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
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Province
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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
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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
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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
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Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
Azam Karimi Vanestanagh
Position
Master's degree in midwifery counseling
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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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