

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of telephone support on health-related quality of life in women with nausea and vomiting of pregnancy

Protocol summary

Summary

The aim of this study was to determine the effect of telephone support on health-related quality of life in women with nausea and vomiting of pregnancy. This clinical trial was done on 64 primiparous women who referred to the selected health care centers in Mashhad city with gestational age 6-10 weeks. Modified Pregnancy-Unique Quantification of Emesis and Nausea questionnaire and Visual Analog stress Scale For eligible women with diagnosed of nausea and vomiting of pregnancy by nausea and vomiting protocol in "Safe Motherhood country program booklet" through interview was completed. If there is mild to moderate nausea and vomiting, necessary educational actions on the basis of the "checklist of patient education with pregnancy nausea and vomiting" was performed by researchers. This checklist according to nausea and vomiting protocol in "Safe Motherhood country program booklet" was prepared by the researcher. Demographic and obstetric questionnaire was completed for units of study (nausea and vomiting in pregnancy, quality of life questionnaire and Multidimensional Scale of Perceived Social Support). Units of study were allocated randomly into control (30 patients) and experimental group (30 patients). In the intervention group, telephone support was twice a week to four weeks, and each time was 15-20 minutes. Telephone support was includes advice on modification of diet and lifestyle, reduce fatigue and improve psychological states of pregnant. Control group was usual care. Again after four weeks, Modified Pregnancy-Unique Quantification of Emesis and Nausea questionnaire, nausea and vomiting in pregnancy quality of life questionnaire, multidimensional Scale of Perceived Social Support and Visual Analog stress Scale were complemented by face to face.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014012316326N1**

Registration date: **2014-05-30, 1393/03/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-05-30, 1393/03/09

Registrant information

Name

Narjes Abbaszadeh

Name of organization / entity

Faculty of nursing and midwifery of Mashhad

Country

Iran (Islamic Republic of)

Phone

+98 79 1333 1199

Email address

abbaszn901@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2013-10-02, 1392/07/10

Expected recruitment end date

2014-02-09, 1392/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of telephone support on health-related quality of life in women with nausea and vomiting of pregnancy

Public title

The effect of telephone support on health-related quality of life in nausea and vomiting of pregnancy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: gestational age 6-10 week, First pregnancy, Having mild or moderate nausea and vomiting by Modified Pregnancy-Unique Quantification of Emesis and Nausea questionnaire, Access to telephone, Would like to participate in the study, Lack of medical disease in pregnancy, Lack of Hearing impairment , Not use anti-nausea drug treatments or alternative medicine during the past week Exclusion criteria: obtain Score more than seven of the visual Analog stress scale, Having symptoms of threatened abortion

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Building Qureshi, Daneshgah Avenue

City

Mashhad

Postal code

Approval date

2013-08-17, 1392/05/26

Ethics committee reference number

research/920084/1/101

Health conditions studied

1

Description of health condition studied

Health-related quality of life in nausea and vomiting of pregnancy

ICD-10 code

O21

ICD-10 code description

Excessive vomiting in pregnancy

Primary outcomes

1

Description

Health-related quality of life in nausea and vomiting of pregnancy

Timepoint

Before the intervention and four weeks after the intervention

Method of measurement

Nausea and vomiting in pregnancy quality of life questionnaire

Secondary outcomes

1

Description

Nausea and vomiting of pregnancy

Timepoint

Before the intervention and four weeks after the intervention

Method of measurement

Modified Pregnancy-Unique Quantification of Emesis and Nausea questionnaire

Intervention groups

1

Description

Control group received just routine care

Category

N/A

2

Description

In the experimental group, 15-20 minutes phone provided twice a week for four weeks. Telephone support, included offering measures to improve diet and life style as well as actions for reducing fatigue and enhancing psychological well- being

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Health care centers no.1, 2, 3, 5 and Samen

Full name of responsible person**Street address****City**

Mashhad

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Building Qureshi, Daneshgah Avenue

City

Mashhad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Faculty of Nursing and Midwifery of Mashhad

Full name of responsible person

Zahra Abedian

Position

Master of midwifery

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*