

Improving services for identifying and treating depression in primary healthcare clinics

Submission date	Recruitment status	<input checked="" type="checkbox"/> Prospectively registered
27/09/2024	Recruiting	<input checked="" type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
07/10/2024	Ongoing	<input type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
30/01/2026	Mental and Behavioural Disorders	<input checked="" type="checkbox"/> 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 March 2027

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

Contact information

Type(s)

Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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: $BMI = \text{weight (kg)} / \text{height (m}^2)$, 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

Completion date

31/03/2027

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

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

100 years

Sex

All

Total final enrolment

0

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

31/03/2026

Locations

Countries of recruitment

Pakistan

Study participating centre**Abdul Majeed Moten Center**

House No. 1265, block 1, Muhammad Khan colony, Ittehad Town
Karachi
Pakistan

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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

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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

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Study participating centre

Musa Soorty Clinic

Plot 4582 & 4583, Somar Khaskahili Goth, Deh Moach, Karachi West
Karachi
Pakistan

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Study participating centre

Engro Polymers and Chemicals

Plot No. A-179, Deh: Hurajee, Goth: Ghulam Muhammad Balouch, Bin Qasim, Malir
Karachi
Pakistan

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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

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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
Karachi
Pakistan

Sponsor information

Organisation

University of York

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		28/01/2026	30/01/2026	Yes	No
Study website		11/11/2025	11/11/2025	No	Yes