

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effectiveness of tele supportive-educational counseling on constipation and heartburn in pregnancy in pregnant women referring to health centers.

Protocol summary

Study aim

Determining the effect of remote educational support counseling on constipation and heartburn in pregnant women referring to health centers.

Design

This study is a semi-experimental clinical trial with pre-test and post-test and control group with parallel groups. The sampling method was accessible. Even days were assigned to the control groups and odd days to the intervention groups.

Settings and conduct

This study was conducted in pregnant women with constipation and heartburn who referred to health centers in Niriz and Estehban cities. Before the intervention, a specific questionnaire for constipation, heartburn and demographic information was provided to the four groups and they were asked to complete it. In the two intervention groups, three emote educational support counseling were given immediately after reviewing the questionnaire, one week later and two weeks. Finally, one week after the intervention, the questionnaire (once after the intervention) were given to the four groups to complete it.

Participants/Inclusion and exclusion criteria

At least reading and writing literacy, being in the third trimester, not having a history of internal diseases and surgery or taking special drugs, having a singleton pregnancy, having access to a telephone, not having hearing and speech problems, not having hemorrhoids.

Intervention groups

The intervention groups included two groups of pregnant women with constipation and one group of pregnant women with heartburn. In the two intervention groups, three emote educational support counseling were given immediately after reviewing the questionnaire, one week later and two weeks. The control groups included a group of pregnant women with constipation and another group

of pregnant women with heartburn who received routine pregnancy care.

Main outcome variables

Reducing constipation and heartburn

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170624034722N3**

Registration date: **2024-01-08, 1402/10/18**

Registration timing: **retrospective**

Last update: **2024-01-08, 1402/10/18**

Update count: **0**

Registration date

2024-01-08, 1402/10/18

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5177

Email address

f_mirzaee@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-04, 1402/11/15

Expected recruitment end date

2024-06-04, 1403/03/15

Actual recruitment start date

2021-01-09, 1399/10/20

Actual recruitment end date

2021-09-01, 1400/06/10

Trial completion date

2021-09-01, 1400/06/10

Scientific title

The effectiveness of tele supportive-educational counseling on constipation and heartburn in pregnancy in pregnant women referring to health centers.

Public title

The effectiveness of tele supportive-educational counseling on constipation and heartburn in pregnancy.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Minimum literacy Being in the third trimester of pregnancy Not having a history of internal diseases and surgery or taking special drugs Having a single pregnancy Having access to a mobile phone Not having hearing and speech problems

Exclusion criteria:

Having a premature labour Having hemorrhoids

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **110**Actual sample size reached: **110****Randomization (investigator's opinion)**

Randomized

Randomization description

Simple 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 Kerman University of Medical Sciences.

Street address

University of Medical Sciences campus, the beginning

of Haft Bagh Alavi axis, Kerman, Iran.

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2019-07-30, 1398/05/08

Ethics committee reference number

97001067

Health conditions studied**1****Description of health condition studied**

Constipation

ICD-10 code

K59.0

ICD-10 code description

Constipation

2**Description of health condition studied**

Heartburn

ICD-10 code

R12

ICD-10 code description

Heartburn

Primary outcomes**1****Description**

Constipation score based on the constipation checklist based on Rome III criteria

Timepoint

Before the intervention and one week after the intervention

Method of measurement

Constipation checklist based on Rome III criteria

2**Description**

Heartburn based on Gastroesophageal reflux disease (GERD)questionnaire.

Timepoint

Before the intervention and one week after the intervention

Method of measurement

Gastroesophageal reflux disease (GERD)questionnaire.

Secondary outcomes

empty

Intervention groups

f_mirzaee@kmu.ac.ir

1

Description

گروه مداخله اول: زنان دارای یبوست بر اساس پرسشنامه یبوست وارد مطالعه شدند و سه جلسه مشاوره تلفنی را به دلیل دوران III کرونای دریافت کردند که هر مکالمه حدود 10-20 دقیقه با رعایت اصول مشاوره انجام شد.

Category

Treatment - Other

2

Description

The first control group included pregnant women with constipation based on the Rome III constipation questionnaire who received routine pregnancy care.

Category

N/A

3

Description

The second intervention group: included women with heartburn based on the Gastroesophageal reflux disease (GERD) questionnaire, who received three phone consultations due to the spread of the corona virus.

Category

N/A

4

Description

The second control group: included women with heartburn based on the Gastroesophageal reflux disease (GERD) questionnaire who received routine pregnancy care.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers of Niriz and Estehban cities

Full name of responsible person

Firoozeh Mirzaee

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University of Medical Sciences campus, the beginning of Haft Bagh Alavi axis, Kerman, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abedin Iranpour

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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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Firoozeh Mirzaee

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Firoozeh Mirzaee

Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Other areas of specialty/work

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

If there is a reasonable request for any of the above items during the registered e-mail, it will be provided to the academic authors after the publication of the article.

When the data will become available and for how long

After publishing the article

To whom data/document is available

Academic individuals

Under which criteria data/document could be used

To help academics in the field of writing papers and after publication of the article.

From where data/document is obtainable

Contact the following email: f_mirzaee@kmu.ac.ir

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

After publishing the article, academics just need to contact the following email address:

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Comments