

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### The effect of web - based education of parents on the level of post-traumatic stress symptom in children

#### Protocol summary

##### Study aim

1. Determine and compare the level of symptoms of post traumatic stress in children in both control and test groups before intervention 2. Determination and comparison of the level of symptoms of post traumatic stress in children in both control and post-interventional groups

##### Design

Clinical trial with control and intervention group, non-blind, non-randomized, Phase does not apply

##### Settings and conduct

Shahid Rajai Faculty of Medicine, Qazvin University of Medical Sciences, web-based psychological education to Parenting

##### Participants/Inclusion and exclusion criteria

Inclusion criteria Child: - The age range of the child is 18-18 years - Childbirth due to a traumatic event - The child is admitted for 3 days to one month after the accident - The child has a score higher than 17 according to the CRIES-8 questionnaire - The child is not harmed by abuse of the parent Parents: - Ability to read and write in Persian language - Have a diploma or higher education level - The ability to use the Internet, Web site and electronic gadgets - Not having any known psychological and physical disorder Exit criteria - Child's death during research - GCS loss and changes in the level of consciousness of the child after entering the study - Lack of parental support for further intervention

##### Intervention groups

Control group: All children with injuries and parents (parents) without intervention Intervention group: All children with injuries and parents (parents) receiving intervention

##### Main outcome variables

The Effective Effect of E-Learning on Parents' Poverty Stress Symptoms in Children

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180218038777N1**

Registration date: **2018-03-05, 1396/12/14**

Registration timing: **prospective**

Last update: **2018-03-05, 1396/12/14**

Update count: **0**

##### Registration date

2018-03-05, 1396/12/14

##### Registrant information

##### Name

Zakieh Omidvar Eshkalak

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 3379 6875

##### Email address

omidvar@edu.ikiu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-03-06, 1396/12/15

##### Expected recruitment end date

2018-04-21, 1397/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of web - based education of parents on the level of post-traumatic stress symptom in children

**Public title**

Effect of web - based education of parents on the level of post-traumatic stress symptom in children

**Purpose**

Education/Guidance

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

Child: The age range of the child is between 10 - 18 years of age, Child:the child is admitted to a traumatic event, including falling, car and motor crashes, limb fracture, multiple injuries, limb injuries, veins, visceral injury, burns, mild head injuries (GCS <14) Child:The child's admission period is 3 days to one month after the accident Child:the child has a score higher than 17 according to the CRIES-8 questionnaire Child:ased on the documentation of the child's injury case due to abuse of the parent. Parents:ability to read and write in Persian Parents:having a higher education level and higher Parents: the ability to use the Internet, website and electronic devices Parents: not having any known psychological and physical impairment

**Exclusion criteria:**

Childbirth during the study GCS loss and changes in the level of consciousness of the child after entering the study the lack of parental cooperation to participate in the intervention

**Age**

From **10 years** old to **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **110**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****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 Iran University of Medical

Sciences

**Street address**

Iran Nursing and Midwifery Faculty, Rashid Yasemi Ave, Vanek

**City**

Tehran

**Province**

Tehran

**Postal code**

3471783381

**Approval date**

2017-09-05, 1396/06/14

**Ethics committee reference number**

IR.IUMS.FMD.REC1396.9211196239

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

Post Traumatic Stress Disorder

**ICD-10 code**

F43.1

**ICD-10 code description**

Post-traumatic stress disorder

**Primary outcomes****1****Description**

The level of stress in the CRIES-8 questionnaire

**Timepoint**

At the beginning of the study and 6 weeks after the intervention

**Method of measurement**

CRIES-8 questionnaire

**Secondary outcomes****1****Description****Timepoint****Method of measurement****Intervention groups****1****Description**

Intervention group: A psychological training and child and parental stress control program for four weeks online from a web site made by a researcher at www. PTSD-pediatric nursing-care.ir

**Category**

Other

**Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Shahid Rajaei Hospital

**Full name of responsible person**

zakiehomidvar

**Street address**

Shahid Rajaei Hospital, padegan street

**City**

Qazvin

**Province**

Qazvin

**Postal code**

3471783381

**Phone**

+98 28 3333 5800

**Email**

zakie.omidvar@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Zakieh Omidvar

**Street address**

Rashid Yasemi Street, Vanak

**City**

Tehran

**Province**

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**Postal code**

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**Phone**

+98 21 4365 1000

**Email**

zakie.omidvar@yahoo.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Zakieh Omidvar

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Shahid Rajaei Hospital, Padehgan Street

**City**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Zakieh Omidvar

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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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**

Not applicable

**Data Dictionary**

Not applicable

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

Unidentifiable data subjects are shared

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

Start access after printing data

**To whom data/document is available**

All people

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

Certain conditions are not considered

**From where data/document is obtainable**

site [www.ptsd-pediatric-nursing-care.ir](http://www.ptsd-pediatric-nursing-care.ir)

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

After requesting a link to the administrator on the site, the data is sent to the person's email

**Comments**