

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The effectiveness of reality therapy on decreasing marital conflict among couples living with HIV/AIDS

Protocol summary

Study aim

Determine the effectiveness of reality therapy on decreasing marital conflict among couples

Design

In this research, 100 eligible patients referring to voluntary and counseling center for HIV will be chosen purposefully and a code will be allocated to each one of them. Then, patients randomly will divide into two control and intervention groups. Block randomization and intervention is group counseling

Settings and conduct

It is a randomized controlled clinical trial without blinding. Setting and conduct: voluntary and counseling testing center of Imam Khomeini Hospital in Tehran.

Participants/Inclusion and exclusion criteria

It's been 6 months since marriage; have psychological problem according to self report.

Intervention groups

7 section of group counseling for intervention group; control group: receiving Iranian HIV protocol

Main outcome variables

Helping to resolve marital conflicts

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180610040037N1**

Registration date: **2018-07-23, 1397/05/01**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-23, 1397/05/01**

Update count: **0**

Registration date

2018-07-23, 1397/05/01

Registrant information

Name

Seyed Ali Dehghan maneshadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6691 1296

Email address

a_dehghanm@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2018-10-07, 1397/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of reality therapy on decreasing marital conflict among couples living with HIV/AIDS

Public title

The effectiveness of reality therapy on decreasing marital conflict

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Six months have passed since couples married. Being Iranian Reading and writing ability Written consent

Exclusion criteria:

Absence in medical sessions Have psychological problem according to self report

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

First, the sampling will be available and according to the active records in the center. Then they will be divided into two groups based on random blocks. Also for statistical matching, the statistical tests are used to match the underlying variables. The randomization method is done using block randomization so that the sample size of both groups is equal.

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

University of Medical Sciences of Tehran

Street address

Central Office of Tehran University of Medical Sciences, Corner of Ghodd Street, Keshavarz Blvd., Tehran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2018-06-12, 1397/03/22

Ethics committee reference number

IR.TUMS.VCR.REC.1397.156

Health conditions studied

1

Description of health condition studied

Human immunodeficiency virus

ICD-10 code

B20

ICD-10 code description

Human immunodeficiency virus [HIV] disease

Primary outcomes

1

Description

Reducing Marital Conflict

Timepoint

At the beginning of the study (before the intervention) at the end of the study and 45 days after the completion of the study

Method of measurement

Marital conflicts questionnaire, this questionnaire was prepared by Torabi and Sanaei (1996).

Secondary outcomes

1

Description

Increase sex

Timepoint

At the beginning of the study (before the intervention) at the end of the study and 45 days after the completion of the study

Method of measurement

Marital conflicts questionnaire, this questionnaire was prepared by Torabi and Sanaei

Intervention groups

1

Description

In the intervention group of people living with HIV we hold 7 consultation sessions weekly based on reality therapy. The time of each session is 90 minute.

Category

Behavior

2

Description

Control group: in the control group they will receive just routine voluntary and counseling protocol for HIV consultation

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Behavioral Disease Counseling Centers

Full name of responsible person

Dr Seyd Ali Dehghan Menshadi

Street address

The Department of Infectious and tropical Disease,
Imam Khomeini Hospital, Keshavarz Blvd.

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a_dehghanm@sina.tums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr Seyd Ali Dehghan Menshadi

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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

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Dr Seyd Ali Deghan Menshadi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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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

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

Title and more details about the data/document

as an English article we published data .

When the data will become available and for how long

12 month later

To whom data/document is available

Iranian research center for HIV/AIDS

Under which criteria data/document could be used

path analysis

From where data/document is obtainable

Iranian research center for HIV/AIDS

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

send an email to Dr.Deghan menshadi

Comments