A RANDOMISED CONTROLLED, SINGLE BLINDED, FEASIBILITY TRIAL OF AN ADAPTED BEHAVIOURAL ACTIVATION INTERVENTION (DiaDeM) FOR PEOPLE WITH DEPRESSION AND DIABETES IN SOUTH ASIA

Participant information sheet- Feasibility Trial

Study Title
Feasibility Trial of an Adapted Behavioural Activation Intervention (DiaDeM) for People with Depression and Diabetes in South Asia.

Invitation to participate
You are being invited to take part in a research study. Before you decide whether or not to take part, it is important to understand what the study is about and what it will involve. Please read this information sheet. If you have any questions, please contact the person named at the end. 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 physical healthcare services generally do not offer treatment for depression.

We aim to develop and test culturally appropriate approaches to the recognition and treatment of depression in people with diabetes in Bangladesh and Pakistan. The intervention will be based on Behavioural Activation and delivered by non-mental health specialists within diabetes care. Behavioural Activation is a relatively simple, flexible and effective psychological therapy for depression, delivered through discussion and talking sessions. In this feasibility trial, we will test the feasibility and acceptability of delivery of an adapted behavioural activation, DiaDeM intervention among people with diabetes and depression, and will test the feasibility and acceptability of carrying out a definitive full trial. The goals of Behavioural Activation are to increase positive behaviours (opportunities to experience positive emotions or rewards, which help to lift depression) and to reduce negative behaviours (those which trigger negative emotions, are unrewarding or aversive, which act to maintain depression).

Who can participate in the study?

Adults (≥18 years old) diagnosed with type 2 diabetes, confirmed by the health care staff of the diabetes centres based on their standardised diagnostic criteria that include HbA1C , clinical presentation and diabetes centre's registration record.
Persons scoring ≥3 on Patient Health Questionnaire-2 (PHQ-2) that will be administered by the health care staff at Diabetes centre as part of depression screening and mild, moderate or severe depression confirmed by Patient Health Questionnaire-9(PHQ-9) and Mini-International Neuropsychiatric Interview (MINI). Participants who are willing to participate and Able to attend therapy sessions in person or remotely.

What is the estimated duration of research participation?

Estimated duration of research participation is 6 months. We expect that some of the study participants will receive four to six, 30-40-minute sessions over a period of 6 weeks, with a minimum of one week between sessions. We will have a detailed interview at the baseline and depending on the random allocation to the intervention group, there will be additional six sessions one week apart during the first one and a half month.

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 2.1) to indicate your willingness to participate in the study.

After that, 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 professional trained nurse or technician will take your small blood sample (approximately 10 cc or 2 teaspoons) to perform analysis including haemoglobin level, kidney and thyroid function tests, and lipid profile (free of cost).

You will then be allocated by chance to either receive optimised usual care, which includes a leaflet and brief advice, or the DiaDeM intervention, which will consist of six, 30-40 minute counselling sessions over a period of 6 weeks. DiaDem intervention will be delivered through hybrid mode (face to face, or/ telephonically) as per your convenience and choice. With your consent, DiaDem intervention delivery sessions will be audio-recorded ensuring anonymity and confidentiality only for the fidelity check. The recordings will be erased once the analysis of process evaluation will be completed.

We expect it to take about 30 minutes to complete the interview and procedures. You will be requested to come back to the health facility three and six months after the first interview to have the same interview, measurements and blood sample taken.

We will also conduct detailed interviews with some of the study participants any time from 3 months to onwards. 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 are the potential risks or discomforts from 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 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. However, in the event that there are any problems, we will provide treatment for that free of cost.

What are the benefits of participating in the study?

You will be reimbursed for your travel costs. You will also have a chance to experience a different kind of treatment which may improve your quality of life. Your responses will also help inform research in depression and diabetes which will help improve management and treatment practices for people such as yourselves and others. 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.

Confidentiality

If you decide to participate in the study, you will be assigned a unique study ID number that will be used for all your study data. No identifying information will be stored with your study data. All study data including (consent sheets and recordings) will be stored 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 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 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, data will be securely archived at each research site, as appropriate, for 10 years.

What if I have questions about participants' rights?

If you have any questions about your rights as a research participant, wish to complain, or have any concerns about how the study is being carried out, or any other aspects of your care during your participation in the study, you may contact:
National bioethics committee, Pakistan health research council, shahrah e jamhuriat, G-5/2, Islamabad
Telephone No. 051-9224325

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 the care that you are already receiving from your mental health care 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 complete the questionnaire. We are not offering any personal incentive to you for taking part in the study. For every study visit, we will reimburse your actual travel expenses. If the session will be delivered telephonically, we will reimburse for your time through easy paisa.

What will happen to the results of the study?

The results from this study will be presented as a report and also published in journals. We may also present the findings at 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 on 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 health care providers if you give us consent to do so.

Ethical approval:

The study has been approved by the University of York, UK, Health Sciences Research Governance Committee, Institutional Research Ethics Forum ( ) and National Bioethics Committee ( )

What if I have 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:

Institution: [Institute of Psychiatry]
Address: [IMPACT office, Institute of Psychiatry, Benazir Bhutto Hospital, Rawalpindi]
Phone: [ ]
Email: [Diadempakistaniop@gmail.com]