

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The effectiveness of coping strategy training on fear of recurrence in patient with Leukemia

Protocol summary

Study aim

General purpose: Determining the impact of teaching coping strategies on the fear of relapse in patients
Specific and practical goals: 1- Determining the effect of teaching coping strategies on the level of fear of disease recurrence in patients 2- Determining the impact of teaching coping strategies on the problem solving skills of patients 3- Determining the improvement of coping strategies when faced with similar stressful conditions after receiving educational intervention in patients 4- Determining the impact of coping strategies on patients' ability to use social support 5- Determining impact of coping strategies on controlling negative emotions

Design

From among the patients referred to Shariati Hospital, according to the specificity of the sample and Cochran's formula, 55 people were selected by available and sampling method.

Settings and conduct

In the pre-test phase, fear of recurrence questionnaires and coping strategies questionnaires were completed by the subjects and after the results of the training program were obtained in 8 90-minute sessions based on the theory of Folkman and Lazarus on the definition of stress and its dimensions, the types of coping styles were explained. The five steps of problem solving, dealing with negative emotions, relaxation technique, use of support systems and self-control training are discussed. Then, the tests will be conducted again in two phases: post-test and follow-up. This study will be conducted in Shariati Hospital.

Participants/Inclusion and exclusion criteria

The criteria for entering the study include age between 30 and 45 years Awareness of the disease and its conditions Chronic leukemia
Exit criteria Lack of knowledge about disease Other types of cancer

Intervention groups

The design of this research is per-test - post-test of one group and follow-up

Main outcome variables

Fear of Recurrence of disease

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140818018842N28**

Registration date: **2022-12-31, 1401/10/10**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-31, 1401/10/10**

Update count: **0**

Registration date

2022-12-31, 1401/10/10

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of coping strategy training on fear of recurrence in patient with Leukemia

Public title

The effectiveness of coping skills training on fear of recurrence

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Receive diagnosis of chronic cancer(A.M.L) Awareness of the disease and its conditions Age between 30 and 45years higher than High school diploma Receive medical treatment Participating in training sessions and practicing Proficiency in Persian language

Exclusion criteria:

More than 45years old diagnose Other types of cancer Failure to participate in training sessions Education less than diploma Lack of proficiency in Persian language Failure to receive medical treatment Lack of knowledge about the disease and its conditions

AgeFrom **30 years** old to **45 years** old**Gender**

Both

Phase

2

Groups that have been masked*No information***Sample size**Target sample size: **55**

More than 1 sample in each individual

Number of samples in each individual: **55**

Between 30 and 45years. Awareness of the disease and its conditions. High school diploma. Chronic CLL cancer

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features

In this study, after the post-test phase, a follow-up phase is conducted using questionnaires with a gap of one month. Before the training, in order to determine the coping strategies of the participants in the study, the coping strategies questionnaire will be completed by the patients. to be added to the training plan based on The coping strategies training program is designed based on the cognitive-behavioral approach and the theory of Folkman and Lazarus in eight sessions for 90 minutes. In this program, problem solving styles, social support, and

