ISRCTN13462277 https://doi.org/10.1186/ISRCTN13462277

Improving services for identifying and treating depression in primary healthcare clinics

Submission date
27/09/2024

Recruitment status
Recruiting

Registration date
07/10/2024

Overall study status
Ongoing

Last Edited
21/05/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

People attending primary or basic health facilities for any physical illnesses such as diabetes, hypertension, and heart disease are more likely to have depression. When people have both depression and physical illnesses, outcomes for both are worse, resulting in poorer health, quality of life, earlier deaths, and increased costs for individuals, families and healthcare services. Depression in people attending primary care, particularly in Pakistan, is usually not identified and treated. Collaborative care is a team approach in which healthcare workers in primary healthcare facilities (who are not mental health specialists) are trained to treat depression alongside physical illness. This study aims to implement collaborative care for depression in primary healthcare facilities in Karachi, Pakistan; and to test, in a trial, i) the effectiveness of collaborative care for treating depression, ii) the extent to which depression care is successfully implemented and iii) costs of collaborative care, compared to usual best practice. The study will also investigate the barriers and facilitators for implementing collaborative care, and how implementation can be improved.

Who can participate?

Participants aged 18 years or above, identified with depression, currently not taking any treatment for depression and attending SINA Health, Education and Welfare Trust primary care facilities in Karachi, Pakistan.

What does the study involve?

Twenty-four clinics will be randomly allocated to the intervention group (12 clinics) or the control group (12 clinics). Collaborative care will be implemented in the intervention clinics, while clinics in the control group will work according to best usual practice. Researchers will recruit about 30 patients per clinic; participants will be assessed at baseline and then 3, 6 and 12 months later to determine whether people in intervention clinics have better outcomes for depression, anxiety, physical health and quality of life, if collaborative care offers value for money, and how successfully it is implemented. Researchers will collect data from consenting participants on these variables, and will also use routinely collected data (including electronic patient records) from clinics.

What are the possible benefits and risks of participating?
The findings will benefit people with depression and physical illnesses, their caregivers, healthcare professionals, policymakers, and researchers. These results and recommendations will guide how to better identify and treat depression in primary care settings in Pakistan. This will enhance the management and treatment practices for individuals with depression who visit primary care facilities.
There are no significant additional risks involved in participating in the study. Those participants who will be taking antidepressants can experience adverse effects associated with using antidepressants. However, the physicians will use antidepressants which are already used in common practice, and their safety has been tested. Also, physicians will monitor any study participants on antidepressants, and experienced psychiatrists will supervise physicians. Participants may be asked about their experience of living with depression and physical illnesses, which may cause them to feel distressed, upset or uncomfortable.

Where is the study run from?
The study is led by the University of York (UK), The Aga Khan University (Pakistan), The Initiative, Islamabad (Pakistan), Institute of Psychiatry, Rawalpindi (Pakistan) and SINA Health, Education & Welfare Trust (Pakistan).

When is the study starting and how long is it expected to run for?
November 2022 to December 2026

Who is funding the study?
NIHR-Global Health Research Centre programme (UK)

Who is the main contact?
Prof. Najma Siddiqi, najma.siddiqi@york.ac.uk

Study website
https://www.impactsouthasia.com/

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
SPiRiT-D-NIHR203248

Study information

Scientific Title
Strengthening primary care for recognising and treating depression (SPiRiT-D)

Acronym
SPiRiT-D

Study objectives
Research Question 1: Is Collaborative Care effective for managing depression in primary care clinics?
Research Question 2: How well is Collaborative Care successfully implemented?
Research Question 3: Is the Collaborative Care model cost-effective for depression in primary care?
Research Question 4: What are the contextual barriers and facilitators encountered in implementing the Collaborative Care model?
Research Question 5: How do implementation strategies affect implementation outcomes?

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 24/05/2024, University of York Health Sciences Research Governance Committee (Department of Health Sciences, University of York, Heslington, York, YO10 5DD, United Kingdom; +44 (0)1904 323253/1; stephen.holland@york.ac.uk), ref: HSRGC/2024/626/H

2. Approved 23/09/2024, National Bioethics Committee, Pakistan (Health Research Institute, Shahrah-e-Jamhuriat, Off Constitution Avenue, Sector G-5/2, Islamabad, -, Pakistan; +92 (0)51 9224325, 9216793; nbcpakistan@nih.org.pk), ref: 4-87/NBC-1005/23/369

Study design
Effectiveness-implementation hybrid type II cluster randomized controlled trial with an embedded economic and a mixed-methods process evaluation

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Depression

Interventions
Twenty-four clinics will be randomised in a 1:1 ratio to either of two arms: i) intervention and ii) control. The method of randomising clinics (clusters) either to the intervention or control group is minimisation. In this method, clusters or individuals are randomly assigned to groups one at a time to achieve balance across different characteristics. In this trial, characteristics such as the availability of electronic health records (available/unavailable), mental health counsellor (available/unavailable), and clinic size (small/ medium/large) will be used for random clinic allocation using minimisation.

