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Wellbeing outcomes of blood sugar control (HbA1c) target-setting in diabetes

Submission date
11/06/2021

Recruitment status
No longer recruiting

Registration date
11/06/2021

Overall study status
Completed

Last Edited
12/01/2026

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
For diabetes doctors, the importance of providing personalised care and treatment goals to people with diabetes is seen to be increasingly important. A diabetes treatment goal known to be important in predicting later health problems is average blood sugar (also known as HbA1c or 'A1c'). The A1c tells us what the blood sugar of people with diabetes has been like over the past 8-12 weeks. Over time, A1c helps predict what the chances are of developing health problems later in life for someone with diabetes.
Despite an improved selection of medications and increased awareness of A1c goals amongst people with diabetes, the achievement of A1c goals has improved very little over the past decade.
Many things can get in the way of achieving A1c goals in people with diabetes. Mental health issues are known to be an obstacle to optimal blood sugar levels. Research tells us that people with diabetes who also have mental health problems struggle to reach their A1c goals. Despite the frequent use of treatment goals such as A1c in the care of people with diabetes, little is known of the reciprocal effect that goal-setting has on the psychological well-being of individuals.
The ATTAINS Study will look at the effect that A1c goal-setting has on the psychological well-being of people with diabetes. This is an early project to see if a bigger project is justified in the future. The psychological impact that A1c goal-setting has on people with diabetes is unknown. A better understanding of this could help people with diabetes achieve their A1c goals.

Who can participate?
Patients aged 18 and over with Type 1 or Type 2 Diabetes, and healthcare professionals directly involved in the care of people with diabetes.

What does the study involve?
The feasibility study involves 3 visits over a 6-month period. After an initial 3-month run-in, we want to see that the effect of setting higher (Group A) or lower (Group B) A1c targets has on participant's wellbeing and blood sugar control. We will test this by randomising (like tossing a coin) participants into each group. At each visit, we will check height, weight, blood pressure and A1c with a finger-prick blood sample. We will check your wellbeing before and after the intervention using a series of short, validated psychometric questionnaires.

As this is a feasibility study, we will be observing the amount of people that are eligible, recruited and retained in the study, alongside response rates to questionnaires.
Alongside the feasibility study, we will be carrying out interviews with participants and healthcare professionals to understand experiences, views and opinions on topics of study acceptability, glycaemic target-setting, individualised treatment targets and barrier to research participation.

What are the possible benefits and risks of participating?
There is a chance that participant's HbA1c may change over the study period. We do not expect this to have an effect on participant health. The research is not meant to provide direct benefit. By taking part, participants will add to our knowledge which could help patients in future. No expenses or payments will be available.

Where is the study run from?
St Helens and Knowsley Teaching Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
September 2020 to April 2022

Who is funding the study?
St Helens and Knowsley Teaching Hospitals NHS Trust (UK)

Who is the main contact?
Dr Sam Westall, sam.westall@nhs.net

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
291254

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 291254

Study information

Scientific Title
HbA1c TargeT AcheIvemeNt in diabeteS. Psychometric and biomedical outcomes of HbA1c target-setting in adults with Type 1 and Type 2 diabetes: A mixed-methods parallel-group randomised feasibility study

Acronym
ATTAINS

Study objectives
This study aims to test the feasibility of conducting a definitive randomised control trial to evaluate the impact HbA1c target-setting has on psychometric outcomes in people with diabetes using a series of pre-defined progression criteria.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/05/2021, Cornwall and Plymouth Research Ethics Committee (Bristol HRA Centre, Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN; UK; +44 (0)207 1048071; cornwallandplymouth.rec@hra.nhs.uk), ref: 21/SW/0043

Study design
Single-centre mixed-methods study consisting of an unblinded interventional randomized feasibility study and semi-structured interviews

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Type 1 and Type 2 diabetes

Interventions
There will be four sub-studies:
Sub-study A: Randomised feasibility study.
Sub-study B: Semi-structured interviews with patients on study acceptability and glycaemic target-setting.

Sub-study C: Semi-structured interviews with healthcare professionals on glycaemic-target setting.
Sub-study D: Semi-structrued interviews with patients on barriers to participation.

STUDY PROCESSES
In the feasibility study, participants will be randomised (stratified [Type 1 or Type 2 diabetes], random permuted block randomisation strategy) to one of two groups. After initial screening and run-in, participants will be reviewed at three months for intervention delivery and six months for follow-up.
Semi-structured interviews will be carried out with a sample of patients and healthcare professionals to explore experiences, views and opinions of participants on the acceptability of study processes, glycaemic target-setting and barriers to participation.

INTERVENTION
Following a three-month run-in period, group one will have an explicit HbA1c target set 5 mmol /mol above their current HbA1c reading. Group two will have an explicit HbA1c target set 5 mmol /mol below their current HbA1c reading. Diabetes treatment of participants will not be altered. A series of validated psychmetric questionnaires will evaluate baseline (pre-intervention) and follow-up (three months post-intervention) metrics of 'health-related quality of life', 'diabetes-related distress', 'wellbeing', 'empowerment' and 'self-care'.

