible

Exclusion criteria

1. Persons with severe visual impairment (disability level 1–6) or hearing impairment (Grade 2–6 disability level *Those with a normal hearing level on one side are included in this category)
2. Those who have a history of spinal disease (surgery)
3. Those who have already received rehabilitation treatment and guidance by physical therapists, etc.
4. Those who wish to retire within one year at the start of the study, or those who are likely to retire during the intervention period or are likely to reach
5. Those who have been advised against participating in the study by their physicians due to medical reasons
6. Those who did not provide consent to participate in the study

Discontinuation criteria

1. Criteria for discontinuation: Those who wish to discontinue participation in the study and request to opt out.
2. Those who have health reasons that make it difficult to participate in the LBP and fall prevention program

Interventions

Individual Therapy Groups (ITG): Online training by physical therapists on LBP and fall prevention would be provided on the study start date. The training session will be pre-recorded and delivered to the participant via chat or email on the study start date, with verification through the facility administrator that they have completed the viewing. The training session will last approximately one hour and will be related to the prevention of physical fitness, falls, LBP, lifestyle-related diseases, and depression. After the course, pamphlets on falls and LBP prevention would be distributed. The content of the pamphlet consists mainly of the muscle strengthening and stretching exercises for the trunk and lower extremities. Based on the results of the baseline (T1) assessment, the physical therapist will provide individualized online instruction according to the exercise guidelines. During the intervention period, the participant will be required to

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perform the exercises and stretches following the instructions of an online physical therapist at least once a week. The type and frequency of exercises and stretches will be tailored to each participant owing to the highly individualized nature of the program. Participants will have unrestricted access to their assigned physical therapist via online meetings, video streaming, or chat and email for 6 months after attending the online seminar.

Usual Group (UG): An online seminar on LBP and fall prevention will be provided by a physical therapist. The delivery method and content will be the same as for the ITG. The pamphlet distributed after the workshop will also be the same as the one distributed at the ITG. A physical therapist not involved in the study would select 3–5 exercises and stretches related to LBP and fall prevention once a week and simultaneously allocate them to the participants via chat and email. This process would continue for up to 6 months after attending the online seminar; however, the participants would not receive advice from the physical therapist.

Outcomes

We chose subjective patient-reported outcomes for all the outcomes because we consider them to be free from evaluation bias of the physical therapy interventionists and allow for appropriate effect judgments. The effect of the intervention will be assessed after 3, 6, and 12 months.

Baseline data

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After registration of the study participants, data such as sex, educational background, employment status, work experience as an employee, type of facility, overtime hours per week, workplace accident-related injury or experience in the previous year, and site of injury will be collected through questionnaires.

Primary outcome

The primary outcome measure of this study is the Oswestry Disability Index (ODI). The primary time point is at 6 months.

ODI

The ODI is used to measure the outcomes of occupation-related disabilities. The Japanese version of ODI has been validated and is the most widely used LBP assessment method in the world. It is characterized by the inclusion of items related to social life.[14,15] Primary outcomes will be assessed at baseline (T1), 3 months post-intervention (T2), 6 months post-intervention (T3), and 1 year post-intervention (T4).

Secondary outcome

Secondary outcomes are measured by the participants self-administered subjective ratings and self-reports. The list of measures of secondary outcomes is shown in Box 2. Participants will be asked to fill out questionnaires concerning the fear of falling and decreased productivity. They will also be asked to self-

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report the number of days absent from work due to LBP and falls. These assessments will be tabulated at each follow-up visit.

Box 2 Outcome measures

Measurements are recorded at 3, 6, and 12 months

Primary outcome measure

1. ODI at 6 months

Secondary outcome measures

1. FES-I
2. HPQ
3. Absenteeism

*See text definition

ODI, Oswestry Disability Index; FES-I, International Falls Evaluation Scale; HPQ; WHO Health and Work Performance Questionnaire.

International Falls Evaluation Scale

The International Falls Evaluation Scale (FES-I) will be used as an outcome measure for occupation-related disability, and a Japanese version of the FES-I has been developed to verify its reliability and validity.[16] The questionnaire consists of two items: fear of falling and falls self-efficacy. Those who have a fear of falling tend to be more eligible for hospitalization attributed to falls than those who are not, which is consistent with the purpose of this study.[17]

WHO Health and Work Performance Questionnaire

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The WHO Health and Work Performance Questionnaire (HPQ) will be used to investigate the impact of the intervention on the presenteeism of the workers; the reliability and validity of the Japanese version of the HPQ have been validated.[18,19]

Absenteeism

In this study, absenteeism due to falls was defined as the frequency of absenteeism of 4 or more days attributed to falls. In addition, absenteeism due to LBP was defined as absenteeism of 4 or more days attributed to LBP. In addition, the frequency of occurrence and the total number of 4 or more days will be recorded as occupation-related injuries, including falls and LBP, and will be monitored during the follow-up period from the start point of the intervention.

Participant timeline

The timelines for enrolment, assessment, and intervention of this study are shown in Table 1. A flow diagram of the study is shown in Figure 1.

Table 1 Schedule of the enrolment, interventions, and assessments

	Study period				
	Enrolment	Allocation	Post allocation		
Time point			3 months	6 months	12 months
Enrolment:					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
Interventions:					
[Individual therapy group]		◆		◆	
[Usual group]		◆	◆	◆	

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Assessments:				
Baseline data	X			
ODI, FES-I, HPQ	X	X	X	X
Absenteeism		X	X	X

*See text definition of absenteeism in this trial.

Sample size

The sample size was calculated using G*Power 3.1. In this study, the primary endpoint was the ODI after 6 months of intervention, with alpha and beta levels set at 0.05 and 0.2, respectively. Based on previous studies examining the effects of individual physical therapy on workers [12], the effect size of individual physical therapy on physical function was estimated to be approximately 0.5. ODI has been found to be associated with items included in the Short Physical Performance Battery (SPPB).[20] The SPPB has been used in previous studies to assess lower extremity We determined that the ODI could indirectly reflect the physical function of the participants because the SPPB has been shown to be a valid assessment battery that characterizes physical function, primarily muscle strength, balance function, and walking ability[21]. Although a dropout rate of 20% is often estimated over the course of a study, it was expected that the participants in this study would be easier to track than in studies involving outpatients since they were

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health care workers. Therefore, we estimated a dropout rate of 10% and set the number of study participants required for this study as 60 in each group.

