

Improving diabetes self-management for people with severe mental illness

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| Submission date 05/10/2022 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 07/10/2022 | Overall study status Ongoing | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 07/10/2024 | Condition category Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year |

Plain English Summary

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

Study website

<https://www.york.ac.uk/healthsciences/research/mental-health/projects/diamonds>

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

316173

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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 hypothesis

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

See trial outputs table

Condition

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:

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 = 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 measure

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

Secondary outcome measures

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

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

Overall study start date

05/09/2022

Overall study end date

30/09/2025

Eligibility

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 380; UK Sample Size: 380

Total final enrolment

431

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

Recruitment start date

20/12/2022

Recruitment end date

30/09/2024

Locations

Countries of recruitment

England

United Kingdom

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

Sponsor details

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York
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United Kingdom
YO10 5DD
+44 (0)1904328693
michael.barber@york.ac.uk

Sponsor type

University/education

Website

<http://www.york.ac.uk/>

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

Publication and dissemination plan

Planned outputs of the study:

1. Detailed knowledge of the practicality and acceptability of the intervention from the perspective of service users and providers
2. Effectiveness of the intervention that could underpin evidence-based treatment recommendations, resource allocation, and service specification for diabetes self-management in severe mental illness
3. An economic model that can predict long-term outcomes and costs for interventions targeting people with severe mental illness and diabetes, which can also be adapted for other long-term conditions such as chronic obstructive pulmonary disease (COPD)
4. The protocol will be published in a peer-reviewed journal. The researchers aim to publish the findings of the main study in peer-reviewed, academic and professional journals to ensure that clinicians and academics have prompt access to the findings.
5. The researchers will produce a short newsletter summary of the results that can be distributed to all trial participants and other relevant stakeholders (e.g. commissioners, third sector organisations) and will use existing social media channels, websites, and knowledge exchange events to communicate our findings beyond academic audiences.

Intention to publish date

03/05/2026

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? |
|---|-------------|--------------|------------|----------------|-----------------|
| 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 |
| HRA research summary | | | 28/06/2023 | No | No |