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Randomized controlled trial of DiaDeM, an adapted behavioural activation intervention, for people with depression and diabetes in South Asia

Submission date
03/03/2023

Recruitment status
No longer recruiting

Registration date
11/04/2023

Overall study status
Completed

Last Edited
11/11/2026

Condition category
Other

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

Plain English summary of protocol

Background and study aims
People with long-term physical health conditions, such as diabetes, are more likely to experience depression. Diabetes is a growing global problem, particularly in South Asia. When people have depression and diabetes, outcomes for both are worse, resulting in poorer health, quality of life, earlier deaths, and increased costs for individuals, families and healthcare services.
This study will test a culturally appropriate treatment for depression in people with diabetes in Bangladesh and Pakistan. This will be based on a relatively simple psychological talking treatment called behavioural activation, which has been shown to treat depression effectively and can be delivered by non-specialist health workers. Behavioural activation helps people make the link between what they do and how they feel and supports them to make changes to improve their health.

Who can participate?
Patients aged over 18 years with confirmed diagnoses of type 2 diabetes and depression, presenting at the diabetes care clinics in the DiaDeM study sites in Bangladesh and Pakistan

What does the study involve?
Participants will be randomly allocated to receive either behavioural activation or usual care. The researchers will follow up with both groups 6 and 12 months later to find out whether behavioural activation improves depression, self-care of diabetes, blood sugar levels, physical health and quality of life, and if it offers value for money. The researchers will also examine what it means to have both depression and diabetes from an economic perspective e.g. how much time and money patients and carers spend in accessing care. This information will help policymakers in their decisions about the provision of appropriate healthcare.

What are the possible benefits and risks of participating?
The findings will be of value to people with depression and diabetes, their families, health professionals, policymakers and researchers. Findings and recommendations will inform on how

to treat depression in diabetes which will help improve management and treatment practices for people with co-morbid depression and diabetes. During the study, laboratory tests of participants will be done on each follow-up visit which will be completely free of cost for the participants, they will receive test results and also if needed referrals for required treatment/ advice.
There are no adverse effects or no major risks involved in participating but during the study, participants may be asked about their experience of living with depression and diabetes which may cause them to feel distressed, upset or uncomfortable.

Where is the study run from?
The study is being led by the University of York, Hull York Medical School, Tees, Esk & Wear Valley NHS Trust. Other collaborators include the University of Southampton, The University of Leeds University College London from the UK, Khyber Medical University, the Institute of Psychiatry, Rawalpindi Medical University and Baqai Institute of Diabetology and Endocrinology from Pakistan, the Diabetic Association of Bangladesh and Ark Foundation from Bangladesh.

When is the study starting and how long is it expected to run for?
September 2020 to December 2024

Who is funding the study?
NIHR Global Health Research 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

National Institute for Health and Care Research (NIHR)
200806

Protocol serial number
DiaDeM-

Study information

Scientific Title
A multicentre, multicountry, randomised controlled trial of effectiveness and cost-effectiveness of DiaDeM, an adapted behavioural activation intervention for people with depression and diabetes in South Asia

Acronym
DiaDeM

Study objectives
Hypothesis 1: DiaDeM behavioural activation intervention is clinically effective in reducing the severity of depression at 6 months when compared to optimised usual care, for people with depression and diabetes.
Hypothesis 2: DiaDeM behavioural activation intervention is cost-effective, over the trial period compared to optimised usual care from the perspective of the healthcare system and other broader perspectives.

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 Health Sciences, c/o Department of Philosophy, Heslington, York, YO10 5DD, 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 Avenue, Shahbag Dhaka 1000, Bangladesh; +880 (0)58616641 50; email: not provided), 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, 9216793, nbcpakistan.org@gmail.com), ref: 4-87/NBC-578/20/1101 and annual extensions: 1. ref: 4-87/NBC-578/22/1607 in 2022; 2. ref4-87/NBC-578/23/1382 in 2023; and, 3. ref: 4-87/NBC-578/23/1382/1519 in 2024.
4. Approved 20/10/2020, Institutional Research and Ethics Forum of Rawalpindi Medical University (Tipu Rd, Chamanzar Colony, Rawalpindi, Punjab 46000, Pakistan; Tel: not provided;

jaber.dme.rmc@gmail.com), ref: 242/IREF/RMU/2020
5. Approved 08/10/2020, Ethics Committee of Office of Research Innovation & Commercialisation (ORIC) (Khyber Medical University [KMU], Khyber Medical University Road, Phase V, Hayatabad, Peshawar, Pakistan; +91 (0)9217258, +91 (0)9217258; oric@kmu.edu.pk), ref: DIR/KMU/UEC/25

Primary study design
Interventional

Study design
Multi-centre multi-country parallel-arm single-blinded randomized controlled trial with an embedded economic and mixed-methods process evaluation

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Co-morbid depression and type 2 diabetes

Interventions
Individuals with a confirmed diagnosis of type 2 diabetes and depression will be screened to confirm eligibility criteria and will be recruited after written informed consent. On completion of the baseline Case Report Form (CRF), each recruited participant will be randomly allocated to either the treatment or control arm. Randomization will use a 1:1 allocation ratio and will follow a computer-generated randomization sequence that will be stratified by country with randomly permuted blocks of varying block sizes and will be generated using Stata version 17 or later.

Participants randomized to the DiaDeM Behavioural Activation (BA) intervention group will receive structured individual therapy delivered by BA facilitators based in diabetes clinics, supported by a treatment manual, and a participant and facilitator booklet, with supervision by a mental health specialist. Six 30-40-minute sessions over a period of 6 to 12 weeks will be offered. The sessions will be delivered preferably face-to-face, or remotely according to the participant's preference. The ‘optimised usual care’ information leaflet will also be offered.

Participants in the control group will receive an ‘optimised usual care’ leaflet that includes information on depression, pharmacological and non-pharmacological treatment options for depression along with the procedures and contacts for accessing help.

Intervention Type
Behavioural

Primary outcome(s)
Severity of depressive symptoms assessed using the PHQ-9 instrument at 6 months post-randomisation

Key secondary outcome(s)
The following secondary outcomes will be assessed at the 6- and 12-month follow-up timepoints:
1. Depression caseness and severity assessed using the PHQ-9 instrument
2. Anxiety assessed using the Generalised Anxiety Disorder (GAD-7)
3. Diabetes self-management assessed using three measures: the Diabetes Empowerment Scale Short Form (DES-SF), the Perceived Diabetes Self-Management Scale (PDSMS) and the Summary

of Self-Care Diabetes Activities scale (SDSCA)
4. Glycemic control (HbA1C) assessed using participant blood samples
5. Body mass index (kg/m²) calculated using height (m) and weight (kg) measurements recorded by the research assistant
6. Diabetes distress assessed using the Problem Areas in Diabetes (PAID-5) scale
7. Cardio-metabolic outcomes:
7.1. Waist circumference: two repeated readings will be recorded in centimetres with a precision of 0.1 cm
7.2. Hip circumference: two repeated readings will be recorded in centimetres with a precision of 0.1 cm
7.3. Waist-hip ratio: measured by dividing the waist circumference by the hip circumference
7.4. Blood pressure and heart rate measured with the help of an automated blood pressure measuring instrument (OMRON®)
7.5. Lipid function including total cholesterol (TC), high-density lipoprotein cholesterol (HDLC) and low-density lipoprotein cholesterol (LDLC)
8. Health-related quality of life measured using the EQ-5D-5L instrument
9. Healthcare costs through participant self-report, recorded in the follow-up questionnaires
10. Adverse and severe adverse events recorded using an adverse event checklist
11. Economic outcomes (employment status, productivity loss, out-of-pocket payments, opportunity costs of time, borrowing and selling of assets, household expenditure and catastrophic health spending) assessed using a set of questions in the follow-up assessment

Completion date
31/12/2024

Eligibility

Key inclusion criteria
Individuals seeking outpatient diabetes care in the DiaDeM study sites in Bangladesh and Pakistan with the following characteristics will be included:
1. Age >18 years old at the time of screening/recruitment
2. Confirmed physician diagnosis of type 2 diabetes based on standardised diagnostic criteria (clinical presentation and HbA1C levels) and registered at the diabetes centre
3. Scoring ≥3 on the Patient Health Questionnaire-2 (PHQ-2) depression screening tool, and subsequently scoring ≥5 on the Patient Health Questionnaire (PHQ-9) and confirmed diagnosis of depression using depression schedule A of the Structured Clinical Interview for DSM-V-Research Version (SCID-V-RV)
4. Willingness to attend BA sessions in person or remotely

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. Currently receiving psychotherapy for depression at the time of screening/recruitment
2. Unable to provide consent due to cognitive impairment or psychological or physical illness severity

Date of first enrolment
06/03/2023

Date of final enrolment
30/09/2023

Locations

Countries of recruitment
Bangladesh

Pakistan

Study participating centre
Baqai Institute of Diabetes and Endocrinology
Plot No 1-2 II-B Block 2
Nazimabad
Karachi, Sind
Pakistan
74600

Study participating centre
BIRDEM General Hospital (Bangladesh Institute of Research and Rehabilitation in Diabetes, Endocrine and Metabolic Disorders)
Shahbag Square
122 Kazi Nazrul Islam Avenue
Dhaka
Bangladesh
1000

Study participating centre

Sugar Hospital, Phase IV, Hayatabad
Plot A-6, Sector B-3, Phase-5
Peshawar, Khyber Pakhtunkhwa
Pakistan
25000

Study participating centre
Sughra Diabetic Centre, Benazir Bhutto Hospital
Benazir Bhutto Hospital
Near Chandni Chowk
Chah Sultan
Murree Road
Rawalpindi
Pakistan
46000

Study participating centre
Sylhet Diabetic Hospital
Sylhet Diabetic Shamiti
Puranlane
Zinda Bazaar
Sylhet
Bangladesh
3100

Sponsor information

Organisation
University of York

ROR
https://ror.org/04m01e293

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 name and email address of the investigator/body who should be contacted for access to the datasets: Najma Siddiqi (Chief Investigator) at najma.siddiqi@york.ac.uk.
The type of data that will be shared: anonymized participant-level data (baseline [sociodemographic information] and follow-up [primary and secondary outcome] data)
Dates of availability: data will be available after the publication of the main results. It will be archived at the York Trials Unit indefinitely.
Whether consent from participants was required and obtained: Yes
Comments on data anonymization: All personal identifiable information will be removed from the database
Any ethical or legal restrictions: not applicable

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications		19/05/2025	20/05/2025	Yes	No
Participant information sheet	version 1.1	09/03/2023	10/03/2023	No	Yes
Protocol (preprint)		16/08/2023	11/11/2026	No	No
Study website		11/11/2025	11/11/2025	No	Yes