Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Calculating the Contribution of Flexibility Components in Predicting Sexual Distress and Satisfaction Based on Intimacy and Attachment Orientation in Men with Sexual Dysfunction and Investigating the Efficacy of Acceptance and Commitment Therapy Based on the Most Contributions Components on Sexual Distress and Satisfaction in Men Recovered from Peyronie's Disease

Protocol summary

Study aim

Determining the efficacy of Acceptance and Commitment Therapy based on the most contributions components on sexual distress and satisfaction in men recovered from peyronie’s disease

Design

The clinical trial does not have a control group, unblinded, and non-randomized. The intervention is performed on 3 patients

Settings and conduct

The clinical trial is conducted in the family health clinic of Shahid Mostafa Khomeini Hospital, during 4 weekly sessions and individually.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Having at least a diploma; Being sexually active; Existence of high sexual distress and low sexual satisfaction Exclusion Criteria: Absence of one session of treatment sessions; Suffering from severe psychological disorders; Suffering from sexual dysfunction; History of diabetes, cardiovascular and neurological diseases; History of prostate or pelvic surgery; Drug and alcohol addiction; Taking psychiatric medications

Intervention groups

Considering that this study using single-subject design, each subject is considered to be his own control group. The intervention sessions are derived from the Acceptance and Commitment Therapy Manual for Anxiety Disorders. This manual is an integrated, transdiagnostic protocol for a wide range of anxiety disorders that has previously been used to improve distress and increase marital satisfaction. In the aforementioned study, the main protocol has experienced changes to adapt to the research sample and study objectives, and in the current study, changes are also applied to adapt the content of the treatment protocol to the problems of Peyronie's patients.

Main outcome variables

The score that a person obtains in the sexual anxiety and sexual depression subscales of the Multidimensional Sexuality Questionnaire; Individual's score in the sexual satisfaction subscale of the Multidimensional Sexuality Questionnaire

General information

Reason for update

Acronym

ACT

IRCT registration information

IRCT registration number: **IRCT20240705062335N1**
Registration date: **2024-08-12, 1403/05/22**
Registration timing: **prospective**

Last update: **2024-08-12, 1403/05/22**
Update count: **0**

Registration date

2024-08-12, 1403/05/22

Registrant information

Name

Mohammad Ahmadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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mohammad-ahmadi@shahed.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-09-22, 1403/07/01
Expected recruitment end date
2024-10-21, 1403/07/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Calculating the Contribution of Flexibility Components in Predicting Sexual Distress and Satisfaction Based on Intimacy and Attachment Orientation in Men with Sexual Dysfunction and Investigating the Efficacy of Acceptance and Commitment Therapy Based on the Most Contributions Components on Sexual Distress and Satisfaction in Men Recovered from Peyronie's Disease

Public title
Investigating the Effect of Acceptance and Commitment Therapy (ACT) in Peyronie’s Disease
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Having at least a diploma Being sexually active Existence of high sexual distress and low sexual satisfaction based on the Multidimensional Sexuality Questionnaire (MSQ)
Exclusion criteria:
Absence of one session of treatment sessions Suffering from severe psychological disorders based on the SCL90 questionnaire Suffering from sexual dysfunction based on the BMSFI screening questionnaire and clinical interview History of diabetes, cardiovascular and neurological diseases History of prostate or pelvic surgery Drug and alcohol addiction Taking psychiatric medications
Age
From **25 years** old to **60 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **3**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahed university Committee for Ethics in Research
Street address
Shahed University, opposite Holy shrine of Imam Khomeini, Khalij Fars Expressway
City
Tehran
Province
Tehran
Postal code
3319118651
Approval date
2024-05-27, 1403/03/07
Ethics committee reference number
IR.SHAHED.REC.1403.022

Health conditions studied

1

Description of health condition studied
Peyronie
ICD-10 code
N48.6
ICD-10 code description
Induration penis plastica

Primary outcomes

1

Description
The score that a person obtains in the sexual anxiety and sexual depression subscales of the Multidimensional Sexuality Questionnaire
Timepoint
Measuring sexual anxiety and sexual depression before starting the intervention and 7, 14, 21, 28 and 60 days after starting to receive the Acceptance and Commitment Therapy
Method of measurement
Multidimensional Sexuality Questionnaire

2

Description
Individual's score in the sexual satisfaction subscale of

the Multidimensional Sexuality Questionnaire

Timepoint

Measuring sexual satisfactory before starting the intervention and 7, 14, 21, 28 and 60 days after starting to receive the Acceptance and Commitment Therapy

Method of measurement

Multidimensional Sexuality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: considering that the current study is a single case intervention, therefore each subject is considered his own control group. In this study, 3 subjects are subjected to a pre-test before the start of the study, and after receiving treatment based on acceptance and commitment, they are evaluated in 4 sessions.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Family Health Clinic of Shahid Mostafa Khomeini Hospital

Full name of responsible person

Seyed kazem Foroutan

Street address

No. 9, Italy St., Palestine St., Keshavarz Boulevard, Valiasr Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Shahriar Bijani

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Shahed University, opposite Holy shrine of Imam Khomeini, Khalij Fars Expressway

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Email

info@shahed.ac.ir

Web page address

https://shahed.ac.ir/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahed University

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

Shahed University

Full name of responsible person

Mohammad Ahmadi

Position

Phd student

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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Position
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Latest degree
Master

Other areas of specialty/work
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Person responsible for updating data

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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