

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the Effects of Multimedia Education and Peer Education on Perceived Stress in Cancer Patients Undergoing Chemotherapy: A Parallel Randomized Clinical Trial

Protocol summary

Study aim

Determining the effect of multimedia Education and peer Education on perceived stress in cancer patients undergoing chemotherapy in the Omid Department of Imam Hossein Shahroud Hospital in 2023

Design

A clinical trial study with a control group, with parallel groups, without blinding, randomized, on 110 cancer patients undergoing chemotherapy, will use statistical consultant with SPSS software for randomization.

Settings and conduct

Online multimedia trainings and face-to-face peer group trainings will be implemented for cancer patients undergoing chemotherapy referred to Imam Hossein (AS) Shahroud Hospital. Trainings are given for four weeks every week on a specific topic.

Participants/Inclusion and exclusion criteria

Inclusion criteria: being literate in reading and writing, understanding and speaking Persian language, ability to use a smartphone, access to ITA internal messengers, confirmation of cognitive status based on Mini-Cog, Exclusion criteria: having education related to medicine, neurological disorders and Psychosis based on the self-report of patients, people in other similar research projects, non-response of people in the multimedia training intervention group during follow-ups for two weeks, non-participation in two face-to-face peer training sessions, participation in educational programs Extracurricular

Intervention groups

The intervention group includes cancer patients undergoing chemotherapy who receive the intervention of multimedia education and peer education for four weeks online and face-to-face according to their placement in the intervention group. The control group includes cancer patients undergoing chemotherapy who only receive routine training at the treatment center

during this period.

Main outcome variables

Perceived Stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191127045524N3**

Registration date: **2023-09-13, 1402/06/22**

Registration timing: **prospective**

Last update: **2023-09-13, 1402/06/22**

Update count: **0**

Registration date

2023-09-13, 1402/06/22

Registrant information

Name

Amirheidar Bakhshiarab

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3222 4816

Email address

bakhshiarab@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effects of Multimedia Education and Peer Education on Perceived Stress in Cancer Patients Undergoing Chemotherapy: A Parallel Randomized Clinical Trial

Public title

The effect of multimedia training and peer training on perceived Stress

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Having literacy in reading and writing Understanding and speaking in Persian language Confirmation of cognitive status based on Mini-Cog Ability to use a smartphone. Ability to use a smartphone, access to Eita internal messengers.

Exclusion criteria:

Having education related to medicine Nervous and mental disorders based on patients' self-report People present in other similar research projects Non-response of the people present in the multimedia training intervention group during follow-ups for two weeks Failure to participate in two face-to-face peer training sessions Participation in extracurricular educational programs

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 110

Randomization (investigator's opinion)

Randomized

Randomization description

The sequence of random allocation will be done by the statistical consultant with the help of Spss software. Patients will be randomly placed in three groups A (multimedia training), B (peer training) and C (control) based on the order determined by the software, and the sampling process will be done consecutively until the end of sampling. Individuals are assigned to the desired group in the order of their entry into the study and randomly through randomized blocks.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee in Research of Shahroud University of Medical Sciences

Street address

7th Square, Research and Technology, Shahroud University of Medical Science, Shahroud Town

City

Shahroud

Province

Semnan

Postal code

3614773955

Approval date

2023-08-30, 1402/06/08

Ethics committee reference number

IR.SHMU.REC.1402.099

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

Cancer and Chemotherapy

ICD-10 code

Z51.1

ICD-10 code description

Encounter for antineoplastic chemotherapy and immunotherapy

Primary outcomes**1****Description**

Perceived stress score in Cohen's questionnaire

Timepoint

At the beginning of the study (before the intervention) and 4 weeks after the intervention

Method of measurement

Cohen's Perceived Stress Questionnaire. The lowest score is 0 and the highest score is 56. A higher score indicates greater perceived stress

