Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 Sadegh Blvd, Imam Jafar Sadeq Alley

City
Yazd

Province
Yazd

Postal code
8916715171

Phone
+98 35 3624 1444

Fax
+98 35 3624 1444

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

Province
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.

City
Yazd

Province
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Postal code
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Email
taherynaier@yahoo.com

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, Timsar Fallahi St., Safaiyeh.

City

Yazd

Province

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Postal code

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Email

mah_bokaie@yahoo.com

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

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

City

yazd

Province

Yazd

Postal code

8915173160

Phone

+98 35 3824 1751

Email

taherynaier@yahoo.com

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