Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The comparison between the effects of online pain education interventions with online and face to face exercise on pain, disability, psychological factors and function in participants with chronic non-specific neck pain

Protocol summary

Study aim
The aim of this study was to compare the effect of online and face-to-face pain education interventions on pain, disability, psychological factors and function in people with chronic nonspecific neck.

Design
Clinical trial with control group, with parallel groups, one-way blind, randomized, phase 2 on 120 patients. Pre-prepared numbers 1 to 120 are used for randomization.

Settings and conduct
This study is performed in the city of Babol on people with chronic nonspecific neck pain. Data evaluators and analyzers are blind to the participants in each group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: men and women aged 18-65 years, VAS scale <3 in these people, minimum neck pain 12 weeks and three days a week, referring to medical centers to treat neck pain, not starting treatment or taking medication Exclusion criteria Pregnancy, dissatisfaction with participation in research, lack of regular participation in training sessions, spinal osteoporosis, history of tumor in the spine, participation in training courses for the treatment of neck pain in the past three years, severe spinal discopathy, having any fractures and Spinal surgery in the last three years, if injured during interventions

Intervention groups
For all participants in the two experimental groups, 3 sessions of familiarity with teaching pain management approaches as well as how to perform quarterly exercises (three sessions per week, each session approximately 20 to 30 minutes) will be explained. For the participants in the control group, biomedical content is explained with a focus on neck biomechanics, as well as three months of training for corrective neck pain movements.

Main outcome variables
pain; disability; psychological factors and function

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20150503022068N5**
Registration date: **2021-09-27, 1400/07/05**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-27, 1400/07/05**
Update count: **0**

Registration date
2021-09-27, 1400/07/05

Registrant information

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Name of organization / entity
kharazmi university

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-23, 1400/06/01

Expected recruitment end date
2021-11-22, 1400/09/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The comparison between the effects of online pain education interventions with online and face to face exercise on pain, disability, psychological factors and function in participants with chronic non-specific neck pain

Public title
The effects of online pain education interventionon pain, disability, psychological factors and function in participants with chronic non-specific neck pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Men and women 18-65 years. VAS scale <3 in these individuals. Minimum history of neck pain 12 weeks and three days a week. Go to medical centers to treat neck pain. Do not start treatment or take medication
Exclusion criteria:
Pregnancy. Dissatisfaction with participating in the research Lack of regular participation in training sessions People with spinal osteoporosis. People with a history of spinal tumors Participate in exercise therapy courses to treat neck pain in the last three years. Having criteria for referral to surgery such as severe cervical vertebral discopathy. Having any fractures and surgery in the cervical spine in the last three years. In case of injury during the interventions
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants are randomized into two active treatment groups and one passive control group, by drawing a number, from 1 to 120, prepared in advance by the trainer and placed in sealed envelopes in a box.
Blinding (investigator's opinion)
Single blinded
Blinding description
Assessor data analyzer were blinded to group allocation. participants were not blinded to exercise study however they were not aware which treatment was considered to be therapeutic.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committee of Kharazmi University of Medical Science (IR.KHU.REC.1400.013).
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Province
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Postal code
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Approval date
2021-07-11, 1400/04/20
Ethics committee reference number
IR.KHU.REC.1400.013

Health conditions studied

1

Description of health condition studied
chronic none specific neck pain
ICD-10 code
ICD-10 code description
neck pain

Primary outcomes

1

Description
the effects of online pain education interventions with online and face to face exercise on pain in participants with chronic non-specific neck pain between 3 and 7 using Numerical Rating Scale
Timepoint
Measurement of pain at the beginning of the study and after three months of exercise.
Method of measurement
Numerical Rating Scale

Secondary outcomes

1

Description
The effetcs of online pain education interventions with online and face to face exercise on pain, disability, psychological factors and function in participants with chronic non-specific neck pain

Timepoint
The effects of online pain education interventions with online and face to face exercise on pain, disability, psychological factors and function in participants with chronic non-specific neck pain before and after three months of interventions

Method of measurement
Comparison of the effects of online training of pain interventions with online and face-to-face exercises on pain, disability, psychological factors and performance in people with chronic nonspecific neck before and after three months of training using pain rating scale, neck disability index, Depression, Anxiety and Stress Scale -21 And after three exercises

Intervention groups

1

Description
Intervention group: For all participants in the two experimental groups, 3 introductory sessions will be held to teach pain management approaches as well as how to perform the exercises over a period of approximately three months. In this study, 3 training sessions will be held in 2 weeks, which will be conducted by the researcher. The schedule is the same for all three treatment groups. The first session will be a group session (duration 30 minutes to an hour) with a maximum of 6 participants in each group, led by a researcher using a PowerPoint presentation. Participants will then be asked to read an instruction booklet containing the same information at home. The second session is home-based online e-learning, which includes 3 explanatory videos. These videos explain the same PowerPoint that was shown during the first session along with its screening. Therefore, in the second session, which is held online, the same issue discussed in the first group session will be explained again. After each clip, participants are asked to complete a questionnaire that will assess their understanding and opinion of the film. The third session will include a 30-minute one-on-one conversation focusing on patients' personal needs: The questions in the second session questionnaire will be analyzed. And how to use this information in the patient's daily life is discussed

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Kharazmi University

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kharazmi University

Full name of responsible person
Zohreh Khosrokiani

Position
PH.d student

Latest degree
Master

Other areas of specialty/work
Corrective movements and prevention of sports injuries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Only part of the data, such as the dependent variables, The average of all samples, can be shared in scientific articles.

When the data will become available and for how long
Access period starts 6 months after the results are published

To whom data/document is available
Personal information is confidential and general results are available to anyone in the article

Under which criteria data/document could be used
Information is not available to anyone. general results are available to anyone in the article

From where data/document is obtainable
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What processes are involved for a request to access data/document
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Comments