

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of cognitive-emotional intervention on the psychological distress, growth and post-traumatic stress of mothers of children with cancer who referred to the chemotherapy department

Protocol summary

Study aim

The purpose of this study was to reduce the psychological distress and post-traumatic stress in mothers with children undergoing chemotherapy

Design

A clinical trial with a control group, pragmatic, with parallel groups, randomized

Settings and conduct

This is a clinical trial study that will be conducted at Ali ibn Abitaleb Hospital in Zahedan. First, by diagnosing cancerous children who are referred to the Department of chemotherapy in 2018, and eligible mothers with the desired characteristics of the target population, eligible participants will be chosen. Then the subjects will complete the informed consent form to participate in this study. The selected mothers will be randomly assigned into two intervention and control groups. The pre-test will be done by completing the psychological distress, post-traumatic growth and post-traumatic stress disorder questionnaires by two groups. The intervention group will receive five sessions of the emotional cognitive education program in two sessions per week in the form of small groups discussion based on the content. After 12 weeks, the research questionnaires will be completed as a post-test by visiting the subjects at home or by an appointment at department of Oncology.

Participants/Inclusion and exclusion criteria

Inclusion criteria: At least 20 years old for mothers, at least the reading and writing skills for mothers
Exclusion Criteria: Not receiving even a single dose chemotherapy step for a child, advanced and severe illness of children

Intervention groups

Intervention group: 5 sessions of 90 minutes of cognitive-emotional training program are received based on specified content. Control group: receive regular training during the intervention period.

Main outcome variables

Post-traumatic growth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160924029954N12**

Registration date: **2018-10-25, 1397/08/03**

Registration timing: **prospective**

Last update: **2018-10-25, 1397/08/03**

Update count: **0**

Registration date

2018-10-25, 1397/08/03

Registrant information

Name

Ali navidian

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 54 3344 2482

Email address

alinavidian@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-01, 1397/08/10

Expected recruitment end date

2018-12-31, 1397/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of cognitive-emotional intervention on the psychological distress, growth and post-traumatic stress of mothers of children with cancer who referred to the chemotherapy department

Public title
The effect of cognitive-emotional training on psychological distress, growth and post traumatic stress in mothers of cancerous children

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Mother is at least twenty years of age. Mother has the least reading and writing skills The mother is not afflicted with psychiatric disorders.
Exclusion criteria:
 The patient has not even received chemotherapy. The disease of the child is advanced and intensive. The mother does not have the consent to enter the study.

Age
From **20 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Firstly, eligible participants will be chosen according to inclusion criteria and will be listed. After obtaining informed consent, they will be randomly assigned to two groups of intervention and control in such a way that the chosen subjects will be assigned in to two groups through the random numbers table. The odd numbers are assigned to the intervention group and the even numbers to the control group.

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 of Zahedan university of Medical Sciences and Health Services
Street address
 Administrative Complex of Medical Sciences Campus, Persian Gulf Blvd, Dr. Hesabi Square, Zahedan, Iran
City
 Zahedan
Province
 Sistan-va-Balouchestan
Postal code
 98167-43463
Approval date
 2018-07-15, 1397/04/24
Ethics committee reference number
 IR.ZAUMS.REC.1397.193

Health conditions studied

1

Description of health condition studied
Mental state of mothers of cancerous child

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Post-traumatic growth

Timepoint
Before intervention and three months after intervention

Method of measurement
Post Traumatic Growth Questionnaire

2

Description
Post Traumatic Stress

Timepoint
Before intervention and three months after intervention

Method of measurement
Post Traumatic Stress Check List

3

Description
Psychological Distress

Timepoint
Before intervention and three months after intervention

Method of measurement
Kessler questionnaire K-10

Secondary outcomes
empty

Intervention groups

1

Description

Intervention group: The intervention group will received five sessions of cognitive-emotional training twice a week for 90 minutes according the confirmed and determined contents. The contents of the emotional cognitive intervention in the first session includes an introduction of the disease, the psychosocial consequences of the disease, especially in the family, the process of disease treatment and the normalization of the emotional reactions in cancers. The second session includes teaching and exercising emotional disclosure techniques, exhausting emotions and self-regulating emotions. The third session includes fears and concerns about cancer and its recurrence, facilitating and exercising cognitive processing and conscious rumination. The fourth session includes a review of achievements and disadvantages following child illness, developing values and prioritizing values, redefining goals, and creating a new philosophy for life. The fifth session consists of spirituality, positive thinking, and teaching patience and endurance.

Category

Other

2

Description

The control group does not receive any counseling and training during this period. At that same time interval, the post-test intervention group is also conducted. After the end of the study, the contents of the training will be provided to the control group too.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ebne Abi Taleb's Hospital, Zahedan, Iran

Full name of responsible person

Arsalan Latifi

Street address

Ali Ebne Abi Taleb's Hospital, Khaliye Fars Blvd,
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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Noor Mohammad Bakhshani

Street address

Administrative Complex of Zahedan Medical Science
Campus, Persian Gulf Blvd. Dr. Hesabi Square,
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bakhshani@zaums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Arsalan latifi

Position

Master Student in Psychiatric Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing & Midwifery, Mashahir Square,
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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Ali Navidian

Position

Ph.D

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for updating data

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Full name of responsible person

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Latest degree

Bachelor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Participants information is confidential

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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

the method of implementation of the plan is explained in
the thesis

When the data will become available and for how long

The post-graduation study protocol is described in the
thesis

To whom data/document is available

Researchers working in academia and academia

Under which criteria data/document could be used

There are no special conditions.

From where data/document is obtainable

The thesis is explained.

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

There is no plan to publish it.

Comments

There is no explanation.