

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Sep 2026

Effectiveness Comparison of Metacognitive Counseling in Virtual and Face To Face method on the Anxiety and Meta-worry of Women with Abortion History

Protocol summary

Study aim

Comparison of the Effectiveness of Metacognitive Counseling in a Virtual and In-Face Surveillance on the Anxiety and Metabolism of Women with Abortion History

Design

Clinical trials with control group, with parallel groups, blind, randomized

Settings and conduct

Samples are selected from among women with a history of abortion that are referred to the clinic and women's ward of Imam Jafar Sadegh Hospital, who are eligible to enter the study. The subjects are divided into two virtual counseling and in-person counseling sessions. Then, both virtual intervention and face-to-face interviews are grouped under a group counseling protocol during eight 90-minute counseling sessions on meta-cognitive therapy advised by supervisors, psychologist, counselor, and observer. Each research unit is said to have 50 percent chance of being assigned to a virtual or personal group.

Participants/Inclusion and exclusion criteria

Aged over 18:Legitimate Pregnancy:Married and permanent marriage:Iranian ethnicity:Both groups have virtual intervention and mobile presenceBoth groups have Internet and mobile Internet literacy and / or IOS:Interest in attending counseling sessions:Having a commitment to carry out the relevant:assignments (attending all meetings or at least 6 sessions and doing more than 75% of the assignments to the consultant's appointment):Pregnancy asked:Not having a history of abortion

Intervention groups

The virtual intervention and the presence of both are grouped under a group counseling protocol during eight 90-minute counseling sessions on meta-cognitive therapy. Each research unit is said to have 50 percent chance of being assigned to a virtual or personal group.

Main outcome variables

Using the results of the study in the health sector to improve and reduce the complications of anxiety and hypertension in people with it if effective interventions are effective.

General information

Reason for update

Enter the end date of the trial

Acronym

IRCT registration information

IRCT registration number: **IRCT20181120041707N1**

Registration date: **2019-05-23, 1398/03/02**

Registration timing: **prospective**

Last update: **2020-09-21, 1399/06/31**

Update count: **1**

Registration date

2019-05-23, 1398/03/02

Registrant information

Name

Mina Ghiyasi Shahmabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3235 8692

Email address

www.m.ghiasi@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-01, 1397/10/11

Expected recruitment end date

2019-01-20, 1397/10/30
Actual recruitment start date
 2019-05-26, 1398/03/05
Actual recruitment end date
 2019-06-26, 1398/04/05
Trial completion date
 2019-09-22, 1398/06/31

Scientific title
 Effectiveness Comparison of Metacognitive Counseling in Virtual and Face To Face method on the Anxiety and Meta-worry of Women with Abortion History

Public title
 Effectiveness Comparison of Metacognitive Counseling in Virtual and Face To Face method on the Anxiety and Meta-worry of Women with Abortion History

Purpose
 Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Age is over 18 years old Pregnancy is legitimate Married and have permanent marriage Have Iranian ethnicity Both groups have virtual intervention and mobile presence Both groups have Internet and mobile Internet literacy and / or IOS Interested in attending counseling sessions Of the obligation to carry out the relevant assignments (attending all meetings or at least 6 sessions and carrying out more than 75% of the assignments to the consultant's appointment) Pregnancy is wanted Have a history of abortion
Exclusion criteria:
 According to the research unit, there is a history of alcohol and tobacco use and drugs such as antidepressants Simultaneously participate in the same study There is a problem that causes an increase in sadness, anxiety and depression, such as close relatives, etc. in the last 2 months The systemic, genetic, or psychiatric diseases are afflicted by a research unit itself Be pregnant

Age
 From **18 years** old

Gender
 Female

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **40**
 Actual sample size reached: **40**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Women with a history of abortion who are eligible for inclusion in the study are divided into two groups of virtual counseling (20 in two groups of ten) and face-to-face counseling (20 in two groups of ten) using a randomized computer table

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 Yazd University of Medical Sciences

Street address

Bahonar Square- Central building of Shahid Sadoughi University of Medical Sciences and Health Services

City

Yazd

Province

Yazd

Postal code

8915173160

Approval date

2018-11-10, 1397/08/19

Ethics committee reference number

IR.SSU.REC.1397.091

Health conditions studied

1

Description of health condition studied

Abortion

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The percentage of people with a Beck Anxiety Scale is above 15.

Timepoint

Determine and compare the mean of anxiety score before the intervention, the end of the eighth week of intervention and the 12th week of intervention

Method of measurement

Beck Anxiety Inventory

2

Description

Percentage of people whose score of questionnaire is above 17.

Timepoint

Determination and comparison of the mean scores of

anesthesia before the onset of intervention, the end of the eighth week of intervention and the 12th week of intervention

Method of measurement

metaworry questionnaires

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Virtual Consultation. Virtual consultancy is provided in multimedia and attractive format and one day a week by virtual method through installing one of the authorized Persian messaging software and having the ability to secure private space suitable for mobile phone research units, and from them You will be asked to submit your questions online and get help from the researcher. It is worth mentioning that for the purpose of providing Internet chat, the package is provided weekly and free of charge to the virtual intervention group by the researcher until the end of the study period. For this purpose, the mobile number of the research units will be designed by the researcher after receiving informed consent and the group will be designed to respond to the researcher. Regarding how to coordinate with research units, such as attending a group chat at the scheduled time, homework reminders, or the desire to have a private chat after the end of the chat group, the necessary information is provided by the researcher.

Category

N/A

2

Description

Intervention group: In-person counseling. Individuals under the group counseling protocol are included in eight 90-minute counseling sessions on meta-cognitive therapy advised by supervisors, psychologist, counselor, and observer.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Jafar Sadeg Hospital

Full name of responsible person

Mina GhiyasiShahmabadi

Street address

Imam Jafar Sadiq Hospital, Basij Boulevard, Basij Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr Masoud Mirzaei

Street address

South Shahid Sadoughi St, Bahonar Square, Third floor university building - Deputy of Research and Technology

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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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Ghiyasi Shahmabadi Mina

Position

Midwife

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Ghiyasi Shahmabadi Mina

Position

Midwif

Latest degree

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information.

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

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable