

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### The effectiveness of cognitive-behavioral play therapy on anxiety, depression, resilience and Symptoms of mourning in children with prolonged grief Disorder: A single- subject research

#### Protocol summary

##### Study aim

The effectiveness of cognitive-behavioral play therapy on anxiety, depression, resilience and Symptoms of mourning in children with prolonged grief Disorder

##### Design

The clinical trial with two-month follow-up, without blinding, is available for 3 children with prolonged grief disorder of single case study type and AB design.

##### Settings and conduct

This study is carried out in the office of the Cultural Vice-Chancellor of Ferdowsi University of Mashhad (Dr. Asghari Nikah's room). The sessions are conducted as 12 individual treatment sessions, once a week for 45 minutes. There are 4 questionnaires that clients must fill before intervention, three times during 12 treatment sessions (fourth, eighth and twelfth sessions) and one month and two months after the end of treatment.

##### Participants/Inclusion and exclusion criteria

The age range is between 7 and 11 years, having lost at least one first-degree relative in the past year and meeting the criteria for prolonged bereavement disorder, according to the DSM-5-TR criteria, and having a conscious and voluntary willingness to participate in the research, the exclusion criteria of having physical diseases and significant mental disorders such as schizophrenia, retardation (diagnosed by an expert) and unwillingness to continue treatment

##### Intervention groups

cognitive-behavioral play therapy

##### Main outcome variables

anxiety, depression, resilience and Symptoms of mourning

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20221105056404N1**

Registration date: **2023-02-18, 1401/11/29**

Registration timing: **retrospective**

Last update: **2023-02-18, 1401/11/29**

Update count: **0**

#### Registration date

2023-02-18, 1401/11/29

#### Registrant information

##### Name

Atefeh sadat Mousavi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3690 9367

##### Email address

atf.mousavi1995@semnan.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2022-11-22, 1401/09/01

#### Expected recruitment end date

2022-12-21, 1401/09/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effectiveness of cognitive-behavioral play therapy on anxiety, depression, resilience and Symptoms of

mourning in children with prolonged grief Disorder: A single- subject research

## Public title

The effect of cognitive behavioral game therapy on long-term bereavement disorder

## Purpose

Education/Guidance

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age range between 7 and 11 years Losing at least one first-degree relative within the past year and meeting criteria for prolonged bereavement disorder, according to criteria DSM-5-TR They had a conscious and voluntary desire to participate in the research Not receiving psychotherapy and medication before entering the research

### Exclusion criteria:

Having significant physical and mental illnesses such as schizophrenia, retardation (with expert diagnosis) Reluctance to continue treatment

## Age

From **7 years** old to **11 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **3**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Semnan Faculty of Medical Sciences

##### Street address

Semnan University of Medical Sciences, Basij Square.

##### City

Semnan

##### Province

Semnan

##### Postal code

35147-99442

## Approval date

2023-02-06, 1401/11/17

## Ethics committee reference number

IR.SEMUMS.REC.1401.296

## Health conditions studied

### 1

#### Description of health condition studied

Anxiety, depression, resilience and Symptoms of mourning in children with prolonged grief disorder

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Symptoms of prolonged grief

#### Timepoint

Before starting the study, the fourth session, the eighth session, the twelfth session, one month after the end of the twelfth session, two months after the end of the twelfth session.

#### Method of measurement

Spuij et al. Inventory of Prolonged Grief for Children(IPC-G), (2011).

### 2

#### Description

Children's depression

#### Timepoint

Before starting the study, the fourth session, the eighth session, the twelfth session, one month after the end of the twelfth session, two months after the end of the twelfth session.

#### Method of measurement

Maria Kovacs, Children Depression Inventory (1958)

### 3

#### Description

Children's anxiety

#### Timepoint

Before starting the study, the fourth session, the eighth session, the twelfth session, one month after the end of the twelfth session, two months after the end of the twelfth session.

#### Method of measurement

Improved short-form children's anxiety scale (2018).

### 4

#### Description

resilience

#### Timepoint

Before starting the study, the fourth session, the eighth session, the twelfth session, one month after the end of

the twelfth session, two months after the end of the twelfth session.

#### **Method of measurement**

Surzykiewicz, Konaszewski and Wagneild (2018) Resilience Scale Short Form.

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

Intervention group: Cognitive-behavioral play therapy, 12 individual therapy sessions, (each session for 45 minutes), at the interval of therapy sessions once a week. Executive protocol based on the model taken from the book combining play therapy with cognitive behavior therapy by Athena Dors (2009), the book 101 play therapy techniques written by Heidi, Gerard Kadusen and Shafer Charles E. (1997).

##### **Category**

Behavior

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Office of Dr. Asghari Nikah (Cultural Management and Voluntary Activities of Ferdowsi University of

###### **Full name of responsible person**

Dr. Seyed Mohsen Asghari Nikah

###### **Street address**

Cultural-Social and Student Vice-Chancellor Building, , Danesh Blvd, Ferdowsi University Campus, Azadi Square

###### **City**

Mashhad

###### **Province**

Razavi Khorasan

###### **Postal code**

9177948963

###### **Phone**

+98 51 3880 6472

###### **Fax**

+98 51 3880 7071

###### **Email**

Farhangi@um.ac.ir

###### **Web page address**

### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

###### **Name of organization / entity**

Semnan University of Medical Sciences

###### **Full name of responsible person**

Dr. Majid Mirmohammadkhani

###### **Street address**

Research and Technology Vice-Chancellor, Central Headquarters of Semnan University of Medical Sciences, Basij Blvd

###### **City**

semnan

###### **Province**

Semnan

###### **Postal code**

3514799442

###### **Phone**

+98 23 3344 8999

###### **Fax**

###### **Email**

rds@semums.ac.ir

###### **Grant name**

###### **Grant code / Reference number**

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

Yes

###### **Title of funding source**

Semnan 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**

Semnan University of Medical Sciences

###### **Full name of responsible person**

Atefeh Sadat Mousavi

###### **Position**

Master's student in clinical psychology

###### **Latest degree**

Bachelor

###### **Other areas of specialty/work**

Psychology

###### **Street address**

No. 14, the first intersection on the left, Tos 39, Tos Blvd.

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###### **Postal code**

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###### **Phone**

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###### **Email**

atf.mousavi1995@semnan.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Atefeh Sadat Mousavi

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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**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

The general results of the research will be published as a scientific article.

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

The documents and research results will probably be published in 2023-2024.

**To whom data/document is available**

The complete document of the research will be provided to Semnan Faculty of Psychology. The results of the research will be provided to researchers in the form of articles.

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

The results can be used by mentioning the number and type of the community and the research sample as well as the intervention carried out.

**From where data/document is obtainable**

Faculty of Psychology and Educational Sciences, Semnan University, Center for Information and Scientific Documents of the country (Iran Doc) or send a message to the researcher

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

Visit Iran Doc or Semnan University library in person or send an email to the researcher one week later (atf.mousavi1995@semnan.ac.ir)

**Comments**