

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Effect of an intervention on health care empowerment among women in reproductive age referring to health centers affiliated to Tehran University of Medical Sciences: Application of the Theory of Planned Behavior

Protocol summary

Study aim

Determining the Effect of an Intervention on Increasing the empowerment of Health Care in Married Women of Reproductive Age Referring to Health Care Centers affiliated to Tehran University of Medical Sciences.

Design

This is a randomized controlled trials. The population of the study is 484 married women of reproductive age, aged 15-49 years old. They are referred to health centers in southern Tehran to receive health care. The method of sampling in each center is done randomly. Intervention for one month and 5 sessions will be held for 30 to 45 minutes as group training. Subsequently, the questionnaire will be completed six months after the intervention for both interventions and comparisons.

Settings and conduct

Health centers in south Tehran, selected centers are randomly selected.

Participants/Inclusion and exclusion criteria

The criteria for entering The study are marriage, being in reproductive age (15-49), consent to participate in the study, women who have literacy and nationality as Iranian. Exit criteria The study participants are reluctant to continue cooperation and absence more than 2 sessions in the training sessions that will be held for 5 sessions for the intervention group

Intervention groups

The intervention group of married women of reproductive age(15-49) referred to Southern health centers with written consent and willingness to participate in studying and receiving educational interventions to increase the ability to receive health care. Control group: Married women of reproductive age referring to the same centers that do not receive any educational intervention

Main outcome variables

empowerment to receive health care, Behavioral intention, attitude towards behavior, normative beliefs and perceived behavior control

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151208025431N6**

Registration date: **2018-08-11, 1397/05/20**

Registration timing: **prospective**

Last update: **2018-08-11, 1397/05/20**

Update count: **0**

Registration date

2018-08-11, 1397/05/20

Registrant information

Name

Elham Shakibazadeh

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 4293 3210

Email address

shakib@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2019-02-20, 1397/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty
Scientific title
Effect of an intervention on health care empowerment among women in reproductive age referring to health centers affiliated to Tehran University of Medical Sciences: Application of the Theory of Planned Behavior

Public title
The Effect of Intervention on Increasing the empowerment health care in married women

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Married women referring to health centers in the south
At the age of fertility (age 49-15) Satisfaction to participate in the study Women who are literate read and write Their nationality is Iranian.

Exclusion criteria:

The unwillingness of the subjects under study to continue cooperation Absence of more than 2 sessions in the training sessions, with 5 sessions for the intervention group.

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **484**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization

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 tehran University of Medical Sciences

Street address

Poursina Street, Quds Ave, Keshavarz Boulevard, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2018-05-09, 1397/02/19

Ethics committee reference number

IR.TUMS.SPH.REC.1397.017

Health conditions studied

1

Description of health condition studied

Empowerment to receive health care in women of reproductive age

ICD-10 code

Z76.1

ICD-10 code description

Health supervision and care of foundling

Primary outcomes

1

Description

Behavioral intention

Timepoint

Before the intervention and 6 months after the intervention

Method of measurement

Researcher made questionnaire based on the Theory of Planned Behavior

2

Description

Attitude towards the behavior

Timepoint

Before the intervention and 6 months after the intervention

Method of measurement

Researcher made questionnaire based on the Theory of Planned Behavior

3

Description

Behavioral beliefs

Timepoint

Before the intervention and 6 months after the intervention

Method of measurement

Researcher made questionnaire based on the Theory of

Planned Behavior

4

Description

Outcom evaluation

Timepoint

Before the intervention and 6 months after the intervention

Method of measurement

Researcher made questionnaire based on the Theory of Planned Behavior

5

Description

Subjective norm

Timepoint

Before the intervention and 6 months after the intervention

Method of measurement

Researcher made questionnaire based on the Theory of Planned Behavior

6

Description

Normative beliefs

Timepoint

Before the intervention and 6 months after the intervention

Method of measurement

Researcher made questionnaire based on the Theory of Planned Behavior

7

Description

motivation to comply

Timepoint

Before the intervention and 6 months after the intervention

Method of measurement

Researcher made questionnaire based on the Theory of Planned Behavior

8

Description

Perceived behavioral control

Timepoint

Before the intervention and 6 months after the intervention

Method of measurement

Researcher made questionnaire based on the Theory of Planned Behavior

9

Description

Control Beliefs

Timepoint

Before the intervention and 6 months after the

intervention

Method of measurement

Researcher made questionnaire based on the Theory of Planned Behavior

10

Description

Perceived Power

Timepoint

Before the intervention and 6 months after the intervention

Method of measurement

Researcher made questionnaire based on the Theory of Planned Behavior

Secondary outcomes

1

Description

Empowerment health care in two dimensions: feeling and importance

Timepoint

Before the intervention and 6 months after the intervention

Method of measurement

Standard (Health Care Empowerment Questionnaire)

Intervention groups

1

Description

Intervention group: Educational interventions to increase the empowerment to receive health care in married women of reproductive age (aged 15-49) with the application of the theory of planned behavior and the needs assessment that was done prior to the beginning of the study and the empowerment to receive health care in women of reproductive age before The intervention will be measured 6 months after the intervention.

Category

Behavior

2

Description

Control group: In the control group, intervention is not performed and only after completing the study for observance of the ethics of all the teaching aids will be provided to this group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

South Tehran Health Centers
Full name of responsible person
Dr. Ghayumzadeh
Street address
No. 2, Alley, Shahid Abbas Shafiee,Vesal SHirazi Ave,
Engelab Ave
City
Tehran
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1417863181
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Gayumzadeh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraeiyan
Street address
Poursina Street, Quds Ave, Keshavarz Boulevard,
Tehran, Iran
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1417653761
Phone
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Email
name@domian.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences
Full name of responsible person
Maryam Saboury
Position
Student Master
Latest degree
Master
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

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Associate professor
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Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
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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