# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Effect of psychosexual rehabilitation versus control group on sexual quality of life and post-traumatic stress disorder in women with near-death experiences related to pregnancy causes: a randomized clinical trial

## Protocol summary


**Study aim**
To assess the effect of psychosexual rehabilitation versus control group on sexual quality of life and post-traumatic stress disorder in women with near-death experiences related to pregnancy causes

**Design**
This is a randomized clinical trial with a control group with parallel groups without blinding, in which 48 eligible patients will be randomly assigned to the intervention and control groups by lottery.

**Settings and conduct**
This study will be conducted at the Kosar Hospital in Urmia, involving 48 eligible women with near-death experiences related to pregnancy causes. The patients will be randomly assigned to the intervention and control groups through the lottery. This trial will not be blinded.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Age 14 to 45 years, Near-death experiences related to pregnancy causes, Educated, Exclusion criteria: Psychiatric disorders

**Intervention groups**
Intervention group: Routine treatment and care for women with near-death experiences related to pregnancy causes plus psychosexual rehabilitation for 60 to 90 minutes, two session per week for 3 weeks Control group: Routine treatment and care for women with near-death experiences related to pregnancy causes

**Main outcome variables**
Primary outcome: Average quality of sextual life score; Average stress score


## General information

**Reason for update**
**Acronym**
**IRCT registration information**


IRCT registration number: **IRCT20120215009014N600**
Registration date: **2026-04-09, 1405/01/20**
Registration timing: **prospective**

Last update: **2026-04-09, 1405/01/20**
Update count: **0**


**Registration date**
2026-04-09, 1405/01/20


**Registrant information**
**Name**
Jalal Poorolajal
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Iran (Islamic Republic of)
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**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2026-04-30, 1405/02/10
**Expected recruitment end date**
2026-08-01, 1405/05/10
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**

Effect of psychosexual rehabilitation versus control group on sexual quality of life and post-traumatic stress disorder in women with near-death experiences related to pregnancy causes: a randomized clinical trial

**Public title**
Effect of psychosexual rehabilitation versus control group on sexual quality of life and post-traumatic stress disorder in women with near-death experiences related to pregnancy causes
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Age 14 to 45 years, Near-death experiences related to pregnancy causes, Educated,
**Exclusion criteria:**
Psychiatric disorders
**Age**
From **14 years** old to **45 years** old
**Gender**
Female

**Phase**
2-3
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **48**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Random allocation of patients to intervention and control groups by lottery. For this purpose, we prepare two sheets, write "intervention" on one and "control" on the other. Then, with each patient's visit, one of the sheets is randomly taken and the patient is assigned to the intervention or control group.
**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**
Vice-chancellor for Research and Technology, Urmia University of Medical Sciences, Pardis Nazlo Road
**City**
Urmia
**Province**
West Azarbaijan
**Postal code**
5714783734
**Approval date**
2026-02-18, 1404/11/29
**Ethics committee reference number**
IR.UMSU.REC.1404.536

## Health conditions studied

### 1

**Description of health condition studied**
Post-traumatic stress disorder (PTSD)
**ICD-10 code**
F43.1
**ICD-10 code description**
Post-traumatic stress disorder (PTSD)

## Primary outcomes

### 1

**Description**
Average quality of sextual life score
**Timepoint**
Before intervention and one month later
**Method of measurement**
Using the sextual quality-of-life questionnaire for women

### 2

**Description**
Average stress score
**Timepoint**
Before intervention and one month later
**Method of measurement**
Using the post-traumatic stress disorder questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Routine treatment and care for women with near-death experiences related to pregnancy causes plus psychosexual rehabilitation for 60 to 90 minutes, two session per week for 3 weeks (including familiar with anatomy and physiology of men and women sextual organ, sextual interaction, effect of such experience on sextual quality of life, physical and mental natural response to traumatic experiences, deep respiratory exercises and relaxation of muscles, writing about postpartum emotions, believes, anxiety, thoughts and methods of their prevention, methods of managing relationship and calmness, expression of experiences,

agitations and individual sextual problems post traumatic pregnancy, evaluation and detection of individual problems, education of stop thought technique, technique of focusing at the moment, evaluation of fears in performing sextual relationship, technique for self-excitement, technique for stress management, technique for adaptation, technique for sextual focus)

**Category**

Rehabilitation

**2**

**Description**

Control group: Routine treatment and care for women with near-death experiences related to pregnancy causes

**Category**

N/A

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Kosar Hospital in Urmia

**Full name of responsible person**

Sahar Pourzeinal

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Kosar Hospital, Hasani Ave.

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Urmia University of Medical Sciences

**Full name of responsible person**

Dr. Saber Gholizadeh

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Urmia University of Medical Sciences, Pardis Nazlo Road

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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**

Sahar Pourzeinal

**Position**

Midwifery Student

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

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## Person responsible for scientific inquiries

**Contact**

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**Position**

Reproductive Health Specialist

**Latest degree**

Ph.D.

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## Person responsible for updating data

**Contact**

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**Position**
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Ph.D.

**Other areas of specialty/work**
Epidemiology

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poorolajal@umsha.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available

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

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

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

**Clinical Study Report**
Undecided - It is not yet known if there will be 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