

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Oct 2026

Investigation the effect of virtually designed resilience improvement program on outcomes of chronic pain patients referred to Shiraz University of Medical Sciences affiliated clinics

Protocol summary

Study aim

Determining the effect of resilience improvement virtual program on outcomes of patients with chronic pain

Design

Three arm parallel group randomised trial (two control groups), two side blinded, with 105 patients.

Settings and conduct

This research is performed in the Shiraz University of Medical Sciences. Participants affiliated clinics, participants, evaluators and statistical analyzer will be blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Age >18 years - Diagnosis of chronic pain according to ICD-11 criteria (all types of non-cancerous chronic pain), according to the patient's report - Willingness to participate in the study - Literacy of reading, writing and speaking in Persian - Having a smart phone with WhatsApp social network and the ability to work with it - Internet access
Exclusion criteria: - Having other chronic physical diseases such as cancer and MS, according to the patient's own report - Known chronic mental illness, according to the patient's own report - Diagnosis of cancer or any other chronic disease (such as MS) during the study - Occurrence of adverse events for the patient's relatives (severe mental or physical illness) such as accident, divorce, death, etc. during the study - Unwillingness to continue participating during the study - Participate in psychotherapy programs or receive psychological counseling in the last 6 months

Intervention groups

Intervention group: In addition to routine care, a "virtualized resilience improvement program" will be implemented for patients in this group. Control group (1): these patients will receive routine care. Control group (2): In addition to routine care, they receive the content of the "Virtual Program for Pain Recognition, Causes and Factors Affecting Pain and Its Treatments".

Main outcome variables

resilience; pain intensity; pain disability; psychological wellbeing; social wellbeing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210719051944N1**

Registration date: **2021-10-31, 1400/08/09**

Registration timing: **prospective**

Last update: **2021-10-31, 1400/08/09**

Update count: **0**

Registration date

2021-10-31, 1400/08/09

Registrant information

Name

hajar haghshenas

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4254

Email address

haghshenah@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-07-11, 1401/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effect of virtually designed resilience improvement program on outcomes of chronic pain patients referred to Shiraz University of Medical Sciences affiliated clinics

Public title

the effect of virtually designed resilience improvement program on outcomes of chronic pain patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Age >18 years Diagnosis of chronic pain according to ICD-11 criteria (all types of non-cancerous chronic pain), according to the patient's report Willingness to participate in the study Literacy of reading, writing and speaking in Persian Having a smart phone with WhatsApp social network and the ability to work with it Internet access

Exclusion criteria:

Having other chronic physical diseases such as cancer and MS, according to the patient's own report Known chronic mental illness, according to the patient's own report Diagnosis of cancer or any other chronic disease (such as MS) during the study Occurrence of adverse events for the patient's relatives (severe mental or physical illness) such as accident, divorce, death, etc. during the study Unwillingness to continue participating during the study Participate in psychotherapy programs or receive psychological counseling in the last 6 months

AgeFrom **18 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **105****Randomization (investigator's opinion)**

Randomized

Randomization description

In this study, at first all of the required patients (105 people) will be selected based on inclusion criteria, using the convenience sampling method based on referring to the office of pain fellowship physicians, internal medicine, neurologists, neurosurgeons and rheumatology subspecialty (Located in Shiraz University of Medical Sciences affiliated clinics). The selected individuals will then be randomly divided into three groups (two control groups and one intervention group). 35 patients are assigned to each group. To do this,

"Random Allocation Software" will be used. In this way, a number is assigned to each selected person from the available sampling stage, then the information is entered into the software and finally, by randomly selecting the numbers by the software, it is determined that whom will be in which group. In order to reduce potential bias, the randomization process will be performed by a person (researcher assisted) who is not involved in other stages of the research.

Blinding (investigator's opinion)

Double blinded

Blinding description

The general introduction of the studied groups will be done, but participants will be unaware of the allocation of study groups. When taking the pre-test and post-test, the assessor will not be informed of which group of data is being evaluated. The statistical analyst will not know which group the data belongs to when analyzing.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics committees of schools of nursing and midwifery, management and medical information s

Street address

Namazi Square, School of nursing and midwifery

City

Shiraz

Province

Fars

Postal code

۷۱۹۳۶ - ۷۱۹۳۶

Approval date

2021-07-03, 1400/04/12

Ethics committee reference number

IR.SUMS.NUMIMG.REC.1400.011

Health conditions studied**1****Description of health condition studied**

chronic pain

ICD-10 code

G89.4

ICD-10 code description

Chronic pain syndrome

Primary outcomes

1

Description

resilience level in CD- resilience questionnaire

Timepoint

before intervention, immediately and 3 months after intervention

Method of measurement

CD- resilience questionnaire

Secondary outcomes

1

Description

pain intensity

Timepoint

before intervention, immediately and 3 months after intervention

Method of measurement

numeric rating scale

2

Description

pain disability

Timepoint

before intervention, immediately and 3 months after intervention

Method of measurement

pain disability index

3

Description

psychological wellbeing

Timepoint

before intervention, immediately and 3 months after intervention

Method of measurement

Ryff psychological wellbeing questionnaire (short form)

4

Description

social wellbeing

Timepoint

before intervention, immediately and 3 months after intervention

Method of measurement

Keyes social wellbeing questionnaire (short form)

Intervention groups

1

Description

Intervention group: In addition to routine care, a "virtualized resilience promotion program" will be implemented for patients in this group. the educational

contents will be sent to them in the form of modules through the WhatsApp application. According to the content of the program, it is expected that 6 educational modules will be designed weekly and the contents of each module (with 6-7 minute duration) will be sent to patients every other day at specific times. Patients will be able to access and use educational materials at all hours of the day and night. Depending on the content of the program, a few short tests will be designed during the intervention to increase the interaction of participants. After reading and completing a module by the patient, the next module will be provided to him at the appointed time.

Category

Behavior

2

Description

Control group (1): these patients will receive routine care.

Category

N/A

3

Description

Control group (2): In addition to routine care, they receive the content of the "Virtual Program for Pain Recognition, Causes and Factors Affecting Pain and Its Treatments". the educational contents will be sent to them in through the WhatsApp application.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Clinic

Full name of responsible person

Dr Mani Ramzi

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Namazi square, next to blood transfusion Building

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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info@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences

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
Shiraz University of Medical Sciences
Full name of responsible person
Dr Niloofar Pasyar
Position

Associate Professor
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Person responsible for scientific inquiries

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Person responsible for updating data

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Phone

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Email

haghshenah@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not 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

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Unidentifiable information of the participants that is related to the main and secondary outcomes of the study (Resilience, pain intensity, pain disability, psychological and social well-being).

When the data will become available and for how long

1-2 months after the publication of the study results

To whom data/document is available

Researchers working in academic and scientific institutions as well as people working in industry.

Under which criteria data/document could be used

The use of the results of the study by mentioning the source is unrestricted.

From where data/document is obtainable

Dr. Niloofar Pasiar, 07136474254 Dr. Maryam Shayegan, 07136474254 Hajar Haghshenas, 07136474254, haghshenah@gmail.com

What processes are involved for a request to access data/document

The requested information can be obtained through the mentioned e-mail address and within a maximum period of one week.

Comments