

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### The effect of group therapy intervention based on Resiliency against child disease in mothers with children suffering from cancer

#### Protocol summary

##### Study aim

The aim of present study is to determine the effect of resiliency against child disease intervention in mothers with children suffering from cancer

##### Design

The clinical trial includes 24 in control group and 24 in intervention groups on mothers of children with cancer, based on resiliency, with parallel groups, not blinded, randomized

##### Settings and conduct

The present study will be done in mothers with a cancerous child referring to the Motahhari Educational Center of Urmia in 2017. In this experimental study, a pre-test-post-test design with control group will be used. In order to conduct this research, 48 people will be selected from the population and randomly will be assigned into two experimental groups (24 people) and controls (24 people). Intervention for the experimental group will be in 6 sessions in a 60 to 90-minute coping program.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include mothers with a child who are diagnosed with a disease under six months. Participants with a GHQ below 23 those who do not use psychosocial drugs or tobacco, have no other sick child, the child's parents live together, child's father does not have addiction, the child's father is not imprisoned, they are aware of their child's illness, they did not participated in similar programs during the last six months and have not lost their relatives in the past six months will be selected. Participants with a GHQ over 23 and not participated in more than one session of intervention will be excluded from the study.

##### Intervention groups

The first group consists of 24 mothers of children with cancer who will undergo intervention resiliency. The second group consisted of 24 mothers of children with cancer and the control group received no intervention.

##### Main outcome variables

Coping with child illness

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140212016564N12**

Registration date: **2018-08-01, 1397/05/10**

Registration timing: **retrospective**

Last update: **2018-08-01, 1397/05/10**

Update count: **0**

##### Registration date

2018-08-01, 1397/05/10

##### Registrant information

##### Name

Molood Radfar

##### Name of organization / entity

Urmia University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 1275 4961

##### Email address

radfar.m@umsu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Personnel costs 0 Total costs of testing and specialist services 0 Total travel expenses 3,470,000 Total equipment costs 1,500,000 Total other costs 0 Credit from other organizations 6,770,000 Rials Total

##### Expected recruitment start date

2017-07-23, 1396/05/01

##### Expected recruitment end date

2017-09-23, 1396/07/01

**Actual recruitment start date**

2017-07-23, 1396/05/01

**Actual recruitment end date**

2017-09-23, 1396/07/01

**Trial completion date**

empty

**Scientific title**

The effect of group therapy intervention based on Resiliency against child disease in mothers with children suffering from cancer

**Public title**

The effect of group therapy intervention based on Resiliency against child disease

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

mothers with a child who are diagnosed with a disease under six months. low GHQ are 23, do not use psychoactive drugs or tobacco have no other sick children live together with parents have no knowledge of their child's illness have not participated in the same 6 months in the same program 6 Last month did not miss someone or relatives Speak Persian or azari residing in Urmia

**Exclusion criteria:**

Being infected with another disease Not attending more than one session of intervention sessions

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **48**

Actual sample size reached: **48**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

They will be assigned into groups randomly. To do so 24 A cards and 24 B cards will be put in the envelope and will be mixed thoroughly (A represents the intervention group and B represents the control group), each individual participating in the study takes one of the cards and enters the study, respectively.

**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 Urmia University of Medical Sciences

**Street address**

Resalat Street

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5714783734

**Approval date**

2017-07-23, 1396/05/01

**Ethics committee reference number**

ir.umsu.rec.1396.154

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

Coping with child disease in mothers with child suffering from cancer

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

cope with child Disease

**Timepoint**

Before the intervention and T immediately after the intervention and three months after the intervention

**Method of measurement**

Coping health inventory for parents (CHIP)

**Secondary outcomes**

empty

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

A total of 48 mothers with cancerous children referred to the Motahari Hospital of Urmia were selected by available sampling method. The subjects were randomly divided into two groups of control and intervention (n = 24). The sessions for the intervention group were grouped in three groups of eight in the hospital hall and between 15 and 17 days on Sunday, Tuesday, and Thursday. A meeting was organized for parents to receive a child-centered pre-test. Then, along with the purpose of the study, an interventional program adjusted for

resilience in three dimensions: familiarity with the concept of resilience and the characteristics of resilient people / internal and external support factors / familiarity with ways to create resilience, and during 6 sessions, each session The intervention group was administered for 60 to 90 minutes. At the end of each meeting, a maternity homework task will be presented and reviewed at the next meeting. At the end of the work, those who received more points were rewarded. After the end of the sessions, the chip Questionnaire was completed at the end of the last session and 3 months after the intervention for both groups.

**Category**

Behavior

**2****Description**

Control group: During the intervention, the control group did not receive any Resiliency and coping skills and in terms of data entry was about control. After completing the intervention, they participated in a meeting on resilience skills. This group controlled and treated with usual and ordinary care approaches that are available in the center.

**Category**

Behavior

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shahid Motahari Education medical Center

**Full name of responsible person**

Moloud Radfar

**Street address**

Kashani Street

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Urmia University of Medical Sciences

**Full name of responsible person**

Mohebbie Erag

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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**

Urmia 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**

Urmia University of Medical Sciences

**Full name of responsible person**

fatemeh hoseinzadeh

**Position**

The Master Science student of nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Faculty of Nursing and Midwifery, Urmia University of Medical Sciences

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Urmia University of Medical Sciences

**Full name of responsible person**

molud radfar

**Position**

Nursing PhD

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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## Person responsible for updating data

**Contact**

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Urmia University of Medical Sciences

**Full name of responsible person**

fatemeh hosseinzadeh

**Position**

the master science student of nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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**

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**

The whole data will be shared after being unidentified.

**When the data will become available and for how long**

Start the access period 6 months after printing the results

**To whom data/document is available**

Researchers working in academia

**Under which criteria data/document could be used**

The data will be available to other researchers in the form of a printed article. Other researchers are allowed from the research team to use the data

**From where data/document is obtainable**

Radfar moloud Email:mradfar1343@gmail.com

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

You will submit your application to Mrs. Radfar, who will send you the requested application within ten days after reviewing your request.

**Comments**