# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Effectiveness of Acceptance and Commitment Therapy (ACT) and Relationship Enhancement Couples Therapy (RECT) on intimacy and sexual activity in women with muliple sclerosis

## Protocol summary

**Study aim**

Effectiveness comparison of two methods of treatment based on acceptance and commitment therapy (ACT) and relationship enhancement couples therapy (RECT) on intimacy and sexual activity in women with multiple sclerosis in online consulting method

**Design**

A clinical trial with a control group, with parallel groups, without blinding, randomized, on 44 patients, the online random allocation site was used for randomization

**Settings and conduct**

Female patients who are members of MS Association of Shahid Sadoughi Hospital in Yazd, after being divided into two groups of acceptance and commitment therapy and relationship enhancement couples therapy, completed the questionnaire of intimacy and sexual activity of multiple sclerosis then receive 8 online counseling sessions.

**Participants/Inclusion and exclusion criteria**

Entry requirements: Relapsing-remitting type of multiple sclerosis based on the diagnosis of the treating physician, Use online consultation with a smart phone and have an Android or iOS smartphone, Being in reproductive age, Shared bed with spouse, Willingness to participate in the study No entry conditions: Pregnancy, Existence of psychotic disorders and severe mental disorders according to the doctor's diagnosis, Addiction, Existence of domestic violence, Existence of extramarital affair, Existence of emotional divorce according to the research unit

**Intervention groups**

8 sessions of acceptance and commitment therapy for the intervention group based on online consulting method 8 sessions of relationship enhancement couples therapy for the control group based on online counseling method

**Main outcome variables**

Intimacy and Sexual activity

## General information

**Reason for update**

Inconsistency of the scientific title of trial in persian and english

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20201226049837N1**
Registration date: **2021-02-15, 1399/11/27**
Registration timing: **prospective**

Last update: **2021-02-27, 1399/12/09**
Update count: **1**

**Registration date**

2021-02-15, 1399/11/27

**Registrant information**

**Name**

fatemeh aliaskari

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 35 3824 1751

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2021-04-20, 1400/01/31

**Expected recruitment end date**

2021-10-22, 1400/07/30

**Actual recruitment start date**

empty

**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Effectiveness of Acceptance and Commitment Therapy (ACT) and Relationship Enhancement Couples Therapy (RECT) on intimacy and sexual activity in women with muliple sclerosis

**Public title**
Effectiveness comparison of two methods of treatment based on acceptance and commitment therapy (ACT) and relationship enhancement couples therapy (RECT) on intimacy and sexual activity in women with multiple sclerosis in online consulting method
**Purpose**
Education/Guidance
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Relapsing-remitting type of multiple sclerosis based on the diagnosis of the treating physician Use online consultation with a smart phone and have an Android or iOS smartphone Being in reproductive age Shared bed with spouse Willingness to participate in the study
**Exclusion criteria:**
Pregnancy Existence of psychotic disorders and severe mental disorders according to the doctor's diagnosis Addiction Existence of domestic violence Existence of extramarital affair Existence of emotional divorce according to the research unit
**Age**
From **15 years** old to **49 years** old
**Gender**
Female

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **44**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
The sample size consists of 44 women. Each woman can be assigned a number between 1 and 44, which is done by referring to the online site random allocation. There are currently three models of random allocation, and since this study is in two groups, the first generation randomization model is used, where each sample is placed in a treatment group and is done through the site. http://www.randomization.com This means that the allocation of samples to each of the two groups does not occur in A and B, respectively, 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**
Ethics committee of Yazd Shahid Sadoughi University of Medical Sciences
**Street address**
Shahid Sadoughi University of Medical Sciences, Building No.1, at the beginning of Shahid Sadoughi Boulevard, Bahonar Square
**City**
Yazd
**Province**
Yazd
**Postal code**
8916978477
**Approval date**
2020-12-21, 1399/10/01
**Ethics committee reference number**
IR.SSU.REC.1399.203

## Health conditions studied

**1**

**Description of health condition studied**
Multiple Sclerosis
**ICD-10 code**
G35
**ICD-10 code description**
Multiple sclerosis

## Primary outcomes

**1**

**Description**
Change in the mean scores of intimacy and sexual activity
**Timepoint**
Beginning of the study, completion of the eighth and twelfth weeks of the study
**Method of measurement**
Multiple Sclerosis Intimacy and Sexual activity Questionnaire

## Secondary outcomes

**1**

**Description**
Change in the average scores of satisfaction from

counseling

**Timepoint**

Completion of the eighth and twelfth weeks of the study

**Method of measurement**

Satisfaction form of counseling

## Intervention groups

### 1

**Description**

Intervention group: For Acceptance and Commitment Therapy Group participants, 8 session 60-minute weekly group counseling with Acceptance and Commitment Therapy approach are held.

**Category**

Behavior

### 2

**Description**

Control group: For Relationship Enhancement Couples Therapy Group participants, 8 session 60-minute weekly group counseling with Relationship Enhancement Couples Therapy approach are held.

**Category**

Behavior

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Shahid Sadoughi Hospital

**Full name of responsible person**

Dr Hossein Soleymani

**Street address**

Shahid Sadooghi Hospital, Sina Rd, Shahid Ghandi

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Yazd

**Province**

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**Email**

Sadoghi-hospital@ssu.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Dr Masoud Mirzayi

**Street address**

Vice Chancellor for Research and Technology, third floor, Shahid Sadoughi University of Medical Sciences, Building No.1, at the beginning of Shahid Sadoughi Boulevard, Bahonar Square

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htd@ssu.ac.ir

**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**

PhD in Reproductive Health

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

**Street address**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Fatemeh Aliaskarizamani
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Masters Student
**Latest degree**
Bachelor
**Other areas of specialty/work**
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sahar.askari777@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be 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**
Undecided - It is not yet known if there will be 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