Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

The effectiveness comparison of online emotion regulation therapy program versus online guided imagery therapy on marital stress in women undergoing amniocentesis

Protocol summary

Study aim

Comparison of the effectiveness of online emotion regulation therapy program with online guided imagery therapy on marital stress in women undergoing amniocentesis

Design

This research is semi-experimental and parallel clinical trial method with two randomized parallel groups without blinding on 64 eligible pregnant women candidates for amniocentesis suffering from marital stress.

Settings and conduct

The research environment is the perinatal clinic in Yazd. Recruitment will done by the third investigator.Sample selection, random assignment, and psychological intervention are performed by the second researcher, under the supervision of the first, third, and fourth researchers.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Married healthy pregnant women who want to do amniocentesis, 20 weeks gestational age based on the pregnancy record, the cases where the screening was positive or abnormality was seen in the ultrasound, ability to have sex one week after amniocentesis with the permission of the attending physician, ability to use online counseling using a smartphone and having an Android or iOS smartphone, willingness to participate in the study, having marital stress based on marital stress questionnaire and having sexual relations with spouse. Exclusion criteria: Having mental disorders and being treated for mental disorders, participating in another simultaneous study, receiving psychological treatment at the time of entering the study, having disorders related to pregnancy, suffering from systemic diseases based on the pregnancy record.

Intervention groups

The first group receives online emotion regulation therapy (ERT) in 8 sessions of 60 minutes. The second group also receives 8 sessions of 60-minute guided imagery therapy (GIT) online.

Main outcome variables

Change in mean marital stress scores

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220712055447N1**
Registration date: **2022-10-23, 1401/08/01**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-23, 1401/08/01**
Update count: **0**

Registration date

2022-10-23, 1401/08/01

Registrant information

Name

Parya Rahmanipiani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3685 7084

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-07, 1401/07/15

Expected recruitment end date

2022-12-06, 1401/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness comparison of online emotion regulation therapy program versus online guided imagery therapy on marital stress in women undergoing amniocentesis

Public title

Comparison of online emotion regulation therapy with online guided imagery therapy on marital stress in women undergoing amniocentesis

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Married healthy pregnant women willing to undergo amniocentesis Gestational age 20 weeks based on the pregnancy record Cases in which the screening was positive or abnormality was seen in the ultrasound The ability to have sex one week after amniocentesis with the permission of the attending physician The ability to use online counseling using a smartphone and having an Android or iOS smartphone Willingness to participate in the study Having marital stress based on marital stress questionnaire Having sex with your spouse

Exclusion criteria:

Having mental disorders and being treated for mental disorders Participating in another concurrent study Receiving psychological treatment at the time of entering the study Having pregnancy-related disorders Suffering from systemic diseases based on pregnancy records

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

After obtaining the ethics committee code and registration in the IRICT system, the researcher will go to the Yazd Perinatal Clinic and after introducing himself and explaining the process and objectives of the research with the help of the third moderator, he will call and invite the women candidates for amniocentesis to study. takes In this way, among the women undergoing amniocentesis, the number of 64 people who met the entry criteria was selected and a code from 1 to 64 was assigned to each of them, and by using the online software (using www.random.org /sequences/) Patients are assigned to two groups, ERT and GIT (32 people each) according to the output of the software. Again, each group is randomly divided into 2 subgroups of 16 people each.

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

Research Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Bahonar Square، Yazd

City

Yazd

Province

Yazd

Postal code

8916189165

Approval date

2022-06-08, 1401/03/18

Ethics committee reference number

IR.SSU.REC.1401.039

Health conditions studied

1

Description of health condition studied

Marital stress

ICD-10 code

F40.2

ICD-10 code description

Specific (isolated) phobias

Primary outcomes

1

Description

Measurement of mean marital stress scores in women undergoing amniocentesis

Timepoint

Baseline, end of intervention at week 8, follow-up at end of study at week 12 in both groups

Method of measurement

Marital stress questionnaire (Omoluabi 1994)

Secondary outcomes

1

Description
Spouse's satisfaction with marital relationship from woman's point of view
Timepoint
Baseline, end of intervention at week 8, follow-up at end of study at week 12
Method of measurement
On the visual scale, the ten-point scale is measured between 1 and 10 with a question from the woman.

2

Description
The occurrence of premature birth
Timepoint
12 week follow-up
Method of measurement
With a question about the frequency of premature birth, in the questionnaire, it is measured in the 12th week follow-up in two groups.

3

Description
premature rupture of the water sac
Timepoint
12 week follow-up
Method of measurement
With a question about the frequency of rupture of the water sac in the questionnaire, it is measured in the 12th week follow-up in two groups

4

Description
Abnormality in the baby in case of premature delivery
Timepoint
12 week follow-up
Method of measurement
With a question about the frequency of Abnormality in the baby in case of premature delivery in the questionnaire, it is measured in the 12th week follow-up in two groups

Intervention groups

1

Description
Intervention group 1: The content of the meetings includes; Session 1: Getting to know and communicating with each other, Session 2: Choosing a situation, Session 3: Choosing a situation, Session 4: Modifying a situation, Session 5: Expanding attention, Session 6: Cognitive evaluation, Session 7: Adjusting the response, Session 8: Evaluation and It is application. At the beginning of each session, a summary of the materials related to the previous sessions is reviewed and the tasks related to the previous session are reviewed by the counselor in order to evaluate the improvement of marital stress in each session. Women are asked to participate in online counseling discussions and ask questions. At the end of each session, a summary of the important topics discussed is presented and the questions of the participants are answered and the participants are asked to do their homework until the next session. After the completion of the training sessions, a post-test will be conducted for both groups in the last session, and a follow-up test will be conducted in both groups one month after the completion of the treatment sessions.The intervention is done online in the Sky Room and WhatsApp as a group in the form of 8 60-minute sessions, once a week, by a senior student of counseling in midwifery under the supervision of a supervisor and a couple therapy consultant.
Category
Behavior

2

Description
Intervention group 2: The contents of the sessions include: session 1: preparation of the therapist, treatment situation and clients, session 2: background exercises for mental imagery in order to stimulate mental images, session 3: relaxation background exercise before mental imagery to prepare for creating mental images Session 4: Evoking mental images and describing them, Session 5: Facilitating new adaptive skills through mental imagery by expanding the mental images of working on these images and trying to make changes in these images, Session 6: Ending the stage of working on mental imagery. In the therapy session, session 7: follow up work with mental images, including reflections, thoughts, interpretations and creating meanings, session 8: presentation of homework and review of materials and re-completion of questionnaires. At the beginning of each session, a summary of the materials related to the previous sessions is reviewed and the tasks related to the previous session are reviewed by the counselor in order to evaluate the improvement of marital stress in each session. Women are asked to participate in online counseling discussions and ask questions. The consultant will also ask questions about the topics of the meeting for the participation of more people in the meeting. At the end of each session, a summary of the important topics discussed is presented and the questions of the participants are answered and the participants are asked to do their homework until the next session. After the completion of the training sessions, in the last session, the post-test will be performed and again, a month after the completion of the treatment sessions, the follow-up test will be performed.The intervention is carried out online in Sky Room and WhatsApp as a group in the form of 8 sessions of 60 minutes, once a week, by a senior student of counseling in midwifery under the supervision of a supervisor and a couple therapy consultant.
Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Baqaipour Clinic, Shahid Sadoughi Hospital, Yazd
Full name of responsible person
Tahmineh Farajkhoda
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr. Amir Hoshang Mehrparvar
Street address
Central Organization of Yazd University of Medical Sciences, Dr. Bahnar Square, Yazd
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8916978477
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Fax
+98 35 3726 3732
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ah.mehrparvar@gmail.com

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
Tahmineh Farajkhoda
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Clinical Psychology
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Person responsible for scientific inquiries

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Person responsible for updating data

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Full name of responsible person

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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
All personal data of study participants can be shared after de-identification
When the data will become available and for how long
After results publication
To whom data/document is available
The data will be available to researchers working in academic and scientific institutions, and people working in industry can apply to receive them.
Under which criteria data/document could be used
Scientific usage
From where data/document is obtainable
farajkhoda@yahoo.com
What processes are involved for a request to access data/document
One week after receiving the applicant's email
Comments