

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Comparison of the Effect of Narrative Therapy with Emotional Disclosure on Emotional Regulation and Unpleasant Emotions in Mothers of Children with Leukemia

Protocol summary

Study aim

Determining the effect of narrative therapy and emotional disclosure on emotion regulation and unpleasant emotions in the mothers of children with leukemia.

Design

A clinical trial with a control group, Two intervention groups, Parallel-group trial with the concealed data collection and data analysis, Block randomize allocation, Enrolled between September 2018 and January 2018.

Settings and conduct

The study settings are Bahrami hospital and Medical center of children affiliated to Tehran University of Medical Sciences (TUMS). After receiving the approval of the ethical committee, the sampling will be done by a convenient method according to inclusion and exclusion criteria. After that, the selected samples will be randomly allocated by a blocking method into 3 groups. At group 1, group narrative therapy will be held according to White and Epstein model and in 10 sessions 2-3 times weekly. At group 2, emotional disclosure, the 4 weekly sessions will be held according to the individual-based approach. Control group do not receive any intervention. The data collection and analysis will be concealed by involving a non-member of the research team.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having a minimum level of literacy, Living child with mother, Not having single-parenting, Child age under 18 years old, Disease diagnosed period more than 1 month Exclusion criteria: Participating in the same program and happening a stressful event during the research period.

Intervention groups

The group intervention 1 is a group narrative therapy adapted from the White and Epstein program. The program will be held in 10 one-hour sessions two or three

times a week. The intervention group 2, emotional self-disclosure will be held in 4 two-hour therapy sessions weekly with an individual-based and homework approach.

Main outcome variables

Emotion regulation; Unpleasant emotions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151003024312N5**

Registration date: **2019-04-17, 1398/01/28**

Registration timing: **retrospective**

Last update: **2019-04-17, 1398/01/28**

Update count: **0**

Registration date

2019-04-17, 1398/01/28

Registrant information

Name

Fataneh Ghadirian Baharanchi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6105 4311

Email address

ghadirian.fataneh@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

2018-08-23, 1397/06/01

Actual recruitment end date

2018-12-22, 1397/10/01

Trial completion date

2019-01-15, 1397/10/25

Scientific title

Comparison of the Effect of Narrative Therapy with Emotional Disclosure on Emotional Regulation and Unpleasant Emotions in Mothers of Children with Leukemia

Public title

Effect of Narrative Therapy and Emotional Disclosure on Emotional Regulation and Unpleasant Emotions

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

The mother has a minimum literacy level (reading and writing) The child lives with the mother and she/he is not a single parent. The maximum limit of the child age is 18 years old. The child is not suffering from chronic or congenital leukemia. At least one month has been passed after the leukemia is diagnosed. The mother does not have any chronic physical or mental condition.

Exclusion criteria:

The mother participates in the same educational program. Stressful event happened during the research period.

AgeFrom **18 years** old to **65 years** old**Gender**

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **90**Actual sample size reached: **90****Randomization (investigator's opinion)**

Randomized

Randomization description

The selected mothers will be allocated into three groups by block randomization method (group 1: Group narrative therapy intervention, Group 2: Individual-based emotional disclosure intervention, and Group 3: Control). Block allocations conceal by non-fixed block randomization.

Blinding (investigator's opinion)

Single blinded

Blinding description

Data collectors at before and after intervention are non-members of the research team. They are the staff of the research setting who are trained. The data analysis will be done by a non-involved member at random allocation.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of School of Nursing Midwifery & Rehabilitation ,Tehran University of Medical Sciences

Street address

School of Nursing Midwifery ,Tehran University of Medical Sciences. Nosrat st. Tohid sq. Tehran I.IRAN

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2018-07-02, 1397/04/11

Ethics committee reference number

IR.TUMS.FNM.REC.1397.031

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

Unpleasant Emotions

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

The Cognitive regulation scores in Garnofsky questionnaire

Timepoint

Before intervention and two weeks after intervention

Method of measurement

Garnofsky Cognitive regulation questionnaire

2**Description**

Unpleasant emotions (Anxiety, depression, and stress) scores on the DASS-21 questionnaire

Timepoint

Before intervention and two weeks after intervention

Method of measurement

The Depression Anxiety, Stress Scales—21/ (DASS-21)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The intervention in the narrative therapy group will be held at 10 group-based sessions adapted from the White and Epston program. The sessions will be one- hour two-three times a week. The therapeutic sessions will be according to the personal history narrations and the discussions around the unpleasant emotions management.

Category

Rehabilitation

2

Description

Intervention group 2: The intervention in the self-disclosure group will be designed in Self-disclose interactive sessions will also be conducted for 4 weekly sessions for 1 month, individually and with a homework approach. Therapeutic communications will focus on the treatment and management of written unpleasant emotions in personal histories of mothers from their child disease.

Category

Rehabilitation

3

Description

Control group: Mothers of children in this group do not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's Medical Center

Full name of responsible person

Fātaneh .Ghadirian

Street address

Tehran Province, Dr. Mohammad Gharib

City

Tehran

Province

Tehran

Postal code

1419733151

Phone

+98 21 6147 2368

Email

f-ghadirianb@tums.ac.ir

2

Recruitment center

Name of recruitment center

Bahrami Children Hospital

Full name of responsible person

Fātaneh .Ghadirian

Street address

Tehran Province, Shahid Kiani st

City

Tehran

Province

Tehran

Postal code

1641744991

Phone

+98 21 7301 3000

Email

f-ghadirianb@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Fataneh.Ghadirian

Street address

Tohid Sq.,Tehran University Of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6105 4113

Email

ghadirian.fataneh@gmail.com

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Fataneh Ghadirian
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Nosrat Ave., Tohid Sq
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6105 4113
Email
f-ghadirianb@tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Fataneh Ghadirian
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Nosrat Ave., Tohid Sq
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6105 4113
Email
f-ghadirianb@tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Fataneh Ghadirian
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Nosrat Ave., Tohid Sq
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6105 4113
Email
f-ghadirianb@tums.ac.ir

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

There is no more information

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

This only available for people working in academic institutions

Under which criteria data/document could be used

Only observation and use of descriptive statistics

From where data/document is obtainable

Contact person: Dr. Fataneh Ghadirian E-mail Address: f-ghadirianb@tums.ac.ir

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

Sending email from an academic email Maximum one month needed to follow through this process

Comments