Allocation

Sequence generation and concealment

After the baseline measurements were completed, a third party not involved in the study would assign the participants to either ITG or UG using a computer random number function in R.

Stratification

Participants randomized to the ITG or UG would be stratified by sex, and subsequent subgroup analyses will examine the effect sizes by sex. Several reports have revealed a higher prevalence and severity of LBP and poorer postoperative outcomes in women compared to men [22–25], The difference in the distribution of the number of women in each group could render the primary outcome, the ODI score, more severe.

Implementation of randomization

The order of allocation would be decided by a physical therapist affiliated with the UOEH, who will not be involved in the study. After obtaining informed consent from the participants, the physical therapist will distribute individual interventions or pamphlets according to the treatment allocation.

Blinding

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The evaluation in this survey will be performed through a questionnaire. The participants can freely choose whether to respond on paper or via the digital questionnaire. The number of incidences of LBP and falls, as well as the number of workdays lost due to LBP and falls, will be reported by the participants and their facility administrators. Owing to the nature of the study, blinding of the participants to the physical therapist conducting the intervention is challenging.

Data collection methods

The questionnaires used in this study, from the baseline assessment to one year after participation in the study, can be completed by the participants either on paper or via a Google form. Participants who have not responded for more than one week will be listed, contacted, and encouraged to respond. The number of occurrences of LBP and falls and the number of days of absence related to LBP and falls will be self-reported by the study participants and evaluated by facility administrators, while the absence rates will be tabulated as outcomes.

Participant retention

Participants may contact the principal investigator directly or through the facility administrator at any time during the study period if they have any questions or concerns about the study, thereby preventing participants from dropping out due to dissatisfaction with the study content. Contact information for the

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principal investigator is provided in the study description. To ensure compliance of the participants assigned to each group with the study protocol, the ITG will receive at least one follow-up e-mail per week from the assigned physical therapist throughout the study period, documenting the frequency and duration of interventions and exercise instruction as they occur.

Data management

Data will be entered and coded in duplicate by two third parties who will not be involved in the study to prevent erroneous data entry. The completed database will be stored at the Department of Rehabilitation Medicine, University of Occupational and Environmental Health.

Statistical methods

Strict randomization is used to address differences in the number of confounders randomly assigned to the two groups, but covariate adjustments are made as appropriate depending on the distribution of confounders. If confounders were found after assignment, analyses would be conducted in models with and without adjustment for confounders as covariates. Intervention effects would also be presented separately for each model. For the primary endpoint, two-way analysis of variance will be used to compare the groups at 6 months post-intervention. Intention-to-treat and per-protocol analyses will be used for group differences. If there is a significant difference in the primary endpoint at 6 months post-intervention,

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the primary and secondary endpoints will be compared at 3 months, 6 months, and 1 year post-intervention. In addition, a subgroup analysis will be performed between males and females to identify the differences in the magnitude of the treatment effect by sex. Any missing values for follow-up results during the study period will be supplemented by multiple assignment. Owing to the difficulty in strictly controlling the intervention time for participants assigned to the ITG group and the video viewing time in the UG group in this study, we did not consider the differences in the amount of individual intervention in our analysis.

Data monitoring and auditions

This is not applicable to the study since it is not an invasive intervention study.

Harm

Muscle pain is wxpected after performing the LBP and fall prevention exercises that are included in the course content. However, these risks are clearly outweighed by their benefits.

ETHICS AND DISSEMINATION

Research ethics approval

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Approval was obtained from the Research Ethics Committee of the University of Occupational and Environmental Health. (Approved on 25 NOV 2021, reception number R3-058). Subsequently, the enrollment in the clinical trial was completed. https://jrct.niph.go.jp/search (jRCT1070210128).

Protocol amendments

After approval by the Ethics Committee, the progress and results of the research at the end of each year will be reported to the University Ethics Committee. If during the research, the expected risk is judged higher than the expected benefit, or in case sufficient results cannot be obtained, the research will be terminated, and if sufficient results are obtained, the research will be terminated even during the research period.

Consent or assent

The significance, purpose, and methods of this study, as well as the possible disadvantages and risks that the participants may face would be explained verbally and in writing, and the participants will be asked to sign a consent form. The contents of the consent form, as well as the study protocol, are published in the Japan registry of clinical trials (https://jrct.niph.go.jp/search [jRCT1070210128]). [supplementary file]

Confidentiality

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No biological samples will be collected in this study; however, the data obtained will be kept in a locked vault in the Department of Rehabilitation Medicine under the supervision of the principal investigator. The data obtained in this study will be stored for 5 years after the completion of the study or 3 years from the date of reporting the study results, whichever is later, and then all the data will be disposed after confirming anonymization.

Data sharing

De-identified individual participant data collected in this study that support the study results will be shared. These data will also be available for up to three years after publication. Access to the data will be granted only to those who intend to conduct research that also addresses topics related to this study. In addition, a pre-designed research plan must be presented, and analysis to achieve the objectives of the application approved as a research plan by the Ethics Committee will be permitted. For data access applications, permission to use the data must be requested from reha@mbox.med.uoeh-u.ac.jp. The applicant must execute a data access agreement. Information on submitting an application and data access can be obtained by visiting the following site and following the contact link. (https://www.uoeh-u.ac.jp/kouza/rihabiri/homepage/contact.html)

Ancillary and post-trial care

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Emergency contact information for this research will be made available to the participants so that they can ask questions at any time during and after the research, and the principal investigators and research staff will have a system in place to respond appropriately.

Dissemination policy

We will disseminate our findings through publication in a peer-reviewed journal and conference presentation, and our study will support the development of international clinical practice guidelines.

