

# Developing and evaluating a diabetes self-management intervention for people with severe mental illness

<b>Submission date</b> 10/03/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/03/2021	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 17/12/2025	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

People with severe mental illness, such as schizophrenia or bipolar disorder, have poorer physical health and a shorter life expectancy by around 20 years compared with the general population. Higher rates and poorer management of physical long-term conditions such as diabetes and heart disease are partly to blame. There may be several reasons for this, including the individual's mental illness and treatment, challenges to engaging in healthy behaviours (e.g. exercise, healthy eating), and wider barriers to accessing healthcare and support (e.g. financial, social).

Self-management (which includes taking medications, monitoring symptoms, preventing complications [e.g. damage to kidneys], and leading a healthier lifestyle) is an important part of staying well with a long-term condition. There are many self-management programmes in the NHS to help people with long-term conditions look after themselves, but they often do not address the challenges faced when also managing a severe mental illness.

The DIAMONDS research programme aims to overcome this problem by developing a self-management intervention that can specifically help people with diabetes and severe mental illness to be healthier. The intervention has been developed in partnership with people with mental illness and diabetes, their family members/friends, and the healthcare staff who support them. It has been designed to address challenges to self-management, which include poor motivation due to mental illness symptoms and medication; limited support from others for self-management; beliefs about their ability to engage in self-management (e.g. physical activity, stopping smoking); limited knowledge and skills for long-term condition management; and beliefs that long-term conditions require less managing than mental illness.

### Who can participate?

Adults over 18 years of age with type 2 diabetes and severe mental illness living in the North East of England.

### What does the study involve?

The DIAMONDS intervention is a 16-week programme that consists of daily self-management tasks (such as goal setting and action planning), weekly 1-to-1 meetings with a trained

facilitator, which we call a DIAMONDS Coach, and monthly peer-support group sessions. In this study, which is phase 3 of the DIAMONDS programme, we will test whether we can deliver our intervention and explore whether it is acceptable to those people delivering and receiving it. We will also test out our research methods so that we can design a larger study in the future to test whether our intervention works.

What are the possible benefits and risks of participating?

Through taking part, participants will become part of a study that could help improve future support for people who have diabetes and a mental illness. Participants may learn more about their diabetes which could help them to manage this better. Participants taking part in the study will be required to attend appointments, have body measurements and blood taken, and complete a study questionnaire which will take time.

Where is the study run from?

Bradford District Care NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?

December 2019 to June 2022

Who is funding the study?

National Institute for Health Research Programme Grants for Applied Research (UK).

Who is the main contact?

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## Contact information

### Type(s)

Public

### Contact name

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Scientific

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## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil known

### **Integrated Research Application System (IRAS)**

279019

### **Protocol serial number**

IRAS 279019, CPMS 48674

## **Study information**

### **Scientific Title**

Developing and evaluating a diabetes self-management intervention for people with severe mental illness: The DIAMONDS programme (Diabetes and Mental Illness, Improving Outcomes and Self-management) - Workstream 3 Feasibility Study

### **Acronym**

DIAMONDS Feasibility Study

### **Study objectives**

Current study hypothesis as of 04/11/2021:

The objectives of the feasibility study are to:

1. Test the feasibility of procedures for recruitment and retention of participants
2. Test the feasibility of quantitative and qualitative data collection
3. Undertake an evaluation of the acceptability and feasibility of the DIAMONDS intervention
4. Undertake an exploratory economic evaluation
5. Undertake an exploratory evaluation of the acceptability and feasibility of continuous glucose monitors among individuals with type 2 diabetes and severe mental illness (SMI)
6. Develop an intervention fidelity framework for use in a future randomised controlled trial (RCT)

Previous study hypothesis:

The objectives of the feasibility study are to:

1. Test the feasibility of procedures for recruitment and retention of participants
2. Test the feasibility of quantitative and qualitative data collection methods
3. Undertake a qualitative evaluation of the delivery and acceptability of the intervention
4. Undertake an exploratory economic evaluation
5. Develop in partnership with Leicester Diabetes Centre (LDC) an intervention fidelity framework for use in a randomised controlled trial (RCT)
6. Produce a finalised, acceptable, and fit for purpose version of the intervention and optimise trial procedures to be used in an RCT (Workstream 4 of DIAMONDS programme)

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 06/04/2021, Leeds West Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 1048 088; leedswest.rec@hra.nhs.uk), REC ref: 21/YH/0059

### **Study design**

Single-group before and after feasibility study with exploratory economic and mixed methods process evaluations

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Type 2 diabetes in people with severe mental illness

### **Interventions**

This study will explore the feasibility of the DIAMONDS intervention, a supported diabetes self-management intervention for people with severe mental illness.

The intervention includes 16 weekly sessions with a trained facilitator ("DIAMONDS Coach") as well as a digital app and a paper-based workbook for participants to work with in between sessions. If possible under COVID-19 restrictions in place at the time, there will also be monthly group sessions for participants.

Clinical data will be collected at baseline and questionnaires completed. An exploratory process evaluation will be conducted.

### **Intervention Type**

Behavioural

### **Primary outcome(s)**

Current primary outcome measures as of 04/11/2021:

1. Recruitment rate, measured as the proportion of the recruitment target (n = 30) achieved at 5 months from the start of recruitment
2. Attrition measured as the proportion of missing outcomes data at the end of the recruitment period (5 months from the start of recruitment) for physiological and self-reported data items

3. Intervention delivery rate recorded as the proportion of planned sessions delivered (measured by the number of completed intervention session logs per participant within 15 weeks of the first intervention session)

Previous primary outcome measures:

1. Recruitment rate recorded as the number of eligible participants who consent to participate in the study by 5 months
2. Attrition rate recorded as the number of participants who consent to participate that remain in the study until the end of follow up at 4 months
3. Intervention delivery rate recorded as the number of intervention sessions delivered to participants completing the study

### **Key secondary outcome(s)**

Feasibility of data collection. Collected at baseline only (unless otherwise indicated):

1. HbA1c - blood test (results recorded as mmol/mol and %)
2. Cholesterol - biochemical lipid profile (blood test including total cholesterol, HDL cholesterol, LDL cholesterol, and triglycerides all recorded as mmol/L)
3. Haemoglobin - blood test (results recorded in g/L)
4. Body Mass Index (BMI) (kg/m<sup>2</sup>)
5. Waist circumference (cm)
6. Blood pressure (mmHg)
7. Smoking status (self report - yes/no/never)
8. Urinary albumin to creatinine ratio (from medical records)
9. Physical activity (International Physical Activity Questionnaire [IPAQ] and wrist-worn accelerometers worn for seven days)
10. Comorbidities (from medical records)
11. Blood glucose level (measured through continuous glucose monitoring for 14 days)
12. Psychological health (psychiatric symptoms: Brief Psychiatric Rating Scale [BPRS]; depressive symptom severity: Patient Health Questionnaire-9 [PHQ-9])
13. Diabetes measures (diabetes distress: Problem Areas In Diabetes [PAID] scale; summary of diabetes self-care activities: Summary of Diabetes Self-Care Activities [SDSCA] measure; insulin use (self report - yes/no); diabetes complications (from medical records)
14. Health related quality of life (EQ-5D-5L)
15. Health economic outcomes (health resource use: from medical records)
16. Mechanisms of Action (MoA: questionnaires at baseline and intervention end [16 weeks])

### **Completion date**

30/06/2022

## **Eligibility**

### **Key inclusion criteria**

1. Adults (aged 18 years or older)
2. Severe mental illness (SMI; schizophrenia, bipolar disorder, schizoaffective disorder)
3. Type 2 diabetes (insulin and non-insulin treated)

The diagnosis of SMI will need to have been made by specialist psychiatric services or general practitioner (GP) and be documented in the patient's medical records in general practice or secondary care. The diagnosis of diabetes needs to be of at least three months duration and documented in the medical record. Self-reported diabetes will be confirmed by primary care medical records

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

99 years

**Sex**

All

**Total final enrolment**

0

**Key exclusion criteria**

1. Cognitive impairments
2. Gestational diabetes
3. Type 1 diabetes
4. Diabetes due to a specific genetic defect or secondary to pancreatitis or endocrine conditions
5. Lack of capacity to participate

**Date of first enrolment**

01/07/2021

**Date of final enrolment**

30/11/2021

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Linfield Mount Hospital**

Bradford District Care NHS Foundation Trust

Bradford

England

BD9 6DP

# Sponsor information

## Organisation

University of York

## ROR

<https://ror.org/04m01e293>

## Organisation

Bradford District Care NHS Foundation Trust

## ROR

<https://ror.org/03yzcrs31>

# Funder(s)

## Funder type

Government

## Funder Name

Programme Grants for Applied Research

## Alternative Name(s)

NIHR Programme Grants for Applied Research, PGfAR

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Jennifer Brown, [jennifer.brown@york.ac.uk](mailto:jennifer.brown@york.ac.uk)

## IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		26/11/2025	17/12/2025	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Protocol (preprint)</a>		07/12/2021	15/02/2022	No	No
<a href="#">Study website</a>		11/11/2025	11/11/2025	No	Yes