ISRCTN57325925 https://doi.org/10.1186/ISRCTN57325925

A youth culturally adapted manual assisted psychological therapy for adolescent Pakistani patients with a recent history of self-harm

Submission date
08/12/2021

Recruitment status
No longer recruiting

Registration date
03/02/2022

Overall study status
Completed

Last Edited
15/09/2025

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Globally suicide is the second leading cause of death in young people aged 15-29 years. A recent review indicated that the reported suicide rates in South Asia are high compared to the global average. These figures are likely to be an underestimate since suicide data from many Low and Middle-Income Countries (LMICs) is lacking. There is little official data on suicide from Pakistan, where suicide and self-harm are criminal acts and are socially and religiously condemned. However, there is accumulating evidence that both self-harm and suicide rates have been increasing in Pakistan. This is the first study of a psychological intervention for self-harm in children and young people in Pakistan. The training is called Youth Culturally adapted Manual Assisted Psychological therapy (Y-CMAP).

Who can participate?
Patients aged 12-18 years with a history of recent self-harm presenting to the participating GPs or emergency departments, admitted after an episode of self-harm to the participating hospitals or self-referrals. Recent self-harm is defined as self-harm occurring within the last 3 months (from the initial identification of a potential participant).

What does the study involve?
Participants and their parent/guardian are first invited to a face-to-face meeting with a researcher lasting around 1.5 to 2 hours (allowing for breaks). This meeting takes place in a private room or through video call either in a clinical setting (e.g. hospital or clinic room), school or college, or in the participant's own home, depending on preference and practicality considering the COVID-19 situation. During this meeting the details of the study would be shared again, along with the Participant Information Sheet, and individuals will have the opportunity to ask questions before written consent is sought. Once consent has been gained, participants will then be asked to complete a series of questionnaires. Following this initial meeting, the participants will be randomly allocated to either receive the Y-CMAP intervention or treatment as usual (TAU). Y-CMAP is a brief psychological intervention based on the principles of Cognitive Behaviour Therapy (CBT), including 8-10 sessions delivered over 3 months. The first four sessions are offered weekly and further sessions fortnightly and

each session lasting about 60 minutes. TAU will be standard routine care delivered by local medical, psychiatric and primary care services according to clinical judgement. A record will be kept of any treatment received by each participant. Participants in both the Y-CMAP and TAU groups are invited to take part in a series of follow-up assessments taking place at 3, 6, 9 and 12 months after the initial assessment.

What are the possible benefits and risks of participating?
Because the training is still being tested, the researchers do not know how helpful it will be. Participants will be helping the researchers to find better ways of supporting and helping people who have problems with self-harm. The study will involve answering questions about things that could be upsetting. Participants will be asked to answer questions about self-harm and how they feel about themselves. They are free to leave the study at any time should they become upset or not want to take part any further. The researchers can help them to get additional support if needed, such as from your local hospital or clinic.

Where is the study run from?
Pakistan Institute of Learning and Living (Pakistan)

When is the study starting and how long is it expected to run for?
March 2019 to September 2022

Who is funding the study?
1. Medical Research Council (MRC) (UK)
2. Department for International Development (DFID) (UK)
3. National Institute for Health Research (NIHR) (UK)

Who is the main contact?
1. Sehrish Tofique, sehrish.tofique@pill.org.pk
2. Tayyaba Kiran, tayyaba.kiran@pill.org.pk

Contact information

Type(s)
Scientific

Contact name
Prof Nasim Chaudhry

ORCID ID
https://orcid.org/0000-0003-4142-868X

Contact details
Suite 201
Dr Plaza
Clifton 2 Talwar
karachi
Pakistan
75600
+92 (0)21 35871845
nasim.chaudhry@pill.org.pk

Type(s)
Scientific

Contact name
Prof Nusrat Husain

ORCID ID
https://orcid.org/0000-0002-9493-0721

Contact details
University of Manchester
Manchester
United Kingdom
M13 9PL
+44 (0)1254 226390
nusrat.husain@manchester.ac.uk

Type(s)
Public

Contact name
Ms Sehrish Tofique

ORCID ID
https://orcid.org/0000-0002-8027-054X

Contact details
Suite 201
Dr Plaza
Clifton 2 Talwar
Karachi
Pakistan
75600
+92 (0)21 35371084
sehrish.tofique@pill.org.pk

Additional identifiers

ClinicalTrials.gov (NCT)
NCT04131179

Protocol serial number
YCMAP- V2

Study information

Scientific Title
Multicenter study to evaluate the clinical and cost-effectiveness of a youth culturally adapted therapy (YCMAP)

Acronym
YCMAP

Study objectives
Is a Youth Culturally adapted Manual Assisted Psychological therapy (Y-CMAP) effective and cost-effective compared to Treatment As Usual (TAU) in adolescent Pakistani patients with a history (within 3 months) of self-harm?

