Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of education based on theory of planned behavior with routine education on preventive behaviors of urinary tract infection in pregnant women referred to Zarrin Shahr health center

Protocol summary

Study aim

Comparison of the effect of education based on theory of planned behavior with routine education on adopting preventive behaviors of urinary tract infection in pregnant women in Zarrin Shahr

Design

The present study is a clinical trial with control group with parallel groups. Simple randomization method is used to assign pregnant women to intervention and control groups using random number table. Sample size in this study will be 88 persons who will be assigned to intervention and control groups with 1: 1 ratio. The study is in the phase of selecting the sample and assigning the samples to the intervention and control groups

Settings and conduct

In this study, after obtaining the necessary authorization for the research, random sampling will be conducted and for the intervention group 5 educational sessions based on the theory of planned behavior will be held in health centers of Zarrin Shahr. The control group will receive routine training.

Participants/Inclusion and exclusion criteria

Inclusion criteria included pregnant women in the first trimester of pregnancy, Having a health record in Zarinshahr health centers, no laboratory-based urinary tract infections, no chronic diseases including diabetes, no antibiotic use, and immunosuppressive drugs and consent to participate in the study . Exclusion criteria included urinary tract infection (UTI) based on laboratory tests, chronic illnesses including diabetes, using antibiotic , and immunosuppressive drugs and lack of consent to participate in the study.

Intervention groups

Intervention group women will receive 5 training sessions on UTI behaviors based on the theory of planned behavior. Women in the control group will receive the routine training provided at the health center.

Main outcome variables

Preventive Behaviors of Urinary Tract Infection
Prevalence of urinary tract infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170214032575N1**
Registration date: **2019-12-12, 1398/09/21**
Registration timing: **retrospective**

Last update: **2019-12-12, 1398/09/21**
Update count: **0**

Registration date

2019-12-12, 1398/09/21

Registrant information

Name
fahime bagherikholenjani

Name of organization / entity
hamadan university of medical sciences

Country
Iran (Islamic Republic of)

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+98 813838002526

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f.bagheri@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-19, 1398/05/28

Expected recruitment end date

2019-11-19, 1398/08/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of education based on theory of planned behavior with routine education on preventive behaviors of urinary tract infection in pregnant women referred to Zarrin Shahr health center

Public title

The effect of education on preventive behaviors of urinary tract infection in pregnant women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Being in the first trimester of pregnancy No urinary tract infection based on laboratory tests Lack of chronic diseases such as diabetes Not taking antibiotics and Immunosuppressive drugs Having a health record in Zarinshahr health centers Consent to participate in the study

Exclusion criteria:

Urinary tract infection based on laboratory tests Having chronic diseases such as diabetes Taking antibiotics and immunosuppressive drugs Lack of consent to participate in the study

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a simple randomization method will be used. The unit of randomization will be a person. Firstly, eligible pregnant woman will be assigned randomly to either the intervention or the control group according to the Random Number Table, and then the randomization will continue until the balance is established in terms of the size of the groups. In order to ensure allocation concealment, the central randomization method will be used so that a random sequence was given to the original researcher at one of the centers and the samplings of pregnant woman in other centers are done simultaneously. Other colleagues at other centers will contact the researcher through the telephone and ask questions about the random allocation of the pregnant woman to the intervention and control group.

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

Isfahan University of Medical Sciences

Street address

Hezarjarib Street

City

ISFAHAN

Province

Isfehan

Postal code

8174673461

Approval date

2019-08-18, 1398/05/27

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.294

Health conditions studied

1

Description of health condition studied

urinary tract infection

ICD-10 code

N39.0

ICD-10 code description

Urinary tract infection, site not specified

Primary outcomes

1

Description

Preventive Behaviors of Urinary Tract Infection

Timepoint

Before and three months after intervention

Method of measurement

Researcher-made questionnaire

Secondary outcomes

1

Description

Prevalence of urinary tract infection

Timepoint

Before and three months after intervention

Method of measurement

Urine culture and urine analysis test

Intervention groups

1

Description

Intervention group women will receive 5 educational sessions based on the theory of planned behavior on preventive behaviors of urinary tract infection in the prenatal care center of the health center. The educational content will also be provided in consultation with specialist groups including physicians and midwives working in health centers and health education and health promotion professionals based on the theory of planned behavior. The intervention group will also receive routine health care of health centers for pregnant women

Category

Prevention

2

Description

Control group: Pregnant women will receive routine care at health center for pregnant women, which include examining the risk signs of UTI and face-to-face training in the prevention and control of symptoms of UTIs that Provided by midwives and health care providers.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Zarinshahr Urban Health Centers covered by Isfahan University of Medical Sciences

Full name of responsible person

Hossein Shahnazi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Sheida Moradpour

Position

Graduate student

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Person responsible for updating data

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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
Not applicable
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available