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Glucose Lowering through Weight Management (GLoW)

Submission date	Recruitment status	[X] Prospectively registered
09/07/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
09/07/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/04/2025	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
Type 2 diabetes is typically characterised as a progressive irreversible condition. However, there is evidence that people with type 2 diabetes can achieve good glucose control or even remission through weight loss. Most studies that demonstrate this have used bariatric surgery or formula diets, which are rarely commissioned in the UK because of their high cost and reliance on specialists. Standard care for people with a new diagnosis of type 2 diabetes is structured diabetes education, which has low uptake and small, short-term effects on weight and blood glucose. The aim of this study is to find out whether a tailored diabetes education and behavioural weight management programme that can be delivered at scale achieves better glucose control and other health outcomes than education alone and whether any improvements in health and wellbeing justify the higher cost of the programme.

Who can participate?
Patients aged 18 and over who are overweight or obese and have been diagnosed with type 2 diabetes within the last 3 years

What does the study involve?
Participants are randomly allocated to either a structured diabetes education programme or a new programme that combines diabetes education and dietitian support with 6 months attendance at a weekly commercial weight management group (Weight Watchers). Participants are followed up at 6 months and 1 year to measure blood glucose, body weight, diet and physical activity, and use of medications and other healthcare resources, to determine which group has better changes in health outcomes and which programme offers best value for money.

What are the possible benefits and risks of participating?
Findings from this trial will inform the decisions of commissioners of services for weight management and diabetes about the most cost-effective use of limited healthcare resources.

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

When is the study starting and how long is it expected to run for?
April 2018 to October 2022

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

Who is the main contact?
Mrs Jenny Woolston
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Study website
http://www.mrc-epid.cam.ac.uk/research/studies/glow-glucose-lowering-weight-management/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 36457

Study information

Scientific Title
A single-blind, parallel-group, randomised trial to evaluate the clinical and cost-effectiveness of a tailored diabetes education and behavioural weight management programme versus diabetes education, in adults with overweight or obesity and a new diagnosis of type 2 diabetes

Acronym
GLoW

Study objectives
1. A tailored diabetes education and behavioural weight management programme is more effective than diabetes education alone in helping people with a recent diagnosis of type 2 diabetes to lower their blood glucose, reduce weight, and improve other markers of cardiovascular risk.
2. A tailored diabetes education and behavioural weight management programme is more cost-effective than diabetes education alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of Scotland Research Ethics Service, 15/05/2018, ref: 18/ES/0048

Study design
Multicentre pragmatic randomized single-blind parallel-group two-arm superiority trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
http://www.mrc-epid.cam.ac.uk/research/studies/glow-glucose-lowering-weight-management/

Health condition(s) or problem(s) studied
Overweight and obesity, type 2 diabetes

Interventions
Participants will be randomised to either the tailored diabetes education and behavioural weight management programme or to diabetes education (standard care) in a 1:1 allocation using individual-level blocked randomisation stratified by sex (male, female) and duration of diabetes (<1 year, 1-3 years) with a block size of 6. The randomisation sequence will be computer-generated by the trial statistician and programmed by the data manager. The sequence will be unknown to all other personnel, including study coordinators, outcome assessors and investigators.

Tailored diabetes education and behavioural weight management programme arm:
The tailored structured education and behavioural weight management programme combines remote diabetes education and dietetic counselling with a supportive group-based behaviour

change programme.
Triage Call: A registered dietitian will contact the participant within 2 days of receiving a referral. Alternatively, participants can call the dietitian directly. During the triage call, the dietitian will explain the programme and its potential benefits, book the patient into their first diabetes education session and send the patient a confirmation of the date/time of their appointment via email, text or letter.
Structured Diabetes Education and dietetic counselling: The core QISMET-accredited structured diabetes education programme will be delivered to participants during two sessions with a registered dietitian, with a specialist interest in diabetes (total session time 1 hr 30 minutes, divided between 2 calls). These sessions will be delivered 1:1 via telephone.
Session 1 will occur within 10 days of referral and will cover orientation and core curriculum topics. Session 2 will occur within 10 days of session 1 and will cover core curriculum topics and ways to tailor the Weight Watchers programme for diabetes. Additional self-help education materials to support the curriculum will be available online and are delivered to all participants via email or mail, depending on the preference of the patient.
Participants can also contact the dietitian proactively during the intervention period for additional support where needed (and are encouraged to do so via the Weight Watchers Coach). A closed social media group will also be formed and all participants in the TDEW arm will be invited to join if they wish to do so – the group will be monitored and supported by the registered dietitian for any questions, frequent support and group social connections. The curriculum will also be signposted to participants via this closed group to drive engagement.

