Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effectiveness of solution- focused therapy counseling with educational pamphlets on improving marital intimacy of women suffering from Down syndrome child

Protocol summary

Study aim

The research question is how effective are 8 solution-oriented sessions compared to 4 sessions of pamphlet educational content?

Design

Parallel clinical trial, with control group, randomized, on 72 samples. Block randomization is used for randomization by visiting the online random allocation site.

Settings and conduct

It is necessary to invite to study and consult online. Both groups and their spouses will be given an online questionnaire. They are provided with a training pamphlet control group, but a counseling program for the test group, in the form of 8 online sessions once a week. Then, the questionnaires will be given to both groups and spouses online after the meetings and one month later.There is no blinding

Participants/Inclusion and exclusion criteria

inclusion criteria: welling to participate in the study؛ Having a smart phone؛ Reading and writing literacy؛ Married and with a spouse؛ Being the only spouse؛ The age of the child is over 2 years, Having Down syn child؛ exclusion criteria: Addiction to alcohol and drugs , drugs may be affect sexual function, such as psychological drugs in oneself or one's spouse, according to the individual؛ Diseases affecting sexual function such as diabetes

Intervention groups

At the beginning of the study, both groups and their spouses will be given a marital intimacy questionnaire online. For control group pamphlets will be provided during 4 sessions. For intervention group, 8 online solution-focused counseling sessions will be designed weekly. The questionnaires will be given online end of the 8th session and one month later.in both groups.

Main outcome variables

The approach of counseling of circulatory solutions in the treatment and management of women with children with mental and physical disorders can be used. The results of this study can be used in the field of sexual health and fertility education and research.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200620047846N1**
Registration date: **2021-01-01, 1399/10/12**
Registration timing: **prospective**

Last update: **2021-01-01, 1399/10/12**
Update count: **0**

Registration date

2021-01-01, 1399/10/12

Registrant information

Name

Naeime Mirshafieian

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3274 3257

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naeime.mir61@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-19, 1399/10/30

Expected recruitment end date

2021-04-20, 1400/01/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of solution- focused therapy counseling with educational pamphlets on improving marital intimacy of women suffering from Down syndrome child

Public title
The effectiveness of solution focused therapy consoling in marital intimacy of women suffering from Down syndrome child
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
The desire to participate the study Having a smart phone Being Iranian Living in Isfahan Reading and Writing literacy Married and with a spouse Being one`s only spouse Down`s age over 2 years Member of Isfahan Sky Blue Association Having an infected child
Exclusion criteria:
Alcohol and drug addiction in oneself or one's spouse, according to the person, use of drugs affecting sexual function such as psychiatric drugs in oneself or one's spouse, diseases affecting sexual function such as diabetes, applicant for other help such as psychological services, Simultaneous participation in other treatment programs
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
The sample size consists of 72 people (women) and due to the fact that counseling sessions are held in the presence of women and online, each person can be assigned a number between 1 and 72, which can be found by visiting the site. Random allocation is done online. There are currently three models of random allocation, and considering that this study is in two groups (intervention and control group), the first generation randomization model is used, where each sample (female) is placed in a treatment group. This is called block randomization and is done through the site. Http://www.randomization.com. Through the blocks on the site, groups A and B are entered in the treatment groups section, and then the number of people, which is 72, is entered in the number of people in the treatment blocks, where the software of each person is entered. Assigns to one of the two groups A and B randomly, which means that the assignment of individuals to each of the two groups does not occur in the order AB, but in the order in which the software output is placed.
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 Yazd University of Medical Sciences
Street address
Yazd - Safaieh - Timsar Fallahi St. - Bouali Sina Alley - School of Nursing and Midwifery
City
Yazd
Province
Yazd
Postal code
8916978477
Approval date
2020-09-08, 1399/06/18
Ethics committee reference number
IR.SSU.REC.1399.152

Health conditions studied

1

Description of health condition studied
Marital intimacy in mothers with children with Down syndrome
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Intimacy score in Bagarozi Marital Intimacy Questionnaire
Timepoint
Intimacy score before, immediately and one month after the intervention
Method of measurement
Bagarozi Marital Intimacy Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: Counseling for the experimental group is done in 8 sessions of 90 minutes once a week and online and doing homework. In the first session, the questionnaire is completed online by the couple separately, which takes 10 minutes. Then, the contents of the first session: the anatomy of the female reproductive system, creating communication and acquaintance, familiarizing the participants with the goals, rules and work process of the sessions, creating hope for change in the participants, asking for their expectations, giving homework, are expressed. In each session, the first 15 minutes of homework review, 45 minutes of content of the same session and 30 minutes of questions and answers. The contents of the second session: review of homework, familiarity with the basic principles of solution-oriented counseling and its application, review of active acceptance of responsibility in a relationship, formulation of problem-solving circles. Session 3: Reviewing assignments, identifying participants' solutions to different problem areas, familiarizing participants with useful solutions and repeating them, and discarding inappropriate solutions, finding a positive story. Session 4: Assignment of tasks, commitment and hope of participants to solve the problem, identify and solve the resistance of participants, talk about the future, talk about tasks, use the technique of scale questions. Session 5: Reviewing assignments, familiarizing members with problem exceptions, strengthening and highlighting problem exceptions, participants realizing their capabilities and capabilities. Session 6: Assessment of assignments, helping participants to identify other ways of thinking, feeling and behaving instead of thinking, feeling and behaving the current problem, helping participants to admire instead of criticizing each other, performing the master key technique. Session 7: Review assignments, help participants imagine a future of interest and a better world, help participants get out of trouble and identify. Session 8: Summarizing the sessions and concluding, using the graded questions, conducting the post-test, thanking and appreciating the members for participating in the meeting.

Category

Treatment - Other

2

Description

Control group: The control group will be given an educational pamphlet during 4 sessions، every other week, during the consultation of the intervention group, without doing homework.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Blue Sky Down Syndrome Association

Full name of responsible person
Dr. Nazhat Ahmadi

Street address
Bahonar St., Khademi St., Third Sub-Alley, Laleh Alley, No. 49 Open in Google Translate

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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
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
Naeime Mirshafieian

Position
University student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
The results of the clinical study will be published in the form of an article.

When the data will become available and for how long
Immediately after printing the results

To whom data/document is available
All researchers

Under which criteria data/document could be used
Scientific use with reference to the article

From where data/document is obtainable
Email: naeime.mir61@gmail.com

What processes are involved for a request to access data/document
Up to one week after correspondence by email

Comments