ISRCTN49540819 https://doi.org/10.1186/ISRCTN49540819

How a low-carbohydrate diet affects blood sugar and health in people living with type 2 diabetes: results from a real-life study

Submission date
21/05/2025

Recruitment status
No longer recruiting

Registration date
15/09/2025

Overall study status
Completed

Last Edited
15/09/2025

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
This study investigates the impact of a low-carbohydrate diet (LCD) on managing Type 2 diabetes (T2D) in a real-world setting, with a focus on both the effectiveness and acceptability of the diet. T2D is commonly managed with lifestyle and dietary changes, and while traditional dietary guidelines suggest up to 50% of daily calories from carbohydrates, recent research points to low-carb diets as potentially beneficial for better blood sugar control. These diets reduce insulin demand and improve insulin sensitivity, which may help with long-term management of T2D, weight loss, and reducing fat in the liver, a key factor in the disease.

Who can participate?
People with T2D who are not on insulin, are not pregnant and have no history of active cancer, or any kidney, gall bladder or pancreas problems.

What does the study involve?
The study uses a non-randomly allocated, observational design to assess how a low-carb diet affects participants' HbA1c levels over 6 months. The intervention is an 8-session health coaching program focused on low-carb eating, including tips for shopping, reading food labels, and managing diabetes. Participants are encouraged to follow a low-carb approach without strict carbohydrate targets, avoiding foods like bread, pasta, and sugary snacks, while still allowing fats from whole foods. Data collection includes initial measurements of HbA1c, cholesterol levels, weight, and diet, followed by reassessments at 3 and 6 months. Additionally, a qualitative part of the study includes interviews with 20 participants who completed the program. These interviews explored participants' experiences with the diet and the program. The results aim to provide insights into how well a low-carb diet can be maintained in everyday life and its potential for improving blood sugar control in individuals with T2D.

What are the possible benefits and risks of participating?
This is an observational component of people already about to undertake The Lighter Life

programme. The potential benefits from being in the study are awareness of the effect of the low-carbohydrate programme on your weight, glucose and cholesterol. The risks come from having a simple blood test.

Where is the study run from?
University of Surrey, Guildford, England (UK)

When is the study starting and how long is it expected to run for?
May 2023 to December 2025

Who is funding the study?
This has been crowd-funded, under the auspices of The Lighter Life charity (UK)

Who is the main contact?
Dr Martin Whyte, The Leggett Building, University of Surrey, m.b.whyte@surrey.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Martin Whyte

ORCID ID
https://orcid.org/0000-0002-2897-2026

Contact details
21PGM00, The Leggett Building, University of Surrey
Guildford
United Kingdom
GU27YW
+44 (0)1483 688669
m.b.whyte@surrey.ac.uk

Additional identifiers

Protocol serial number
FHMS 22-23 241 EGA

Study information

Scientific Title
The lifestyle club feasibility study

Acronym
TLC Feasibility

Study objectives

It is feasible to run an observational study of an 8-week The Lifestyle Club (TLC) programme, with the aim of obtaining specific information on: recruitment, attrition, user engagement, barriers to acceptability, in addition to secondary efficacy measures of glycaemic control and bodyweight over a period of 6 months.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 28/11/2023, University of Surrey Faculty Health & Medical Science (FHMS) Ethics Committee (Research Integrity & Governance Office (RIGO), 4th Floor Senate House, Guildford, GU2 7XH, United Kingdom; +44 (0)1483 68 9103/2051; ethics@surrey.ac.uk), ref: FHMS 22-23 241 EGA

Primary study design
Observational

Study design
Prospective observational study

Study type(s)
Treatment, Efficacy

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

Interventions
An 8-week online dietary and lifestyle program, to facilitate a low-carbohydrate diet (LCD)

The intervention was a health coaching service delivered by The Lifestyle Club (TLC), part of the Public Health Collaboration, a UK-registered charity (Charity no. 1171887/SC052248). Patients were directed by their surgery to a booking website to register for an information session delivered via Zoom or Microsoft Teams. Multiple sessions were offered at different times (morning, afternoon, evening). A health coach led each session, explaining the course and low-carbohydrate approach. Registrants received an email with a course enrolment form to collect contact, medical, medication details, and consent. After enrolling, participants were sent confirmation emails with their coach’s name, session details, and access link. The 8-session course covered topics including T2D, LCDs, shopping tips, understanding food labels, eating out, and intermittent fasting. Coaches used discovery learning to assess participants' prior knowledge and foster group interaction to overcome challenges. The GRIN model for behaviour change was incorporated, encouraging participants to set goals, reflect on resources, plan Incremental changes, and notice progress in health aspects such as energy, sleep, mood, and weight. A WhatsApp group was created for participants to connect, ask questions, and share progress. After the course, participants were invited to monthly catch-up sessions, Facebook and WhatsApp communities, and local TLC peer support groups. Participants were advised to follow an LCD, but without a specific target of carbohydrate g/day. No specific restrictions were placed on fat intake, provided that it was derived from whole, unprocessed foods, rather than artificial or processed foods. Foods high in carbohydrates, such as bread, pasta, rice, and sugary items, were encouraged to be avoided if possible.

Baseline measurements included HbA1c, lipid profiles (total cholesterol, LDL-cholesterol, HDL-cholesterol, triglycerides), anthropometric data (weight, height, BMI), and a food frequency questionnaire to estimate carbohydrate intake. Whole blood samples were immediately transported to the neighbouring Berkshire and Surrey Pathology Service at The Royal Surrey Hospital. This is an accredited NHS laboratory. Participants attended follow-up visits at 3 months and 6 months, where HbA1c and lipid profiles were reassessed, along with weight and dietary adherence. At 6-months, the dietary composition was again determined.

Intervention Type
Behavioural

Primary outcome(s)
1. Serum cholesterol measured using standard laboratory procedures at an accredited NHS laboratory (Berkshire and Surrey Pathology Service, at The Royal Surrey Hospital) at baseline, 3 months and 6 months
2. Weight measured using a Tanita weighing scale at baseline, 3 months and 6 months
3. Waist circumference measured using a tape measure at baseline, 3 months and 6 months
4. Body fat and lean body mass measured using bioimpedance at baseline, 3 months and 6 months
5. Food frequency measured using a questionnaire evaluated through interviews at baseline and 6 months

Key secondary outcome(s)
1. Glucose-lowering medication usage for type 2 diabetes measured using recall at baseline and 6-months
2. Blood HbA1c measured using standard laboratory procedures at an accredited NHS laboratory (Berkshire and Surrey Pathology Service, at The Royal Surrey Hospital) at baseline, 3 months and 6 months

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Over 18 years age
2. Diagnosis of type 2 diabetes as defined by an HbA1c over 47mmol/mol

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Pregnant or planning pregnancy in the ensuing 12 months
2. Active treatment for cancer or terminal illness
3. Kidney disease or renal stones
4. Proliferative retinopathy
5. Recovering from acute surgery
6. Gout
7. Gallbladder disease
8. Pancreatic disease

Date of first enrolment
01/02/2025

Date of final enrolment
31/07/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Surrey
Stag Hill Campus
Guildford
United Kingdom
GU2 7XH

Sponsor information

Organisation
Public Health Collaboration

Funder(s)

Funder type
Charity

Funder Name
Public Health Collaboration

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.Martin Whyte, 21PG00 Leggett Building, University of Surrey, Guildford, UK. Email: m.b.whyte@surrey.ac.uk. Data will be in batched, anonymised form and available for up to 10 years after completion of the study.

IPD sharing plan summary
Available on request