The DIAMONDS intervention to support self-management of type 2 diabetes in people with severe mental illness: study protocol for a single-group feasibility study

Jennifer V E Brown, Ramzi Ajjan, Sarah Alderson, Jan R Böhnke, Claire Carswell, Patrick Doherty, Keith Double, Simon Gilbody, Michelle Hadjiconstantinou, Catherine Hewitt, Richard I G Holt, Rowena Jacobs, Vicki Johnson, Ian Kellar, David Osborn, Steve Parrott, David Shiers, Johanna Taylor, Jacqui Troughton, Judith Watson, Najma Siddiqi, Peter A Coventry

doi: https://doi.org/10.1101/2021.12.05.21267169

Abstract

Introduction The DIAMONDS programme aims to evaluate a novel supported diabetes self-management intervention for people with severe mental illness (the “DIAMONDS intervention”). The purpose of this study is to test the feasibility of intervention delivery and data collection procedures to inform a definitive randomised controlled trial (RCT).

Methods Adults aged 18 years or over with a diagnosis of type 2 diabetes and severe mental illness (schizophrenia, schizoaffective disorder, or bipolar disorder) will be eligible for inclusion. Individuals with other types of diabetes or non-psychotic mental illness and those lacking capacity to consent will not be eligible. Participants will be recruited from NHS mental health trusts and general practices across the North of England. All participants will receive the DIAMONDS intervention: weekly one-to-one sessions with a trained facilitator (“DIAMONDS Coach”) to support goal setting, action planning,

and diabetes education; ongoing self-management supported by a paper-based workbook and optional digital application (app); and monthly peer-support group sessions with other participants. The primary outcomes are: 1. Recruitment rate, measured as proportion of the recruitment target (N=30) achieved at 5 months from start of recruitment, 2. Attrition measured as the proportion of missing outcomes data at the end of the recruitment period (5 months from 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). Secondary outcomes include completeness of data collection at baseline and of process evaluation data at follow-up as well as the feasibility and acceptability of the intervention and of wearing a blinded continuous glucose monitoring device. An intervention fidelity framework will also be developed. Recruitment started in July 2021. The study was prospectively registered: ISRCTN15328700 (12th March 2021).

Discussion The results of this feasibility study will inform the refinement of the content and delivery of the DIAMONDS intervention, as well as research procedures, including recruitment and data collection, in preparation for the main DIAMONDS RCT.

Competing Interest Statement

RIGH has received honoraria for speaker engagement, conference attendance or advisory boards from: AstraZeneca, Boehringer-Ingelheim, European Association for the Study of Diabetes, Eli Lilly, Janssen, Menarini, Mylan, Novo Nordisk and Omniamed, Otsuka. RIGH was a member of the HTA Prioritisation Committee C (Mental Health, Women and Childrens Health) until July 2019. VJ is employed by the Leicester Diabetes Centre, University Hospitals of Leicester (UHL) NHS Trust which holds the background Intellectual Property rights for the DIAMONDS training and Intervention fidelity framework c/o DESMOND (a suite of self-management programmes). UHL receives not-for-profit income through licensing fees to support the implementation of DESMOND. CH: member of the NIHR HTA commissioning committee (2015-) and deputy chair (2019-). DS is expert advisor to the NICE centre for guidelines; Board member of the National Collaborating Centre for Mental Health (NCCMH); views are personal and not those of NICE or NCCMH. RA received honoraria, consultancy fees and research funding from Abbott Diabetes Care. MH, JRB, JW, JTa, JTr, PAC, KD, SA, SP, RJ, JVEB, CC, SG, NS, DO, IK, PD have nothing to declare.

Clinical Trial

ISRCTN15328700

Clinical Protocols

https://www.isrctn.com/ISRCTN15328700

Funding Statement

This project is funded by the National Institute for Health Research (NIHR) Programme for Applied Research (project number RP-PG-1016-20003). The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the NHS, NIHR, or the Department of Health. The NIHR did not have any involvement in the study design or the decision to submit the article for publication.

