Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effects of the midwifery students' counseling and education on the mothers' attitudes towards delivery alternatives and women's attitudes to and skill of BSE in Hamadan city's clinics 2012

Protocol summary

Summary

This quasi-experimental study with two-group pre- and post-test design is conducted to determine the effects of the midwifery students' consultation and education on the referred mothers' attitudes toward delivery alternatives and the attitudes and skills of the referred women in breast self-examination in two health-care centers in Hamadan city, 2012. A center was randomly designated for experimental group sampling and another for the control ones. The study population includes all referred women/mothers to the research environments. 60 eligible primiparous women (n=30 in each experimental and control groups) and 60 non-pregnant women (n=30 in each experimental and control groups) are selected by convince sampling. in the first week of training, each group of midwifery students is prepared via the role-playing educational strategy to provide the counseling and education in the small group of mothers/women. Then, the counseling and educational intervention will be organized by these students for the small groups (maximum 6 participants) in the 2nd and 3rd weeks. All interventions will be done during two months. The research tools will be completed by interview/observation just before and after each counseling session in the experimental group and when the control ones come to clinic and before they leave it. The outcomes of this study are 1-the pregnant women's attitudes toward the delivery alternatives, 2-the women attitudes toward the BSE and 3-skills of the breast self exam.

General information

Acronym

NVD (Normal Vaginal Delivery) , SC (Cesarian section), BSE (Breast Self Exam)

IRCT registration information

IRCT registration number: **IRCT201205269862N1**
Registration date: **2012-07-06, 1391/04/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-07-06, 1391/04/16

Registrant information

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Mahnaz Khatiban
Name of organization / entity
Hamadabn University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2012-04-04, 1391/01/16

Expected recruitment end date

2012-06-20, 1391/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of the midwifery students' counseling and

education on the mothers' attitudes towards delivery alternatives and women's attitudes to and skill of BSE in Hamadan city's clinics 2012

Public title
The effects of the midwifery counseling on the Mothers' attitudes toward delivery alternatives and women's attitudes to and skill of BSE

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion Criteria for the first objective (to determine the effects of the education and counseling presented by midwifery students on the primipara pregnant women's attitudes toward delivery alternatives): The inclined women who are pregnant, primparous, with any physical and mental disease, in the last month of pregnancy. They have been undergoing routine prenatal care from at least 12 weeks of pregnancy. Inclusion Criteria for the 2nd and 3rd objectives (to determine the effects of the education and counseling presented by midwifery students on the women's attitudes to and skills of BSE): The inclined women who are not pregnant, with any physical and mental disease.

Age
No age limit

Gender
Female

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description

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
Hamadan University of Medical Sciences

Street address
Fahmideh Ave, Across the Mardom park

City
Hamadan

Postal code

Approval date
2012-06-11, 1391/03/22

Ethics committee reference number
1005/9/35/16/د/پ

Health conditions studied

1

Description of health condition studied
The pregnant women counselling about delivery alternatives by the midwifery students

ICD-10 code
Z71.9

ICD-10 code description
Counselling, unspecified

2

Description of health condition studied
The women counselling about self breast exam by the midwifery students

ICD-10 code
Z71.9

ICD-10 code description
Counselling, unspecified

3

Description of health condition studied
The education of the small group counseling method to the midwifery students via role-playing strategy

ICD-10 code
Z55.9

ICD-10 code description
Problem related to education and literacy, unspecified

Primary outcomes

1

Description
Women's attitudes towards BSE

Timepoint
Before and after the counseling session presented by midwifery students

Method of measurement
Questionnaire

2

Description
Pregnant women's attitudes to the delivery alternatives

Timepoint
Before and after the counseling session presented by midwifery students

Method of measurement
Questionnaire

3

Description

Women's skills in BSE

Timepoint

Before and after the counseling session presented by midwifery students

Method of measurement

Observational Checklist

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention: The midwifery students are going to be prepared to hold up the sessions of an small group counseling and education via role-playing strategy

Category

Behavior

2

Description

Intervention: the prepared midwifery students are going to present the delivery alternatives education and counseling to the primipara pregnant women in Imam Clinic./Control: the primipara pregnant women who are got routine counseling and education by personnel in the Shohada Clinic.

Category

Behavior

3

Description

Intervention: the prepared midwifery students are going to present the BSE education and counseling to the women in Imam Clinic./Control: the women who are got routine counseling and education by personnel in the Shohada Clinic.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Clinic- Hamadan University of Medical Sciences

Full name of responsible person

Mahnaz Khatiban

Street address

Sadaf St.

City

Hamadan

2

Recruitment center

Name of recruitment center

Shohada Clinic- Hamadan University of Medical Sciences

Full name of responsible person

Mahnaz Khatiban

Street address

Takhti St.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Dr. Haydar Tavilani

Street address

Fahmideh Ave. across te Mardom Park-Hamadan Medical Sciences University, Vice-Chancellor for Research & Technology

City

Hamadan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamadan 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

Hamadan University of Medical Sciences

Full name of responsible person

Mahnaz Khatiban

Position

PhD

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person
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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