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 05/11/2019, National Bioethics Committee (NBC) Pakistan (Pakistan Health Research Council, Shahra e Jamhuriat, Off Constitution Avenue, Islamabad, Sector G-5/2, Pakistan; +92 (0)51 9224325; nbcpakistan.org@gmail.com), ref: 4-87/NBC-419/19/1213

2. Approved 30/05/2019, Research Ethics Committee of University of Manchester (2nd Floor Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, United Kingdom; +44 (0)161 275 2206/2674; research.ethics@manchester.ac.uk), ref: 2019-5024-10755

Primary study design
Interventional

Study design
Multi-centre randomized controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Self harm

Interventions
The participant will be randomised to either receive Y-CMAP or TAU. Randomisation will be undertaken by an independent statistician. Treatment assignment will be determined by using stochastic minimization controlling for gender, age and type of self-harm behaviour.

Y-CMAP is a manual assisted brief psychological intervention based on the principles of Cognitive Behaviour Therapy (CBT), including 8-10 sessions delivered over 3 months. The first four sessions are offered weekly and further sessions fortnightly and
each session lasting about 60 minutes.

TAU will be standard routine care delivered by local medical, psychiatric and primary care services according to clinical judgement. A record will be kept of any treatment received by each participant.

Intervention Type
Behavioural

Primary outcome(s)

Repetition of self-harm measured using the Suicide attempt Self Injury Interview at baseline and 12 months

Key secondary outcome(s)
1. Suicidal ideation assessed with the Beck Scale for Suicide Ideation (BSS) at baseline, 3, 6, 9 and 12 months
2. Hopelessness assessed with the Beck Hopelessness scale at baseline, 3, 6, 9 and 12 months
3. Distress assessed with the Psychological Distress Scale at baseline, 3, 6, 9 and 12 months
4. Health status measured using EQ-5D Y at baseline, 3, 6, 9 and 12 months
5. Participant satisfaction with services measured using the Client Satisfaction Questionnaire (CSQ) at 3 and 12 months
6. Information on the use of health services (including the informal sector such as faith healers /Imams) collected using the Client Service Receipt Inventory (CSRI) at baseline, 3, 6, 9 and 12 months

Completion date
08/09/2022

Eligibility

Key inclusion criteria
1. Age 12-18 years
2. Presenting to the participating GPs, emergency departments or admitted after an episode of self-harm to the participating hospitals or self-referrals
3. History of recent self-harm, defined as self-harm occurring within the last 3 months (from the initial identification of a potential participant)
4. Participants living within the catchment area of the participating practices and hospitals
5. Not needing inpatient psychiatric treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
12 Years

Upper age limit
18 Years

Sex
All

Total final enrolment
684

Key exclusion criteria
1. Severe mental illness (such as psychotic disorder) as self-harm commonly co-occurs with other mental health difficulties
2. Conditions limiting engagement with assessment or intervention, including developmental and communication disorders, intellectual disabilities and autistic spectrum disorders
3. Temporary resident unlikely to be available for follow up

Date of first enrolment
05/11/2019

Date of final enrolment
31/08/2021

Locations

Countries of recruitment
Pakistan

Study participating centre
Pakistan Institute of Learning and Living
Suite 201
Dr Plaza
Clifton 2 Talwar
Karachi
Pakistan
75600

Study participating centre
Pakistan Institute of Living and Learning
Suite No. 310, 3rd Floor, Al Qadir Heights
New Garden Town
Lahore
Pakistan
54000

Study participating centre
Institute of Psychiatry Rawalpindi
Benazir Bhutto Hospital
Rawalpindi
Pakistan
46000

Study participating centre

Pakistan Institute of Living and Learning
House no 1922 A/96 Mohalla Faiz Mohammed Street
Salawat Para
Hyderbad
Pakistan
71500

Study participating centre
Nawaz Sharif University
Multan
Pakistan
60000

Study participating centre
Balochistan Institute of Psychiatry and Behavioral Sciences (BIPBS)
Balochistan
Pakistan
87000

Study participating centre
Rahim Medical Center
Peshawar
Pakistan
25000

Sponsor information

Organisation
Pakistan Institute of Learning and Living

ROR
https://ror.org/046aqw930

Funder(s)

Funder type
Government

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Department for International Development, UK Government

Alternative Name(s)
Department for International Development, UK, DFID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

All personal information will be held securely in accordance with local data protection legislation and according to Pakistan Institute of Living and Learning (PILL) guidelines, which are GDPR compliant. PILL will store paper copies of questionnaires and consent forms in a locked cabinet for the period of time required by the Research Team.
To maintain confidentiality, any data, forms, reports, audio recordings, and any other records will be identified only by a participant identification number (Participant ID, PID). The key to this PID and all records will be kept in a locked file cabinet. All computer entry and networking programs will be done using PIDs only.
No personally-identifiable data will be shared with non-Research staff, except in the case of safety or clinical concerns.
Individual de-identified participant data will be shared after the review of the protocol by the chief investigator or a delegated member of the research team once the main results of the study have been published. In line with the MRC's policies on data sharing, anonymised study data will be made available for use by other researchers. However, the project team reserve the right to withhold data up until the point at which the primary project results have been successfully published. Contact person: Nusrat Husain (nusrat.husain@manchester.ac.uk), Nasim Chaudhry (nasimchaudhry@btinternet.com).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/09/2025	15/09/2025	Yes	No
Protocol article		13/05/2022	09/04/2024	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes