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The healthy eating & active lifestyles for diabetes trial

Submission date
15/04/2024

Recruitment status
No longer recruiting

Registration date
24/05/2024

Overall study status
Ongoing

Last Edited
14/11/2025

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Background and study aims
Type 2 diabetes (T2D) is more common, and develops at a younger age, in people of black African and black Caribbean heritage in the UK than in people from white ethnic backgrounds. Diabetes can have serious health consequences e.g. blindness and kidney failure, which affect people's quality of life and are costly to the healthcare system. One of the most important ways to avoid diabetes complications is to follow a healthy diet and increase physical activity. This study aims to assess a diet and physical activity education and support programme for people of African and Caribbean heritage who have type 2 diabetes to help them manage their condition and avoid diabetes complications. The programme, called 'Healthy Eating and Active Lifestyles for Diabetes' (or 'HEAL-D'), was created with African and Caribbean people with lived diabetes experience to ensure its content is culturally relevant.

Who can participate?
Adults with T2D of black African or black Caribbean heritage.

What does the study involve?
Adults of black African and black Caribbean heritage with type 2 diabetes will be recruited from primary care, through referral to existing diabetes education services, or via community engagement activities. A short information video will be sent to potential participants to explain the study in more detail. A total of 300 people will be recruited over a 10-month period. Those who are eligible and consent to participation will be randomly assigned to one of two groups:
• The intervention group, who will receive the HEAL-D programme.
• The control group, who will receive the usual diabetes education course that is provided by the NHS in their local area.
Participants will decide if they want to attend their course face-to-face or using online video calling facilities. The HEAL-D programme includes eight sessions, each of 2 hrs duration, delivered over a 6-month period. The time commitment of the diabetes education programmes for the control group varies depending on the programme, but is typically 6-12 hours. All participants will undergo measurement of HbA1c, blood lipids, blood pressure, weight, waist circumference and body composition, alongside a range of questionnaire measures (e.g. quality of life, diabetes knowledge) at baseline, before attending their education programme, and 6, 12 and 24 months later. The measurements will be used to assess the effectiveness and the value

for money of the HEAL-D programme against current diabetes education programmes. The study will also investigate which parts of HEAL-D are helpful by interviewing a group of participants and the people who delivered HEAL-D, meaning participants may also be offered to take part in an interview or workshop.

What are the possible benefits and risks of participating?
Participants will need to invest time in the study and attend measurement visits for the collection of research data, for which they will receive modest monetary reimbursement. Participants will receive regular health measurements, as well as diabetes information and support that can help to manage diabetes and improve health and wellbeing. In the longer term, the results of this research study will be shared with black African or black Caribbean communities and may improve healthcare treatment for people of black African or black Caribbean heritage.
There are minimal risks associated with the study. During screening or assessment visits, previously unknown conditions may be revealed for which participants may want support. Blood tests can be uncomfortable, but these will be performed by professional staff, with care taken to minimise any discomfort.

Where is the study run from?
The research study will be coordinated by the University of Leicester's Diabetes Research Centre, with delivery centres in London, Birmingham, Manchester and Leicester.

When is the study starting and how long is it expected to run for?
August 2023 to July 2027

Who is funding the study?
The National Institute for Health Research (NIHR), Health Technology Assessment programme; Grant/award number: NIHR151372.

Who is the main contact?
Professor Louise Goff; louise.goff@leicester.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Prof Louise Goff

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
326064

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 61759, IRAS 326064, Grant NIHR151372

Study information

Scientific Title
HEAL-D (Healthy Eating & Active Lifestyles for Diabetes): a multicentre, pragmatic randomised controlled trial comparing effectiveness and cost-effectiveness of culturally tailored versus standard diabetes self-management programmes in Black-African and Black-Caribbean adults with type 2 diabetes

Acronym
HEAL-D

Study objectives
In adults of black African and black Caribbean heritage living with type 2 diabetes, a culturally tailored diabetes self-management education and support programme ('HEAL-D') will improve glycaemic control to a greater extent than standard diabetes education programmes at 12 months follow-up.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/04/2024, East Midlands – Leicester South Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8193; Leicestersouth.rec@hra.nhs.uk), ref: 24/EM/0079

Study design
Multi-centre randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions
Intervention group: The HEAL-D programme consists of 16 hours of group-based education and support (eight 2-hr sessions) delivered using face-to-face or online delivery modes. Sessions 1-7 are delivered on a weekly or fortnightly schedule and session 8 is delivered at 6 months. Culturally tailored resources will be used to deliver the curriculum, including diet booklets, portion size guides, interactive games focusing on cultural foods and dishes, and videos including health and motivational messages. HEAL-D will be delivered by a diabetes specialist dietitian (no specified ethnicity), a community trainer of black African or black Caribbean ethnicity and exercise instructors (no specified ethnicity). Sessions are scheduled for daytime, evening, and weekend delivery. Participants are invited to bring a 'significant other' but this is not compulsory. HEAL-D face-to-face is delivered in community settings, such as church halls and community centres, aiming for 8-12 patients in each group. HEAL-D online is delivered via a video-conferencing platform, aiming for 6-8 patients in a group.

