Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

The effect of education based on planned behavioral model in vitamin D supplement taking in lactating women.

Protocol summary

Study aim
Determine the effect of education on the use of vitamin D supplementation by lactating women

Design
Randomized clinical trial with community-based control group and randomized groups.

Settings and conduct
The present study is a randomized clinical trial. In this study, lactating women referring to health centers in Takab city, having access to the criteria for inclusion in the study, completed the ethical consent, and completed the demographic questionnaire, a researcher-made questionnaire based on the planned behavioral pattern of vitamin D Will complete. Initially, the total serum vitamin D levels of women entering the study are measured, then women with a serum concentration of vitaminD of less than 30 will be studied and randomly divided into two groups. Then, in the intervention group, vitamin D will be prescribed by the local specialist in the clinic based on the scientific method,depending on the deficiency. The 4-session-based modeling education will be held a week.Thereafter, a three-week follow-up phone call will take place for 3 months. After three months, the levels of vitamin D, knowledge, attitude, abnormal norms, behavioral control and behavioral intention of two groups were measured and compared before intervention using T-test, paired T-test, chi square test, Mann-Whitney test and Wilcoxon test.

Participants/Inclusion and exclusion criteria
Criteria for entering the study: marriage; physical health and absence of specific illness; non-use of certain medications; having infants; absent in educational sessions; unwillingness to cooperate; kidney or liver diseases and immigration abroad from the study will be excluded.

Intervention groups
Impact of education based on planned behavioral model

Main outcome variables
Improvement of vitamin D levels in lactating women and their infants

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110425006284N15**
Registration date: **2019-03-14, 1397/12/23**
Registration timing: **retrospective**

Last update: **2019-03-14, 1397/12/23**
Update count: **0**

Registration date
2019-03-14, 1397/12/23

Registrant information

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Name of organization / entity
Tehran university of Medical sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-23, 1397/05/01

Expected recruitment end date
2018-09-01, 1397/06/10

Actual recruitment start date
2018-07-23, 1397/05/01

Actual recruitment end date
2018-09-01, 1397/06/10

Trial completion date
empty

Scientific title
The effect of education based on planned behavioral model in vitamin D supplement taking in lactating women.

Public title
The effect of education based on planned behavioral model in vitamin D supplement taking in lactating women

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Reading and writing literacy Married females Physical well-being and the absence of specific disease (such as kidney disease, liver, heart, heart disease) No use of glycosylated cardiac drugs, thiazide diuretics, phenobarbital, Technical Tween Having an infant Willing to participate

Exclusion criteria:
Pregnancy Absence from more than one session at training sessions Unwillingness to cooperate Kidney or liver disease Immigration outside the city

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
First, the total vitamin D levels of women entering the study will be measured. Women with a serum concentration of vitamin D of less than 30 will be studied and then divided into two groups by random block method.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences Faculty of Nursing and Midwifery and Rehab

Street address
Tehran, Tohid Square, Dr. Mirkhani St. (East Nursing) Nursing Midwifery Faculty

City
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Province
Tehran

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1419733171

Approval date
2018-06-11, 1397/03/21

Ethics committee reference number
IR.TUMS.FNM.REC.1397.004

Health conditions studied

1

Description of health condition studied
Lactating women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The number of lactating women with vitamin D is less than 30.

Timepoint
The beginning of the study (before the intervention) and three months after taking vitamin D and training.

Method of measurement
Serum vitamin D measurement by the laboratory and completion of a researcher-made questionnaire based on the planned behavioral pattern of vitamin D

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, a researcher-made questionnaire (including questions: knowledge, attitude, abstract norms, behavioral control, and behavioral intention) should be completed by nursing mothers. Then, vitamin D will be prescribed by the local specialist in the clinic based on the scientific method, depending on the deficiency.1-Serum Hydroxyvitamin D is less than 10 ng / ml: 50,000 units of vitamin D2 or D3, orally once a week for 6 to 8 weeks, and then 800 units of vitamin D3 per day.2. Serum vitamin D concentration greater than 10 and less than 20 ng / ml: 800 to 1000 units per day followed by follow up

after three months.3. Serum concentrations of vitamin D of 20 and less than 30 ng / ml: 600 to 800 units of vitamin D3 are sufficient to maintain the levels of 25 hydroxyvitamin D in the target.Also, training based on the planned behavior of the model in 4 sessions, one week in face to face will be held as follows. At the first meeting, the group will discuss the experiences of friends and other people familiar with the use of vitamin D supplementation. The discussion and exchange of thoughts will be guided by the trainer to identify positive attitudes and beliefs that will guide people in giving people a positive impulse for taking vitamin D tablets and creating new attitudes and improving the negative attitude toward taking vitamin D, which lasts for 30 minutes Will take. In the second training session, considering the unpreparedness and emotionality obtained during the first session, along with the abstract norms that affect the use of vitamin D, vitamin D and its nutritional supplementation will be explained by the presentation of educational slides, and will seek to further motivate the necessity Vitamin D will be consumed during lactation, and thereafter, discussions will be held on the use of different types of foods and foods containing vitamin D among women, as well as misconceptions about the use of vitamin D tablets. Will reduce the intensity of these misconceptions and prepare the ground for a change of attitude and a new belief. In this meeting, a family member or close friend who will have a great impact on the person will be invited to attend the meeting. The second session will take up to 30 minutes. The third session of the training will focus on the determination of taking action on taking vitamin D tablets by providing solutions that will be thought through by the research itself. This session will end with a cohort of behavioral mediation that will take 30 minutes. The fourth session will focus on the maternal and infant deficiencies in vitro D and the benefits of vitamin D supplementation for mother and baby and the intention of the mother to take vitamin D by slideshows and teaching methods for lectures, questions and answers, and sentimental thoughts like all other sessions. The duration of the meeting will be 30 minutes. At the end of each training session, research units will be reminded if they have questions in the field of knowledge of the researcher. At the end of the fourth session of the educational pamphlet, a training pamphlet will include information and training on vitamin D, vitamin D products, and Vitamin D-containing foods will be given to the intervention group, followed by a three-week phone call within 3 months. After three months, the level of vitamin D was measured and a researcher-made questionnaire including knowledge, attitude, abstract norms, behavioral control, and behavioral intention intentionally measured and pre-intervention using T-test, t-test, paired t-test, chi square test, Mann-Whitney test And the Wilcoxon test will be compared.

Category

Behavior

2

Description

Control group: At first, knowledge, attitude, abstract norms, behavioral control, and behavioral intention were measured by a researcher-made questionnaire. Then, vitamin D will be administered according to the routine clinic, which is a pill, and will not be given. After three months, the level of vitamin D, knowledge, attitude, abnormal norms, behavioral control and rehearsal intention will be measured and compared with before three months using t-test, paired t-test, chi square test, Mann-Whitney test and Wilcoxon test.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers in Takab

Full name of responsible person

Roghayeh Faraji

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Tehran University of Medical Sciences

Proportion provided by this source
50

Public or private sector
Private

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
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Full name of responsible person
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Assistant Professor

Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available