

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

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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

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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

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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

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Safe Care Trust International, main motorway chowk
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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

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Punjab

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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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

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