Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effectiveness of cognitive behavior therapy (CBT) and Twelve steps program on alcohol consumption

Protocol summary

Study aim
To evaluate the influence of cognitive behavioral therapy and twelve steps program on alcohol abuser.

Design
Two groups will participate in it experimental and control groups. Participants will be randomly assigned, 20 participants included, Double blind.

Settings and conduct
Data analysts responsible for conducting statistical analyses and interpreting study outcomes will be blinded to the group assignments.The trial will be conducted in Rehabilitation centers Lahore, Pakistan.

Participants/Inclusion and exclusion criteria
the participants age range will be chose 18 to 45 years . Participants will include in the research their severity level will be moderate.The individuals will included in present study who using the alcohol last 5 years.Individuals with a history of severe mental health disorders The individuals are using the alcohol 5 years above, they have not include in our study.

Intervention groups
Participants randomly divide into two groups through the www.random org. com website in which experimental group will receive the treatment of 12 Steps program ,Conduct CBT sessions for the participants. These sessions will focus on helping them recognize and challenge cognitive distortions related to alcohol use, develop coping strategies to manage triggers and cravings, build better problem-solving skills and restructuring their thinking .CBT Sessions will be conduct 8 week, the frequency (1,weekly), and the duration will be (40, 60 minutes) of each session. And 12 steps program to be implemented, such as attendance requirements and meeting frequency. Twelve steps meetings encourage participants to attend regular twelve steps meetings. These meetings can provide social support.

Main outcome variables
Severity of Alcohol consumption.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230909059381N1**
Registration date: **2023-09-23, 1402/07/01**
Registration timing: **registered_while_recruiting**

Last update: **2023-09-23, 1402/07/01**
Update count: **0**

Registration date
2023-09-23, 1402/07/01

Registrant information

Name
Aamir Hayat

Name of organization / entity
University of Sahiwal

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Pakistan

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-15, 1402/06/24

Expected recruitment end date
2023-10-20, 1402/07/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of cognitive behavior therapy (CBT) and Twelve steps program on alcohol consumption

Public title
Effectiveness of CBT and Twelve steps program on alcohol

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Male gender will become the part of present study, The age range will be chose 18 years and above Each individual in the sample will exhibits a moderate level of alcohol abuse or dependence, as assessed by the Alcohol Dependence Scale (ADS) during the baseline assessment. The individuals are using the alcohol less than 5 years, they have included in our study.

Exclusion criteria:
Females will not include in our study Individuals with a current diagnosis of severe alcohol dependence, as their treatment needs may require a different level of care. they will not included in present study. The individuals are using the alcohol more than 5 years they have not include in our study. Individuals who are currently enrolled in another formal alcohol treatment program or receiving concurrent medicine for alcohol-related issues. They will be not participate of present study. Individuals with a history of severe mental health disorders (e.g., schizophrenia, bipolar disorder, Major depression) that may significantly impact their ability to participate in the interventions.

Age
From **18 years** old to **45 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants randomly divide into two groups through the www.random org. com website in which 10 Adults will be in the experimental group and 10 Adults will be in the control group for this study. The control group may receive standard care, other group will waiting the intervention of experimental group. There will be 20 participants in the groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
The data analysts responsible for conducting statistical analyses and interpreting study outcomes will be kept unaware of the group assignments of participants. other hand outcome assessors, responsible for conducting interviews, assessments, and collecting data related to study outcomes, will also be blinded to participant group assignments.

Placebo
Not used

Assignment
Parallel

Other design features
quasi experiment design

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
University of Sahiwal

Street address
Fareed town sahiwal

City
Sahiwal

Postal code
57000

Approval date
2023-08-22, 1402/05/31

Ethics committee reference number
MSPSY-08

Health conditions studied

1

Description of health condition studied
Alcohol

ICD-10 code
F10.1

ICD-10 code description
Alcohol abuse

Primary outcomes

1

Description
Severity of Alcohol consumption

Timepoint
The primary outcome will be measured after 8 weeks of intervention.

Method of measurement
Alcohol dependence scale (ADS) to measure severity of alcohol

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group name: Experimental group, In the starting conduct pre-assessment: scale (ADS) administered that measure the severity of alcohol consumption to gather baseline data on alcohol consumption.after that the conduct cognitive behavior therapy (CBT). These sessions of CBT will focus on helping them recognize and challenge cognitive distortions related to alcohol use, manage triggers and cravings, Along with restructuring their thinking. CBT sessions will be conduct 8 weeks, The frequency of sessions will be once a week. and each session will be approximately 40 to 60 minutes. It will be typically conducted through one-on-one session. Purpose of CBT intervention to reduce the alcohol consumption. .Participants in the experimental group will engage in the Twelve Steps program as part of their intervention. This will involve attending Twelve Steps meetings.participants will be attend two meetings per week. post-assessment (ADS) scale after the intervention to evaluate changes in severity of alcohol consumption.

Category

Rehabilitation

2

Description

Control group: Participants in the control group will undergo the same baseline assessment as the experimental group. This assessment will include the measurement of the severity of alcohol consumption using the Alcohol Dependence Scale (ADS).control group will not receiving the specific CBT and Twelve Steps program interventions, Just conduct Support Group Meetings related to alcohol abuse, recovery, and coping. related topics will include triggers, cravings, stress management, and personal goals for reducing alcohol consumption. these meeting will be held 8 weeks, each meeting time will be 30 to 50 minutes.The frequency of sessions will be once a week. than conduct a post-intervention assessment for the control group. This assessment will be include the same measures and assessments used at the baseline to track changes in alcohol consumption. After the intervention comparison of both group to check the effective in reducing alcohol consumption among participants in the experimental group as compared to those in the control group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Aamir Hayat

Full name of responsible person
Aamir Hayat

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name
Saqib javeed

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
university

Proportion provided by this source
10

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
University of Sahiwar

Full name of responsible person
Aamir Hayat

Position
Professional

Latest degree
Master

Other areas of specialty/work

Psychology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Study on Alcohol Abusers
When the data will become available and for how long
This process time will be 15-09-2023 to 15-10-2023
To whom data/document is available
Data and documents related to research participants will be handled with strict confidentiality and privacy protections. Access to these data/documents should be limited to individuals who have been authorized and trained to handle sensitive information in accordance with ethical and legal guidelines.
Under which criteria data/document could be used
Intervention plan will be provided
From where data/document is obtainable
amirhayatkallu02@gamil.com
What processes are involved for a request to access data/document
in the starting baseline assessment of both group than treatment will give to the experimental group and control group will be waiting than the check severity level after the intervention, the hypothesis present study is, CBT and Twelve steps program effectively reduce alcohol consumption of experimental group as compare to control group.
Comments