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Assessing the feasibility of delivering a behavioural activation intervention to people with diabetes and depression in South Asia

Submission date
07/04/2022

Recruitment status
No longer recruiting

Registration date
14/04/2022

Overall study status
Completed

Last Edited
10/01/2025

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
Type 2 diabetes is one of the most common chronic illnesses in South Asia. Among people with diabetes, the risk of having depression is two to three times higher. The presence of depression alongside diabetes is known to affect the quality of life and lead to poor health outcomes. Treatment of depression among individuals with diabetes is therefore needed, however, there is a lack of evidence on the type of treatments that may work in such individuals, specifically in South Asian settings. Behavioural activation (BA) is a low-cost treatment that can be delivered by non-mental health personnel in low resource settings. The aim of this study is to test the feasibility of delivering BA to patients with diabetes and depression in two South Asian countries, i.e. Bangladesh and Pakistan.

Who can participate?
Adults aged 18 years and over with confirmed type 2 diabetes mellitus with mild, moderate or severe depression

What does the study involve?
The researchers will identify adult patients from six health facilities in Bangladesh and Pakistan. Patients with confirmed diabetes will be screened for depression using a set of questions and then invited to participate in the study. Those who consent to participate will be randomly assigned to receive BA or usual care. Participants assigned to usual care will receive an information leaflet on depression, its treatment options and where to seek help. Participants assigned to BA will have six sessions (30-40 minutes each) with a trained counsellor over a period of 6 to 12 weeks, either face to face or over the phone. A questionnaire will collect information at the time of recruitment and at 3 and 6 months. Information on personal and household characteristics, health behaviours, diabetes, mental health and quality of life will be collected. Blood samples will be taken to evaluate diabetes control as well as overall physical health. To evaluate the feasibility, the researchers will report recruitment rates, reasons for non-participation, length of time taken to recruit all participants and retention of participants in the study at 3 and 6 months.

What are the possible benefits and risks of participating?
Given the nature of the treatment, participants are not expected to suffer any serious harm. The study procedures will be carried out by trained staff, and participants will be contacted regularly to check their well-being. Specialist support will be available through participating hospitals and referral services. Participants will benefit from free transport, lab tests and treatment.

Where is the study run from?
The trial is being run from the University of York (UK), with recruitment sites based in Peshawar and Rawalpindi in Pakistan, and in Dhaka and Sylhet in Bangladesh.

When is the study starting and how long is it expected to run for?
October 2021 to February 2023

Who is funding the study?
National Institute of Health Research (NIHR) (UK)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Version 1.2

Study information

Scientific Title

A protocol for a randomised controlled, single-blinded, feasibility trial of an adapted behavioural activation intervention (DiaDeM) for people with depression and diabetes in South Asia

Acronym
DiaDeM feasibility trial

Study objectives
An adapted behavioural activation intervention for depression treatment will be feasible and acceptable to deliver and evaluate among adults with depression and diabetes in Bangladesh and Pakistan

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 02/10/2020, Health Sciences Research Governance Committee (HSRGC, University of York, Department of Philosophy, Heslington, YO10 5DD, York, UK; +44 (0)1904 323253; smh12@york.ac.uk), ref: HSRGC/2020/409/B
2. Approved 12/12/2020, Diabetic Association of Bangladesh (122 Kazi Nazrul Islam Venue Shahbag, Dhaka, Bangladesh; +880 (0)58616641-50; email: not available), ref: BADAS-ERC/EC/20/00300
3. Approved 05/01/2021, National Bioethics Committee Pakistan (Pakistan Health Research Council, Shahrah-e-Jamhuriat, Off Constitution Avenue, Sector G-5/2, Islamabad, Pakistan; +92 (0) 51 9224325, +92 (0)51 9216793; nbcpakistan.org@gmail.com), ref: 4-87/NBC-578/20/1101
4. Approved 20/10/2020, Institutional Research and Ethics Forum of Rawalpindi Medical University (Research Unit, Main Campus, Tipu Road, Rawalpindi Pakistan; +92 (0)51 9330068; researchunit@rmur.edu.pk), ref: 242/IREF/RMU/2020
5. Approved 08/10/2020, Ethics Committee of Office of Research Innovation & Commercialization (ORIC) Khyber Medical University (KMU, Phase 5, Hayatabad, Peshawar Pakistan; +91 (0)9217258; oric@kmu.edu.pk), ref: DIR/KMU/UEC/25

Study design
Parallel-arm assessor-blinded randomized controlled feasibility trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Type 2 diabetes with confirmed mild, moderate or severe depression

Interventions
A computer-generated blocked stratified (by country) randomisation sequence is created using Stata version 15, with an allocation ratio of 1:1.

