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Movement as medicine for type 2 diabetes

Submission date
11/01/2012

Recruitment status
No longer recruiting

Registration date
23/01/2012

Overall study status
Completed

Last Edited
25/02/2021

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
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
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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 objectives
A theory-based behavioural intervention will be more effective than standard clinical care for impacting positively on levels of free living physical activity and concomittant 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

Health condition(s) or problem(s) studied
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

Completion date
01/12/2014

Eligibility

Key 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

Key exclusion criteria
Contra-indications to performing physical activity

Date of first enrolment
01/07/2012

Date of final enrolment
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