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Effects of the couple-based mobile program delivered at each stage of the procedure to improve the quality of life of infertile couples undergoing intrauterine insemination

Submission date
03/08/2023

Recruitment status
No longer recruiting

Registration date
05/08/2023

Overall study status
Completed

Last Edited
04/08/2023

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Infertility is a personal and social problem that interferes with a couple's normal life, threatens their marriage, and even causes physical damage. Infertile couples experience physical and psychological pain, economic problems, and marital difficulties during fertility treatments and procedures, and their quality of life decreases. In this study, the researchers developed and applied a couple-based mobile program to improve infertile couples' quality of life for infertile couples undergoing intrauterine insemination (IUI). They have also identified variables that affect infertile couples' quality of life as infertility stress, anxiety, infertility self-efficacy, marital relationship, social support, and infertility quality of life. This study aims to evaluate the effects of a couple-based mobile program to improve the fertility quality of life of couples undergoing IUI on infertility stress, anxiety, self-efficacy, marital relationship, social support, and quality of life.

Who can participate?
Infertile couples undergoing IUI who attend Metropolitan City Seoul Medical Center & Dongtan Cheil Hospital in South Korea. Participants' ages range from 32 to 49 years for men and 28 to 43 years for women.

What does the study involve?
The experimental group was provided with a couple-based mobile program for 3 weeks and the control group received conventional written information over the same time period. Infertility stress, anxiety, self-efficacy, marital relationship, social support, and quality of life were measured. Participants will be required to complete two questionnaires during their participation in the study. This will take a total of 3 weeks, from the first day of the IUI process to the day of the post-IUI pregnancy test. To prevent the spread of the study, the control group was recruited before the experimental group, and the recruitment and intervention of the

experimental group began after the intervention and surveys of the control group were completed. Participants were also informed that a couple-based mobile program would be offered to all couples undergoing IUI procedures after the study was completed.

What are the possible benefits and risks of participating?
This study is a survey to determine the effectiveness of a couple-based mobile program. Participants will receive two surveys, one on the first day and one on the last day of the IUI process, with no known side effects or risks. The researchers have discussed that the program developed will be beneficial to couples undergoing IUI in the future. The control group will receive conventional written information about the procedure, so there are no special benefits or risks. The experimental group will have the opportunity to receive mobile-based information about the procedure. All participants who complete the survey will receive a small gift.

Where is the study run from?
Metropolitan City Seoul Medical Center & Dongtan Cheil Hospital (South Korea)

When is the study starting and how long is it expected to run for?
July 2019 to October 2021

Who is funding the study?
The study received no external funding

Who is the main contact?
SooKyoung Hann, ruruhan@naver.com

Study website
https://www.seoulmc.or.kr/site/gaimk/1.html, https://www.seoulmc.or.kr/site/gaimk/2.html, https://www.seoulmc.or.kr/site/gaimk/3.html, https://www.seoulmc.or.kr/site/gaimk/4.html

Contact information

Type(s)
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Development and effectiveness of a couple-based mobile program to improve quality of life for infertile couples undergoing intrauterine insemination

Study objectives
Hypothesis 1: The experimental group provided with a couple-based mobile program to improve fertility quality of life will experience less fertility stress than the control group.
Hypothesis 2: The experimental group provided with the couple-based mobile program to improve fertility quality of life will have less anxiety than the control group.
Hypothesis 3: The experimental group receiving the couple-based mobile program for fertility quality of life will have increased fertility self-efficacy than the control group.
Hypothesis 4: Couples who receive the couple-based mobile program for fertility quality of life will have improved marital relationships compared to the control group.
Hypothesis 5: The experimental group will have increased social support compared to the control group after receiving the couple-based mobile program for fertility quality of life.
Hypothesis 6: The experimental group will have better fertility quality of life than the control group after receiving the couple-based mobile program for fertility quality of life.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/09/2019, Seoul Metropolitan City Seoul Medical Center IRB Institutional Review Board (156, Sinnae-ro, Jungnang-gu, Seoul, 02053, Korea, South; +82 (0)2 2276 7433; seoulmc.irb@gmail.com), ref: SEOUL 2019-08-009-001

Study design
This quasi-experimental study used a nonequivalent control group non-sunchronized pretest-post-test design

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)

Hospital

Study type(s)
Quality of life, Efficacy

Participant information sheet
Not applicable

Health condition(s) or problem(s) studied
Infertility

Interventions
This quasi-experimental study used a nonequivalent control group non-synchronized pretest-post-test design. The recruitment process for the experimental and control groups was as follows

Data collection for this study was conducted at the Fertility Center of Seoul General Hospital and the Fertility Center of Gyeonggi Women's Hospital. Data collection consisted of recruitment of the experimental group and pre- and post-surveys after completion of the pre- and post-surveys for the control group to prevent the spread of the intervention. The control group (n = 24 couples) was recruited from the fertility center of a general hospital in Seoul. The 26 couples in the experimental group were recruited from the fertility center of a general hospital in Seoul (n = 16 couples) and the fertility center of a women's hospital in Gyeonggi Province (n = 10 couples). The experimental group was planned to be recruited from a general hospital in Seoul. At the time of recruitment of the 16 couples in the experimental group, the general hospital in Seoul was designated as a COVID-19 public hospital, making it difficult to recruit more couples, so an additional 10 couples were recruited from the fertility center of a women's hospital in Gyeonggi Province, for a total of 26 couples in the experimental group. Both centers are fertility centers of similar size and the same researcher personally explained the purpose and method of the study to the subjects and collected data after obtaining their consent to participate in the study.

The mobile program to improve the quality of life of infertile couples provided to the experimental group of the study consisted of five sessions over a total of 3 weeks, beginning with the first visit for IUI on the day of ovulation. Sessions 1-4 consisted of a couple-based mobile program that provided step-by-step information about the IUI process and a customized couple's conversation program, and session 5 consisted of phone counseling.

The control group was informed in the traditional method of providing written materials, which is to provide information through corresponding instructions according to the IUI process. On the first day of the IUI process, they were provided with the ' IUI Procedure' and explained the procedure, and on the first day of the injection, they were provided with the 'Self-Injection Guide'. When the date of the IUI procedure was determined, the ‘IUI brochure’ was provided and the procedure was explained. On the day of the IUI procedure, the patient was given the 'Post-IUI Notice' and was given information on post-procedure precautions and the date of the pregnancy test.

Intervention Type
Behavioural

Primary outcome measure

General and infertility-related characteristics (10 questions) and the study variables (infertility stress, anxiety, infertility self-efficacy, marital relationship, social support, and infertility quality of life) measured using a pre-survey on the first day of the IUI process

Secondary outcome measures
Infertility stress, anxiety, infertility self-efficacy, couple relationship, social support, and infertility quality of life, measured using a second survey after completing all interventions

Overall study start date
01/07/2019

Completion date
20/10/2021

Eligibility

Key inclusion criteria
Women and their husbands (couples) who were having IUI were eligible to participate. The inclusion criteria were:
1. Couples who understood the purpose of the study and gave written consent to participate in the study
2. Couples diagnosed with infertility and undergoing IUI
3. Couples without health problems other than infertility, such as mental illness
4. A couple who can use the Internet through a mobile device

Participant type(s)
Patient

Age group
Adult

Lower age limit
28 Years

Upper age limit
49 Years

Sex
Both

Target number of participants
110

Total final enrolment
100

Key exclusion criteria

1. Couples in which at least one of the couples is taking medications such as anti-anxiety drugs or tranquilizers
2. Cases in which at least one of the couples does not use a mobile device, those who did not agree to participate voluntarily

Date of first enrolment
01/10/2019

Date of final enrolment
20/10/2021

Locations

Countries of recruitment
Korea, South

Study participating centre
Fertility Care Center of Metropolitan City Seoul Medical Center
Metropolitan City Seoul Medical Center
156, Sinnae-ro, Jungnang-gu
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02053

Study participating centre
Fertility Clinic of Dongtan Cheil Hospital
Dongtan Cheil Hospital
144-6, Samsung 1-ro, Hwaseong-si
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Sponsor information

Organisation
Seoul Medical Center

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Sponsor type
Hospital/treatment centre

Website
https://www.seoulmc.or.kr/fertilitycenter/site/main/main.do

ROR
https://ror.org/002nav185

Funder(s)

Funder type
Industry

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
We are currently planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
Participants' raw data generated during the study is stored in a file after anonymization. The data can be shared if necessary on request from Hee Sun Kang (goodcare@cau.ac.kr).

IPD sharing plan summary
Available on request