Intervention: Behavioural Activation - structured individual therapy delivered by Behavioural Activation facilitators based in diabetes services, supported by a treatment manual and participant’s and facilitator’s booklets, with supervision by a mental health specialist. Six 30-40

minutes sessions over a period of 6 to 12 weeks will be offered. The sessions will be delivered either face to face or remotely according to the participant's preference. The 'optimised usual care' information leaflet will also be offered.

Control group: Provision of an 'optimised usual care' information leaflet, describing depression and its treatment and details of how to access help locally.

Intervention Type
Behavioural

Primary outcome(s)
1. Recruitment rates, assessed as the number of participants eligible, consenting and randomised out of those screened at recruitment. These will be assessed on the completion of the recruitments at all study sites.
2. Reasons for ineligibility/non-participation/non-consent of participants assessed through a review of trial screening logs. This will be assessed on the completion of the recruitments at all study sites
3. Retention rates for the feasibility trial: proportion of randomised participants who were successfully followed up at 3 and 6 months post-randomisation
4. Retention rates for the DiaDeM intervention: number of intervention sessions attended out of the total number of sessions offered. This will be assessed 6 months post-randomisation for all recruited and randomised participants.
5. Reasons for discontinuation of BA intervention sessions assessed through a review of the BA facilitators' logs. This will be assessed 6 months post-randomisation for all recruited and randomised participants. The logs will record the information regarding session appointments, attendance, drop-out and delivery. The qualitative analysis of the in-depth interviews of participants and facilitators during process evaluation will also provide additional information regarding the barriers affecting the intervention delivery.
6. The length of time taken to attain the required sample size will be assessed as the mean of the number of days taken from the date of commencement of recruitment till the date of last recruitment at each site
7. Data completeness for all the baseline and follow-up variables and tools at baseline, 3 and 6 months. Problem areas and solutions will be identified for DiaDeM-Work Stream 3 full trial

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
23/11/2022

Eligibility

Key inclusion criteria
1. Adults (≥18 years old) with confirmed type 2 diabetes mellitus
2. Score ≥3 on the PHQ-2 scale
3. Classified as having mild, moderate or severe depression (using a cut-off score of ≥5) on the PHQ-9
4. Confirmatory diagnosis of depression using the MINI mental-state examination scale
5. Willing to participate and able to attend therapy sessions in person or remotely.

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
128

Key exclusion criteria
1. Patients who are already receiving psychotherapy for depression
2. Lack the capacity to provide informed consent and/or to take part in therapy because of cognitive impairment, or severity of mental or physical illness

Date of first enrolment
26/03/2022

Date of final enrolment
26/05/2022

Locations

Countries of recruitment
Bangladesh

Pakistan

Study participating centre
BIRDEM General Hospital
122 Kazi Nazrul Islam Ave
Dhaka
Bangladesh
Dhaka 1000

Study participating centre
Sylhet Diabetic Hospital
Puranlane Road

Sylhet
Bangladesh
Sylhet 3100

Study participating centre
Sugar Hospital
A-6 B/3, Phase 5
Peshawar
Pakistan
Peshawar, 25100

Study participating centre
District Headquarters Hospital
Kohat Development Authority (KDA)
Kohat
Pakistan
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Study participating centre
Benazir Bhutto Hospital
Murree Rd
Rawalpindi
Pakistan
Rawalpindi, 23000

Study participating centre
District Headquarters Hospital
Kashmiri Bazaar Road
Raja Bazar
Rawalpindi
Rawalpindi
Pakistan
Punjab 46000

Sponsor information

Organisation
University of York

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Government

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
To maintain the scientific integrity of the study, data will not be released prior to the end of the trial, either for publication or oral presentation purposes, without the permission of the Project Management Team and the Chief Investigator. The full data-sharing plan will be made available at a later date.

IPD sharing plan summary
Stored in non-publicly available repository, Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		06/12/2024	10/01/2025	Yes	No
Participant information sheet	version 2.1	21/03/2022	12/04/2022	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol (preprint)		02/09/2022	10/01/2025	No	No
Protocol file	version 1.2	03/03/2022	27/03/2024	No	No

Study website	Study website	11/11/2025	11/11/2025	No	Yes