Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jun 2026

Investigating the effect of an educational program based on emotion regulation on death anxiety and psychological disturbance of patients undergoing chemotherapy

Protocol summary

Study aim
Determining the effect of a training program based on emotion regulation on death anxiety and psychological disturbance of patients undergoing chemotherapy

Design
Clinical trial with control group, with parallel groups, randomized, on 60 patients. Random allocation software is used for randomization.

Settings and conduct
The current research is a clinical trial with a pre-test and post-test design in the form of two test and control groups, which will be carried out on 60 patients with leukemia referred to Seyed al-Shohada Hospital who are being treated with chemotherapy. After obtaining the necessary permits from Isfahan University of Medical Sciences, the samples will be selected using available sampling method and then they will be randomly assigned to two intervention and control groups. The intervention group will participate in six training sessions based on emotion regulation during three weeks in a virtual way using smartphones.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Leukemia patients undergoing chemotherapy Having a smart phone and being able to work with it Exclusion criteria: Having mental retardation, blindness and deafness

Intervention groups
Intervention group: In 6 sessions, they will receive emotion regulation training using a smartphone through the WhatsApp social network. And the control group will receive the prescribed routine treatments during this period. The interventions include 6 emotion regulation training sessions based on the Grass model, which are held virtually (two sessions per week). The duration of each session is 60 minutes. that the multimedia files designed using the social network will be provided to the participants. Control group: only the questionnaires before and after the study are completed.

Main outcome variables
Death anxiety, psychological disturbance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141127020108N5**
Registration date: **2022-09-07, 1401/06/16**
Registration timing: **prospective**

Last update: **2022-09-07, 1401/06/16**
Update count: **0**

Registration date
2022-09-07, 1401/06/16

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3778 2856

Email address
musarezaie@nm.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-23, 1401/07/01

Expected recruitment end date
2023-03-20, 1401/12/29

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of an educational program based on emotion regulation on death anxiety and psychological disturbance of patients undergoing chemotherapy

Public title

Investigating the effect of a training program based on emotion regulation on death anxiety and psychological disturbance

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who have leukemia and are undergoing chemotherapy. Have a good general condition to complete the questionnaire. Having a smart mobile phone and the ability to work with it

Exclusion criteria:

Unwillingness to participate in the study

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization is of size 4. Randomization unit: individual. Randomization tool: random allocation software. Hiding the random chain is by placing patient codes in opaque envelopes.

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

Research Ethics Committees of Nursing, Rehabilitation and Management schools- Isfahan University of

Street address

Hazar Jarib St., Isfahan University of Medical Sciences and Health Services, central headquarters

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Approval date

2022-08-29, 1401/06/07

Ethics committee reference number

IR.MUI.NUREMA.REC.1401.069

Health conditions studied

1

Description of health condition studied

leukemia

ICD-10 code

C91

ICD-10 code description

Lymphoid leukemia

Primary outcomes

1

Description

death anxiety

Timepoint

Immediately before and three weeks after the start of the study

Method of measurement

Templer Death Anxiety Scale

Secondary outcomes

1

Description

psychological distress

Timepoint

Immediately before and three weeks after the start of the study

Method of measurement

Kessler psychological distress questionnaire

Intervention groups

1

Description

Intervention group: In 6 sessions, they will receive emotion regulation training using a smartphone through the WhatsApp social network. And the control group will receive the prescribed routine treatments during this period. The interventions include 6 emotion regulation training sessions based on the Grass model, which are

held virtually (two sessions per week). The duration of each session is 60 minutes. that the multimedia files designed using the social network will be provided to the participants. In order to evaluate the commitment of the participants to the sent content, they will be investigated using telephone follow-up. The intervention is carried out by a senior psychiatric nurse who has the necessary skills to provide an emotion regulation program and has previously conducted intervention studies in this field.

Category

N/A

2

Description

Control group: no intervention is done by the researcher for the control group, and only immediately before the study and three weeks after the start of the study, the questionnaires are completed by the patients of the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Seyed al-Shohda Hospital, Isfahan
Full name of responsible person
Amir Musarezaie
Street address
Motahari street
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Isfahan
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81746-73461
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musarezaie@nm.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Gholamreza Asgari
Street address
Hazar Jarib Street, Isfahan University of Medical Sciences
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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

Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Amir Musarezaie
Position
Nursing faculty instructor
Latest degree
Master
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

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

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

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