

Movement as medicine for type 2 diabetes

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| Submission date 11/01/2012 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 23/01/2012 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 25/02/2021 | Condition category Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Individual participant data |

Plain English Summary

Background and study aims

Research has shown that increasing levels of physical activity can produce significant improvements in blood glucose control in people with Type 2 diabetes. What is not well understood is how best to support people with Type 2 diabetes to become more physically active and maintain this over time. This study aims to find out whether the use of structured support provided by healthcare professionals in primary care is feasible, acceptable and effective for increasing levels of physical activity and improving glucose control in people with Type 2 diabetes.

Who can participate?

Adults aged 18 years or over with Type 2 diabetes (diabetes controlled by diet, oral medication or both, not insulin)

What does the study involve?

All primary care practices in the County Durham and Darlington region are invited to take part in the study. 40 practices are selected to take part and randomly allocated to one of two groups: structured support or usual clinical care. Healthcare professionals from practices allocated to the structured support group are specifically trained to provide evidence-based support to their patients to help them to become more physically active and maintain this over time. They do this with the help of a specially developed Movement as Medicine toolkit. Every patient who joins the study in practices allocated to structured support receives their own toolkit. All the patients in the structured support group have to attend four diabetes review appointments over a 12-month period, complete a questionnaire at the start of the study, and again one, three, six and 12 months later. Patients have to wear a physical activity monitor for 7 days at the start of the study, and again one, three, six and 12 months later. Practices allocated to the usual clinical care group are asked to deliver care as they usually would during diabetes review appointments.

What are the possible benefits and risks of participating?

Structured support provided by healthcare professionals in primary care may help people with Type 2 diabetes in increasing levels of physical activity and improving glucose control. There are no risks associated with participating in the study.

Where is the study run from?

The study is run by Newcastle University; however, it will be carried out in primary care practices across the County Durham and Darlington region.

When is the study starting and how long is it expected to run for?

July 2012 to December 2014

Who is funding the study?

1. NHS Health Innovation and Education Cluster (HIEC) (UK)
2. Medical Research Council (MRC) (UK)

Who is the main contact?

Prof. Mike Trenell

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Contact information

Type(s)

Scientific

Contact name

Prof Michael Trenell

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Feasibility, acceptability and effectiveness of a multi-faceted behavioural intervention targeting levels of physical activity in adults with type 2 diabetes in primary care: movement as medicine for type 2 diabetes

Study hypothesis

A theory-based behavioural intervention will be more effective than standard clinical care for impacting positively on levels of free living physical activity and concomitant levels of glycated hemoglobin) (HbA1c).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Sunderland REC committee, 13/04/2012, ref: 12/NE/0037

Study design

Single-centre clustered randomised controlled with parallel groups

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Condition

Non-insulin-dependent type 2 diabetes

Interventions

A theory-based accredited online training programme for primary care practitioners and a toolkit of paper-based materials, activity planners and trackers, a pedometer and DVD.

Intervention group: Patients will attend four face to face diabetes review appointments over a 12-month period (baseline, 1, 6 and 12 months) where they will be supported using the toolkit to increase their levels of physical activity. In addition both the intervention and control group will receive a telephone call at 3 months.

Control group: standard clinical care

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Primary care practitioners:

Counselling and behaviour change skills

Patients:

Objectively and subjectively assessed physical activity behaviour

Secondary outcome measures

Primary care practitioners:

1. Diabetes and physical activity-related knowledge and attitudes/beliefs
2. Self efficacy for delivering physical activity-related counseling to adults with type 2 diabetes

Patients:

1. Glucose control (HbA1c)
2. Blood pressure
3. Body mass index (BMI) and waist circumference
4. Diabetes and physical activity related knowledge and attitudes/beliefs
5. Physical activity related self efficacy
6. Health-related quality of life

Overall study start date

01/07/2012

Overall study end date

01/12/2014

Eligibility**Participant inclusion criteria**

Current inclusion criteria as of 15/07/2013:

1. Adults aged ≥ 18 years
2. Diagnosis of non-insulin dependent type 2 diabetes for a minimum of two years
3. Capacity to provide informed consent
4. Ability to write and converse in English

Previous inclusion criteria:

1. Adults aged ≥ 18 years
2. Diagnosis of non-insulin dependent type 2 diabetes for a minimum of two years
3. Physical activity/ exercise is below recommendations (i.e. 30 minutes per day three times per week)
4. Capacity to provide informed consent
5. Ability to write and converse in English

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

A total of 200 adults with type 2 diabetes will be randomly selected. An equal number (100 per group) will be entered in to the intervention and control arm of the trial

Participant exclusion criteria

Contra-indications to performing physical activity

Recruitment start date

01/07/2012

Recruitment end date

01/12/2014

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Newcastle University

Newcastle upon Tyne

United Kingdom

NE2 4HH

Sponsor information

Organisation

NHS County Durham and Darlington (UK)

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://www.countydurham.nhs.uk/>

ROR

<https://ror.org/03vamsh08>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

NHS North East Health Innovation Education Cluster (UK)

Results and Publications

Publication and dissemination plan

Not provided at the time of registration

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

Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|------------------------------------|---|--------------|------------|----------------|-----------------|
| Protocol article | protocol | 03/02/2014 | | Yes | No |
| Abstract results | results presented at Diabetes UK Professional Conference at | 01/03/2015 | | No | No |
| Other publications | intervention development | 19/07/2016 | | Yes | No |