Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Oct 2026

Survey the effect of educational intervention using mobile application on health literacy in pregnant women attending Alzahra education, research & remedial Center in Rasht city 2019_2020

Protocol summary

Study aim

Determining the effect of educational intervention using mobile application on health literacy in pregnant women attending Alzahra education, research & remedial center in Rasht city 2019_2020

Design

In this study, 140 pregnant women who are referred to the pregnancy care clinic of Alzahra medical and research center of Rasht, are selected in two groups of tests and control.

Settings and conduct

The test group will be based on mobile software training. The place of the study is the Pregnancy Care Clinic of Alzahra education Center in Rasht city.

Participants/Inclusion and exclusion criteria

Entry criteria: nulliparity; gestational age 12_6 weeks; reading and writing literacy; Iranian citizenship; minors aged 18 and up to 45; mobile phone with android system; software installation; no chronic and underlying illness; no education in medical fields; inability to use and work with mobile software; lack of experience in the pregnancy care program and satisfaction and interest in participating in the study. Exit criteria: unwillingness to continue participating in a work study.

Intervention groups

Before completing the maternity health education questionnaire, a mother-in-law interview is completed in two groups of test and control, and then the software will be installed on the smartphone of the test group. The control group is not subject to any intervention. Patients in the test group will not have any contact with the control group mothers after the software installation. Then, 8 weeks later, the date for the referral of the mothers of the test and control group to the clinic will be determined.

Main outcome variables

Maternal health literacy is considered as the main outcome. The maternity health literacy questionnaire has 14 items. The rating range for this questionnaire is from 14 to 70

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180707040364N1**
Registration date: **2019-03-27, 1398/01/07**
Registration timing: **prospective**

Last update: **2019-03-27, 1398/01/07**
Update count: **0**

Registration date

2019-03-27, 1398/01/07

Registrant information

Name

Parisa Farzi karamolahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-09, 1398/01/20

Expected recruitment end date

2019-06-20, 1398/03/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Survey the effect of educational intervention using mobile application on health literacy in pregnant women attending Alzahra education, research & remedial Center in Rasht city 2019_2020

Public title
Survey the effect of educational intervention using mobile application on health literacy in pregnant women
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Nullie Parithe Gestational age 6 to 12weeks Reading and writing literacy Iranian citizenship Minors aged 18 and up to 45 Having a mobile phone with the Android system and the ability to install the software Not having chronic and underlying disease Lack of medical education, Inability to use and operate with mobile software No history of participation in a pregnancy care education program Satisfaction and interest in participating in the study
Exclusion criteria:
Unwillingness to continue participating in a work study
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **140**
Randomization (investigator's opinion)
Randomized
Randomization description
Research units are selected based on gradual referral if they have criteria for entering the study. Assigned units will be assigned numbers 1 to 140, respectively. A table with 35 rows is called a block, and each part of the block will be named with the letters A and B. In the next step, numbers are placed in each house, respectively. Then all the numbers are embedded in the blocks. 35 blocks are randomly drawn. Random blocks are placed in a lacquered envelope and will be kept in the center of research and social factors affecting health. The Hawzah Bloc is selected after the beginning of the study by an individual who is not aware of the type of blocks. People at Home A will be placed in the test group in the test group and those at Home B will be placed in the control group.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Participants are unaware of the allocation of study groups. The outcome evaluator will not be aware of the random assignment of the test and control group and will examine the data related to the outcome variables, regardless of the groups of individuals. After collecting data, groups are named in alphabetical order so that the analyst from the test and control group is not informed.
Placebo
Not used
Assignment
Parallel
Other design features
All items are in the summary section.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee of Guilan University of Medical Sciences
Street address
Rasht, Namji Street, Shahid Siadati Street, opposite the 17th Shahrivar Hospital
City
Rasht
Province
Guilan
Postal code
4146939114
Approval date
2019-03-09, 1397/12/18
Ethics committee reference number
IR.GUMS.REC.1397.490

Health conditions studied

1

Description of health condition studied
health literacy in pregnant women
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Health literacy in pregnant women
Timepoint
Before and after intervention
Method of measurement
Will be measured by maternal health literacy tool. The maternity health literacy questionnaire has 14 rows. The maternal health literacy scores range from 14 to 70. The

items in this questionnaire are based on Likert Five Degrees of Totally Agree (Score 5), Agree (Score 4), I have no idea (Score 3), Disagree (Score 2), and Absolutely Disagree (Score 1), More Score The donor is better educated. The maternal health literacy questionnaire was created by Maguonilla (2011) in Nigeria and is localized by Peyman et al. (2016).

