

# 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.

**City**

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**Postal code**

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**Email**

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**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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## 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**