Control group: Participants allocated to the control arm will receive the standard NHS diabetes education course that is delivered in their local area at the time of the study. They will be offered the choice of attending face-to-face or online virtual delivery where both modalities are offered.

Randomisation will be performed by an appropriate delegated member of staff using a validated web-based system. Randomisation will use randomly permuted blocks of variable block length and be stratified by centre, accounting for the provision of different standard education programmes between centres, and baseline HbA1c (<53, 53-76, 77-100 mmol/mol). Allocation will be assigned in a 1:1 ratio to one of the two study arms. Following randomisation, participants will attend their allocated course within 4 weeks where possible and time from randomisation to attendance will be recorded.

Intervention Type
Behavioural

Primary outcome(s)
Glycaemic control measured as HbA1c (mmol/mol) at 12 months

Key secondary outcome(s))
1. Glycaemic control measured as HbA1c (mmol/mol) at 6 and 24 months.
2. Blood lipids measured as total cholesterol and HDL-cholesterol (mmol/L) at 6, 12 and 24 months
3. Blood pressure measured as systolic and diastolic blood pressure (mmHg) at 6, 12 and 24 months
4. Body weight (kg) measured using scales at 6, 12 and 24 months
5. Body mass index (kg/m2) calculated from height and weight measurements at 6, 12 and 24 months
6. Waist circumference (cm) measured using a tape measure at 6, 12 and 24 months
7. Body composition measured as fat mass and lean mass (kg) using bioelectrical impedance analysis at 6, 12 and 24 months
8. Quality of life measured using the EQ5D-5L at 6, 12 and 24 months
9. Diabetes-related distress measured using the Problem Areas In Diabetes-5 questionnaire at 6, 12 and 24 months
10. Depressive symptoms measured using the Patient Health Questionnaire at 6, 12 and 24 months

11. Diabetes knowledge measured using the Short Diabetes Knowledge Instrument at 6, 12 and 24 months
12. Diabetes self-efficacy measured using the Diabetes Management Self-Efficacy Scale questionnaire at 6, 12 and 24 months
13. Diabetes dietary competence measured using the Perceived Diabetes & Dietary Competence questionnaire at 6, 12 and 24 months
14. Multimorbidity treatment burden measured using the Multimorbidity Treatment Burden Questionnaire at 6, 12 and 24 months
15. Physical activity measured using the short International Physical Activity Questionnaire at 6, 12 and 24 months
16. Physical activity measured using accelerometery at 12 months
17. Diet quality measured using the Diet Quality Questionnaire at 6, 12 and 24 months
18. Health service resource utilisation measured using the adapted Adult Service Use Schedule at 6, 12 and 24 months

Completion date
30/06/2027

Eligibility

Key inclusion criteria
1. Adult ≥18 years of age
2. People of Black African, Black Caribbean, Black British, Black other, and Mixed race with either African or Caribbean ancestry
3. Type 2 diabetes
4. HbA1c ≤100 mmol/mol (or fructosamine <450 µmol for individuals with sickle cell trait/disease)
5. Suitable for group-based training
6. Suitable for participation in physical activity
7. Willing to undergo randomisation
8. Able to provide informed consent

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. Current pregnancy
2. Complex medical or lifestyle needs that require personalised advice or for which group-based training is unsuitable e.g. advanced chronic kidney disease
3. Complex learning needs that require personalised advice or for which group-based training is unsuitable e.g. people with learning disabilities
4. Need for language translation services (spoken or written)
5. Unable or unwilling to provide informed consent
6. Current participation in a competing clinical trial

Date of first enrolment
15/08/2024

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
Guy’s Hospital
Great Maze Pond
London
England
SE1 9RT

Study participating centre
The University of Manchester
School of Health Sciences
Oxford Road
Manchester
England
M13 9PL

Study participating centre
The University of Warwick
-
Coventry

England
CV4 7AL

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
England
M13 9WL

Study participating centre
West Midlands Regional Research Delivery Network (RRDN)
-
-
England
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Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
England
LE1 5WW

Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Data that support the findings of this trial will be available from the CI (Prof. Louise Goff; louise.goff@leicester.ac.uk) upon reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		30/09/2025	01/10/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.1	09/05/2024	19/07/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes