

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

Effectiveness of Group Counseling with Acceptance and Commitment Therapy(ACT) on the Degree Sexual Satisfaction of HIV Positive Women and with HIV Positive Husband

Protocol summary

Study aim

Determine the effect of group counseling with Acceptance and Commitment Therapy (ACT) on the degree sexual satisfaction of HIV positive women and women with HIV positive husband

Design

Clinical trials with community based and pragmatic control group, with parallel groups, Not blinded, randomized

Settings and conduct

This research is a semi-experimental study type (RCT) with parallel study and control group. The statistical population of this study was purposeful sampling and included all HIV positive women and with HIV-infected wife, referred to the Behavioral Counseling Center in Yazd and Meybod. According to similar studies, the sample size is 32, and individuals qualifying for entry criteria are selected. After obtaining written consent, the participants are randomly assigned to two groups of study and control, and complete the Larson sexual satisfaction questionnaires. The test group then participates in ACT sessions. But the control group does not receive treatment. After the end of treatment sessions, one month afterwards, the post-test is performed from both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: . Having Iranian citizenship • The participant or his / her spouse has HIV • Spend at least one year of living together • Permanent monogamy living together Exclusion criteria: . Not willing to cooperate in research . Acute and debilitating mental illness in yourself and your spouse • Having a sexual dysfunction in yourself and your spouse

Intervention groups

The intervention group participates in admission and commitment treatment sessions in 10 sessions of 90 minutes in group and weekly sessions based on the ACT

treatment plan; the intervention group does not receive the intervention.

Main outcome variables

Sexual Satisfaction Score

General information

Reason for update

Acronym

ACT

IRCT registration information

IRCT registration number: **IRCT20181213041956N1**

Registration date: **2019-10-14, 1398/07/22**

Registration timing: **retrospective**

Last update: **2019-10-14, 1398/07/22**

Update count: **0**

Registration date

2019-10-14, 1398/07/22

Registrant information

Name

Nairsadat Taheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3726 5508

Email address

n.taheri@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

2018-12-09, 1397/09/18

Actual recruitment end date

2019-02-12, 1397/11/23

Trial completion date

2019-03-16, 1397/12/25

Scientific title

Effectiveness of Group Counseling with Acceptance and Commitment Therapy(ACT) on the Degree Sexual Satisfaction of HIV Positive Women and with HIV Positive Husband

Public title

Effect of ACT on the Sexual Satisfaction Women Involved with HIV

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Have at least one year of common life history The participant or his wife is HIV-positive Iranian citizenship The common life of permanent monogamy

Exclusion criteria:

Not willing to cooperate in research Acute and debilitating mental illness in yourself and your spouse Having a sexual dysfunction in yourself and your spouse

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **32**

Actual sample size reached: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Using simple randomization method by random number 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 Shahid Sadoughi University of Medical Sciences, Yazd

Street address

End of Yas, Hariri Alley, Motahari Ave.

City

Yazd

Province

Yazd

Postal code

8917698148

Approval date

2018-12-01, 1397/09/10

Ethics committee reference number

IR.SSU.REC.1397.110

Health conditions studied**1****Description of health condition studied**

Sexual satisfaction

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Sexual Satisfaction Score

Timepoint

Measurement of sexual satisfaction score before, after and one month after the completion of counseling

Method of measurement

Larson Sexual Satisfaction Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: For the intervention group, routine care and 10 sessions of 90 minutes group counseling with acceptance and commitment approach were held once a week.

Category

Behavior

2**Description**

Control group: received only routine care at the center.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Counseling Centers for Behavioral Illnesses in Yazd

Full name of responsible person

Naiersadat Taheri

Street address

Imam Jafar Sadeq Blvd, Imam Jafar Sadeq Alley

City

Yazd

Province

Yazd

Postal code

8916715171

Phone

+98 35 3624 1444

Fax

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Email

taherynaier@yahoo.com

Web page address

2

Recruitment center

Name of recruitment center

Counseling Centers for Behavioral Illnesses in Maybod

Full name of responsible person

Nairsadat Taheri

Street address

Counseling Center for Behavioral Illnesses, Bfrooyeh, Meybod.

City

Maybod

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Yazd

Postal code

8963113131

Phone

+98 35 3234 3007

Email

seyedrohollah@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Massoud Mirzaei

Street address

Faculty of Midwifery Nursing, Bu'ali Alley, Timsar Fallahi Avenue, Safaiyeh, Yazd

City

Yazd

Province

Yazd

Postal code

8915173160

Phone

+98 35 3824 1751

Fax**Email**

taherynaier@yahoo.com

Web page address**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

Nairsadat Taheri

Position

Master's degree in midwifery counseling

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Faculty of Midwifery and Nursing, Bouali Sina Alley, Timsar Fallahi St., Safaiyeh.

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Mahshid Bokaie

Position

PhD in Reproductive Health

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Faculty of Midwifery and Nursing, Bouali Sina Alley,
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Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Nairsadat Taheri

Position

Master's degree in midwifery counseling

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

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City

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Web page address

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 as a article

When the data will become available and for how long

Immediately after publishing the results

To whom data/document is available

all researchers

Under which criteria data/document could be used

Scientific use with reference to article

From where data/document is obtainable

Naiersadat Tahery, taherynaier@yahoo.com

What processes are involved for a request to access data/document

Up to one week after correspondence by email

Comments