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

Participant information sheet-V1.1 (31.01.2023)

Invitation to participate

You are being invited to take part in a research study. Before you decide whether to take part, it is important to understand what the study is about and what it will involve. Please read this information sheet carefully, or have someone read it out for you. If you have any questions, please contact the person named at the end of this document. Your participation is important to us but is entirely voluntary.

What is the purpose of this study?

Diabetes and depression are both growing global problems, particularly in South Asia. People with long-term physical health conditions, such as diabetes, are more likely to experience depression. However, at the moment facilities that offer treatment for physical conditions generally do not offer treatment for depression.

We aim to test culturally appropriate methods to recognise and treat depression in people with diabetes in Bangladesh and Pakistan. The treatment is called behavioural activation, which is a simple and flexible form of therapy for depression and is delivered through discussion and talking sessions by a trained facilitator/provider. It is designed to increase positive behaviours which help to lift depression) and to reduce negative behaviours which act to maintain depression).

Who can participate in the study?

Adults (≥18 years old) with type 2 diabetes, who are identified as having depression based on researcher-administered checklists, and are able to participate in the treatment sessions in person or through video call or telephone, will be eligible to participate in this study.
We will not include individuals who are already receiving counselling therapy/talking therapy for depression treatment, and those whose physical and mental health is severely impaired.

What will I be asked to do if I take part?

If you are willing to take part in this study after reading the information that we have provided to you, we will ask you to write your name and signature at the bottom of the informed consent document (V 1.1) to indicate your willingness to participate in the study.

After signing the consent form, a researcher will invite you for a face-to-face interview where s/he will ask you a series of questions on topics related to your disease such as lifestyle, your physical and mental health, quality of life and use of healthcare facilities. You will also have your height and weight measured and a professionally trained nurse or technician will take your small blood sample

(approximately 10 cc or 2 teaspoons) to perform analysis including haemoglobin level, HbA1c, random blood glucose, kidney and thyroid function test, and lipid profile (free of cost).

We have two study groups one is the optimised usual care group and the second is the DiaDeM group. Half of our study participants will be allocated to each group. You will be allocated to either group merely based on chance to either receive optimised usual care or the DiaDeM intervention The allocation is decided randomly by a computer-generated list, and each participant has an equal chance of being assigned to the study group.

If allocated to the optimised usual care group you will receive optimised usual care that comprises an information leaflet and brief advice, or if allocated to the DiaDeM intervention group you will receive, six, 30–40-minute counselling sessions over a period of 6 weeks. DiaDeM intervention will be delivered face to face or through video call or telephone. The BA sessions will be delivered by trained staff members who have been trained by international experts. With your consent, DiaDeM intervention delivery sessions will be audio-recorded ensuring the anonymity and confidentiality of the participants. The audio files/tapes will be password protected and labelled with the study IDs without any mention of the identifiable information of the participants. The intervention sessions will be recorded and listened to in order to see how the sessions were delivered and to supervise the facilitators. The recordings will be erased once the analysis of the process evaluation will be completed.

The completion of the trial procedures including the interview, measurements and drawing of the blood sample and randomisation after recruitment will take about 45-50 minutes. You will be requested to come back to the health facility six months and one year after the first interview to have the same interview, measurements (i.e., blood pressure, weight, height, waist & hips circumference) and the blood sample taken.

We will also conduct detailed interviews with some of the study participants any time from 6 months onwards to help us understand what parts of the intervention worked, and what can be improved. However, those who will be approached to participate will receive separate information about this and do not have to take part in the detailed interview if they do not want to.

What is the estimated duration of research participation?

The estimated duration of research participation is 1 year for all the participants whether allocated to the optimised usual care or the DiaDeM intervention group. After the recruitment and the baseline interviews, every participant will be invited again for the follow-up procedures, at the health facility, completing six months and one year after the first interview If you are assigned to receive behavioural activation, you will additionally have four to six, 30-40-minute sessions with a trained facilitator, face-to-face and if participant is unable to attend face-to-face session then through video call or telephone over a period of 6 weeks, with a minimum of one week gap between sessions.

What are the potential risks or discomforts of participating in the study?

During the study, you may be asked about your experience of living with depression and diabetes which may cause you to feel distressed, upset or uncomfortable. Our procedures involve interviews and discussions during Behavioural Activation, where you will be asked questions that you might find uncomfortable to answer. If you feel distressed, you can ask the facilitator/provider or the researcher to take a break or stop the interview altogether. The researcher will also seek help from clinic staff (e.g., psychiatrists, counsellors) on your behalf if you feel you need such help. Our trained nurses and technicians will draw your blood sample and there should not be any adverse effects.

What are the benefits of participating in the study?

The laboratory tests that will be done on each visit will be completely free of cost. We will give you your test results and referrals for required treatment/ advice as well without any cost to you.Your participation will also inform research on how to treat depression in diabetes which will help improve management and treatment practices for people such as yourselves and others.

Confidentiality

If you decide to participate in the study, you will be assigned a unique identification number that will be used for all your study data. No identifying information will be stored with your study data. All study data will be stored electronically on a secure server that can only be accessed by project staff with password protection. Any paper copies (e.g., informed consent forms) will be stored in locked cabinets in locked offices at the research site. You will find that some of the questions that you will be asked when completing questionnaires are about your age, sex, marital status and occupation. These data will only be used to produce summaries of the characteristics of the people who have participated in the study. The summaries will not contain your name or any information that can be used to identify you. You will be asked to write your name and sign at the bottom of an informed consent form. However, the informed consent form and any other documents that we might have that contain any information that can be used to identify you will be stored securely, separated from the study data. All data collected will be kept confidential in line with the Data Protection Act (Bangladesh, Pakistan and the UK). Access to participants' personal details will be restricted to research staff only. Monitors and auditors may also need to access the data. For example, the National Bioethics Committee/Ethical Review Committee of the Diabetic Association of Pakistan may wish to monitor the study, in which case they will be granted access to private information that identifies your name. At the end of the

study, anonymised data will be securely archived at the University of York. This data may be made available to other researchers upon request in order to support future research.

Do I have to participate in this study?

You do not have to take part in the study if you do not wish to. Participating in this study is entirely voluntary. If you do not want to take part, your rights, and in case, the care that you are already receiving from your healthcare team will not be affected in any way. Even if you agree to participate in this study, you can still change your mind and decide not to participate at any time without providing a reason by informing the researcher. In that case, no further data will be collected from you. However, we will keep the data that we have already collected up to that point and use it for analysis unless you clearly let us know that you do not wish for these data to be kept and used in this way, in which case all data will be destroyed.

What will the study cost me, and do I receive any compensation for participation in the study?

Participating in the study is not expected to cost you anything, except taking time out of your normal schedule to take part in the study activities such as to attend the treatment sessions and/or complete the questionnaires . We are not offering any financial incentive to take part in the study. However, for every study visit, we will reimburse your actual travel expenses. If the session is delivered telephonically, we will reimburse you for your time through [easy paisa in Pakistan and bkash, nagad or rocket in Bangladesh].

What will happen to the results of the study?

The results from this study will be presented as a report and published in journals. We will also present the findings at scientific conferences. However, you will not be identified in any reports, publications or presentations. If you wish to get feedback on findings and progress of the study, please contact the country lead at the contact details provided below and we will give you this information. Any new information that affects the study or data that has clinical relevance to you (including incidental findings) will be made available to you. We will also inform your healthcare providers if you give us consent to do so.

Ethical approval:

This study has been approved by the Health Sciences Research Governance Committee (HSRGC), University of York (Ref:HSRGC/2020/409/B), Diabetic Association of Bangladesh (Ref: BADAS-ERC/EC/20/00300), National Bioethics Committee Pakistan (Ref:No.4-87/NBC-578/20/ 1101), Institutional Research and Ethics Forum of Rawalpindi Medical University (Ref:242/IREF/RMU/2020) and Ethics Committee of Office of Research Innovation & Commercialization (ORIC), Khyber Medical University (KMU), Pakistan (Ref:DIR/KMU/UEC/25).

What if I have further questions about the study?

If you want to know more about the study or if you have a concern about any aspect of this study you may ask the researcher now. You can also contact the lead researcher of this study later with any questions you might have either personally, by e-mail or by telephone at:

For participants in Rawalpindi, Pakistan:
Institution: [Institute of Psychiatry]
Address: {Research wing, Institute of Psychiatry, Benazir Bhutto Hospital, Rawalpindi]
Phone: 0310-8043289
Email: [Diadempakistaniop@gmail.com]

OR
For participants in Peshawar, Pakistan:
Institution: Institute of Public Health
Address: DiaDeM office, Institute of Public Health, Khyber Medical University Phase V Hayatabad Peshawar
Phone:
Email: Diadem@kmu.edu.pk

OR
For participants in Karachi, Pakistan:
Baqai Institute of Diabetology and Endocrinology
Plot 1-2, II-B, Nazimabad No. 2, Karachi 74600, Sindh, Pakistan
Telephone: +92 21 3362492, 24/7 Helpline: 0334 3330909

OR
For participants in Dhaka, Bangladesh:
Centre for Health Research and Implementation(BADAS-CHRI)
Diabetic Association of Bangladesh
Room 301, BIRDEM Building, Shahbagh, Dhaka 1000
Telephone: (+88)0241060502, Ext. 2202

OR
For participants in Sylhet, Bangladesh:
DiaDeM, BADAS CHRI Project Office,
Room 202, Sylhet Diabetic Hospital, Puran Lane, Zinda Bazar,Sylhet 3100
Telephone: (+88)02996633516-518, Ext. 215