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Reproductive health program for young women

Submission date
19/10/2020

Recruitment status
No longer recruiting

Registration date
21/10/2020

Overall study status
Completed

Last Edited
17/11/2023

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Young adult women might face reproductive health issues without being aware of them and tend to lack preventive health behavior. Therefore, in order to promote the reproductive health of young adult women, it is important to identify the stage of their health behavior and to develop a program that can induce behavior change. The aim of this study is to develop a reproductive health promotion program based on the Precaution Adoption Process Model (PAPM) for young adult women and to evaluate its effects.

Who can participate?
Healthy young adult women volunteers aged 18-25, women who had coitus in the last 3 months and had partners, and women in Stages 1, 2, and 3 of the PAPM for reproductive health via an online survey

What does the study involve?
The reproductive health promotion program developed in this study is strategically applied to each stage of the PAPM (Stages 1, 2, and 3). For Stage 1 participants in the intervention group, the program consists of strategies such as lectures, providing periodic information, small group discussions, Q&A sessions, and practical training. For Stage 2 participants in the intervention group, the program includes the strategies of stage 1 and additionally consists of strategies such as case experience using videos and individual counselling using the 5 Rs. For Stage 3 participants in the intervention group, the program includes the strategies of stage 1 and additionally consists of strategies such as individual counselling using the 5 As and providing tailored information according to the individual's needs. The program is replaced with educational material for the control group. In both groups, the total duration of the intervention is 8 weeks and the outcomes are measured at three times: baseline, 1 week after the seminar and 1 week after completion of the interventions.

What are the possible benefits and risks of participating?
As possible benefits of participating, participants will play an active role in their own health care. Also, by contributing to this research, they can help in many other ways. However, the participants should also consider the following risks: participating in the program may cause unpleasant feelings or the intervention may not be effective for participants.

Where is the study run from?
Korea University (Korea, South)

When is the study starting and how long is it expected to run for?
May 2017 to November 2018

Who is funding the study?
The Health Fellowship Foundation (Korea, South)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
1

Study information

Scientific Title

Development and evaluation of a reproductive health promotion program based on the Precaution Adoption Process Model for young adult women

Study objectives
1. There will be differences in variables of the primary outcome (reproductive health-promoting behavior, rate of contraception use) between the intervention group who were provided with the reproductive health promotion program and the control group.
2. There will be differences in variables of the secondary outcome (reproductive health knowledge, reproductive health belief, reproductive health motivation, reproductive health self-efficacy) between the intervention group who were provided with the reproductive health promotion program and the control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/12/2017, Korea University Institutional Review Board (145 Anam-ro, Seongbuk-gu, Seoul, 02841, Korea; +82 (0)2 3290 1137; kuirb@korea.ac.kr), ref: 1040548-KU-IRB-17-169-A-3

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Reproductive health

Interventions
After conducting a preliminary, experimental investigation procedure, the program for promoting reproductive health based on the PAPM was applied step by step to the intervention group, and the program was replaced with educational material for the control group. The random allocation sequence was conducted with a 1:1 ratio using a computer-generated program (https://www.randomizer.org/) after the pretest.

The program is a tailored program whereby each stage of the PAPM (Stages 1, 2, and 3) is outlined, using components of the Information-Motivation-Behavioral skills model. The program comprises intervention strategies, such as lectures; periodic information and information tailored to individuals' needs; small group discussions; question and answer sessions (Q&A); individual counselling; case experience using videos; and practical training.

The total duration of the intervention is 8 weeks. Outcomes are measured at three timepoints: T0 indicates the baseline, T1 indicates 1 week after the seminar (2 weeks after baseline) and T2 indicates within 1 week after completion of the interventions (8 weeks after baseline).

Intervention Type
Behavioural

Primary outcome(s)
1. Reproductive health-promoting behavior measured using self-reported questionnaire via online survey at T0 (baseline), T1(2 weeks after baseline), and T3 (after completion of intervention/8 weeks after baseline)
2. Rate of contraception use measured using self-reported questionnaire via online survey at T0, T3

Outcomes are measured at three timepoints: T0 indicates the baseline, T1 indicates 1 week after the seminar (2 weeks after baseline) and T2 indicates within 1 week after completion of the interventions (8 weeks after baseline).

Key secondary outcome(s))
1. Reproductive health knowledge measured using self-reported questionnaire via online survey at T0, T1, T3
2. Reproductive health belief measured using self-reported questionnaire via online survey at T0, T1, T3
3. Reproductive health motivation measured using self-reported questionnaire via online survey at T0, T1, T3
4. Reproductive health self-efficacy measured using self-reported questionnaire via online survey at T0, T1, T3

Outcomes are measured at three timepoints: T0 indicates the baseline, T1 indicates 1 week after the seminar (2 weeks after baseline) and T2 indicates within 1 week after completion of the interventions (8 weeks after baseline).

Completion date
05/11/2018

Eligibility

Key inclusion criteria
1. Young adult women aged between 18 and 25
2. Women who had coitus in the last 3 months and had partners

Phase 2 of the study:
3. Women in Stages 1, 2, and 3 of the PAPM for reproductive health via an online survey

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex

Female

Total final enrolment
60

Key exclusion criteria
Women in Stages 4, 5, and 6 of the PAPM for reproductive health

Date of first enrolment
26/12/2017

Date of final enrolment
13/04/2018

Locations

Countries of recruitment
Korea, South

Study participating centre
Korea University
145 Anam-ro, Seongbuk-gu
Seoul
Korea, South
02841

Sponsor information

Organisation
Korea University

Funder(s)

Funder type
Charity

Funder Name
The Health Fellowship Foundation (Korea, South)

Results and Publications

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/10/2022	17/11/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes