Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jul 2026

The effect of prenatal supportive care of midwives in pregnant women with chronic diseases: Randomized Controlled Trial

Protocol summary

Study aim
The effect of prenatal supportive care of midwives in pregnant women with chronic diseases

Design
A clinical trial with a control group, with parallel design, without blinding, will be performed on 204 pregnant women (102 people in each group For randomization, 4 random blocks with a 1: 1 allocation ratio will be used. After listing all possible modes of 4 blocks and assigning a number to each of them using a computer random number table, with a 1: 1 allocation ratio, individuals will be divided into two groups receiving routine care and supportive care. To hide the allocation, the type of intervention will be written on paper and numbered in a series of matte envelopes.

Settings and conduct
This study will be performed in the pregnancy clinic in Imam Khomeini Hospital in Ahvaz. Participants will be eligible for pregnant women with chronic illness. Pregnant women will be randomly divided into intervention and control groups, the intervention group will receive supportive care and the control group will receive routine pregnancy care.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Pregnant women with one or more chronic diseases؛ between 16-20 weeks of pregnancy؛ single pregnancy؛ able to understand Persian speech and writing؛ resident of Ahvaz, having a mobile phone؛ consent to participate in the study. Exclusion criteria: self-report history of substance abuse؛ self-report of mental disorder and use of psychiatric drugs؛ unwillingness to continue participating in the study.

Intervention groups
Intervention group, supportive care and pregnancy control control group will receive the routine.

Main outcome variables
The length of hospital stay (mean and standard deviation) is measured from the time of admission to the study until 2 weeks after delivery.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220203053927N1**
Registration date: **2022-02-10, 1400/11/21**
Registration timing: **prospective**

Last update: **2022-02-10, 1400/11/21**
Update count: **0**

Registration date
2022-02-10, 1400/11/21

Registrant information

Name
solmaz mohammadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3321 9122

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-26, 1400/12/07

Expected recruitment end date
2022-12-21, 1401/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of prenatal supportive care of midwives in pregnant women with chronic diseases: Randomized Controlled Trial

Public title

The effect of prenatal supportive care of midwives in pregnant women with chronic diseases

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

1.Pregnant women with one or more chronic diseases that are diagnosed more than 6 months before pregnancy, with continued recurrence and need for medical treatment 2.Be between 16-20 weeks pregnant at the time of enrollment in the study 3.Single pregnancy 4.Be able to understand Persian speech and writing 5.To live in Ahvaz 6.Having a cell phone 7.Satisfaction to participate in the study

Exclusion criteria:

1.Self-report history of substance abuse 2.Self-report of mental disorder and use of psychiatric drugs 3.Reluctance to continue participating in the study

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **204**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible women will randomly assign into two groups of routine (individual) prenatal care or group prenatal care using block randomization with a block size of 4 and an allocation ratio of 1:1. Thus, after listing all possible situations of 4 blocks and assigning a number to each of them using a computer random number table with a 1: 1 ratio, participants will be allocated into two groups, namely routine prenatal care and supportive care care. For allocation concealment, each woman will receive a code and all codes will be kept in an opaque envelope until the time of intervention. Sequencing of allocation and preparation of envelopes will be done by a person that will not involve sampling and data collection. The researcher and the participant will not aware of the groups and the intervention that they received until the commencement of intervention

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

Shahroud University of Medical Sciences

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Shahroud ,7th of Tir Square - Shahroud University of Medical Sciences and Health Services

City

Shahroud

Province

Semnan

Postal code

۳۶۱۴۷-۷۳۹۴۳

Approval date

2020-12-01, 1399/09/11

Ethics committee reference number

IR.SHMU.REC.1399.123

Health conditions studied

1

Description of health condition studied

prenatal supportive care

ICD-10 code

O36.7

ICD-10 code description

Maternal care for viable fetus in abdominal pregnancy

Primary outcomes

1

Description

The length of hospital stay (mean and standard deviation) is measured from the time of admission to the study until 2 weeks after delivery.

Timepoint

Evaluation of this outcome will be done 2 weeks after delivery.

