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Improving diabetes self-management for people with severe mental illness

Submission date
05/10/2022

Recruitment status
No longer recruiting

Registration date
07/10/2022

Overall study status
Completed

Last Edited
10/01/2025

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
People with severe mental illness, such as schizophrenia, bipolar disorder, or severe depression, 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 barriers to accessing healthcare and support. Self-management (which includes taking medications, monitoring symptoms, preventing complications, 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 of people who also have a severe mental illness. The DIAMONDS research programme aims to overcome this problem by developing and testing 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; and limited knowledge and skills for long-term condition management.

Who can participate?
Patients aged 18 years or older with a severe mental illness (schizophrenia, bipolar disorder, schizoaffective disorder, psychosis, severe depression) and type 2 diabetes

What does the study involve?
Participants are randomly allocated to either the intervention group or the control group. The intervention group will be offered one-to-one self-management sessions with a DIAMONDS coach over a period of 6 months. The control group will continue with their routine care. All participants will be followed up 6 and 12 months later.

What are the possible benefits and risks of participating?
Participants in both groups may gain insight into their own lifestyle and behaviours. The participants in the intervention group may develop strategies to manage their diabetes more efficiently. For participants using the digit app, they may develop new skills by engaging with digital technology. Taking part in the study will require participants to attend appointments, have body measurements and blood taken, and complete a study questionnaire which will take time.

Where is the study run from?
University of York (UK)

When is the study starting and how long is it expected to run for?
September 2022 to September 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Dr Lucy Sheehan, lucy.sheehan@york.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
316173

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 53712, IRAS 316173

Study information

Scientific Title
Evaluating a diabetes self-management intervention for people with severe mental illness: the DIAMONDS programme (Diabetes and Mental Illness, Improving Outcomes and Self-management)

Acronym
DIAMONDS

Study objectives
The objectives are:
1. Undertake a 12-month internal pilot to obtain robust estimates of recruitment and retention and to confirm trial viability
2. Determine the effects of the DIAMONDS intervention on HbA1c at 12 months post-randomisation
3. Determine the effects of the DIAMONDS intervention on clinical outcomes taken at baseline, 6 months and 12 months post-randomisation
4. Conduct a detailed economic evaluation to assess the cost-effectiveness of the DIAMONDS intervention
5. Conduct a process evaluation that will harness data from both qualitative and quantitative sources to address questions about whether the intervention was delivered as intended and how outcomes were produced. Additionally, the process evaluation will aim to identify barriers and enablers to post-trial implementation and scale-up, including whether the intervention can support the self-management of other long-term conditions (LTCs) in people with severe mental illness (SMI).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 05/09/2022, West of Scotland REC 3 (Research Ethics, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, United Kingdom; +44 (0)141 314 0212; WoSREC3@ggc.scot.nhs.uk), ref: 22/WS/0117

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diabetes self-management for people with severe mental illness

Interventions
Current interventions as of 05/04/2024:
The DIAMONDS RCT is a multi-centre, two-armed, parallel, individually randomised control trial with embedded process and economic evaluations. The trial includes a 12-month internal pilot phase to assess recruitment assumptions and optimise trial processes. The trial has an 18-month recruitment period (including a 12-month pilot period). Once a participant has been enrolled into the study (i.e. after full consent has been given), they will be asked to complete a number of pen-and-paper questionnaires (supported by the R&D team at the participating site), provide a blood sample, have their blood pressure, weight, height, and waist circumference measured. All participants will also be offered to wear a wrist-worn accelerometer (a device to measure physical activity). Participants will then be randomised on a 1:1 basis to either the DIAMONDS intervention (n = 190) or the usual care group (n = 190) using computer-generated permuted blocks of random sizes.

The intervention group will be offered individual 1-to-1 sessions over a 6-month period with a trained facilitator (DIAMONDS Coach). The first session will last between 60-90 minutes, the Coach will introduce the intervention and set up the supporting workbook. The following sessions will last 30-60 minutes and the participant will continue to engage with the intervention between these sessions using the workbook. An accompanying app is also available for participants who wish to use it to be used alongside the workbook. Participants who are randomised into the control group will access usual care for people with severe mental illness and diabetes.

All participants will be followed-up for 1 year with outcome assessments conducted at 6 and 12 months post-randomisation. These assessments will be the same as those conducted at baseline (with the exception of the wrist-worn accelerometer at the 12-month timepoint).

At the end of the intervention period, some participants, as well as carers, and DIAMONDS Coaches will be invited to take part in semi-structured interviews. These interviews will focus on their experience of being part of the DIAMONDS randomised control trial and will inform our process evaluation.

Previous interventions:
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sample, have their blood pressure, weight, height, and waist circumference measured. All participants will also be offered to wear a wrist-worn accelerometer (a device to measure physical activity). Participants will then be randomised on a 1:1 basis to either the DIAMONDS intervention (n = 225) or the usual care group (n = 225) using computer-generated permuted blocks of random sizes.

The intervention group will be offered individual 1-to-1 sessions over a 6-month period with a trained facilitator (DIAMONDS Coach). The first session will last between 60-90 minutes, the Coach will introduce the intervention and set up the supporting workbook. The following sessions will last 30-60 minutes and the participant will continue to engage with the intervention between these sessions using the workbook. An accompanying app is also available for participants who wish to use it to be used alongside the workbook. Participants who are randomised into the control group will access usual care for people with severe mental illness and diabetes.

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Intervention Type
Behavioural

Primary outcome(s)
Glycated haemoglobin (HbA1c) measured using blood test at baseline, 6 months and 12 months

Key secondary outcome(s))
1. Cholesterol measured using blood test at baseline, 6 months and 12 months
2. Haemoglobin measured using blood test at baseline, 6 months and 12 months
3. BMI measured using weight and height measurements at baseline, 6 months and 12 months
4. Waist circumference measured using standard trust procedures at baseline, 6 months and 12 months
5. Blood pressure measured using standard trust procedures at baseline, 6 months and 12 months
6. Smoking status assessed through participant self-report at baseline, 6 months and 12 months
7. Urinary albumin to creatinine ratio extracted from patient's medical notes at baseline
8. Physical activity measured using the International Physical Activity Questionnaire (IPAQ) at baseline, 6 months and 12 months
9. Psychiatric symptoms assessed using the Brief Psychiatric Rating Scale (BPRS) at baseline, 6 months and 12 months
10. Depressive symptoms assessed using the Patient Health Questionnaire-9 (PHQ-9) at baseline, 6 months and 12 months
11. Diabetes distress assessed using the Problem Areas in Diabetes (PAID) scale at baseline, 6 months and 12 months
12. Summary of diabetes self-care activities assessed using the Summary of Diabetes Self-Care Activities Measure (SDSCA) at baseline, 6 months and 12 months
13. Insulin use assessed through participant self-report at baseline, 6 months and 12 months

14. Diabetes complications extracted from medical records at baseline, 6 months and 12 months
15. Health-related quality of life assessed using the EQ-5D-5L at baseline, 6 months and 12 months
16. Health resource use using a bespoke health resource use questionnaire at baseline, 6 months and 12 months
17. Mechanism of action measured using a set of self-report processes at baseline, 6 months and 12 months

Completion date
30/09/2025

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 25/10/2024:
1. Adults (aged 18 years or older)
2. Confirmed diagnosis of severe mental illness (SMI; schizophrenia, bipolar disorder, schizoaffective disorder, psychosis, severe depression) and type 2 diabetes

Previous participant inclusion criteria:
1. Adults (aged 18 years or older)
2. Confirmed diagnosis of severe mental illness (SMI; schizophrenia, bipolar disorder, schizoaffective disorder, severe depression) and type 2 diabetes

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
431

Key exclusion criteria
Current participant exclusion criteria as of 25/10/2024:
1. Cognitive impairments
2. Gestational diabetes, type 1 diabetes, diabetes due to a specific genetic defect or secondary to pancreatitis or endocrine conditions
3. Impaired capacity to participate
4. Current inpatient in an acute or mental health hospital

Previous participant exclusion criteria:
1. Cognitive impairments
2. Gestational diabetes, type 1 diabetes, diabetes due to a specific genetic defect or secondary to pancreatitis or endocrine conditions
3. Impaired capacity to participate

Date of first enrolment
20/12/2022

Date of final enrolment
30/09/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Bradford District Care NHS Foundation Trust
New Mill
Victoria Road
Saltaire
Shipley
United Kingdom
BD18 3LD

Study participating centre
Leeds and York Partnership NHS Foundation Trust
2150 Century Way
Thorpe Park
Leeds
United Kingdom
LS15 8ZB

Study participating centre
Sheffield Health & Social Care NHS Foundation Trust
Centre Court
Atlas Way
Sheffield
United Kingdom
S4 7QQ

Study participating centre
Humber Teaching NHS Foundation Trust
Trust Hq, Willerby Hill
Beverley Road
Willerby
Hull
United Kingdom
HU10 6ED

Study participating centre
Tees, Esk and Wear Valleys NHS Foundation Trust
Trust Headquarters
West Park Hospital
Edward Pease Way
Darlington
United Kingdom
DL2 2TS

