

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of educational intervention with mobile health (mHealth) technology on sexual health literacy and marital satisfaction of couples

Protocol summary

Study aim

Determining the effect of educational intervention with health technology in comparison to regular education on sexual health literacy and marital satisfaction of couples

Design

Two-arm parallel-group randomized trial with analysts blinded with a sample size of 140 couples

Settings and conduct

Couples referring to comprehensive health service centers in Gonabad in the summer of 1402, for each couple in the educational intervention group with mobile phone-based health technology (mHealth). In the control group, couples will receive pamphlets and educational booklets about sexual health.

Participants/Inclusion and exclusion criteria

Inclusion criteria include being between the ages of 18 and 45, living together for one year, informed consent, elementary School literacy, first marriage, and having a mobile phone or tablet with the ability to connect to the Internet and membership in one of the social networks Itta or Rubika. The non-entry criteria include pregnancy or premature menopause, being barren, having acute marital problems or intending to divorce, and having a known mental disorder.

Intervention groups

For each of the couples in the educational intervention group with mobile phone-based health technology (mHealth) about sexual health in the form of audio, video, and text files on the platform of authorized social networks such as Eitaa and Rubika, the intervention group's research unit's cell phone will be provided. The prepared educational content will include 4 sessions of 20 minutes over 4 weeks. Couples in the control group will receive pamphlets and educational booklets related to sexual health.

Main outcome variables

sexual health literacy, marital satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230507058107N1**

Registration date: **2023-05-09, 1402/02/19**

Registration timing: **prospective**

Last update: **2023-05-09, 1402/02/19**

Update count: **0**

Registration date

2023-05-09, 1402/02/19

Registrant information

Name

mahnaz karimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5722 5080

Email address

mahnazkarimi.pao@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of educational intervention with mobile health (mHealth) technology on sexual health literacy and marital satisfaction of couples	
Public title	The effect of education with mobile health on sexual health literacy and marital satisfaction of couples
Purpose	Supportive
Inclusion/Exclusion criteria	
Inclusion criteria:	Couples have at least one year of life together Informed consent to participate in the research The first marriage should be couples Having a minimum elementary school literacy Have a mobile phone or tablet with an Internet connection and subscribe to one of the social networks of Eitaa or Rubika
Exclusion criteria:	The woman is pregnant The woman have premature menopause. Couples diagnosed with infertility or undergoing infertility treatment Couples have severe marital problems or intend to divorce couples have a known mental disorder
Age	From 18 years old to 45 years old
Gender	Both
Phase	N/A
Groups that have been masked	Data analyser
Sample size	Target sample size: 140 More than 1 sample in each individual Number of samples in each individual: 2 couple (man and his wife)
Randomization (investigator's opinion)	Randomized
Randomization description	Allocation of people to intervention and control groups using the permutation blocks method
Blinding (investigator's opinion)	Single blinded
Blinding description	The two intervention and control groups are marked with the abbreviations A and B, and the analyst will not know about them
Placebo	Not used
Assignment	Parallel
Other design features	In this study, couples in the control group will receive regular training with pamphlets and training booklets
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics Committee of Gonabad University of Medical Sciences
Street address	Nurse Blv, Gonabad University of Medical Sciences
City	Gonabad
Province	Razavi Khorasan
Postal code	9691793718
Approval date	2023-04-04, 1402/01/15
Ethics committee reference number	IR.GMU.REC.1402.012
Health conditions studied	
<u>1</u>	
Description of health condition studied	Sexual health literacy
ICD-10 code	
ICD-10 code description	
<u>2</u>	
Description of health condition studied	Marital Satisfaction
ICD-10 code	
ICD-10 code description	
Primary outcomes	
<u>1</u>	
Description	Sexual health literacy score from Masoumi health literacy questionnaire
Timepoint	At the beginning of the study (before the start of the intervention), after the end of the intervention and one month after the intervention
Method of measurement	sexualhealth literacy for adults (SHELA) questionnaire
<u>2</u>	
Description	Marital satisfaction score from Enrich Marital Satisfaction Questionnaire
Timepoint	At the beginning of the study (before the start of the intervention), after the end of the intervention and one month after the intervention
Method of measurement	Enrich marital satisfaction questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For each of the couples in the educational intervention group with mobile phone-based health technology (mHealth) about sexual health in the form of audio, video and text files on the platform of authorized social networks such as Eitta and Rubika, the intervention group's research unit's cell phone will be provided. . The prepared educational content will include 4 sessions of 20 minutes during 4 weeks, which will be sent to couples in the intervention group via mobile phone.

Category

Rehabilitation

2

Description

Control group: Couples in the control group will receive pamphlets and educational booklets related to sexual health.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive urban health service centers of Gonabad

Full name of responsible person

Dr. Hossein Ebrahimi

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Nasser Khosrow St., Health Deputy

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Gonabad

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<https://behdasht.gmu.ac.ir/pages/1674917684838>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

lila Sdeghmoghadam

Street address

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Gonabad

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research@gmu.ac.ir

Web page address

<https://res.gmu.ac.ir/index.html>

Grant name

It is a thesis and has no budget

Grant code / Reference number

-

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

Yes

Title of funding source

Gonabad University of Medical Sciences

Proportion provided by this source

1

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

Gonabad University of Medical Sciences

Full name of responsible person

Mahnaz Karimi

Position

MSc student of Midwifery

Latest degree

Bachelor

Other areas of specialty/work

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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

Not applicable

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

By written request from the corresponding author

When the data will become available and for how long

2 years

To whom data/document is available

For researchers working in academic and scientific institutions

Under which criteria data/document could be used

Citing the source of the article or research is allowed

From where data/document is obtainable

Mahnaz Karimi mahnazkarimi.pao@gmail.comfh

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

By written request

Comments