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

1

Description
گروه مداخله اول: زنان دارای یبوست بر اساس پرسشنامه یبوست وارد مطالعه شدند و سه جلسه مشاوره تلفنی را به دلیل دوران IIIارم کرونا دریافت کردند که هر مکالمه حدود 20-10 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
Street address
University of Medical Sciences campus, the beginning of Haft Bagh Alavi axis, Kerman, Iran.
City
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f_mirzaee@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Abedin Iranpour
Street address
University of Medical Sciences campus, the beginning of Haft Bagh Alavi axis, Kerman, Iran.
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f_mirzaee@kmu.ac.ir
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
Street address
Kerman, the beginning of Haft Bagh Alavi axis, University of Medical Sciences campus
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Person responsible for scientific inquiries

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Person responsible for updating data

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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: f_mirzaee@kmu.ac.ir
Comments