Method of measurement

medical records

Secondary outcomes

1

Description

World Health Organization 5-item Welfare Index

Timepoint

The evaluation will be performed at the beginning of the study (baseline), at 33-37 weeks of gestation and 6 weeks after delivery

Method of measurement

World Health Organization 5-item Welfare Scale World

Health Organization 5-item Welfare Scale Questionnaire

2

Description
Pregnancy and postpartum depression
Timepoint
The evaluation will be performed at the beginning of the study (baseline), at 33-37 weeks of gestation and 6 weeks after delivery
Method of measurement
Edinburgh Postpartum Depression Scale

3

Description
Pregnancy worries
Timepoint
The evaluation will be done at the beginning of the study (baseline) and at 33-37 weeks of pregnancy
Method of measurement
Cambridge Pregnancy Anxiety Scale Questionnaire

4

Description
Health-related quality of life
Timepoint
The evaluation will be performed at the beginning of the study (baseline), at 33-37 weeks of gestation and 6 weeks after delivery
Method of measurement
Health-related quality of life questionnaire

5

Description
Quality prenatal care from the perspective of service recipients
Timepoint
Evaluation 6 weeks after delivery
Method of measurement
Quality of Prenatal Care Questionnaire

6

Description
Satisfaction with childbirth
Timepoint
Evaluation 2 weeks after delivery
Method of measurement
Maki Maternity Satisfaction Scale

7

Description
Economic consequences of health (use of health services)
Timepoint
Evaluation 6 weeks after delivery
Method of measurement
Researcher-made questionnaire

8

Description
Prenatal health behaviors
Timepoint
The evaluation will be done at the beginning of the study (baseline) and at 33-37 weeks of pregnancy
Method of measurement
Prenatal health behaviors scale

9

Description
Consequences of pregnancy and childbirth
Timepoint
Evaluation 6 weeks after delivery
Method of measurement
Researcher-made questionnaire

Intervention groups

1

Description
InterIntervention group: Supportive prenatal care in the intervention group consists of 3 components: (1) active and passive telephone counseling before and after delivery, (2) coordination of care and case management, (3) continuous care buyDedicated midwife during pregnancy, during labor and delivery.Individuals in the prenatal care intervention group will receive the researcher in the specialized clinic of the selected hospital in weeks 30-24, 34-31, 37-35, 38, 39, 40.The researcher works in consultation with a perinatologist.At each visit, while examining the individual needs and desires of each woman, counseling and training appropriate to the gestational age will be provided individually and face to face.During the intervention period, the researcher will have one phone call per week with the participants and in each post-greeting call, she will examine three main areas: physical-mental health status and pregnancy health, evaluation-based recommendations, and discussion about Any other additional issues that are important to the mother.In this intervention, each participant can contact the midwife whenever they need to be consulted.Care coordination will be done by the researcher during the intervention period.The researcher identifies the specific needs and wants of each woman and discusses the optimal care of the woman with the obstetrician who is responsible for her medical care.The intervention group will be supported by the researcher as a companion midwife (Dola) from the beginning of the mother's hospitalization (beginning of the active phase of labor in the expansion of the cervix 3-4 cm) until the first 2 hours after delivery.The researcher will provide supportive measures for the mother during labor, classified into psychological, emotional, educational, and physical categories.The researcher will also be able to follow up and respond to maternal problems by phone and, if necessary, in person after the first 2 hours of labor.
Category
N/A

2

Description
Control group: The control group will receive routine care at the prenatal care clinic of the selected hospital by the resident on duty and under the supervision of a perinatologist. Routine pregnancy care based on national protocol includes 8 visits (in weeks 6-10, 20-16, 30-24, 34-31, 37-35, 38, 39, 40) which Based on the severity of the chronic disease and the risks associated with pregnancy, the treating physician will set up an individual care plan for each person's visit and care.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Pregnancy care clinic is an Imam Khomeini Hospital in Ahvaz (referral level 3 Hospital)

Full name of responsible person
Solmaz Mohammadi

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Ahvaz - Azadegan St. - Imam Khomeini Medical Center of Ahvaz.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Shahroud 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
Shahroud University of Medical Sciences

Full name of responsible person
Zahra Motaghi

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Not applicable

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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
The data can be published after the completion of the dissertation

When the data will become available and for how long
One year after completing the dissertation

To whom data/document is available
Shahroud and Ahvaz University of Medical Sciences, Hospital Officials, Researchers

Under which criteria data/document could be used
Data analysis through publication in scientific research journals in They will be available to others

From where data/document is obtainable
solmaz mohammadi, E mail: sl.mohammadi89@yahoo.com

What processes are involved for a request to access data/document
The information will be available through the publication of the article. But if more information is needed, the request should be sent via email

Comments