dealing with negative emotions are taught. In the first meeting, members are introduced and familiarized, the rules of the group are discussed (participation on time and active presence in the meetings and doing homework outside the group). The second session will discuss the definition of stress and identify its dimensions, the third session will be presented on various coping styles of education. In fact, problem-oriented coping styles (seeking more information about the problem, cognitively changing the structure of the problem), emotion-oriented (dealing with fault-finding behaviors, being nervous and upset, mental preoccupation and fantasizing (and avoidance) include behaviors such as coming to society) is explained. The fourth session of problem-solving skills will be taught, and in this session, things like the five steps of problem-solving (problem definition, accurate analysis of anxiety-provoking situations, list of solutions) will be mentioned. In the fifth session: Dealing with negative emotions by teaching how to control the body and teaching relaxation. In the sixth session, teaching how to use support systems including (how to get emotional support, teaching how to get emotional support, teaching how to get practical support, teaching how to get informational support, recommending to use the help of experts) and teaching self-control in the seventh session which includes things (comparing the characteristics of people with external and internal sources of control, teaching self-control or self-management skills, teaching control of behavior and emotions through role playing in the eighth session, as well as summarizing and concluding the materials and teachings presented in the previous sessions which includes (transferring the experience to real life, evaluation of the course by the participants)..The coping strategies training program is designed based on the cognitive-behavioral approach and the theory of Folk man and Lazarus in eight sessions for 90 minutes. In this program, problem solving styles, social support, and dealing with negative emotions are taught. In the first meeting, members are introduced and familiarized, the rules of the group are discussed (participation on time and active presence in the meetings and doing homework outside the group). The second session will discuss the definition of stress and identify its dimensions, the third session will be presented on various coping styles of education. In fact, problem-oriented coping styles (seeking more information about the problem, cognitively changing the structure of the problem), emotion-oriented (dealing with fault-finding behaviors, being nervous and upset, mental preoccupation and fantasizing (and avoidance) include behaviors such as coming to society) is explained. The fourth session of problem-solving skills will be taught, and in this session, things like the five steps of problem-solving (problem definition, accurate analysis of anxiety-provoking situations, list of solutions) will be mentioned. In the fifth session: Dealing with negative emotions by teaching how to control the body and teaching relaxation. In the sixth session, teaching how to use support systems including (how to get emotional support, teaching how to get emotional support, teaching how to get practical support, teaching how to get

informational support, recommending to use the help of experts) and teaching self-control in the seventh session which includes things (comparing the characteristics of people with external and internal sources of control, teaching self-control or self-management skills, teaching control of behavior and emotions through role playing in the eighth session, as well as summarizing and concluding the materials and teachings presented in the previous sessions which includes (transferring the experience to real life, evaluation of the course by the participants).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

research Ethics committees of research institute for Oncology, Hematology and cell therapy/ tehran un

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13th floor,Block A, Central Headquarters of the Ministry of Health, Treatment and Medical Educationbetween South Flamek and Zarafshan, Simai Iran s.t , Quds town (west),

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tehran

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Postal code

33336-94139

Approval date

2022-08-17, 1401/05/26

Ethics committee reference number

IR.TUMS.HORCSCT.REC.1401.014

Health conditions studied

1

Description of health condition studied

Chronic leukemia (C.L.L/C.M.L)

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

coping strategy

Timepoint

Pr-test and post-training. Follow-up stage

Method of measurement

Coping Action Preference Questionnaire (COPE) by Carver et al

2

Description

Fear of relapse

Timepoint

Pr-test and post-training. Follow-up stage

Method of measurement

Questionnaire of fear of recurrence Simard et al

Secondary outcomes

1

Description

fear of recurrence

Timepoint

In the pre-test stage, using Simard's Fear of Recurrence Questionnaire, then receiving 8/ 90-minute sessions of coping strategies training based on Folkman and Lazarus' theory, with an emphasis on teaching problem-solving styles, social support, dealing with negative emotions, again in the post-test stage of this The test is repeated to determine the effectiveness of coping strategies training on this variable. A month later, in the follow-up phase, this test will be performed again to measure the continuity of the training received by the patients.

Method of measurement

Simard's Fear of Recurrence Questionnaire

2

Description

Coping strategies

Timepoint

Pre-test, post-test and follow-up

Method of measurement

cope operations preference equerry

Intervention groups

1

Description

Intervention group:

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان شریعتی تهران

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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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
Tehran 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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
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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

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

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

Title and more details about the data/document

Regarding the coping strategies training protocol, we will explain the full description of the sessions along with the goals and tasks presented to the patients in the article.

When the data will become available and for how long

First, the pre-test stage is performed by implementing two questionnaires of coping strategies and fear of disease recurrence, then intervention is done on the patients based on the results of the questionnaires and the educational protocol. Then, the post-test phase will be done by completing the questionnaires again by the participants, after that, the follow-up phase will be done with an interval of one month. Then the data is collected and analyzed in SPSS software. The whole process takes about 4 months.

To whom data/document is available

Professors and researchers who intend to use the data for their further studies.

Under which criteria data/document could be used

Professors and researchers who intend to use the data for their further studies.

From where data/document is obtainable

Data Center of Blood, Hematology and Tuberculosis
Research Center of Shariati Hospital

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

The data with descriptive and inferential statistics of the analysis and its results will be published in the form of an article.

Comments