Group-based behaviour change programme:
Following session 1, participants will be sent free of charge membership of Weight Watchers for 6 months. This includes access to community based meetings and digital tools, including the app. Weight Watchers meetings are held weekly in local community settings (e.g. schools, community centres) and last approximately 1 hour. They are open-group meetings (new people may join or leave the group at any time) and are led by a coach (trained lay person with experience of changing their lifestyles and losing weight on the programme). Meetings include a confidential weigh in with the coach and a 30-minute interactive education session led by the coach that includes advice on diet, physical activity, positive mindset, using behavioural strategies (e.g. goal setting, self-monitoring, problem solving, modifying the personal food environment, and relapse prevention), and peer support is available from coaches and other group members. Participants can contact their coach for support/advice between meetings. Participants can be accompanied by a friend, relative or carer.
Participants will also have access to digital tools and online materials for the duration of the intervention. This includes food, weight and activity tracking, feedback loops, thousands of meal and recipe ideas and cooking skills, activity inspiration and videos, educational content, a closed digital community called ‘connect’ and access to an online coach 24/7 (service provided by real life coaches) for in the moment motivation and advice.

Diabetes education arm:
In the local region, the diabetes education programme commissioned by the CCG is the Diabetes and Education Self Monitoring for Ongoing and Newly Diagnosed (DESMOND) programme. This is a structured diabetes education programme for people with a new diagnosis of type 2 diabetes (<3 years since diagnosis). Participants can attend 6 hours of structured self-management group education, covering: thoughts and feelings about diabetes; understanding diabetes and glucose - what happens in the body; understanding risk factors and complications associated with diabetes; understanding monitoring and medication; how to take control - food choices and physical activity; and planning for the future. The structured education is delivered in 1 day or 2 half days by two trained healthcare professionals in local health care or community venues. Sessions are delivered in groups of up to 10 participants, and participants can bring a

friend or partner with them. The education sessions are supported by specially developed resources.

Intervention Type
Behavioural

Primary outcome measure
12 month change from baseline in HbA1c, adjusted for baseline

Secondary outcome measures
1. 6 month change from baseline in HbA1c, adjusted for baseline
2. 6 and 12 month changes from baseline, adjusted for baseline, in body weight, body fat percentage, systolic and diastolic blood pressure, total cholesterol, HDL cholesterol, and LDL cholesterol
3. Probability of achieving good glycaemic control (HbA1c <53 mmol/mol) at 6 and 12 months
4. Probability of achieving remission (HbA1c <48 mmol/mol and without medication for ≥2 months) at 6 and 12 months
5. Probability of losing ≥5% and ≥10% of initial body weight at 6 and 12 months
6. Modelled cardiovascular risk (UKPDS) at 12 months

Overall study start date
15/04/2018

Completion date
01/10/2022

Eligibility

Key inclusion criteria
1. BMI ≥25kg/m2
2. Age ≥18 years
3. Diagnosis of type 2 diabetes within previous 36 months
4. Capable of giving informed consent
5. Have a good understanding of the English language (study materials are not tailored to support non-English language speakers)
6. Willing to be randomised
7. Willing to attend follow up visits at a local participating GP practice

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 576; UK Sample Size: 576

Total final enrolment
577

Key exclusion criteria
1. Using insulin
2. Previous/planned bariatric surgery
3. Current/planned pregnancy
4. Current diagnosis of eating disorder
5. Already received a structured diabetes education programme
6. GP considers unsuitable
7. Participation in another structured behaviour change programme for diet and/or physical activity within the past 3 months

Date of first enrolment
18/07/2018

Date of final enrolment
06/08/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Sponsor information

Organisation
University of Cambridge

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Sponsor type
University/education

Website
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https://ror.org/013meh722

Organisation
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
National Institute for Health 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

Publication and dissemination plan
All specified analyses will be written up as scientific papers and submitted for publication in peer-reviewed open-access journals. Members of the research team will be involved in reviewing drafts of the manuscripts, abstracts, and any other publications arising from the trial. The Principal Investigators will have final approval on all publications and any press release, where appropriate. Authorship will be determined using ICMJE criteria. Upon publication of the main findings, participants will be sent a newsletter that describes the results and gives details of who to contact to ask questions or obtain further information. Newsletters will be prepared with input from PPI representatives. Where appropriate, the trialists will communicate their findings to local and national stakeholders via tailored summaries of the key findings, and by presentations at meetings of local and national networks. Representatives from these groups will be involved in the research throughout and will support the trialists in identifying opportunities for dissemination.

Intention to publish date
31/07/2023

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan	version 9	05/10/2022	11/10/2022	No	No
Statistical Analysis Plan	Health Economic Analysis Plan (HEAP) for the 12-month within-trial analysis version 1.1	19/02/2023	19/05/2023	No	No

Statistical Analysis Plan	Health Economic and Decision Modelling Analysis Plan (HEDMAP) version 2.2		19/05/2023	No	No
HRA research summary			28/06/2023	No	No
Other publications		01/11/2023	24/11/2023	Yes	No
Results article		23/01/2025	27/01/2025	Yes	No