

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### The effect of counselling on coping with decision to continue an unplanned pregnancy: a randomized controlled clinical trial

#### Protocol summary

##### Study aim

Determine the effect of counselling on coping with decision to continue an unplanned pregnancy

##### Design

The study is a randomized controlled clinical trial on 82 unplanned pregnant women referring to health centers of Tabriz. The participants will be randomly assigned in two groups of counselling and control with a 1: 1 ratio, using RAS software according to 4 and 6 blocks.

##### Settings and conduct

From 80 health centers of Tabriz, 16 will be selected randomly. Then the participants will be selected through convenience sampling. After obtaining written consent form, pre-test questionnaires including socio-demographic questionnaire, NU-PCI, PRAQ-R2, and worries and perceived threats of unplanned pregnant women will be completed. 4-8 weeks after the intervention, post-test questionnaires (NU-PCI, PRAQ-R2, and worries and perceived threats of unplanned pregnant women) will be completed.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 15-49 years old married women, Unplanned pregnant women with decision to continue the pregnancy, Gaining 14 or higher scores in avoiding domain of the NU-PCI tool, Gaining 27 or higher scores in worries and perceived threats questionnaire. Exclusion criteria: known psychiatric disorders according to women statements, Illegal pregnancies, Fetal anomaly, High risk Pregnancies, Family problems

##### Intervention groups

For the intervention group, four counselling sessions, once a week for 60 to 90 minutes would be held. The Control group will receive only routine prenatal care.

##### Main outcome variables

The main outcome of the study is comparing the mean scores of coping strategies of unplanned pregnant women between the two groups, before and 4-8 weeks after intervention.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170506033834N5**

Registration date: **2018-05-03, 1397/02/13**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-05-03, 1397/02/13**

Update count: **0**

##### Registration date

2018-05-03, 1397/02/13

##### Registrant information

##### Name

Roghaiyeh Nourizadeh

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3479 6770

##### Email address

nourizadehr@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-03-24, 1397/01/04

##### Expected recruitment end date

2018-06-24, 1397/04/03

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effect of counselling on coping with decision to continue an unplanned pregnancy: a randomized controlled clinical trial

## Public title

The effect of counselling on coping with decision to continue an unplanned pregnancy: a randomized controlled clinical trial

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

15-49 years old married women Women with unplanned pregnancy with the decision to continue pregnancy Getting 14 or higher scores in avoiding domain of the NU-PCI tool Getting 27 or higher scores in tool of perceived worries and threats

### Exclusion criteria:

known psychological disorders according to women statements Illegal pregnancies Fetal abnormalities high risk Pregnancies family problems

## Age

From **15 years** old to **49 years** old

## Gender

Female

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **82**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Randomly allocation to intervention and control groups

## 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 Tabriz University of Medical Sciences

##### Street address

Golgasht Street

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5138947-977

##### Approval date

2017-12-03, 1396/09/12

##### Ethics committee reference number

IR-TBZMED.REC.1396.793

## Health conditions studied

### 1

#### Description of health condition studied

Problems related to unwanted pregnancy

#### ICD-10 code

z64

#### ICD-10 code description

Problems related to certain psychosocial circumstances

## Primary outcomes

### 1

#### Description

Women's coping with decision to continue an unplanned pregnancy

#### Timepoint

Before the intervention and 4-8 weeks after the intervention

#### Method of measurement

Revised Prenatal Coping Inventory: NU-PCI

## Secondary outcomes

### 1

#### Description

Anxiety in women with unplanned pregnancy

#### Timepoint

Before the intervention and 4-8 weeks after the intervention

#### Method of measurement

Revised Pregnancy Related Anxiety Questionnaire: PRAQ-R2

### 2

#### Description

Worries and perceived threats

#### Timepoint

Before the intervention and 4-8 weeks after the intervention

#### Method of measurement

Unplanned pregnant women's worries and perceived threats Questionnaire

## Intervention groups

### 1

#### Description

For intervention group, four consultation sessions, once a week, for 60 to 90 minutes would be held.

**Category**

Behavior

**2**

**Description**

The control group will receive only routine prenatal care.

**Category**

Behavior

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Sardrood health center

**Full name of responsible person**

Nayyer Bayrampour

**Street address**

Seyed Ahmad Street, Above Asra kindergarten

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**Postal code**

5361765794

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**2**

**Recruitment center**

**Name of recruitment center**

Eram health center

**Full name of responsible person**

Nayyer Bayrampour

**Street address**

Eram Town, District 8, Almahdi Street

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**3**

**Recruitment center**

**Name of recruitment center**

Azadi health center

**Full name of responsible person**

Nayyer Bayrampour

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Mofatteh, Telecommunication station

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**4**

**Recruitment center**

**Name of recruitment center**

Emamieh health center

**Full name of responsible person**

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Hakim Nezami Street, Meraj Avenue

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**5**

**Recruitment center**

**Name of recruitment center**

Hokmabad health center

**Full name of responsible person**

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Bahar Street, Infront of Asadabadi Hospital

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**6**

**Recruitment center**

**Name of recruitment center**

Sadeginejad health center

**Full name of responsible person**

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**Street address**

Hojjati Street (Professor Jafari), Teacher Blvd

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**7**

**Recruitment center**

**Name of recruitment center**

Gomtapeh health center

**Full name of responsible person**

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**Street address**

Yekah Dokkan, Shahid Gharabaghi Street

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**8**

**Recruitment center**

**Name of recruitment center**

Jamshid Abad health center

**Full name of responsible person**

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**Street address**

Monajjem Street

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**9**

**Recruitment center**

**Name of recruitment center**

Sayad Shirazy health center

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**10**

**Recruitment center**

**Name of recruitment center**

Ebnesima health center

**Full name of responsible person**

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**11**

**Recruitment center**

**Name of recruitment center**

Mojahedin health center

**Full name of responsible person**

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**12**

**Recruitment center**

**Name of recruitment center**

Montazeri health center

**Full name of responsible person**

Nayyer Bayrampour

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**Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Reza Rashidi

**Street address**

Golgasht Ave, Azadi Street

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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**

Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Nayyer Bayrampour

**Position**

MSc Student of Counseling in Midwifery

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

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### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

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Assistant Professor

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### Person responsible for updating data

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### Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

I have no plans for publication yet

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available  
**Informed Consent Form**  
No - There is not a plan to make this available  
**Clinical Study Report**  
Yes - There is a plan to make this available  
**Analytic Code**  
No - There is not a plan to make this available  
**Data Dictionary**  
No - There is not a plan to make this available  
**Title and more details about the data/document**  
RCT report as scientific paper  
**When the data will become available and for how long**

15 months  
**To whom data/document is available**  
Editor in chief and reviewers of the journals, Authors of systematic review and meta-analysis  
**Under which criteria data/document could be used**  
For ensuring the data originality and evidence based decision- making  
**From where data/document is obtainable**  
Corresponding author  
**What processes are involved for a request to access data/document**  
Formal request  
**Comments**