

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

The effect of Mobile App-based education on reproductive health awareness and self-care behaviors in married students: a Randomized Controlled Trial

Protocol summary

Study aim

Determining the effect of Mobile app-based education on reproductive health awareness and self-care behaviors in married students

Design

Two arm parallel group randomized controlled field trial without blinding consist of eighty-two individuals in each intervention and control group, enrollment between September to December 2019

Settings and conduct

After obtaining a written informed consent and investigating eligibility criteria, questionnaires will be completed at all 8 female student dormitories. Four dormitories will be allocated into for each intervention and control group. The counseling program will be presented for the intervention group in two sessions for 45-60 minutes once a week, as 12 people groups . At the end of the session, the reproductive health education software program will be installed on the mobile phone of the intervention group. Duration of the training will be 4 weeks, which two educational fundamentals of reproductive health will be presented every week by researcher. Participants will follow and study the training content according to a message posted on the WhatsApp channel. Before intervention and 8 weeks after intervention, awareness and self care questionnaires will be completed by all the students.

Participants/Inclusion and exclusion criteria

The main criteria for inclusion: being married, student and female. Exclusion criterion: end of education

Intervention groups

The intervention group: receives two sessions of counseling and educational software for reproductive health. Control group: no education

Main outcome variables

Score of awareness and self care behavior before and 8 weeks after intervention in the study groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170520034052N4**

Registration date: **2019-09-15, 1398/06/24**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-15, 1398/06/24**

Update count: **0**

Registration date

2019-09-15, 1398/06/24

Registrant information

Name

Niloofar Sattarzadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3477 2699

Email address

sattarzadehn@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-01, 1398/06/10

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Mobile App-based education on reproductive health awareness and self-care behaviors in married students: a Randomized Controlled Trial

Public title

The effect of Mobile App-based education on reproductive health awareness and self-care behaviors i

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Being married Student studying at Tabriz University of Medical Sciences or Tabriz University Having a smartphone Ability to use WhatsApp and mobile software. Female sex

Exclusion criteria:

End of education (graduation, dispensing, expulsion, ...) and end of the course for guest students at the time of this study

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **164**

Randomization (investigator's opinion)

Randomized

Randomization description

Tabriz University and Tabriz University of Medical Sciences each have 4 government dormitories that sampling will be placed at every 8 dormitories. In order to avoid contamination, 4 dormitories will be allocated into the intervention and 4 dormitories into the control group by non-researcher person (random allocation). Considering the fact that knowledge and self-care is likely to be higher among married students of the medical university, stratification will be done in terms of type of dormitory. For stratification, the first 4 envelopes will be dedicated to Tabriz medical university and 4 next envelopes to Tabriz University. In this condition, for each intervention dormitory, there will be a control group at the same university. Then, in order to allocation concealment, the name of dormitories will be written on the matte and closed envelopes based on the random allocation sequence, and the type of intervention will be placed in a paper inside envelope by the same person. In the next step, 20-22 eligible married students from each dormitory will be included in the study through availability sampling. The researcher and the participants will not be informed about the allocation type until the stage of opening the envelopes (after completing the questionnaires).

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 Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2019-06-17, 1398/03/27

Ethics committee reference number

IR.TBZMED.REC.1398.315

Health conditions studied**1****Description of health condition studied**

Knowledge regarding reproductive health

ICD-10 code

Z71

ICD-10 code description

Persons encountering health services for other counseling and medical advice, not elsewhere classified

2**Description of health condition studied**

Self-care behaviors regarding reproductive health

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Score of knowledge on reproductive health

Timepoint

Before the intervention, 8 weeks after the intervention

Method of measurement

Researcher- made knowledge questionnaire

2

Description

Score of self-care behavior on reproductive health

Timepoint

Before the intervention, 8 weeks after the intervention

Method of measurement

Researcher-made self-care questionnaire

Secondary outcomes

1

Description

Change in students awareness' score on reproductive health 8 weeks after the intervention compared to pre-intervention in each study group

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Awareness Questionnaire

2

Description

Change in students self-care behaviors' score on reproductive health 8 weeks after the intervention compared to pre-intervention in each of the study groups

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Self-care questionnaire

Intervention groups

1

Description

Intervention group: The counseling program for the intervention group will be presented in two sessions for 45-60 minutes, in the 12 people' groups once a week. Invitational counseling in this intervention will be based on William w.Purkey. During counseling sessions, combined methods such as; face-to-face training, question and answer, and group discussion, will also be used. At the end of the session, the reproductive health education software program will be installed on the mobile phone of the intervention group and will be studied by the participants within the next four weeks.

Category

Prevention

2

Description

Control group: There will be no action for the control group at the time of the intervention. If the training be effective for the intervention group, after the completion of the study, educational materials for reproductive health will be provided to the control group in the form of a book.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz University and Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Hossein Somi - Mir Reza Majidi

Street address

No. 2 Central building of the university, Golgasht street, Azadi street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3335 7310

Fax

+98 41 3334 4280

Email

aa.karimi.v@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Abolghasem Jouyban

Street address

No. 2 Central building of the university, Golgasht street, Azadi street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3335 7310

Fax

+98 41 3334 4280

Email

research-vice@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Azam Karimi Vanestanagh

Position

Master's degree in midwifery counseling

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Tabriz University of Medical Sciences, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5471895481

Phone

+98 41 4322 4562

Email

aa.karimi.v@gmail.com

Web page address<http://nursing.tbzmed.ac.ir>**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Azam Karimi Vanestanagh

Position

Master's degree in midwifery counseling

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

End of Dr. Shariati, Faculty of Nursing and Midwifery

City

Tabriz

Province

East Azarbaijan

Postal code

5471895481

Phone

+98 41 4322 4562

Email

aa.karimi.v@gmail.com

Web page address<http://nursing.tbzmed.ac.ir>**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Azam Karimi Vanestanagh

Position

Master's degree in midwifery counseling

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

End of Dr. Shariati Street, Faculty of Nursing and Midwifery

City

Tabriz

Province

East Azarbaijan

Postal code

5471895481

Phone

+98 41 4322 4562

Email

aa.karimi.v@gmail.com

Web page address<http://nursing.tbzmed.ac.ir>**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Requested information will be provided to researchers for statistical analysis of the submitted proposal.

When the data will become available and for how long

Start the access period immediately after printing the results

To whom data/document is available

Data will be available to researchers as well as to journals

Under which criteria data/document could be used

Data will be available to researchers upon request and submission of a proposal to perform a meta-analysis using ipd data after unidentifiable individuals. Also, exceptionally, data will be exclusively for checking the data available to journals.

From where data/document is obtainable

En Refer to email address.(aa.karimi.v@gmail.com)

What processes are involved for a request to access data/document

Requests will be sent by email and the data will be available within a week.

Comments