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The number of 3 patients who had a

history of successful treatment with chemotherapy and were selected as peers in consultation with the medical personnel of the relevant department and after obtaining informed consent from the individuals and during three one-hour sessions, two of which were training sessions. necessary in the field of disease recognition, chemotherapy nursing care, nutrition care, drug therapy care and important training and necessary nursing care in cancer and chemotherapy by trained nurses and with the guidance of specialized nursing personnel in this field, In the training room of the chemotherapy department of the hospital environment, training will be provided and finally a meeting will be held with the aim of measuring the level of preparation of peers. Also, during the meeting, these people will be emphasized that the training will only be given to the people who have been introduced to They will do it according to random allocation and during this period they will be monitored and controlled by the specified nurses of the relevant department and after confirming their complete preparation they will be introduced to the people of the peer education intervention group in a meeting and then The steps of the intervention will be conducted under the supervision of a trained nurse during 4 sessions, a one-hour session every week, and at the end of the sessions, the level of their learning will be measured by the question and answer method (at the end, the training related to each session is attached). and each person will be excluded from the study if he does not participate in the meetings and does not respond for two consecutive weeks, which is determined according to the activity and inactivity form attached at the end) and then after one week from the last The perceived stress questionnaire session will be completed again. Also, the trainings of the multimedia training group are also provided by videos prepared by nurses specializing in cancer patients in the form of 10-15 minute videos, as well as providing educational and care materials in the field of cancer and chemotherapy on a weekly and coordinated basis. A specific day with peer group training in the group created for 4 weeks will be sent to individuals through internal messengers (at the end, the training related to each session is attached, and each person, in case of not participating in the sessions and not responding) for two consecutive weeks, which is determined according to the activity and inactivity form attached at the end, will be removed from the study) and then after one week from the last sent item, the perceived stress questionnaire will be completed again. In the control group, patients will be given routine training including educational pamphlets and training given by nurses during the treatment period. During these 4 weeks of follow-up of people to participate in peer training sessions and also to observe multimedia training, a trained nurse will follow up on this through phone calls.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein (AS) Shahroud Hospital

Full name of responsible person

Amirheidar Bakhshiarab

Street address

7th Square, Research and Technology, Shahroud
University of Medical Science, Shahroud Town

City

Shahroud

Province

Semnan

Postal code

3614773955

Phone

+98 23 3222 4816

Email

amirheidari770@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mohammad Hassan Emamian

Street address

7th Square, Research and Technology, Shahroud
University Medical Science, Shahroud Town

City

Shahroud

Province

Semnan

Postal code

3614773955

Phone

+98 23 3222 4816

Email

amirheidari770@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Amirheidari Bakhshiarab

Position

Faculty of Shahroud University of Medical Sciences

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

7th Square, Research and Technology, Shahroud
University Medical Science, Shahroud Town

City

Shahroud

Province

Semnan

Postal code

3614773955

Phone

+98 23 3222 4816

Email

amirheidari770@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Amirheidari Bakhshiarab

Position

Faculty of Shahroud University of Medical Sciences

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

7th Square, Research and Technology, Shahroud
University Medical Science, Shahroud Town

City

Shahroud

Province

Semnan

Postal code

3614773955

Phone

+98 23 3222 4816

Email

amirheidari770@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Amirheidari Bakhshiarab

Position

Faculty of Shahroud University of Medical Sciences

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

7th Square, Research and Technology, Shahroud
University Medical Science, Shahroud Town

City

Shahroud

Province

Semnan

Postal code

3614773955

Phone

+98 23 3222 4816

Email

amirheidari770@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

Undecided - It is not yet known if there will be 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

Part of the patient's demographic information is shared after people have not been identified. All information related to measuring worry and blood pressure in patients can be shared after people have not been identified.

When the data will become available and for how long

En Access starts 6 months after results are published

To whom data/document is available

Researchers and students of academic and scientific institutions

Under which criteria data/document could be used

Raw data for correlation studies

From where data/document is obtainable

Amirheidari Bakhshiarab amirheidari770@gmail.com

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

Clear explanation of the reason for the need to access data and provide data after two weeks

Comments