

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 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,  
Zahedan, Iran

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9816743111

##### Phone

+98 54 3723 0390

##### Fax

##### Email

Bsn.latifi@gmail.com

## 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,  
Zahedan, Iran

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9816743463

##### Phone

+98 54 3723 0390

##### Email

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,  
Zahedan, Iran

##### City

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816743463

**Phone**

+98 54 3723 0390

**Email**

Bsn.latifi@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Ali Navidian

**Position**

Ph.D

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

**Street address**

Faculty of Nursing & Midwifery, Mashahir Square,  
Zahedan, Iran

**City**

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**Province**

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**Phone**

+98 54 3344 2482

**Email**

alinavidian@gmail.com

**Person responsible for updating data****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**

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**Postal code**

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+98 54 3723 0390

**Email**

Bsn.latifi@gmail.com

**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.