Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the Effect of Expressive Writing on the Severity of Post-Traumatic Stress Disorder in Mothers of Children with Cancer.

Protocol summary

Study aim
Determining the Effect of Expressive Writing on the Severity of Post-Traumatic Stress Disorder in Mothers of Children with Cancer.

Design
This study will be a randomized controlled clinical trial conducted on 76 participants (38 in the intervention group and 38 in the control group). Sampling will be performed using the convenience sampling method, and random allocation will be carried out using SPSS software.

Settings and conduct
Mothers of children with cancer visiting Seyyed Al-Shohada Hospital, Isfahan, who meet the eligibility criteria will be enrolled. After reaching the required sample size, participants will be individually randomized into intervention and control groups. The intervention consists of four consecutive individual expressive writing sessions, each lasting at least 45 minutes, for the experimental group.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Fluency in Persian (ability to read and write), A score of 33 or higher on the Post-Traumatic Stress Disorder Checklist, At least two months have passed since the child's cancer diagnosis, No concurrent participation in similar research or educational studies, Exclusion Criteria: Unwillingness to cooperate, Incomplete completion of 20% or more of the questionnaires (prior to randomization), Experience of severe stress during the last six months

Intervention groups
The experimental group will receive four consecutive individual sessions of at least 45 minutes each, involving expressive writing to freely express emotions, based on Pennebaker and Beall's guidelines and tailored to the child's hospitalization period. The control group will receive only routine care and education, and the intervention content will be provided to them afterward.

Main outcome variables
Post-traumatic stress disorder severity

General information

Reason for update

Acronym
-

IRCT registration information
IRCT registration number: **IRCT20240310061242N2**
Registration date: **2026-03-08, 1404/12/17**
Registration timing: **registered_while_recruiting**

Last update: **2026-03-08, 1404/12/17**
Update count: **0**

Registration date
2026-03-08, 1404/12/17

Registrant information

Name
Fatemeh Ghaedi-Heidari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3792 7607

Email address
fatemeh.ghaedi@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-01-21, 1404/11/01

Expected recruitment end date
2026-03-21, 1405/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the Effect of Expressive Writing on the Severity of Post-Traumatic Stress Disorder in Mothers of Children with Cancer.

Public title
Investigating the Effect of Expressive Writing on the Severity of Post-Traumatic Stress.

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Participants must be fluent in the Persian language and possess basic reading and writing literacy. Participants must have obtained a score of 33 or higher on the Post-traumatic Stress Disorder Checklist (PCL-5) questionnaire. A minimum of two months must have elapsed since the child's cancer diagnosis. The child must not have concurrent comorbid conditions (e.g., respiratory, cardiac, psychiatric disorders) or congenital anomalies. There must be no other family member with a chronic illness for whom the mother is currently providing care. Based on self-report, participants must not have a diagnosed psychiatric disorder that has resulted in hospitalization or psychotropic medication use. Participants must not have participated in any similar educational or research programs during the same time period or prior to the study.

Exclusion criteria:
Does not have willingness to participate in the study. Incomplete completion of 20% or more of the questionnaires (before randomization) Has experienced severe stressors in the past six months, such as the death of relatives or loved ones, a major stressful event at work, or divorce.

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **76**

Randomization (investigator's opinion)
Randomized

Randomization description
After obtaining written informed consent, sampling will be conducted using the convenience method. For the random allocation of participants (76 individuals, considering a 10% attrition rate) into two groups of 38 (intervention and control), random numbers will first be generated in SPSS software and sorted using the following commands: Transform → Compute Variable Target Variable: Random Numeric Expression: RV.UNIFORM(0,1) Data → Sort Cases Sort by: Random (Ascending) After sorting, 38 participants will be assigned to the intervention group and 38 to the control group. Based on this, the random sequence of groups (a list of 76 individuals for intervention and control) will be prepared. This sequence will be placed in opaque, sealed, and sequentially numbered envelopes (1 to 76). After the enrollment of each participant, the envelope corresponding to that number will be opened, and their group assignment will be determined.

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 School of Nursing, Management and Rehabilitation – Isfahan Medical University

Street address
Nursing and Midwifery Faculty., Isfahan University of Medical Sciences., Hezerjerib Ave., Isfahan

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Isfahan

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Isfehan

Postal code
8174673461

Approval date
2025-12-29, 1404/10/08

Ethics committee reference number
IR.MUI.NUREMA.REC.1404.142

Health conditions studied

1

Description of health condition studied
Posttraumatic Stress Disorder

ICD-10 code
F43.1

ICD-10 code description
Post-traumatic stress disorder (PTSD)

Primary outcomes

1

Description
The severity score of post-traumatic stress disorder in the post-traumatic stress disorder questionnaire.

Timepoint

At three time points: before the start of the intervention, immediately after the completion of the four expressive writing sessions, and one month after the end of the intervention (follow-up).

Method of measurement

he severity of post-traumatic stress disorder in mothers of children with cancer will be measured using the Post-Traumatic Stress Disorder Checklist Fifth Edition (PCL-5). Demographic information, including maternal age, education level, occupation, marital status, and other demographic characteristics, will be collected using a demographic information form.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention consists of expressive writing based on Pennebaker's guidelines, designed by the researcher under the supervision of the academic advisor. It will be delivered individually and in-person over four consecutive sessions, each lasting at least 45 minutes, and scheduled to align with the child's hospitalization in the oncology ward. Mothers will participate in the child's hospital room with appropriate lighting and relative quiet. During the sessions, mothers will be asked to write their thoughts and feelings—including their experience of the child's cancer diagnosis, the long-term effects of the child's illness on the mother and family, the importance of finding meaning in difficult experiences, and the integration of identity after crisis—continuously for 15 to 20 minutes per session. The session content will be identical for all participants, and confidentiality of the writing will be emphasized; attention to grammar will not be required. In case of severe anxiety or distress during writing, measures such as temporary pauses or relaxation techniques will be applied. At the end of each session, mothers will be encouraged to discuss their feelings and experiences if they wish.

Category

Behavior

2

Description

Control group: No intervention will be administered to this group, and the care provided will be limited to the continuation of their children's routine treatment and standard ward education. At the end of the study, the complete content of the expressive writing sessions will be made available to them, and upon their request, the possibility of conducting similar sessions will be provided.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Seyyed Al-Shohada Hospital

Full name of responsible person

Fatemeh Ghaedi-Heidari

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Seyed al-Shohada Hospital, Farshadi Creek Area, End of Motahari St., Isfahan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Asgari

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Research and Technology Deputy, Building No. 4, Isfahan University of Medical Sciences, Hezar Jerib Ave., Isfahan

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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

Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Fatemeh Ghaedi-Heidari

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Nursing and Midwifery Faculty., Isfahan University of Medical Sciences., Hezerjerib Ave., Isfahan

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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
Shareable data will include de-identified individual participant data obtained from questionnaires (including the PCL-5 and baseline demographic variables), the final study protocol, the statistical analysis plan, and the data dictionary. No personally identifiable or participant-identifying information will be shared.

When the data will become available and for how long

Access period starts 6 months after results are published.

To whom data/document is available

Researchers affiliated with recognized academic, research, or clinical institutions.

Under which criteria data/document could be used

The data may be used solely for scientific and research purposes, including secondary analyses, systematic reviews, or meta-analyses. Commercial use is not permitted. Applicants must submit a proposed analysis plan and sign a data confidentiality agreement.

From where data/document is obtainable

Requests should be submitted to the principal investigator of the study. Contact details will be provided at the time of publication of the study results.

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

After submission of a written request including the study objective and analysis plan, the request will be reviewed by the principal investigator. Upon approval, de-identified data will be shared within 4–6 weeks.

Comments

-Data sharing will be conducted in accordance with ethical research principles and the regulations of the ethics committee.