AUTHORS' CONTRIBUTIONS

Shuto Higuch, Kouhei Funatsu, Keishi Nawata, Satoshi Kuhara, Yoshihisa Fujino, and Satoru Saeki were involved in major parts of the study design, and Shuto Higuch was the principal investigator. The manuscript was prepared by Shuto Higuch, and all members actively participated and contributed to the writing of the manuscript; Kouhei Funatsu, Keishi Nawata, and Yoshihisa Fujino were responsible for the preparation of figures and tables and statistical analysis. All authors reviewed the text and approved the final manuscript.

FUNDING

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COMPETING INTERESTS

None declared.

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FIGURE LEGENDS

Figure 1. Flow chart of the trial. Individual therapy group (ITG) and usual group (UG)

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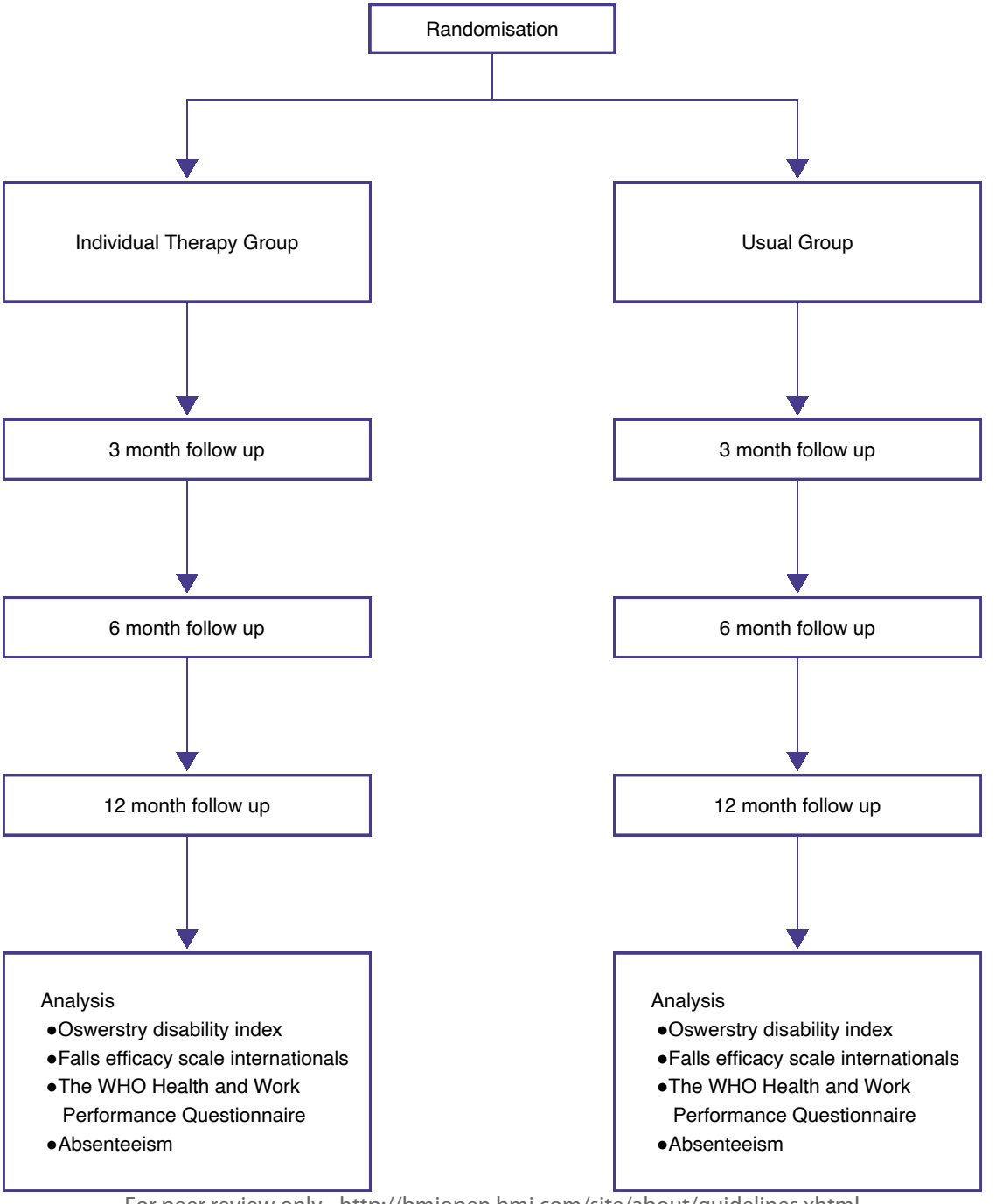

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Figure 1 Flow chart of the trial. Individual therapy group(ITG) and usual group(UG)

同　意　書

産業医科大学　学長 殿

私は、西暦2022年1月から西暦2024年12月までの期間、産業医科大学医学部リハビリテーション医学講座で実施される「社会福祉施設の介護従事者に対するオンライン転倒・腰痛プログラムの有効性に関する研究」について、事前に説明文書を受け取り、研究実施担当者から、説明文書に基づいて、研究の目的、意義、方法、対象者が受ける不利益及び危険性、個人情報の保護などに関して、十分な説明を受けました。

また、私が、研究参加に同意した後も、何時でも自らの意思で研究参加を取止めることができること、及び研究参加を取止めた後も何ら不利益を受けないことについても説明を受けました。

以上のことを理解した上で、私の意思により、この研究に参加することに同意します。

説明を受け理解した項目　（　確認欄にご自身で〇を記入してください。）

確認欄	項　　目	説明文書項目
	研究の目的、意義及び方法	4，5
	研究対象者として選定された理由	6
	予測される利益、リスクと不利益	7
	研究参加の任意性とその同意の撤回の自由	8，9
	研究に関する情報公開の方法	10，11
	個人情報の保護	12
	個人情報などの保管及び廃棄方法	13
	研究の資金源と利益相反	14
	研究により得られた結果等の取扱い	15
	研究対象者等からの相談等への対応	16
	費用の負担に関すること	17
	通常の診療を超える研究について	18，19
	研究業務の一部を委託する場合の業務内容と監督方法について	20
	研究対象者の健康等への影響について	21
	研究対象者から得た情報などの将来的活用	22
	モニタリング及び監査方法	23
	知的財産の発生について	24
	その他	25

（本人）
同意年月日　西暦　　年　　月　　日

ご署名＿＿＿＿＿＿＿＿＿＿＿＿

（代諾者）・・・必要な場合のみ
同意年月日　西暦　　年　　月　　日

ご署名＿＿＿＿＿＿＿＿＿＿（続柄　　）

上記の研究について私が説明をしました。
説明年月日　西暦　　年　　月　　日

所属名＿＿＿＿＿＿＿＿　氏名＿＿＿＿＿＿＿＿

連　　絡　　先：産業医科大学リハビリテーション医学講座　電話番号 093-691-7266
研究実施責任者：産業医科大学リハビリテーション医学講座　教授　佐伯　覚

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Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	17,18
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	17,18
Protocol version	#3	Date and version identifier	18
Funding	#4	Sources and types of financial, material, and other support	20,21
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1,20

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Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	n/a
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	n/a
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	20
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5,6
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	6
Objectives	#7	Specific objectives or hypotheses	6
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	7
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will	7,8

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		perform the interventions (eg, surgeons, psychotherapists)	
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8,9
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	18,19,20
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	15,16
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	7,8
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	10,11,12
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	12,13
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	13,14
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	7
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	14

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Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	14
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	14
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	14,15
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	19,20
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	15
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	16
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	16
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	16,17
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	16,17

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Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	16,17
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	n/a
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	18
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	17
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	17,18
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	18
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	18
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect	18,19

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		confidentiality before, during, and after the trial	
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	20
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	19
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	19,20
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	20
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	19
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	18
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

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Effect of Online Physical Therapy on Workplace Accident-Related Outcomes in Nursing Care Worker : Study Protocol of a Multicenter Randomized Controlled Trial

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Effect of Online Physical Therapy on Workplace Accident-related Outcomes in Nursing Care Worker: Study Protocol of a Multicenter Randomized Controlled Trial

Shuto Higuchi,[1,2*] Kouhei Funatsu,[2] Keishi Nawata,[2] Satoshi Kuhara,[2]

Yoshihisa Fujino[3] and Satoru Saeki[1]

[1]Department of Rehabilitation Medicine, University of Occupational and Environmental Health, Kitakyushu, Japan

[2]Department of Rehabilitation Center, University of Occupational and Environmental Health, Kitakyushu, Japan

[3]Department of Environmental Epidemiology, Institute of Industrial Ecological Sciences, University of Occupational and Environmental Health, Kitakyushu, Japan

***Corresponding author:**

Shuto Higuchi

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Department of Rehabilitation Medicine, University Hospital of Occupational and Environmental Health, 1-1 Iseigaoka, Yahatanishi-ku Kitakyushu-shi, Fukuoka 807-8556, Japan

Phone number: +81-93-603-1611

Fax number: +81-93-603-6691

E-mail: shuto.higu@gmail.com

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ABSTRACT

Introduction: According to the 2017 data, occupational accidents are more common in social welfare facilities compared to other industries; in particular, the number of occupational accidents resulting in four or more days of absence from work due to low back pain (LBP) or falls has increased and is considered problematic. Although physical therapy has been demonstrated to be effective in preventing LBP and falls in older adults living in the community, no randomized controlled trials have examined whether individual online physical therapy can prevent LBP and falls in nursing care workers (NCW).

Methods and analysis: A total of 120 NCW aged 20 years or older will be randomly assigned to an online individualized therapy group (ITG) or usual group (UG) after obtaining informed consent. We defined a NCW as a person who assists disabled and elderly persons with eating, bathing, and toileting activities in social welfare facilities. We will follow up the participants 12 months after the start of the intervention and compare the results at 3, 6, and 12 months. The primary endpoint will be the Oswestry Disability Index (ODI); ITG participants will receive professional advice on LBP and musculoskeletal problems from a physical therapist via online interview and e-mail as often as they wish over a 6-month period; UG participants will only have access to brochures and video feeds related to LBP and fall prevention. Owing to the nature of the study, blinding the participants and interventionists is not possible; however, the outcomes will be assessed via a web-based questionnaire to prevent detection bias. The null hypothesis is

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that there is no clinically important difference in the primary outcome between the two treatment groups and that a decrease in the ODI score of at least 20% is clinically meaningful.

Ethics and dissemination: The Ethics Committee of the Japanese Society of Occupational Medicine approved the protocol of this study. The results of this study will be disseminated through peer-reviewed journals and conference presentations.

Strengths and limitations of this study

Strengths:

- Recruitment of the participants from multiple sites
- Difficulty in introducing researcher bias in the evaluation of the outcomes

Limitations:

- Only cooperative participants will be included, which reduces generalizability
- Lack of blinding of the participants and interveners, which does not exclude the possibility of bias

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INTRODUCTION

Japan's population is aging owing to the decline in the birth rate and increase in life expectancy; it is estimated that by 2025, those aged 65 and over will account for 30% of Japan's total population, and the working-age population will decrease by 10 million people by 2040. [1] As of 2016, there will be a shortage of 0.55 million nursing care workers working (NCW) in social welfare facilities; [2] thus, securing the NCW workforce is an urgent issue. [1,2] Data from 2017 shows that social welfare facilities in Japan have more occupational accidents than other industries, and the percentage of occupational accidents requiring four or more days of absence from work among all industries is increasing every year. This has become a major problem resulting in a shortage of human resources for NCW. [3] Back injuries and falls are particularly common in occupational accidents, accounting for nearly half of the cases, and mostly occurring in social welfare facilities. [3] Low back pain (LBP) and falls have generally been shown to be events that increase in frequency with age; the same trend has been observed in the NCWs. [4] Particularly among workers in their 40s and older, occupational accidents have occurred owing to the physically burdensome assistance unique to NCWs and work in areas with poor footholds. [4] This situation may lead to a decrease in the workforce of NCWs at social welfare facilities, which could reduce productivity and the quality of care, thereby warranting countermeasures.

