

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of educational intervention based on social cognitive theory on marital burnout in pregnant women

Protocol summary

Study aim

Determining the effect of educational intervention based on Social Cognitive Theory on marital burnout in pregnant women

Design

87 pregnant women were randomly assigned to parallel intervention and control groups and participants are given a code. The intervention is conducted in 4 sessions of 90 minutes for the intervention group.

Settings and conduct

Place of intervention is Gonabad city health centers. The intervention group is trained based on social cognitive theory and the control group does not receive any training and they are evaluated with a questionnaire after two months.

Participants/Inclusion and exclusion criteria

Entry requirements: pregnant women aged 45 to 15 years old; satisfaction to participate in the study; having at least elementary education. Exit criteria: gestational age more than 30 weeks; cancel continued cooperation; absence more than once in educational sessions; acute or chronic mental illness.

Intervention groups

The intervention group consisted of 87 pregnant women in two groups of 43 exams and 44 controls. The intervention group provides training based on the effective structures of social cognitive theory, while the control group only receives routine health care.

Main outcome variables

Marital burnout pregnant women

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160917029843N6**

Registration date: **2018-05-29, 1397/03/08**

Registration timing: **retrospective**

Last update: **2018-05-29, 1397/03/08**

Update count: **0**

Registration date

2018-05-29, 1397/03/08

Registrant information

Name

Mohammad Vahedian-Shahroodi

Name of organization / entity

Social Determinants of Health Research Center,
Mashhad University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-29, 1396/08/07

Expected recruitment end date

2017-12-28, 1396/10/07

Actual recruitment start date

2017-10-29, 1396/08/07

Actual recruitment end date

2017-12-28, 1396/10/07

Trial completion date

empty

Scientific title

Effect of educational intervention based on social cognitive theory on marital burnout in pregnant women

Public title

The impact of education on marital burnout pregnant women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women aged 45 to 15 years old Having at least basic literacy Have desire and cooperation to participate in the research

Exclusion criteria:

Having acute or chronic mental disorders Unwillingness to continue cooperation Absence more than once in training sessions Gestational age more than 30 weeks

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Actual sample size reached: **87**

Randomization (investigator's opinion)

Randomized

Randomization description

Using a random number table

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 Mashhad University of Medical Sciences

Street address

University 18 Ave., School of Public Health

City

mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2016-11-12, 1395/08/22

Ethics committee reference number

IR.MUMS.REC.1395.407

Health conditions studied

1

Description of health condition studied

Marital Burnout pregnant women

ICD-10 code

Z34.0

ICD-10 code description

Encounter for supervision of normal first pregnancy

Primary outcomes

1

Description

Marital Burnout pregnant women

Timepoint

Before intervention, immediately after intervention, 2 months after intervention

Method of measurement

Marital Burnout Questionnaire(CBM)

Secondary outcomes

1

Description

knowledge

Timepoint

Before intervention, immediately after intervention, 2 months after intervention

Method of measurement

Questionnaire

2

Description

Expect the outcome

Timepoint

Before intervention, immediately after intervention, 2 months after intervention

Method of measurement

Questionnaire

3

Description

The value of the outcome

Timepoint

Before intervention, immediately after intervention, 2 months after intervention

Method of measurement

Questionnaire

4

Description

Self efficacy

Timepoint

Before intervention, immediately after intervention, 2 months after intervention

Method of measurement

Questionnaire

5

Description

Self-efficacy overcoming obstacles

Timepoint

Before intervention, immediately after intervention, 2 months after intervention

Method of measurement

Questionnaire

6

Description

Availability

Timepoint

Before intervention, immediately after intervention, 2 months after intervention

Method of measurement

Questionnaire

7

Description

Social support

Timepoint

Before intervention, immediately after intervention, 2 months after intervention

Method of measurement

Questionnaire

8

Description

Observational learning

Timepoint

Before intervention, immediately after intervention, 2 months after intervention

Method of measurement

Questionnaire

9

Description

Skill

Timepoint

Before intervention, immediately after intervention, 2 months after intervention

Method of measurement

Questionnaire

10

Description

Understand the situation

Timepoint

Before intervention, immediately after intervention, 2 months after intervention

Method of measurement

Questionnaire

11

Description

Self-regulatory

Timepoint

Before intervention, immediately after intervention, 2 months after intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: the intervention group includes 43 pregnant women. In addition to routine care, training is provided over four 90-minute sessions based on the more effective structures of social cognitive theory.

Category

Behavior

2

Description

Control group: the control group has 44 pregnant women who only receive routine care at the health centers.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Gonabad city health centers

Full name of responsible person

Mahin Moravejjifar

Street address

Gonabad, Asian Roads, Gonabad University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

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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

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohammad Vahedian Shahroodi

Position

Assistant Professor of Health Education and Health Promotion

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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

Yes - There is 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

Title and more details about the data/document

Potential data can be shared only after identification

When the data will become available and for how long

Get started one month after the results are published.

To whom data/document is available

Researchers working in academia and academic

Under which criteria data/document could be used

The data are sent by official request through academic or organizational emails of the researchers after confirmation and identification of the sender.

From where data/document is obtainable

Dr. Mohammad Vahedian-Shahroodi
vahedianm@mums.ac.ir

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

The data are sent by official request through academic or organizational emails of the researchers after confirmation and identification of the sender.

Comments