

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

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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

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Tabriz

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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

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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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

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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