Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Mindfulness Based Relapse Prevention Therapy in Individuals with Amphetamine Use Disorder

Protocol summary

Study aim

To see the efficacy of the psychological factor, i.e. craving, uncontrolled aggression, and impulsivity in MBRP in comparison with TAU in Amphetamine type stimulant(ATS) users. To find out enhancing the effect of the psychological factor, i.e. coping, quality of life, and self-efficacy in MBRP in comparison with TAU in ATS users.

Design

This randomized control trial comprises pre-test and post-test with a follow-up period. Participants will be assigned to either MBRP + TAU or TAU, with repeated assessments at baseline, mid-treatment, post-treatment (after 8 weeks)and follow up.

Settings and conduct

90 amphetamine-type stimulants users who are receiving inpatient treatment (approximately 60 to 90 days) beyond the period of detoxification and could complete the program were selected by convenient sampling and were randomly assigned into two groups (MBRP and TAU). The data were analyzed by SPSS-15 using the Multivariate Analysis of Covariance (MANCOVA).

Participants/Inclusion and exclusion criteria

Inclusion: who have completed detoxification, age 18-40 years; referred by a psychiatrist (diagnosis of stimulant use disorder) based on DSM-V; medical detoxification from any substances. Exclusion: The absence of over two sessions; are suffering from severe medical and neuropsychiatric complications or any psychotic illness; already completed any mindfulness-based programme.

Intervention groups

The experimental group will complete 8 sessions (each session is 120 minutes) of Mindfulness-based relapse prevention for the experimental group. While the control group will receive standard 12 steps relapse prevention program for 8 weeks.

Main outcome variables

The variables in this research are Quality Of Life, self efficacy, coping.craving, aggression, impulsivity, and Relapse Prevention.

General information

Reason for update

Acronym

MBRP RCT 21

IRCT registration information

IRCT registration number: **IRCT20210525051403N1**
Registration date: **2021-06-06, 1400/03/16**
Registration timing: **prospective**

Last update: **2021-06-06, 1400/03/16**
Update count: **0**

Registration date

2021-06-06, 1400/03/16

Registrant information

Name

Aftab Hussain

Name of organization / entity

Islamia university bahawalpur

Country

Pakistan

Phone

+92 51 5494233

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-10, 1400/03/20

Expected recruitment end date

2021-11-10, 1400/08/19

Actual recruitment start date

2021-06-21, 1400/03/31

Actual recruitment end date
2021-11-21, 1400/08/30
Trial completion date
2021-11-26, 1400/09/05

Scientific title
Mindfulness Based Relapse Prevention Therapy in Individuals with Amphetamine Use Disorder

Public title
Mindfulness Based Relapse Prevention Therapy in Individuals with Amphetamine Use Disorder
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 40 years age and therefore legally eligible to consent. A history of use of methamphetamine and a diagnosis of stimulant use disorder as described in the Mental Disorders Diagnostic and Statistical Manual (DSM-5); the passage of more than a week from complete methamphetamine detoxification and negative urine test. Be able to speak and read Urdu, sign a written consent for the participants to take part in the study, be mindful. Apart from signing into a written agreement, they have their rights, including the protection of personal data, the immunity to physical or mental harm, and the possibility of quitting the study they wish. All participants would go through urinalysis to make sure that they are not intoxicated
Exclusion criteria:
Unwilling to attend the meetings, absenteeism of more than two sessions, engage concurrently in other health services, and have a long-term dependency on multi-drug concurrently; Requisite medical detoxification from any substances Those are suffering from severe medical and neuropsychiatric complications or any psychotic illness at the time of screening for intake Participants those are unavailable or hesitant to be a part of the study for the 20 weeks An individual having a history of using illicit substance use (e.g. cocaine, heroin) Already completed MBRP sessions.
Age
From **18 years** old to **40 years** old
Gender
Male

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **90**
More than 1 sample in each individual
Number of samples in each individual: **45**
The individual with methamphetamine use disorder will be included in each MBRP and Treatment as usual TAU group. We will include 20 percent more participants for expected dropouts.
Actual sample size reached: **70**
More than 1 sample in each individual
Actual sample size in each individual: **35**
The individual with methamphetamine use disorder will be included in each MBRP and Treatment as usual TAU group.
Randomization (investigator's opinion)
Randomized
Randomization description
Following initial instruction with recruited groups, subjects were randomly allocated using randomization to one of the two groups. An online "Clinical trial randomizer" (www.randomization.com) (Suresh, 2011) was conducted the treatment selection randomly. Participants were assigned to either MBRP + TAU or TAU, with repeated assessments at baseline. Parallel assignments were given to both groups. These procedures were conducted in a group setting.
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
Department of Psychology Ethics Committee (DPEC)The Islamia University Bahawalpur
Street address
Baghdad ul jadeed campus, Hasilpur road, Bahawalpur, Pakistan
City
Bahawalpur
Postal code
63100
Approval date
2021-02-26, 1399/12/08
Ethics committee reference number
112/A-Psy/21

Health conditions studied

1

Description of health condition studied
Amphetamine-type stimulants
ICD-10 code
304.40 (F1
ICD-10 code description
AMPHETAMINE-TYPE SUBSTANCE USE DISORDER

Primary outcomes

1

Description
To measure impulsivity in ATS users
Timepoint
Baseline; During Intervention the beginning of week 5 Post-intervention, the end of the week (PRIMARY ENDPOINT); a 3-month follow-up.
Method of measurement
Barratt Impulsiveness Scale-11

2

Description
Craving in ATS users
Timepoint
Baseline; During Intervention the beginning of week 5 Post-intervention, the end of the week (PRIMARY ENDPOINT); a 3-month follow-up.
Method of measurement
Penn Alcohol Craving Scale (PACS) adopted for methamphetamine

3

Description
Aggression in ATS users
Timepoint
Baseline;During Intervention the beginning of week 5 Post-intervention, the end of the week (PRIMARY ENDPOINT);3-month follow-up.
Method of measurement
Aggression Questionnaire (Buss & Perry, 1992)

Secondary outcomes

1

Description
Self efficacy in ATS users
Timepoint
Baseline; During Intervention the beginning of week 5 Post-intervention, the end of the week (PRIMARY ENDPOINT); a 3-month follow-up.
Method of measurement
General Self-Efficacy Scale (GSES)

2

Description
Coping skills in ATS users
Timepoint
Baseline; During Intervention the beginning of week 5 Post-intervention, the end of the week (PRIMARY ENDPOINT); a 3-month follow-up.
Method of measurement
Brief COPE inventory (Carver, 1997)

3

Description
Quality of life in ATS users
Timepoint
Baseline; During Intervention the beginning of week 5 Post-intervention, the end of the week (PRIMARY ENDPOINT); a 3-month follow-up.
Method of measurement
WHOQOl-BREF (WHO, 1998)

4

Description
Measuring risk of relapse in ATS users
Timepoint
Baseline; the end of the week (PRIMARY ENDPOINT); a 3-month follow-up.
Method of measurement
Stimulant Relapse Risk Scale (SRRS)

Intervention groups

1

Description
Intervention group: This group contains individuals with amphetamine use disorder. Following consenting procedures and randomization, all participants in the experimental group underwent an initial baseline assessment. We had an assessment at four different time points at baseline, mid-treatment, post-treatment and end of follow-up. The intervention comprises eight weekly two-hour group therapy sessions delivered by two facilitators with 10-12 people. Each session focused on a novel concept, such as understanding personal triggers, immediate attention, and allowing/letting go, skillfully reacting to emotional and physical interactions, intrusive thought comprehension, or compassion in action. This group will also receive usual treatments like pharmacotherapy and 12 steps program as control group participants are receiving.
Category
Behavior

2

Description
Control group: This group contains individuals with amphetamine use disorder. Following consenting procedures and randomization, all participants in the control group underwent an initial baseline assessment. We had an assessment at four different time points at baseline, mid-treatment, post-treatment and end of follow-up. In this group, individuals were received continued in their ongoing treatment and management plan provided by the rehab centre to support his sobriety through a 12- step, process-focused model.This group will receive usual treatments like pharmacotherapy and 12 steps program.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Safe care trust international
Full name of responsible person
Farooq ahmad
Street address
Safe care Trust International main motorway chowk near almizan college Islamabad
City
Islamabad
Postal code
44000
Phone
+92 51 5494233
Email
sctrwp@gmail.com
Web page address
http://safecaretrustinternational.com/

2

Recruitment center
Name of recruitment center
Wada clinic
Full name of responsible person
Dr.Abid Khan
Street address
IJP Road, Sector-1 House-4, Service Road, Near Al Makka Shadi Hall, Khayaban e Sir Syed Rawalpindi
City
Rawalpindi
Postal code
46000
Phone
+92 51 2321527
Email
wada4life@gmail.com
Web page address
http://wadaclinic.blogspot.com/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Self funded
Full name of responsible person
Aftab hussain
Street address
Safe Care Trust International, main motorway chowk near almizan college Islamabad
City
Islamabad
Postal code
44000
Phone
+92 51 5494233
Email
aftab_hussain12@yahoo.com
Grant name
Self funded by researcher
Grant code / Reference number
Not available
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Self funded by researcher
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Islamia University Bahawalpur
Full name of responsible person
Aftab Hussain
Position
Student
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Safe Care Trust International, main motorway chowk near almizan college, Islamabad
City
Islamabad
Province
Punjab
Postal code
44000
Phone
092629250235
Email
aftab_hussain12@yahoo.com
Web page address
https://www.iub.edu.pk/department-of-applied-psychology

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamia University Bahawalpur
Full name of responsible person
aftab Hussain
Position
Student
Latest degree
Ph.D.

Other areas of specialty/work
Psychology
Street address
Safe Care Trust International, main motorway chowk near almizan college, Islamabad
City
Islamabad
Province
Capital territory
Postal code
44000
Phone
+92 51 5494233
Email
aftab_hussain12@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Islamia university Bahawalpur
Full name of responsible person
Aftab Hussain
Position
Student
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Safe Care Trust International, main motorway chowk near almizan college, Islamabad
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aftab_hussain12@yahoo.com

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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not 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
No - There is not a plan to make this available
Title and more details about the data/document
After the study is completed, the participant's data will be provided without identifying information. Clinical study report: After the study is completed, the clinical study report will be available.
When the data will become available and for how long
From Jan 2022,
To whom data/document is available
Researchers of mental health studies
Under which criteria data/document could be used
For systematic reviews and meta-analysis, studies are permitted.
From where data/document is obtainable
Safe care trust international main motorway Chowk near Almazan college; Email sctrwp@gmail.com
What processes are involved for a request to access data/document
The data request needs to clearly define data needs. The study contact person will provide data within a 2week after receiving the request.
Comments