

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Sep 2026

The effect of counseling on childbirth satisfaction in primiparous women based on Fordyce's happiness model

Protocol summary

Study aim

The effect of counseling on childbirth satisfaction in primiparous women based on Fordyce's happiness model in mothers referring to Zanjan health centers in 1401

Design

clinical trial with a control group, randomized, sample size= 80 people

Settings and conduct

Sampling will be done in Zanjan comprehensive health centers. 4 centers for the intervention group and 4 centers for the control group were selected by lottery. in the selected centers, Pregnant women, who meet the inclusion criteria, will be selected by simple random method. From the 29th week of pregnancy, the intervention group will receive group counseling based on Fordyce's happiness model. there is no blinding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age range from 18 to 42; Obtaining a score lower than 12.5 in the Edinburgh depression questionnaire; Absence of serious underlying disease; A healthy fetus without abnormalities and a singleton
Exclusion criteria: People who do not want to continue participating in the study; People who do not participate in more than one counseling session; the occurrence of stressful events; Elective and emergency cesarean sections

Intervention groups

From the 29th week of pregnancy, the intervention group will receive Fordyce's happiness group counseling in 6 sessions virtually (twice a week) and consecutively for 60-90 minutes using the WhatsApp application and sending clips and pictures in groups of 8 people. did At the same time, the control group will also receive routine prenatal care. In order to comply with ethics, after completing the study, all the educational videos prepared by me will be available to the control group

Main outcome variables

The level of satisfaction with childbirth; the level of happiness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201113049377N2**

Registration date: **2022-09-06, 1401/06/15**

Registration timing: **prospective**

Last update: **2022-09-06, 1401/06/15**

Update count: **0**

Registration date

2022-09-06, 1401/06/15

Registrant information

Name

Parvin Mohebbi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3344 6258

Email address

p.mohebbi11@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-16, 1401/06/25

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of counseling on childbirth satisfaction in primiparous women based on Fordyce's happiness model		Blinding (investigator's opinion)	Not blinded
Public title	The effect of counseling on childbirth satisfaction based on Fordyce's happiness model	Blinding description	
Placebo		Assignment	Not used
Purpose	Education/Guidance	Other design features	Parallel
Inclusion/Exclusion criteria		Secondary Ids	empty
Inclusion criteria:	Willingness to participate in the study Age range 18 to 42 Having the facilities and literacy to use the internet network in virtual space Obtaining a score lower than 12.5 in the Edinburgh Depression Questionnaire A singleton fetus (because Multiple pregnancy are candidates cesarean births and will be excluded from the study) Healthy fetus with no abnormalities No history of serious illness (heart, vascular, chronic kidney disease) Absence of psychological disorders Absence of drug, alcohol and street drug use	Ethics committees	
Exclusion criteria:	People who do not want to continue participating in the study People who do not participate in more than one counseling session Existence of mental disorders based on mothers' self-report Occurrence of stressful events in the research process such as: death of loved person, accident, separation from spouse and migration Elective and emergency cesarean sections such as bleeding, dystocia, meconium	1	
Age	From 18 years old to 42 years old	Ethics committee	
Gender	Female	Name of ethics committee	کمیته اخلاق دانشگاه علوم پزشکی زنجان
Phase	N/A	Street address	No. 3539, Badr 9 Ave, Zanjan city
Groups that have been masked	No information	City	زنجان
Sample size	Target sample size: 80	Province	Zanjan
Randomization (investigator's opinion)	Randomized	Postal code	4514913459
Randomization description	Sampling will be done by multi-stage random allocation. In the first stage, each urban area is considered as a cluster. There are a total of 22 comprehensive health centers and bases in Zanjan city, which are located in 4 urban areas. Then, from each cluster, two comprehensive health centers (one intervention center, one control center) will be selected by a simple random method through lottery. Based on this, we will have 8 comprehensive health centers, 4 centers for the intervention group and 4 centers for the group. will be controlled. In this way, the names of both centers are written on two separate sheets and placed in the lottery bag, then the first paper removed will be assigned to the intervention group and the remaining paper to the control group. In the next stage, in the selected centers, eligible pregnant women will be selected by a simple random method, and mothers who are in the twenty-ninth week of pregnancy and are willing to participate in the study and meet the inclusion criteria will be included in the study.	Approval date	2022-08-23, 1401/06/01
		Ethics committee reference number	IR.ZUMS.REC.1401.174
		Health conditions studied	
		1	
		Description of health condition studied	Satisfaction with childbirth
		ICD-10 code	
		ICD-10 code description	
		Primary outcomes	
		1	
		Description	Satisfaction with childbirth
		Timepoint	24 hours after delivery
		Method of measurement	McKay's childbirth satisfaction questionnaire
		Secondary outcomes	
		1	
		Description	level of Happiness
		Timepoint	In the first face-to-face meeting before the consultation,

in the 36th week of pregnancy and 24 hours after delivery

Method of measurement

Oxford Happiness Questionnaire

Intervention groups

1

Description

Intervention group: Participants in the intervention group will receive 6 virtual group counseling sessions based on Fordyce's happiness model, weekly and consecutively through the WhatsApp application for 60 to 90 minutes. The duration of the course is three weeks, and the contents of the sessions include the necessity of happiness, teaching the technique of expressing emotions and showing them, the technique of increasing optimism and intimate relationships, avoiding worrying thoughts, coping with stress, planning and the technique of living in the present, The art of being real is to lower expectations and give priority to happiness

Category

Behavior

2

Description

Control group: The control group consists of 40 people who will receive routine pregnancy care that includes measuring vital signs, weight, uterine height, fetal heart rate, examining danger signs and health education, and requesting and reviewing the required para-clinical measures. and in order to comply with ethics, all educational videos prepared by me will be sent to the control group after the study is completed.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Zanjan Comprehensive health centers

Full name of responsible person

Parvin Mohebbi

Street address

No. 3539, Badr 9 Ave, Zanjan city

City

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Samad Nadri

Street address

ZUMS Central Office, Azadi Square, Zanjan, Zanjan.

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Province

Zanjan

Postal code

4513956184

Phone

+98 24 3342 0677

Email

nadri_s@zums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Elham Bagheri Nia

Position

Msc Student in Midwifery Counseling

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

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Zanjan University of Medical Sciences
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The possibility of dissatisfaction of the participants

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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