

A randomised controlled trial of the benefits of exercise early in the management of Type 2 diabetes

Submission date
21/02/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
25/07/2005

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
19/04/2022

Condition category
Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

A randomised controlled trial of the benefits of exercise early in the management of Type 2 diabetes

Acronym

The Early ACTID Study

Study objectives

An ideal treatment for diabetes would improve glycaemic control by decreasing insulin resistance and improving insulin secretion without the side effect of weight gain. To date no pharmacological agents have been able to satisfy all of these criteria. In contrast, increased physical activity has the potential to offer all of these benefits with little or no side-effects. Hence it should represent the ideal first line treatment for Type 2 diabetes and for maximal benefit should be instituted early. Whilst we know that lifestyle intervention can be an effective treatment for those individuals with impaired glucose tolerance, i.e. in a pre-diabetic state, what we seek to establish is whether increased physical activity (using a simple home-based exercise programme) and dietary changes can alter the course of established type 2 diabetes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Type 2 diabetes

Interventions

1. Intensive dietary intervention
2. Increased exercise and intensive dietary intervention
3. Control: Usual Care

Individuals recruited into all 3 arms of the trial will have their diabetes and blood pressure management taken over by Early ACTID for the duration of the trial. Both intervention arms are based on regular counselling sessions with a research nurse and/or dietitian to encourage changes to the patients lifestyle.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Glycaemic control as measured by HbA1c and systolic and diastolic blood pressure, at 6 months.

Secondary outcome measures

Lipids, insulin resistance, weight/body composition, and amount of medication required to control diabetes and blood pressure at 12 months.

Overall study start date

01/07/2005

Completion date

31/07/2008

Eligibility

Key inclusion criteria

This a multicentre trial recruiting 750 participants from across the South West of England. Individuals must satisfy the following criteria before they can be considered eligible:

1. Type 2 diabetes mellitus (T2DM) as defined by: body mass index (BMI) >25, no ketosis, no significant weight loss prior to diagnosis, aged above 30 at diagnosis
2. Between 5 and 8 months from clinical diagnosis of T2DM

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

750

Total final enrolment

Key exclusion criteria

1. Age over 80 at diagnosis
2. HbA1c of greater than 10%
3. Blood pressure greater than 180/100
4. Low-density lipoprotein (LDL) greater than 4
5. Patients already receiving a maximum dose of a sulphonylurea
6. Have a current diagnosis of unstable angina
7. Have had a myocardial infarction within the previous three months
8. Unable to increase their physical activity
9. Subject is pregnant or is of childbearing age and not surgically sterile, 2 years postmenopausal or does not practice one method of contraception

Date of first enrolment

01/07/2005

Date of final enrolment

31/07/2008

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Joint Clinical Research Unit

Bristol

United Kingdom

BS2 8HW

Sponsor information**Organisation**

University of Bristol (UK)

Sponsor details

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Sponsor type

University/education

ROR

<https://ror.org/0524sp257>

Funder(s)

Funder type

Charity

Funder Name

Diabetes UK (UK) (ref: BDA:R04/0002750)

Alternative Name(s)

DIABETES UK LIMITED, British Diabetic Association

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Funder Name

National Health Service (NHS) (UK) - ad hoc funding

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan**

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		09/07/2011		Yes	No
Other publications	Effect on inflammatory markers	08/05/2014		Yes	No
Other publications	Qualitative analysis of motivation	31/01/2018		Yes	No
Other publications	Analysis of association of glycaemic control with diet independent of weight change	18/04/2022	19/04/2022	Yes	No