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

Submission date
10/03/2021

Recruitment status
No longer recruiting

Registration date
12/03/2021

Overall study status
Completed

Last Edited
17/12/2025

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
Jennifer Brown, jennifer.brown@york.ac.uk
Dr Peter Coventry, peter.coventry@york.ac.uk

Contact information

Type(s)
Public

Contact name
Mrs Jennifer Brown

ORCID ID
https://orcid.org/0000-0003-0943-5177

Contact details
MHARG, Department of Health Sciences
ARRC Building
University of York
York
United Kingdom
YO10 5DD
+44 (0)1904321661
jennifer.brown@york.ac.uk

Type(s)
Scientific

Contact name

Dr Peter Coventry

ORCID ID
https://orcid.org/0000-0003-0625-3829

Contact details
MHARG, Department of Health Sciences
ARRC Building
University of York
York
United Kingdom
YO10 5DD
+44 (0)1904 321528
peter.coventry@york.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
279019

ClinicalTrials.gov (NCT)
Nil known

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/m²)
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-0 [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

IPD sharing plan summary

Available on request

Study outputs

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