Study participating centre
South West Yorkshire Partnership NHS Foundation Trust
Trust Headquarters
Fieldhead Hospital
Ouchthorpe Lane
Wakefield
United Kingdom
WF1 3SP

Study participating centre
Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust
St Nicholas Hospital
Jubilee Road
Gosforth
Newcastle upon Tyne
United Kingdom
NE3 3XT

Study participating centre
Southern Health NHS Foundation Trust
Tatchbury Mount Hospital
Calmore

Southampton
United Kingdom
SO40 2RZ

Study participating centre
Springfield University Hospital
South West London & St Georges Mental Health NHS Trust
Shaftesbury Building
9 Springfield Drive
London
United Kingdom
SW17 0YF

Study participating centre
Gloucestershire Health and Social Care NHS Foundation Trust
Trust Headquarters, Edward Jenner Court, 1010 Pioneer Avenue, Gloucester Business Park,
United Kingdom
Brockworth, Gloucester
United Kingdom
GL3 4AW2

Study participating centre
Cornwall Partnership NHS Foundation Trust
Carew House, Beacon Technology Park, Dunmere Road
Bodmin
United Kingdom
PL31 2QN

Study participating centre
Musgrove Park Hospital (taunton)
Somerset NHS Foundation Trust
Taunton
United Kingdom
TA1 5DA

Study participating centre
Devon Partnership NHS Trust
Wonford House Hospital
Dryden Road

Exeter
United Kingdom
EX2 5AF

Study participating centre
Herefordshire and Worcestershire Health and Care NHS Trust
Unit 2 Kings Court
Charles Hastings Way
Worcester
United Kingdom
WR5 1JR

Study participating centre
Surrey and Borders Partnership NHS Foundation Trust
18 Mole Business Park
Randalls Road
Leatherhead
United Kingdom
KT22 7AD

Study participating centre
Lincolnshire Partnership NHS Foundation Trust
St George's
Long Leys Road
Lincoln
United Kingdom
LN1 1FS

Study participating centre
South London and Maudsley NHS Foundation Trust
Bethlem Royal Hospital
Monks Orchard Road
Beckenham
United Kingdom
BR3 3BX

Study participating centre
Cambridgeshire and Peterborough NHS Foundation Trust
Elizabeth House,
Fulbourn Hospital
Fulbourn

Cambridge
United Kingdom
CB21 5EF

Study participating centre
Livewell Southwest
Local Care Centre
200 Mount Gould Road
Plymouth
United Kingdom
PL4 7PY

Study participating centre
Lancashire and South Cumbria NHS Foundation Trust
Sceptre Point, Sceptre Way
Walton Summit, Preston
United Kingdom
PR5 6AW2

Study participating centre
Essex Partnership University NHS Foundation Trust
The Lodge
Lodge Approach
Runwell
Wickford
United Kingdom
SS11 7XX

Study participating centre
Rotherham Doncaster and South Humber NHS Foundation Trust
Woodfield House
Tickhill Road
Doncaster
United Kingdom
DN4 8QN

Study participating centre
Cheshire and Wirral Partnership NHS Foundation Trust
Trust Headquarters Redesmere
The Countess of Chester Health Park
Liverpool Road

Chester
United Kingdom
CH2 1BQ

Study participating centre
Pennine Care NHS Foundation Trust
225 Old Street
Ashton-under-lyne
United Kingdom
OL6 7SR

Study participating centre
Birmingham and Solihull Mental Health NHS Foundation Trust
The Uffculme Centre
52 Queensbridge Road
Moseley
Birmingham
United Kingdom
B13 8QY

Study participating centre
Midlands Partnership University NHS Foundation Trust
Trust Headquarters
St Georges Hospital
Corporation Street
Stafford
United Kingdom
ST16 3SR

Study participating centre
Camden and Islington NHS Foundation Trust
St Pancras Hospital
4 St Pancras Way
London
United Kingdom
NW1 0PE

Study participating centre
Barnet, Enfield and Haringey Mental Health NHS Trust
Trust Headquarters Block B2
St Ann's Hospital

St Ann's Road
London
United Kingdom
N15 3TH

Study participating centre
Kent and Medway NHS and Social Care Partnership Trust
Farm Villa
Hermitage Lane
Maidstone
United Kingdom
ME16 9PH

Sponsor information

Organisation
University of York

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-1016-20003

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 Dr Lucy Sheehan (lucy.sheehan@york.ac.uk) or Jude Watson (jude.watson@york.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	version 2.0	25/08/2022	07/10/2022	No	Yes
Protocol file	version 1.0	28/06/2022	07/10/2022	No	No
Statistical Analysis Plan	version 1.0	20/09/2024	10/01/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes