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
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target 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
۱۳۱۱۹ - 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 mounts after intervention
Method of measurement
CD- resilience questionnaire

Secondary outcomes

1

Description
pain intensity
Timepoint
before intervention, immediately and 3 mounts after intervention
Method of measurement
numeric rating scale

2

Description
pain disability
Timepoint
before intervention, immediately and 3 mounts after intervention
Method of measurement
pain disability index

3

Description
psychological wellbeing
Timepoint
before intervention, immediately and 3 mounts after intervention
Method of measurement
Ryff psychological wellbeing questionnaire (short form)

4

Description
social wellbeing
Timepoint
before intervention, immediately and 3 mounts 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
Street address
Namazi square, next to blood transfusion Building
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۷۱۳۴۸۱۴۷۳۴
Phone
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2

Recruitment center
Name of recruitment center
Shahid Motahari Clinic
Full name of responsible person

Dr Mani Ramzi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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Postal code
۱۴۳۳۶ - ۷۱۳۴۸
Phone
+98 71 3230 5410
Email
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
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Full name of responsible person
Dr Maryam Shayegan
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Associate Professor
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Other areas of specialty/work
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Person responsible for updating data

Contact
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Shiraz University of Medical Sciences
Full name of responsible person
Hajar Haghshenas
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PhD Candidate
Latest degree
Master
Other areas of specialty/work
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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