Intervention:
The intervention involves implementing a Collaborative Care model for depression in primary healthcare units. This model includes five key components: systematic identification of depression, provision and adjustment of evidence-based care (both antidepressants and brief behavioural treatment), tracking treatment outcomes, and weekly case review and supervision meetings. A Collaborative Care model for identifying and managing depression will be introduced in all intervention clinics using various implementation strategies.

Control:
Clinics randomised to the control group will follow optimised usual care. This includes information about depression, its management, and guidance on accessing local services.

Participants will be assessed at baseline and then 3, 6 and 12 months later.

Intervention Type
Mixed

Primary outcome measure
1. Effectiveness: Depression severity (mean change) will be measured using Patient Health Questionnaire-9 (PHQ-9) at the 6-month timepoint.
2. Implementation: Reach of depression treatment (RT) using RT= st/ne, where "st" represents the number of individuals who participated in the treatment for depression and "ne" represents the number of people eligible for such treatment at 6 months.

Secondary outcome measures
The following secondary outcomes related to clinical effectiveness will be measured at the participant level during follow-ups at 3, 6, and 12 months, unless otherwise specified below:
1. Body mass index (BMI) calculated using the formula: BMI = weight (kg) / height (m^2), where height is measured in meters and weight is measured in kilograms
2. Blood pressure measured using an automated blood pressure instrument
3. Waist circumference measured in centimetres
4. Depression severity measured using PHQ-9 at 3 and 12 months
5. Depression caseness measured using PHQ-9
6. Anxiety caseness and severity measured using Generalised Anxiety Disorder Questionnaire (GAD-7)
7. Quality of life measured using Euroqol's instrument EQ-5D-5L at 6 and 12 months

8. Functional impairment measured using the WHO Disability Assessment Schedule (WHODAS 2.0) at 6 and 12 months
9. Healthcare resource measured using modified Client Service Receipt Inventory (CSRI) at 6 and 12 months
10. Adverse events measured using a modified adverse event

The following clinic-level aggregated secondary outcomes related to implementation effectiveness will be calculated at 3, 6, and 12 months follow-up timepoints, unless otherwise specified below:
11. Reach of screening (RS) calculated using the formula RS = sd/nc, where "sd" represents the number of individuals screened for depression and "nc" denotes the total number of individuals attending the clinics
12. Reach of depression treatment (RT) calculated using RT = st/ ne, where “st” represents the number of individuals who participated in the treatment for depression and “ne” represents the number of people eligible for such treatment at 3 and 12 months
13. Adoption (AD) calculated using AD = r/ nr, where “r” denotes the number of people referred for the treatment of depression and “nr” denotes the number of people eligible for referrals at 6, and 12 months
14. Treatment enrolment (TE) calculated using TE = te/ ne, where “te” represents the number of people enrolled in the treatment of depression and “ne” represents the number of people eligible for such treatment
15. Treatment completion (TC) calculated using TC = tc/ te, where “tc” represents the number of people completed the depression treatment and “te” the number of people enrolled in such treatment
16. Treatment drop (TD) calculated using TD = td/ te, where “td” represents the number of people dropped out of the depression treatment and “te” the number of people enrolled in such treatment
17. Sustainability calculated using change in percentage from baseline to follow-up time-points in reach, adoption, treatment enrolment, completion, and dropout
18. Equity by comparing reach, adoption, treatment enrolment, completion, and dropout across different levels of socioeconomic status, gender, and ethnicity

Overall study start date
01/11/2022

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Attending primary care clinics
2. Aged 18 years or above
3. Score on PHQ-9 ≥10

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
24 clinics (clusters), 30 participants per clinic and 720 overall

Key exclusion criteria
1. Participants already receiving any kind of psychological therapy
2. Participants lacking the capacity to provide informed consent, or not willing to consent

Date of first enrolment
02/06/2025

Date of final enrolment
31/10/2025

Locations

Countries of recruitment
Pakistan

Study participating centre
Abdul Majeed Moten Center
House No. 1265, block 1, Muhammad Khan colony, Ittehad Town
Karachi
Pakistan
-

Study participating centre
Aisha, Zainab and Abdul Majeed Center
Plot # 178 & 179, Village Ali Muhammad Goth, Pipri, Bin Qasim Town
Karachi
Pakistan
-

Study participating centre
Amin Ahmad Bawani Center
Plot # 6 & 7, Deh: Landhi, Ghareebad Goth, Bin Qasim, Malir
Karachi
Pakistan
-

Study participating centre
Anita Rakla Center
Plot # 1, Block-C, Muhammad Yousuf Sahib Khan Goth, Malir
Karachi
Pakistan
-

Study participating centre
Bilwani Center
Plot # 45 & 46, Category-A, Sector-8C, Korangi Township
Karachi
Pakistan
-

Study participating centre
Dr. Ali Bhai Dr. Patel Memorial clinic
B-174 Block W North Nazimabad, Opposite Paposh Graveyard
Karachi
Pakistan
-

Study participating centre
ILL Center
Plot No. 9/K & 9/L sector No. 1 Scheme Township Metroville-2 (Landhi)
Karachi
Pakistan
-

Study participating centre
Momin Adamjee Center
3423/A, Block 5, Street 12, Near Gulshan e Sikandarabad, Kemari
Karachi
Pakistan
-

Study participating centre
Mr. Salim N Mukaty and Mrs Hamida S Mukaty
Plot # 232, Deh: Halkani, Khairabad Goth, Karachi West
Karachi

Pakistan
-

Study participating centre
Molti Foam
Plot No 1422, Lalabad Rehri Goth, Bin Qasim Town, Malir
Karachi
Pakistan
-

Study participating centre
Musa Soorty Clinic
Plot 4582 & 4583, Somar Khaskahili Goth, Deh Moach, Karachi West
Karachi
Pakistan
-

Study participating centre
Engro Polymers and Chemicals
Plot No. A-179, Deh: Hurajee, Goth: Ghulam Muhammad Balouch, Bin Qasim, Malir
Karachi
Pakistan
-

Study participating centre
Zainab and Shine Humanity Center
Plot # 3-D, Old No. 1726/696, Kokan colony, Baldia town
Karachi
Pakistan
-

Study participating centre
VPT Clinic
Gadap Town
Karachi
Pakistan
-

Study participating centre

Muhammad Jafar Ebrahim Center
Plot # 1339, Deh: Safooran, Goth, Dani Bux, District East
Karachi
Pakistan
-

Study participating centre
Getron Chemicals
Manzil Pump Landhi
Karachi
Pakistan
-

Study participating centre
VPT Clinic
Orangi Town near Toori Bangash Colony
Karachi
Pakistan
-

Study participating centre
VPT Clinic
Qasba Colony near Katti Pahari
Karachi
Pakistan
-

Study participating centre
VPT clinic
Suhrab Goth Gadap Town
Karachi
Pakistan
-

Study participating centre
Qureshi Memon Clinic
Plot # 260, Yousuf Goth Part-II, Deh Surjani, Karachi West
Karachi
Pakistan
-

Study participating centre
Raghib's Foundations and Shahnaz Memorial Center
Plot no. 42, (Old Plot No. B-20), Saindad Goth, sector 11-A Scheme-33 Karachi
Karachi
Pakistan
-

Study participating centre
ShahJahan Siddiqui Center
Plot # 12, Category-A, Sector # 1A2, Zareena Colony, North Karachi Township, Karachi
Karachi
Pakistan
-

Study participating centre
Tabba Center
Plot No. 148, Deh: Nagan, Sindh Goth Abad Scheme, Khair Muhammad Goth Karachi
Karachi
Pakistan
-

Study participating centre
Hajiani Amina Hasham Clinic
Plot # L 825 & 826, Sector 48-F Korangi Dhai
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-

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Sponsor type
University/education

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Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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

Publication and dissemination plan
The research team has developed a comprehensive plan to publish their findings in high-impact, peer-reviewed journals. Additionally, the team plan to disseminate the findings in Pakistan through various means such as dissemination events, leaflets, infographics, posters, websites, and conference presentations. The Community Advisory Panel (CAP) will be regularly updated on the study's procedures and findings through scheduled meetings.

Intention to publish date
31/12/2027

Individual participant data (IPD) sharing plan

The chief investigator should be contacted for access to the datasets: Najma Siddiqi (najma.siddiqi@york.ac.uk). The type of data that will be shared is anonymised participant-level data (baseline [sociodemographic information] and follow-up [primary and secondary outcome] data).

Data will be available after the publication of the main results and will be archived at the York Trials Unit indefinitely. Consent from participants would be obtained prior to enrollment in the study. All personally identifiable information will be removed from the database. There are no ethical or legal restrictions applicable.

IPD sharing plan summary

Available on request