Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Nov 2026

Developing of Acceptance and Commitment Therapy (ACT) protocol based on psychological problems in people with prostate cancer and its effectiveness on health-related quality of life and psychological distress of them.

Protocol summary

Study aim

If the research hypotheses are proven, Acceptance and Commitment therapy (ACT) can be used in treatment centers to help treat patients with prostate cancer and have a significant role in improving the quality of life associated with the health and psychological distress of these patients.

Design

Controlled clinical trial, not blind, randomized design

Settings and conduct

At the Labafi Nejad Hospital, patients' files are reviewed and interviewed in the presence of the Dr. Mofid. If satisfied, patients complete the questionnaires in the pre-test and post-test stages.The treatment protocol is performed in 8 sessions on the intervention group at the Dr. Clinic.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 50 and 75 years; Diagnosed prostate cancer in patients who completed standard therapies; Exclusion criteria: Mental disorders and other cancers.

Intervention groups

The ACT Therapy protocol will be administered to the experimental group to improve health-related quality of life and reduce psychological distress in patients with prostate cancer, and the control group will continue their treatment.

Main outcome variables

The main implications of this study are: psychological problems as measured by the DASS-21 scale; Quality of life is dependent on health as measured by the questionnaire (SF 36). The main consequences are pre-test and post-test.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200209046424N1**
Registration date: **2020-03-14, 1398/12/24**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-14, 1398/12/24**
Update count: **0**

Registration date

2020-03-14, 1398/12/24

Registrant information

Name

Fatemeh Baniasadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4471 9445

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-01, 1398/10/11

Expected recruitment end date

2020-03-18, 1398/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Developing of Acceptance and Commitment Therapy (ACT) protocol based on psychological problems in people with prostate cancer and its effectiveness on health-related quality of life and psychological distress of them.

Public title
The Effect of Acceptance and Commitment Therapy on prostate cancer

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Willingness to participate in the research project Age 75 - 50 years Minimum literacy At least one year under treatment (with expert approval) No addiction to any drug Completion of consent to participate in the research Low score of health related quality of life questionnaire and psychological problems scale

Exclusion criteria:
Kidney and liver diseases Use of psychoactive drugs

Age
From **50 years** old to **75 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Based on the inclusion criteria and a pre-test session, 40 men who scored lower than average after completing the Depression, Anxiety and Stress Questionnaire (DASS 21) had health-related quality of life (SF 36). Since the study groups have equal sample size, we use simple random allocation law which is one of the limited randomization methods and we divide people into two groups of intervention and control. Keep notes of patients on 40 separate sheets and place the sheets inside the draw container and then we randomly record the 20 sheets out of the container into the intervention group and place the remaining 20 sheets in the control group. If there is a loss in treatment sessions, the sample size will be randomly eliminated in order to equalize the sample size and eventually the number of subjects in both groups should be the same. The experimental group (n=20) will have 8 sessions of 120-minute Acceptance and Commitment therapy and the control group will receive no intervention.

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
Ethics committee of Hormozgan University of Medical Sciences

Street address
Shahid Chamran Blvd., Hormozgan University of Medical Sciences

City
Bandar Abbas

Province
Hormozgan

Postal code
7916613885

Approval date
2019-12-07, 1398/09/16

Ethics committee reference number
IR.HUMS.REC.1398.341

Health conditions studied

1

Description of health condition studied
Prostate Cancer

ICD-10 code
C61

ICD-10 code description
Malignant neoplasm of prostate

Primary outcomes

1

Description
Psychological Problem Score on the Short Form of Depression, Anxiety and Stress Scale (DASS 21); Physical and Mental Health Score in Health Related Quality of Life Questionnaire (SF 36)

Timepoint
At the beginning of the study (before the intervention) and after 8 sessions of acceptance and commitment group therapy

Method of measurement
The Short Form of Depression, Anxiety and Stress Scale (DASS 21); Health Related Quality of Life Questionnaire (SF 36)

Secondary outcomes

1

Description
Health-related quality of life score and psychological problems score

Timepoint
Health-related Quality of Life Questionnaires (SF 36) and Depression, Anxiety and Stress Short Form (DASS 21) at baseline (before intervention) and after treatment protocol

Method of measurement
The Depression, Anxiety and Stress Questionnaire (DASS 21) Health-related quality of life (SF 36)

Intervention groups

1

Description
Acceptance and Commitment Therapy (ACT) has six central processes that lead to psychological flexibility. These six processes are: "Acceptance, Faulting, self as context, present-day communication, recognizing values and committed action Intervention group". In fact the purpose of Acceptance and Commitment therapy, is not to make a direct change in the client. Rather, its purpose is to help clientele communicate their experiences in different ways and be able to engage completely with meaningful, value-based life. The proposed protocol is based on the Acceptance and Commitment Book by Hayes, Straussell and Wilson. In the intervention group: Twenty patients have prostate cancer before the protocol is implemented In the pre-test, they completed the Short Form of Depression, Anxiety and Stress Questionnaire (DASS-21) and Health-Related Quality of Life (SF-36) with full specifications. In the intervention group, the Acceptance and Commitment Therapy protocol (ACT) will be conducted in eight consecutive 90-minute sessions in 4 consecutive weeks.

Category
Behavior

2

Description
Control group:Twenty patients with prostate cancer who complete the pre-test questionnaire of depression, anxiety and stress (DASS-21) and health-related quality of life (SF-36) with complete the specification. The group will receive routine care during this 4-week period and will not perform any additional work. After 4 weeks post-test this group will also complete the questionnaires.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Labafi Nejad Hospital, Dr. Mofid Office

Full name of responsible person
Dr. Bahman Mofid

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9th Boulevard (Jaafari), Pasdaran st.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
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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
Islamic Azad 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

Islamic Azad University

Full name of responsible person
Fatemeh Baniasadi

Position
Student

Latest degree
Master

Other areas of specialty/work
Psychology

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Associate Professor of Health Psychology

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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
Not applicable

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