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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
Prof Michael Trenell

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# Additional identifiers

### Protocol serial number
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

## Study type(s)
Treatment

## 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(s)
Primary care practitioners:
Counselling and behaviour change skills

Patients:
Objectively and subjectively assessed physical activity behaviour

## Key secondary outcome(s))
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

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### 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
United Kingdom

England

### Study participating centre
**Newcastle University**
Newcastle upon Tyne
United Kingdom
NE2 4HH

## Sponsor information

### Organisation
NHS County Durham and Darlington (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

### 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 |