Secondary outcomes

empty

Intervention groups

1

Description

Control group: the control group is not subject to any intervention by the researcher. To avoid contacting the mothers of the test and control group with each other, mothers are called to the prenatal care unit individually, and the researcher will read the questions individually for mothers and the mother will answer them. Pregnant women in the test group will not have any contact with the control group's mothers after the software is installed. Mothers of the control group are trying to avoid knowing the software installation on the test group smartphones

Category

Other

2

Description

Intervention group: Before the implementation of the maternity health literacy questionnaire, the mother-tongue questionnaire was completed by a researcher by interviewing the mothers in two groups of test and control, then the software will be installed on the smartphone of the test group, one week after the installation of the program They will be contacted on the cell phone of the mothers of the test group and will be asked questions and problems related to the use of the software. It should be noted that the control group is not subject to any intervention by the researcher. To avoid contacting the mothers of the test and control group with each other, mothers are called to the prenatal care unit individually, and the researcher will read the questions individually for mothers and the mother will answer them. Pregnant women in the test group will not have any contact with the control group's mothers after the software is installed. Mothers of the control group are trying to avoid knowing the software installation on the test group smartphones. Then, 8 weeks later, the date for the referral of the mothers of the test and control group to the prenatal care clinic of Alzahra's educational and research center will be determined by the researcher. If the mothers do not go to a pregnancy care clinic of al-Zahra hospital on a definite date When the researcher comes to the door, the same questionnaire will be given back to the mothers. The mothers of the test group will be given the opportunity to study the contents of the software in the course of 8 weeks, once a week. At intervals of 8 weeks, weekly counseling is provided once a week for 10 minutes with the mothers of the test group to remind and ask mothers about the study of the software. The time of making phone calls is determined by the consideration of pregnant mothers. In order to comply with the ethical standards of mobile software, after the end of the study, the pregnant women will also be placed in the control group. In this study, educational content includes design and software development by a skilled programmer based on explaining body changes and adaptations during pregnancy, fetal development, prenatal care, testing, vaccination, nutrition, dietary supplements Personal hygiene, employment, travel, rest, exercise, sex, addiction, drug use, risk of pregnancy, neonatal care, bathing and breastfeeding, neonatal risk, use of vitamins, infant status and coverage is. The educational content provided in the software is derived from the book of pregnancy and childbirth education provided by the Ministry of Health and Medical Education, the Health and Welfare Department of the Population Health, Family, Schools and Mental Health Administration. The book includes 5 parts of pregnancy, childbirth, postpartum, baby care and stretching exercises, respiratory pattern, relaxation and massage, which in the first part about reproductive system, changes in body adaptation in pregnancy, growth and Embryo development, Prenatal care, Nutrition during pregnancy, Supplements during pregnancy, Individual health, Pregnancy risk symptoms, Pregnancy and maternity, Part II on delivery and methods for reducing labor pain , In the third section on postpartum organ changes, postpartum and postnatal risk symptoms, and in the fourth section about me Neonatal birth, Neonatal screening, Vaccination, Bathing and Breastfeeding, and in the fifth part, about tensile and respiratory exercises during pregnancy, modifying the condition during pregnancy and the pattern of respiration and sedation during pregnancy and postpartum, expressing and The description of the material has been discussed.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra education, research & remedial Center in Rasht city

Full name of responsible person

Zahra Bostani Khalesi

Street address

Rasht-Flick Ice-Park-Student-Faculty of Nursing-Midwifery Martyr Dr. Beheshti

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
Zahra Bostani Khalesi
Position
Assistant Professor
Latest degree
Ph.D.
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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Main and general data
When the data will become available and for how long
The start of the access period is 8 months after the results are printed
To whom data/document is available
Academic and academic institutions
Under which criteria data/document could be used
If you cite the article
From where data/document is obtainable
executor of plan
What processes are involved for a request to access data/document
Contact the plan implementer and conduct a moral agreement
Comments