Intervention Type
Behavioural

Primary outcome(s)
Sub study A:
1. Eligibility rate recorded as number of screened patients who were eligible against inclusion /exclusion criteria per month.
2. Recruitment rate recorded as number of eligible patients who consented to participate in the study by 4 months.
3. First follow-up retention rate recorded as the number of participants who consent to participate and remain in the study until first follow-up at 3 months.
4. Last follow-up retention rate recorded as the number of participants who consent to participate and remain in the study until the final study visit at 6 months.
5. Response rate of the 3-month and 6-month psychometric questionnaires, recorded as the number of participants who consent to participate who fully complete the questionnaires pre- (3 months) and post-intervention (6 months).

Key secondary outcome(s))
Sub-study A:
1. Health-related quality of life, measured using the EuroQoL 5D-5L (EQ-5D-5L) questionnaire, pre- (3 months post-randomisation) and post-intervention (6 months post-randomisation).
2. Diabetes-related distress, measured using the Problem Areas in Diabetes (PAID), pre- (3 months post-randomisation) and post-intervention (6 months post-randomisation).
3. Self-care in diabetes, measured using the Summary of Diabetes Self-care Activities (SDSCA), pre- (3 months post-randomisation) and post-intervention (6 months post-randomisation).
4. Wellbeing, measured using the Well Being Questionnaire-12 (WBQ-12), pre- (3 months post-randomisation) and post-intervention (6 months post-randomisation).
5. Diabetes empowerment, measured using the Diabetes Empowerment Scale-Long Form (DES-LF), pre- (3 months post-randomisation) and post-intervention (6 months post-randomisation).
6. Glycaemic control, measured using point-of-care glycated haemoglobin (HbA1c) at baseline, 3

months and 6 months.
7. Clinical outcomes such as height, weight and blood pressure at baseline, 3 months and 6 months.
Sub-study B:
8. Semi-structured interviews with participants enrolled in sub-study A during the trial period at a convenient time for participants. Interviews will be transcribed and analysed using the framework method of content analysis.
Sub-study C:
9. Semi-structured interviews with healthcare professionals during the trial period at a convenient time for participants. Interviews will be transcribed and analysed using the framework method of content analysis.
Sub-study D:
10. Semi-structured interviews with patients who declined to enrol in sub-study A during the trial period at a convenient time for participants. Interviews will be transcribed and analysed using the framework method of content analysis.

Completion date
16/04/2022

Eligibility

Key inclusion criteria
Sub-study A:
1. Aged 18 and over.
2. Has Type 1 or Type 2 Diabetes.
3. HbA1c >/=64; </=125 mmol/mol.

Sub-study B:
1. Enrolled in study A.

Sub-study C:
1. Healthcare professional directly involved in the care of people with diabetes.

Sub-study D:
1. Eligible patients declining entry into sub-study A will be approached for inclusion in study D.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
110 years

Sex
All

Total final enrolment
50

Key exclusion criteria
Sub-study A:
1. Patients at risk of CVD events.
2. Patients with an episode of severe hypoglycaemia with the past 12 months.
3. Patients with hypoglycaemia unawareness (defined as a GOLD score ≥4).
4. Patients unwilling to self-monitor blood glucose at home (if clinical management requires).
5. Patients unwilling to inject insulin (if clinical management requires).
6. BMI ≥45 kg/m².
7. Patients who have opted-out from being contacted by researchers under the NHS national data opt-out service.
8. Patients with other serious illnesses which may limit survival or factors which may limit adherence to study interventions.
9. Patients currently participating in another clinical trial.
10. Patients with a transplanted organ.
11. Pregnancy.
12. Patients with requirements for regular blood transfusion or venesection.
13. Ongoing medical therapy known to cause difficulties with glycaemic control (e.g. corticosteroid therapy).

Date of first enrolment
16/06/2021

Date of final enrolment
28/10/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St Helens Hospital
St Helens and Knowsley Teaching Hospitals NHS Trust
Diabetes Centre
Marshalls Cross Road
St Helens
England
WA9 3DA

Sponsor information

Organisation
St Helens and Knowsley Teaching Hospitals NHS Trust

ROR
https://ror.org/02e6wxz44

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
St Helens and Knowsley Teaching Hospitals NHS Trust

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository (Pure – Research Information System https://www.edgehill.ac.uk /services/pure/) for a period of 5 years unless there is legal or ethical reason for destruction, at which point further retention of the data will be reviewed. The data will be available following publication of the trial manuscripts. Anonymised participant-level data will only be shared for participants who have consented to their data to be used in future research or shared anonymously with other researchers. Data-sharing agreements will be agreed upon before the data is released, outlining usage purpose, obligations for ethical approval, confidentiality, data security, archiving/destruction, onwards transfer and acknowledgements.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/01/2026	12/01/2026	Yes	No
Protocol article		27/10/2022	28/10/2022	Yes	No
Abstract results	Abstracts P300, P302 and P303. Presented at the Diabetes UK Professional Conference 2023.	25/04/2023	04/08/2023	No	No
Abstract results	Presented at the American Diabetes Association (ADA) conference	20/06/2023	04/08/2023	No	No

HRA research summary	28/06/2023	No	No