Author Declarations

I confirm all relevant ethical guidelines have been followed, and any necessary IRB and/or ethics committee approvals have been obtained.

Yes

The details of the IRB/oversight body that provided approval or exemption for the research described are given below:

Ethical approval was obtained from the Research Ethics Committee Leeds West (reference: 21/YH/0059)

I confirm that all necessary patient/participant consent has been obtained and the appropriate institutional forms have been archived, and that any patient/participant/sample identifiers included were not known to anyone (e.g., hospital staff, patients or participants themselves) outside the research group so cannot be used to identify individuals.

Yes

I understand that all clinical trials and any other prospective interventional studies must be registered with an ICMJE-approved registry, such as ClinicalTrials.gov. I confirm that any such study reported in the manuscript has been registered and the trial registration ID is provided (note: if posting a prospective study registered retrospectively, please provide a statement in the trial ID field explaining why the study was not registered in advance).

Yes

I have followed all appropriate research reporting guidelines and uploaded the relevant EQUATOR Network research reporting checklist(s) and other pertinent material as supplementary files, if applicable.

Yes

Abbreviations:

BCT

behaviour change technique

BMI

Body Mass Index

CGM

continuous glucose monitoring

CTC

consent-to-contact

GP

general practitioner

HbA1c

glycated haemoglobin A1c

LTC

long-term condition

MoA

Mechanism of Action

NHS

National Health Service

NIHR

National Institute for Health Research

RCT

randomised controlled trial

R&D

research and development

SMI

severe mental illness

TFA

Theoretical Framework of Acceptability

Tweets referencing this article:

Jeabp
@Jeabp13

RT @JveWagner: Pretty awesome feeling to see this out in the open!😊On PDF page 18 and 19, you'll see my PhD plans to offer #CGM to people w…

09 Dec 2021

Peter Coventry
@Peteyc73

RT @JveWagner: Pretty awesome feeling to see this out in the open!😊On PDF page 18 and 19, you'll see my PhD plans to offer #CGM to people w…

08 Dec 2021

Ian R. Boehnke

medRxiv Comment Policy

Comments are moderated for offensive or irrelevant content (can take ~24 hours).
Duplicated submission is unnecessary.
Please read our Comment Policy before commenting.

Back to top

Previous Next

Posted December 07, 2021.

Download PDF
Author Declarations
Supplementary Material
Data/Code
XML

Email
Share
Citation Tools

COVID-19 SARS-CoV-2 preprints from medRxiv and bioRxiv

Subject Area

Psychiatry and Clinical Psychology

Subject Areas

All Articles

- Addiction Medicine
- Allergy and Immunology
- Anesthesia
- Cardiovascular Medicine
- Dentistry and Oral Medicine
- Dermatology
- Emergency Medicine
- Endocrinology (including Diabetes Mellitus and Metabolic Disease)
- Epidemiology
- Forensic Medicine
- Gastroenterology
- Genetic and Genomic Medicine
- Geriatric Medicine
- Health Economics
- Health Informatics
- Health Policy
- Health Systems and Quality Improvement
- Hematology
- HIV/AIDS
- Infectious Diseases (except HIV/AIDS)
- Intensive Care and Critical Care Medicine
- Medical Education
- Medical Ethics
- Nephrology
- Neurology
- Nursing
- Nutrition

Obstetrics and Gynecology

Occupational and Environmental Health

Oncology

Ophthalmology

Orthopedics

Otolaryngology

Pain Medicine

Palliative Medicine

Pathology

Pediatrics

Pharmacology and Therapeutics

Primary Care Research

Psychiatry and Clinical Psychology

Public and Global Health

Radiology and Imaging

Rehabilitation Medicine and Physical Therapy

Respiratory Medicine

Rheumatology

Sexual and Reproductive Health

Sports Medicine

Surgery

Toxicology

Transplantation

Urology