Several studies have reported on the factors associated with LBP and falls among workers. A study examining the causes of LBP among NCW in social welfare facilities in Japan found that human lifting

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movements and improper posture during bathing were some of the problems. [5] Inappropriate posture generally includes excessive forward bending and twisting movements of the lower back.[6] Studies focusing on the factors that cause workers to fall on the job have found that in addition to being female and over the age of 45, poor balance and lower extremity muscle strength are risk factors for falls. [7-9] The internal factors that contribute to falls and LBP are familiar territory for physical therapists, and systematic reviews of community-dwelling elderly patients have shown that exercise therapy by physical therapists can prevent falls and LBP. [10,11] In recent years, individualized exercise instruction by physical therapists to workers has been shown to improve physical function. [12] however, it is not clear whether physical therapist interventions for workers ultimately contribute to work-related outcomes and work-related injury prevention. Therefore, this study aimed to examine whether individual instruction by physical therapists to NCW in social welfare facilities has an impact on the outcomes related to occupational accidents.

METHODS AND ANALYSIS

Checklist

The protocol for this study was drafted as per the check-list from the Standard Protocol Items for Clinical Trials (SPIRIT). [13]

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Patient and public involvement

There was no involvement of the general public or patients in the development of this study.

Study setting

This is a multicenter, randomized, controlled trial comparing a study group that received only pamphlet distribution and video delivery on LBP and falls with a control group that received individualized management by a physical therapist online. Participating facilities and candidates were recruited through the website of the Department of Rehabilitation Medicine and Development of Rehabilitation Medicine, School of Occupational and Environmental Medicine. In addition, flyers were distributed to social welfare facilities in Kitakyushu City, Fukuoka Prefecture, through interested parties.

Eligibility criteria

Members of the study group will assess the eligibility of the institutions and candidates (20 years of age or older) for participation in the study. Eligibility and exclusion criteria are presented in Box 1. Eligibility for participation in the study is defined as NCW working in a social welfare facility and who provide assistance with eating, bathing, and toileting activities for disabled and elderly persons. All the participants who meet the eligibility criteria would be provided with detailed information regarding the study, and consent will be obtained via a signed informed consent form.

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Box 1 Inclusion and exclusion criteria used in the randomized controlled trial

Inclusion criteria

1. Age: 20 years and older, but less than 60 years of age at the start of the study
2. Sex: Any sex possible

Exclusion criteria

1. Persons with severe visual impairment (disability level 1–6) or hearing impairment (Grade 2–6 disability level *Those with a normal hearing level on one side are included in this category)
2. Those who have a history of spinal disease (surgery)
3. Those who have already received rehabilitation treatment and guidance by physical therapists, etc.
4. Those who wish to retire within one year at the start of the study, or those who are likely to retire during the intervention period or are likely to reach
5. Those who have been advised against participating in the study by their physicians due to medical reasons
6. Those who did not provide consent to participate in the study

Discontinuation criteria

1. Criteria for discontinuation: Those who wish to discontinue participation in the study and request to opt out.
2. Those who have health reasons that make it difficult to participate in the LBP and fall prevention Program

Interventions

Individual Therapy Groups (ITG): Online training by physical therapists on LBP and fall prevention would be provided on the study start date. Training sessions will be pre-recorded and distributed to participants via chat or email on the study start date, 3 months, and 6 months, and viewing completion will be verified by the facility manager. The training session will last approximately one hour and will be related to the prevention of physical fitness, falls, LBP, lifestyle-related diseases, and depression. After the course, pamphlets on falls and LBP prevention would be distributed. The content of the pamphlet consists mainly of the muscle strengthening and stretching exercises for the trunk and lower extremities. Based on the results of the baseline (T1) assessment, the physical therapist will provide individualized online instruction

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according to the exercise guidelines. During the intervention period, the participant will be required to perform the exercises and stretches following the instructions of an online physical therapist at least once a week. The type and frequency of exercises and stretches will be tailored to each participant owing to the highly individualized nature of the program. Participants will have unrestricted access to their assigned physical therapist via online meetings, video streaming, or chat and email for 6 months after attending the online seminar.

Usual Group (UG): An online seminar on LBP and fall prevention will be provided by a physical therapist. The delivery method and content will be the same as for the ITG. The pamphlet distributed after the workshop will also be the same as the one distributed at the ITG. A physical therapist not involved in the study would select 3–5 exercises and stretches related to LBP and fall prevention once a week and simultaneously allocate them to the participants via chat and email. This process would continue for up to 6 months after attending the online seminar; however, the participants would not receive advice from the physical therapist.

Outcomes

We chose patient subject-reported outcomes other than absenteeism because we believe that there would be no assessment bias by the physical therapy interventionists and that appropriate effectiveness determinations can be assessed in a short period of time and with a realistic sample size. The effectiveness

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of the interventions will be assessed at 3, 6, and 12 months. Absenteeism will be evaluated at similar time points and reported by the facility administrator or the individual, along with a physician's diagnosis.

Baseline data

After registration of the study participants, data such as sex, educational background, employment status, work experience as an employee, type of facility, overtime hours per week, workplace accident-related injury or experience in the previous year, and site of injury will be collected through questionnaires.

Primary outcome

The primary outcome measure of this study is the Oswestry Disability Index (ODI). The primary time point is at 6 months.

ODI

The ODI is used to measure the outcomes of occupation-related disabilities. The Japanese version of ODI has been validated and is the most widely used LBP assessment method in the world. It is characterized by the inclusion of items related to social life. [14,15] Primary outcomes will be assessed at baseline (T1), 3 months post-intervention (T2), 6 months post-intervention (T3), and 1 year post-intervention (T4).

Secondary outcome

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Secondary outcomes are measured by the participants self-administered subjective ratings and self-reports. The list of measures of secondary outcomes is shown in Box 2. Participants will be asked to fill out questionnaires concerning the fear of falling and decreased productivity. They will also be asked to self-report the number of days of absence from work due to LBP and falls, along with a physician's note. These assessments will be tabulated at each follow-up visit.

Box 2 Outcome measures

Measurements are recorded at 3, 6, and 12 months

Primary outcome measure

1. ODI at 6 months

Secondary outcome measures

1. FES-I
2. HPQ
3. Absenteeism

*See text definition

ODI, Oswestry Disability Index; FES-I, International Falls Evaluation Scale; HPQ; WHO Health and Work Performance Questionnaire.

International Falls Evaluation Scale

The International Falls Evaluation Scale (FES-I) will be used as an outcome measure for occupation-related disability, and a Japanese version of the FES-I has been developed to verify its reliability and validity. [16] The questionnaire consists of two items: fear of falling and falls self-efficacy. Those who have a fear of falling tend to be more eligible for hospitalization attributed to falls than those who are not, which is consistent with the purpose of this study. [17]

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WHO Health and Work Performance Questionnaire

The WHO Health and Work Performance Questionnaire (HPQ) will be used to investigate the impact of the intervention on the presenteeism of the workers; the reliability and validity of the Japanese version of the HPQ have been validated. [18,19]

Absenteeism

In this study, absenteeism due to falls was defined as the frequency of absenteeism of 4 or more days attributed to falls. In addition, absenteeism due to LBP was defined as absenteeism of 4 or more days attributed to LBP. In addition, the frequency of occurrence and the total number of 4 or more days will be recorded as occupation-related injuries, including falls and LBP, and will be monitored during the follow-up period from the start point of the intervention.

Participant timeline

The timelines for enrolment, assessment, and intervention of this study are shown in Table 1. A flow diagram of the study is shown in Figure 1.

Table 1 Schedule of the enrolment, interventions, and assessments

	Study period				
	Enrolment	Allocation	Post allocation		
Time point			3 months	6 months	12 months
Enrolment:					
Eligibility screen	X				
Informed consent	X				
Allocation		X			

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Interventions:					
	[Individual therapy group]		◆-----	----◆	
	[Usual group]		◆	◆ ◆	
Assessments:					
	Baseline data	**X**			
	ODI, FES-I, HPQ	**X**	**X**	**X**	**X**
	Absenteeism		**X**	**X**	**X**

***See text definition of absenteeism in this trial.**

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Sample size

The sample size was calculated using G*Power 3.1. In this study, the primary endpoint was the ODI after 6 months of intervention, with alpha and beta levels set at 0.05 and 0.2, respectively. Based on previous studies examining the effects of individual physical therapy on workers in manufacturing industries, [12] the effect size of individual physical therapy on physical function was estimated to be approximately 0.5. ODI has been found to be associated with items included in the Short Physical Performance Battery (SPPB). [20] The SPPB was validated in a random sample of 5,000 individuals aged 70 years and above from three regions of the United States-East Boston, Massachusetts, and Washington, D.C. Although originally developed to assess lower extremity function in the elderly, the SPPB has proven to be a feasible assessment of physical function of workers in the manufacturing industry. [12, 21] We determined that the ODI could indirectly reflect the physical function of the participants because the SPPB has been shown to be a valid assessment battery that characterizes physical function, primarily muscle strength, balance

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function, and walking ability. [21] Although a dropout rate of 20% is often estimated over the course of a study, it was expected that the participants in this study would be easier to track than in studies involving outpatients since they were health care workers. Therefore, we estimated a dropout rate of 10% and set the number of study participants required for this study as 60 in each group.

Allocation

Sequence generation and concealment

After the baseline measurements were completed, a third party not involved in the study would assign the participants to either ITG or UG using a computer random number function in R.

Stratification

Participants randomized to the ITG or UG would be stratified by sex, and subsequent subgroup analyses will examine the effect sizes by sex. Several reports have revealed a higher prevalence and severity of LBP and poorer postoperative outcomes in women compared to men, [22–25] The difference in the distribution of the number of women in each group could render the primary outcome, the ODI score, more severe.

Implementation of randomization

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The order of allocation would be decided by a physical therapist affiliated with the UOEH, who will not be involved in the study. After obtaining informed consent from the participants, the physical therapist will distribute individual interventions or pamphlets according to the treatment allocation.

Blinding

The evaluation in this survey will be performed through a questionnaire. The participants can freely choose whether to respond on paper or via the digital questionnaire. The number of incidences of LBP and falls, as well as the number of workdays lost due to LBP and falls, will be reported by the participants and their facility administrators. Owing to the nature of the study, blinding of the participants to the physical therapist conducting the intervention is challenging. Therefore, there is a potential for bias in the projected effects of this research. We will mention them as research limitations when discussing this study's findings.

Data collection methods

The questionnaires used in this study, from the baseline assessment to one year after participation in the study, can be completed by the participants either on paper or via a Google form. Participants who have not responded for more than one week will be listed, contacted, and encouraged to respond. The number of occurrences of LBP and falls and the number of days of absence related to LBP and falls will be self-reported by the study participants and evaluated by facility administrators, while the absence rates will be tabulated as outcomes.

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Participant retention

Participants may contact the principal investigator directly or through the facility administrator at any time during the study period if they have any questions or concerns about the study, thereby preventing participants from dropping out due to dissatisfaction with the study content. Contact information for the principal investigator is provided in the study description. To ensure compliance of the participants assigned to each group with the study protocol, the ITG will receive at least one follow-up e-mail per week from the assigned physical therapist throughout the study period, documenting the frequency and duration of interventions and exercise instruction as they occur.

Data management

Data will be entered and coded in duplicate by two third parties who will not be involved in the study to prevent erroneous data entry. The completed database will be stored at the Department of Rehabilitation Medicine, University of Occupational and Environmental Health.

Statistical methods

Strict randomization is used to address differences in the number of confounders randomly assigned to the two groups, but covariate adjustments are made as appropriate depending on the distribution of confounders. Regarding confounding factors, a study of healthcare workers, primarily nurses, found that

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the odds ratio (OR) of developing low back pain increased by 1.06 for every 1-year increase in age. Previous studies have also found that being female increases the risk of developing low back pain by 1.79 ORs. Based on previous studies and discussions with researchers, we decided to consider age and sex as confounding factors, considering that these two variables ensure convenient information collection and are likely to influence outcomes [26-28]. Other confounders, such as high body mass index [28], premenstrual tension [29], number of manual patient lifts per day, and low job satisfaction [30], were considered in previous studies to be associated with low back pain and were therefore treated as potential confounders in this study. Furthermore, if the distribution of baseline data other than age and sex is not equal, it is up to the experts, including the coauthors, to decide whether to treat them as confounders. Statistical significance will not be used to determine confounding factors, and experts will discuss only the presence or absence of significance based on the descriptive distribution of the data. If confounders were found after assignment, analyses would be conducted in models with and without adjustment for confounders as covariates. Intervention effects would also be presented separately for each model. For the primary endpoint, two-way analysis of variance will be used to compare the groups at 6 months post-intervention. Intention-to-treat and per-protocol analyses will be used for group differences. If there is a significant difference in the primary endpoint at 6 months post-intervention, the primary and secondary endpoints will be compared at 3 months, 6 months, and 1 year post-intervention. In addition, a subgroup analysis will be performed between males and females to identify the differences in the magnitude of the treatment effect by sex. Any

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missing values for follow-up results during the study period will be supplemented by multiple assignment. Owing to the difficulty in strictly controlling the intervention time for participants assigned to the ITG group and the video viewing time in the UG group in this study, we did not consider the differences in the amount of individual intervention in our analysis.

Data monitoring and auditions

This is not applicable to the study since it is not an invasive intervention study.

Harm

Muscle pain is expected after performing the LBP and fall prevention exercises that are included in the course content. However, these risks are clearly outweighed by their benefits.

ETHICS AND DISSEMINATION

Research ethics approval

Approval was obtained from the Research Ethics Committee of the University of Occupational and Environmental Health. (Approved on 25 NOV 2021, reception number R3-058). Subsequently, the enrollment in the clinical trial was completed. https://jrct.niph.go.jp/search (jRCT1070210128).

Protocol amendments

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After approval by the Ethics Committee, the progress and results of the research at the end of each year will be reported to the University Ethics Committee. If during the research, the expected risk is judged higher than the expected benefit, or in case sufficient results cannot be obtained, the research will be terminated, and if sufficient results are obtained, the research will be terminated even during the research period.

Consent or assent

The significance, purpose, and methods of this study, as well as the possible disadvantages and risks that the participants may face would be explained verbally and in writing, and the participants will be asked to sign a consent form. The contents of the consent form, as well as the study protocol, are published in the Japan registry of clinical trials (https://jrct.niph.go.jp/search [jRCT1070210128]). [supplementary file]

Confidentiality

No biological samples will be collected in this study; however, the data obtained will be kept in a locked vault in the Department of Rehabilitation Medicine under the supervision of the principal investigator. The data obtained in this study will be stored for 5 years after the completion of the study or 3 years from the date of reporting the study results, whichever is later, and then all the data will be disposed after confirming anonymization.

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Data sharing

De-identified individual participant data collected in this study that support the study results will be shared. These data will also be available for up to three years after publication. Access to the data will be granted only to those who intend to conduct research that also addresses topics related to this study. In addition, a pre-designed research plan must be presented, and analysis to achieve the objectives of the application approved as a research plan by the Ethics Committee will be permitted. For data access applications, permission to use the data must be requested from reha@mbox.med.uoeh-u.ac.jp. The applicant must execute a data access agreement. Information on submitting an application and data access can be obtained by visiting the following site and following the contact link. (https://www.uoeh-u.ac.jp/kouza/rihabiri/homepage/contact.html)

Ancillary and post-trial care

Emergency contact information for this research will be made available to the participants so that they can ask questions at any time during and after the research, and the principal investigators and research staff will have a system in place to respond appropriately.

Dissemination policy

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We will disseminate our findings through publication in a peer-reviewed journal and conference presentation, and our study will support the development of international clinical practice guidelines.

AUTHORS' CONTRIBUTIONS

Shuto Higuch, Kouhei Funatsu, Keishi Nawata, Satoshi Kuhara, Yoshihisa Fujino, and Satoru Saeki were involved in major parts of the study design, and Shuto Higuch was the principal investigator. The manuscript was prepared by Shuto Higuch, and all members actively participated and contributed to the writing of the manuscript; Kouhei Funatsu, Keishi Nawata, and Yoshihisa Fujino were responsible for the preparation of figures and tables and statistical analysis. All authors reviewed the text and approved the final manuscript.

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COMPETING INTERESTS

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None declared.

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FIGURE LEGENDS

Figure 1. Flow chart of the trial. Individual therapy group (ITG) and usual group (UG)

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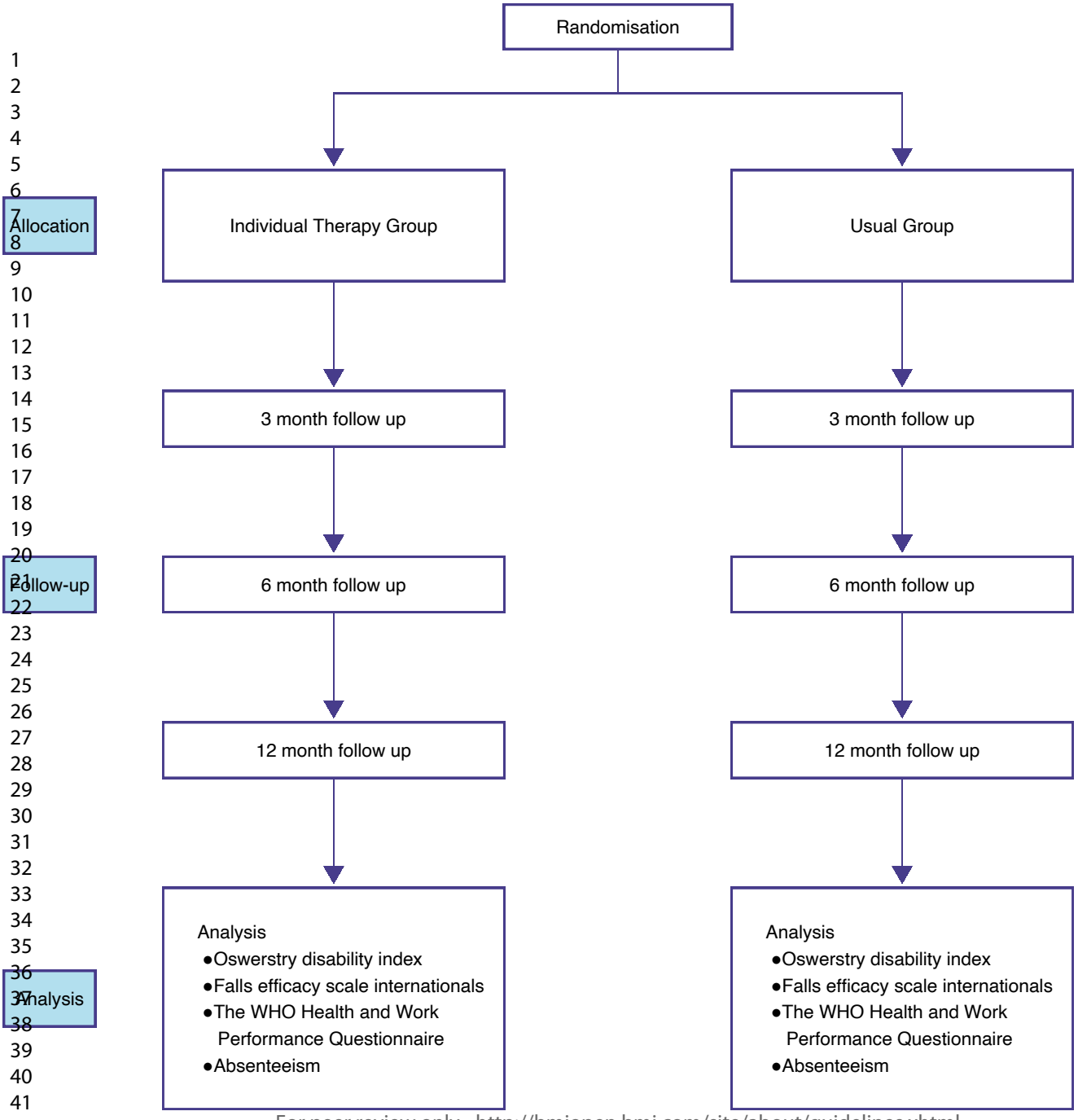

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Figure 1 Flow chart of the trial. Individual therapy group(ITG) and usual group(UG)

同　意　書

産業医科大学　学長 殿

私は、西暦2022年1月から西暦2024年12月までの期間、産業医科大学医学部リハビリテーション医学講座で実施される「社会福祉施設の介護従事者に対するオンライン転倒・腰痛プログラムの有効性に関する研究」について、事前に説明文書を受け取り、研究実施担当者から、説明文書に基づいて、研究の目的、意義、方法、対象者が受ける不利益及び危険性、個人情報の保護などに関して、十分な説明を受けました。

また、私が、研究参加に同意した後も、何時でも自らの意思で研究参加を取止めることができること、及び研究参加を取止めた後も何ら不利益を受けないことについても説明を受けました。

以上のことを理解した上で、私の意思により、この研究に参加することに同意します。

説明を受け理解した項目　（　確認欄にご自身で〇を記入してください。）

確認欄	項　　目	説明文書項目
	研究の目的、意義及び方法	4，5
	研究対象者として選定された理由	6
	予測される利益、リスクと不利益	7
	研究参加の任意性とその同意の撤回の自由	8，9
	研究に関する情報公開の方法	10，11
	個人情報の保護	12
	個人情報などの保管及び廃棄方法	13
	研究の資金源と利益相反	14
	研究により得られた結果等の取扱い	15
	研究対象者等からの相談等への対応	16
	費用の負担に関すること	17
	通常の診療を超える研究について	18，19
	研究業務の一部を委託する場合の業務内容と監督方法について	20
	研究対象者の健康等への影響について	21
	研究対象者から得た情報などの将来的活用	22
	モニタリング及び監査方法	23
	知的財産の発生について	24
	その他	25

（本人）
同意年月日　西暦　　年　　月　　日

ご署名＿＿＿＿＿＿＿＿＿＿＿＿

（代諾者）・・・必要な場合のみ
同意年月日　西暦　　年　　月　　日

ご署名＿＿＿＿＿＿＿＿＿＿＿＿（続柄　　）

上記の研究について私が説明をしました。
説明年月日　西暦　　年　　月　　日

所属名＿＿＿＿＿＿＿＿　氏名＿＿＿＿＿＿＿＿

連　　絡　　先：産業医科大学リハビリテーション医学講座　電話番号 093-691-7266
研究実施責任者：産業医科大学リハビリテーション医学講座　教授　佐伯　覚

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Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

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		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	18
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	18
Protocol version	#3	Date and version identifier	18
Funding	#4	Sources and types of financial, material, and other support	20,21
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1,21

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Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	n/a
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	n/a
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	18,19
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5,6
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	6
Objectives	#7	Specific objectives or hypotheses	6
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	7
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will	7,8

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		perform the interventions (eg, surgeons, psychotherapists)	
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8,9
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	18,19,20
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	16
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	7,8
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	10,11,12
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	12
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	13,14
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	7
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	14

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Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	14
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	14
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	14,15
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	19,20
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	15
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	15
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	16
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	16,17,18
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	16,17,18

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Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	16,17,18
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	n/a
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	18
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	18
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	18
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	17,18
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	19
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect	19

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		confidentiality before, during, and after the trial	
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	21,22
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	20
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	20
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	20,21
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	20,21
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	19
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

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