Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Explanatory phenomenological study of childbearing and parenting of primiparas women ,design,implementation and evaluation of empowerment program based on theory of planned behavior: mixed method study

Protocol summary

Study aim
Design implementation and evaluation of primipara women empowerment program based on TPB theory and phenomenological study
Design
Randomized clinical trial with control group
Settings and conduct
Health centers of Tehran University of Medical Sciences
Participants/Inclusion and exclusion criteria
Inclusive criteria:Primipara,20to30 ages,healthy baby,less than 9 months. Exclusive criteria:Phsycological patient.responsible for family.withdrawal women
Intervention groups
Effect of educational intervention and educational package about primipara women empowerment program
Main outcome variables
The constructs of theory of planned behavior: awareness,attitude, subjective norms ,perceived behavioural control, behavioural intention, behavior

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180123038487N1**
Registration date: **2018-10-14, 1397/07/22**
Registration timing: **prospective**

Last update: **2018-10-14, 1397/07/22**
Update count: **0**
Registration date
2018-10-14, 1397/07/22

Registrant information

Name
Nilowfar Salighehdar iran
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 6687 4437
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-10-20, 1397/07/28
Expected recruitment end date
2019-05-20, 1398/02/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Explanatory phenomenological study of childbearing and parenting of primiparas women ,design,implementation and evaluation of empowerment program based on theory of planned behavior: mixed method study

Public title
Evaluation of empowerment program on primipara women based on theory
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
They are primiparas. They are in rage of 20 to 30 ages.

They are in 9 months after from birth.

Exclusion criteria:

They are not psychological patient. They are not responsible of family. They are not withdrawal women. They do not have abnormal baby.

Age

From **20 years** old to **30 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

It is done with simple randomization by random number table with cluster unit.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

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

Qods st.Poor sina st.Health collage.TUMS

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2018-05-22, 1397/03/01

Ethics committee reference number

IR.TUMS.VCR.REC.1397.033

Health conditions studied

1

Description of health condition studied

Enable primipara women about childbearing and parenting after interventional-educational program based on theory

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Enable of primipara women based on evaluation of constructs of TPB

Timepoint

Before, exact after intervention,4 months after intervention

Method of measurement

Questionnaire (empowerment program of primipara based on TPB)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 6 sessions include meeting, educational package,,discussion based on qualitative study,theory and need assessment before of study.After intervention it is done post test and 4 months after that with valid and reliable instrument (questionnaire).

Category

Lifestyle

2

Description

Control group:without educational intervention and with pretest and post test according to intervention group.Finally it is given to them educational package for their participation.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers of Tehran University of Medical Sciences

Full name of responsible person

Nilowfar Salighehdar Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr Mohammad Ali Sahraian

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http://rmo.tums.ac.ir/

Grant name
Dr Mohammad Ali Sahraian

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
Hassan Eftekhar Ardebily

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Others

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Just results of research without private data of samples are presented.
When the data will become available and for how long
Accessible 6 months after printing of results
To whom data/document is available
Instructors and students
Under which criteria data/document could be used
Complete and innovation
From where data/document is obtainable
TUMS.Health collage.Library
What processes are involved for a request to access data/document
Search in library of collage(Health) and find it.Then you use of data of dissertation
Comments