

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The efficacy of Reproductive Life Plan-based counselling in improving knowledge and attitudes of women towards healthy reproduction

Protocol summary

Summary

1) Objectives: The aim of this study is to assess the efficacy of Reproductive Life Plan (RLP)-based counseling in improving women's knowledge and attitudes towards healthy reproduction. 2) Design: This is a randomized-controlled trial. 3) Setting and conduct: A health care services centre no. 7 in Sari city, Mazandaran. 183 women will be randomly allocated in three groups of intervention (n=61) and two control groups of each 61 women. 4) The study population will consist of reproductive-aged women (15-44 year) who will attend a primary health care center to receive health care services including pap smear, vaccination and routine health check-up. The study exclusion criterion is having permanent contraceptive methods. 5) At baseline, the intervention group will receive an RLP-based information session of 5-15 minutes duration plus an informative brochure regarding health reproduction. Intervention and two control groups all will receive routine care. The study tool is a questionnaire developed by the investigators using a literature search. Its validity and reliability were confirmed. The study questionnaire includes questions about demographic, reproductive history, knowledge and attitudes towards reproduction. At the follow-up visit, which is two months after the baseline visit, all participants in the three groups will fill in the study questionnaire. The intervention group will receive additional questions on their views and opinion about the intervention. 6) main outcome measures: Knowledge about folic acid intake prior to pregnancy and healthy reproduction

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016091929880N1**

Registration date: **2016-11-14, 1395/08/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-14, 1395/08/24

Registrant information

Name

Ensieh Fooladi

Name of organization / entity

Mazandaran University of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 7342

Email address

ensieh.fooladi@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences, Sari, Mazandaran, Iran

Expected recruitment start date

2016-10-03, 1395/07/12

Expected recruitment end date

2017-04-03, 1396/01/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of Reproductive Life Plan-based counselling in improving knowledge and attitudes of women towards healthy reproduction

Public title

The efficacy of Reproductive Life Plan-based counselling in improving knowledge and attitudes of women towards

healthy reproduction

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 15-44 year-old women referred to a health care services center no. 7 in Sari. Exclusion criteria: Having used a permanent method of contraception such vasectomy or tubal ligation

Age

From **15 years** old to **44 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **183**

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

Ethics committee of Mazandaran University of Medical Sciences

Street address

Vice Chancellor for Research, Moallem Street, Sari, Mazandaran University of Medical Sciences

City

Sari

Postal code

4816715793

Approval date

2016-10-02, 1395/07/11

Ethics committee reference number

IR.MAZUMS.REC.95.2535

Health conditions studied

1

Description of health condition studied

Contraceptive Counselling

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Knowledge of women towards taking folic acid before pregnancy and healthy reproduction

Timepoint

Before and two months after intervention

Method of measurement

questionnaire

Secondary outcomes

1

Description

Attitude towards reproductive health and evaluation of the intervention by participants

Timepoint

2 months after intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

After filling the questionnaire at baseline and receiving the routine health care, the intervention group will receive an RLP-based information session of 5-15 minutes duration plus an informative brochure regarding healthy reproduction.

Category

Prevention

2

Description

Two control groups all will receive routine care

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

A Health Care Center in Sari, No. 7

Full name of responsible person

Dr .Ensieh Fooladi

Street address

Nasibeh Nursing and Midwifery School, Vesal Street, Sari, Mazandaran

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Mazandaran University of Medical Sciences

Full name of responsible person

Ahmad Ali Enayati

Street address

Vice Chancellor for Research building, Moallem Street, Sari, Mazandaran University of Medical Sciences

City

Sari

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

Yes

Title of funding source

Vice Chancellor for Research, Mazandaran 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**

Mazandaran University Of Medical Sciences

Full name of responsible person

Dr. Ensieh Fooladi

Position

PhD

Other areas of specialty/work**Street address**

Nasibeh Nursing and Midwifery Faculty, Vesal Street, Sari, Mazandaran

City

Sari

Postal code

4816715793

Phone

+98 11 3336 7342

Fax**Email**

ensieh.fooladi5@gmail.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Mazandaran University Of Medical Sciences

Full name of responsible person

Dr.Ensieh Fooladi

Position

PhD

Other areas of specialty/work**Street address**

Nasibeh Nursing and Midwifery Faculty, Vesal street, sari, Mazandaran

City

Sari

Postal code

4816715793

Phone

+98 11 3336 7342

Fax**Email**

ensieh.fooladi5@gmail.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Mazandaran University Of Medical Sciences

Full name of responsible person

Dr.Ensieh Fooladi

Position

PhD

Other areas of specialty/work**Street address**

Nasibeh Nursing and Midwifery Faculty, Vesal street, sari, Mazandaran

City

Sari

Postal code

4816715793

Phone

+98 11 3336 7342

Fax**Email**

ensieh.fooladi5@gmail.com

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