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The PRomotion Of Physical activity through structured Education with differing Levels of ongoing Support for those with pre-diabetes (PROPELS)

Submission date
22/05/2012

Recruitment status
No longer recruiting

Registration date
14/06/2012

Overall study status
Completed

Last Edited
13/03/2024

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Type 2 diabetes is an inability to adequately regulate blood glucose levels and currently affects over 2 million people in England alone and this number is predicted to rise to over 4 million by 2025. In between having normal blood glucose levels and having type 2 diabetes, there exists a state where blood glucose levels are raised above the normal range but do not meet the criteria for type 2 diabetes; this has been called impaired glucose regulation (IGR). IGR can progress to diabetes so targeting those people with IGR provides an opportunity for preventing this disease. Research suggests that type 2 diabetes can be prevented or delayed in people with IGR through changes in lifestyle such as increasing physical activity. This study will investigate whether an intervention to support physical activity behaviour change and maintenance can lead to sustained increases in physical activity over four years & improvement in IGR as well as evaluating the effectiveness of the intervention when delivered at two levels of intensity.

Who can participate?
Participants will be 40-74 years of age (25-74yrs old if South Asian) with a diagnosis of IGR in the past five years.

What does the study involve?
Participants will be invited to attend three clinic visits; at baseline, 12 months and 48 months. These clinical visits involve Oral Glucose Tolerance Test (OGTT) together with other blood tests such as HbA1c, Urea & Electrolytes, Liver Function Tests, Full Lipid profile, Vitamin C & D, Insulin and inflammatory biomarkers & an optional genetics sample. Participants will also be asked to complete a questionnaire on diet, lifestyle and illness perception during their clinical visit. Participants will also be offered the option of having a scans to determine muscle & fat distribution throughout the body during the study. After their baseline visit participants will be randomly chosen to be in one of three groups: the control group (receive an advice leaflet), an

intervention group with annual support (annual education sessions) or an intervention with ongoing behaviour change maintenance support (annual education session, telephone support and text messages/use of website).

What are the possible benefits and risks of participating?
All people taking part in the study receive information about reducing their risk of developing type 2 diabetes as well as results such as cholesterol levels, blood pressure and other health markers which are also passed on to your GP. Taking part involves minimal risk to the participant with only staff trained to take blood doing so to minimise any discomfort in this procedure.

Where is the study run from?
This study involves two centres, the Leicester Diabetes Centre in association with the University of Leicester who will be running the study together with the MRC Cambridge.

When is the study starting and how long is it expected to run for?
August 2013 to December 2019 (as of 04/10/2018)

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
Professor Kamlesh Khunti
kk22@le.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Kamlesh Khunti

Contact details
Leicester Diabetes Centre
Leicester General Hospital
Leicester
United Kingdom
LE5 4PW

Additional identifiers

Integrated Research Application System (IRAS)
96298

Protocol serial number
HTA 09/162/02

Study information

Scientific Title

The PRomotion Of Physical activity through structured Education with differing Levels of ongoing Support for those with pre-diabetes (PROPELS): randomised controlled trial in a diverse multiethnic community

Acronym
PROPELS

Study objectives
Can an intervention to support physical activity behaviour change lead to sustained increases in physical activity over four years in those with a high risk of type 2 diabetes.
We also aim:
1. To develop an intervention package to support maintenance of behaviour change.
2. To investigate the effectiveness of the intervention when delivered at two levels of intensity.
3. To investigate the effect of the intervention within White Europeans and South Asians subgroups.
4. To conduct an economic evaluation of both intervention conditions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leicester Research Ethics Committee , 04/05/2012, ref:12/EM/0151

Study design
Multi-site randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diabetes

Interventions
Control Group
Control subjects will receive a booklet detailing information on risk factors for type 2 diabetes mellitus (T2DM) and cardiovasular disease (CVD) and how physical activity can be used to prevent T2DM and CVD.

Intervention group with annual support
Participants in this group will receive the same booklet as group 1 and will also be offered a group–based structured educational programme aimed at promoting increased ambulatory activity by targeting perceptions and knowledge of diabetes risk, physical activity self–efficacy, barriers to physical activity and self–regulatory skills based on pedometer use. The programme will employ a person–centred approach to patient education that is based on self–management programmes for individuals with type 2 diabetes and prediabetes that have been developed and tested by our research group. The programme will be designed to be delivered to 5–10

participants by two trained educators and is 3.5 hours long. Participants will be offered annual followup support through the attendance of a 2 hour group based session aimed at revisiting the key messages of the initial structured education programme.

Intervention group with ongoing behaviour change maintenance support
Participants in this group will receive the same booklet as group 1 and the same structured education and annual followup group sessions as group 2. In addition, they will receive ongoing support in the form of phone calls 6 months after each education session, access to an interactive website and text messages on a regular basis.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Current primary outcome measure as of 12/07/2019:
Change in ambulatory activity (steps/day) between baseline and 48 months, assessed by accelerometer (Actigraph GT3X+). Acceleration data are captured and stored at 100 Hz. Data processing will be undertaken on a commercially available analysis tool (KineSoft). Data will be integrated into 60-second epochs. At least 3 valid days of wear will be required, with a valid day defined as at least 10 hours of wear. Non-wear time will be determined by 1 hour or more of consecutive zero counts

Previous primary outcome measure:
Change in ambulatory activity (steps per day) at 48 months

Key secondary outcome(s))
Current secondary outcome measures as of 12/07/2019:
1. Change in ambulatory activity (steps/day) between baseline and 12 months assessed by accelerometer (Actigraph GT3X+)
2. Assessed by accelerometer between baseline and 12 months, and between baseline and 48 months:
2.1 Number of censored steps/day (i.e. steps taken above an intensity used to distinguish between purposeful and incidental ambulation)
2.2 Time spent sedentary (mins)
2.3 Time spent in light physical activity (mins)
2.4 Time spent in moderate-to-vigorous physical activity (mins)
2.5 Compliance with recommendation to undertake at least 21.4 minutes/day (150 mins /week) of moderate-to-vigorous intensity physical activity in bouts of at least 10 minutes
2.6 Compliance with recommendation to undertake at least 21.4 minutes/day (150 mins/week) of moderate-to-vigorous intensity physical activity without bout restriction
3. Assessed by activPAL3 between baseline and 12 months, and between baseline and 48 months:
3.1 Time spent sitting or lying down (mins)
3.2 Time spent standing (mins)
3.3 Time spent walking (mins)
4. Assessed by Recent Physical Activity Questionnaire (RPAQ) between baseline and 12 months, and between baseline and 48 months:
4.1 Overall physical activity expenditure (kJ/day)

4.2 Time sedentary (mins), in light (mins), moderate-to-vigorous (mins) intensity physical activity
5. Main biochemistry outcomes between baseline and 12 months, and between baseline and 48 months:
5.1 HbA1c (mmol/mol)
5.2 HbA1c (%)
5.3 Total cholesterol (mmol/l)
5.4 HDL cholesterol (mmol/l)
5.5 LDL cholesterol (mmol/l)
5.6 Triglycerides (mmol/l)
5.7 Vitamin D (nmol/l)
6. Other biochemistry outcomes between baseline and 12 months, and between baseline and 48 months:
6.1 Sodium (mmol/l)
6.2 Potassium (mmol/l)
6.3 Urea (mmol/l)
6.4 Estimated glomerular filtration rate (eGFR; ml/min/1.73m2)
6.5 Total bilirubin (umol/l)
6.6 Alkaline phosphatase (IU/l)
6.7 Alanine transaminase (IU/l)
6.8 GGT (IU/l)
6.9 Urine albumin creatinine ratio (mg/mmol)
7. Cardiovascular risk between baseline and 12 months, and between baseline and 48 months:
7.1 Modelled cardiovascular risk based on the Framingham risk equation (D'Agostino 2008) (%)
8. Anthropometry between baseline and 12 months, and between baseline and 48 months:
8.1 Weight (kg)
8.2 BMI (kg/m2)
8.3 Waist circumference (cm)
8.4 Body fat percentage (%)
8.5 Fat mass (kg)
8.6 Fat free mass (kg)
9. Depression and anxiety measured using the HADS, between baseline and 12 months, and between baseline and 48 months:
9.1 Depression score
9.2 Anxiety score
10. Diet measured by self-report, between baseline and 12 months, and between baseline and 48 months:
10.1 Frequency (portions/week) of fresh fruit, green leafy vegetables, other vegetables, oily fish, other fish, chicken, meat, eggs, cheese, wholemeal/brown bread.
10.2 Alcohol: Frequency (drinks/day)
10.3 Number of days/week on which individual reported limiting total fat intake
10.4 Number of days/week on which individual reported limiting saturated fat intake
10.5 Number of days/week on which individual reported limiting sugar intake
10.6 Number of days/week on which individual reported limiting salt intake
11. Sleep measured using self-report between baseline and 12 months, and between baseline and 48 months:
11.1 Time spent asleep last night (hrs)
11.2 Average sleep duration (hrs/night)
12. Health-related quality of life between baseline and 12 months, and between baseline and 48 months:
12.1 Summary mental and physical component scores from SF-8
12.2 Summary index from EQ-5D-5L
12.3 Self-related health based on the Visual Analogue Scale questionnaire

13. Diabetes (yes/no) at 12 months and 48 months
14. Intermediate outcomes
Change in theoretical behavioural constructs hypothesised to be determinants of behaviour change will be considered "intermediate outcomes" and assessed between baseline and 12 months, and between baseline and 48 months.
14.1 Walking self-efficacy measured using confidence (0-100%) to walk for a short (10 minutes), moderate (30 minutes) and long (60 minutes) duration each day
14.2 Illness perception measure using scores (0-10) for each item of the illness perception questionnaire:
14.2.1 How much does your risk of diabetes affect your life?
14.2.2 How long do you think your risk of diabetes will continue?
14.2.3 How much control do you feel you have over your risk of diabetes?
14.2.4 How much do you think treatment can help your risk of diabetes?
14.2.5 How much do you experience symptoms from your risk of diabetes?
14.2.6 How concerned are you about your risk of diabetes?
14.2.7 How well do you feel you understand your risk of diabetes?
14.2.8 How much does your risk of diabetes affect you emotionally? (e.g. does it make you angry, scared, upset or depressed?)
14.3 Self-regulation measured using categorical responses (most of the time, some of the time, rarely, never) for self-regulation items (assessed at 12 and 48 month follow-up only):
14.3.1 Set yourself regular goals detailing the amount of exercise you would do each day
14.3.2 Regularly set yourself a plan detailing where, when and how you would exercise
14.3.3 Worn a pedometer
14.3.4 Kept an exercise log recording your activity levels
14.3.5 Been aware of your activity levels
14.3.6 Tried to exercise regularly

Previous secondary outcome measures:
1. Time spent in sedentary, light, moderate and vigorous intensity physical activity assessed by accelerometer and selfreport (RPAQ)
2. Website use and text messages sent/received (intervention group 3 only)
3. Fasting and 2hour postchallenge glucose and HbA1c
4. Fasting lipid profile, fasting insulin, highly sensitive C-reactive protein, key adipokines (interleukin 6 and tumour necrosis factor alpha), urea & electrolytes (sodium, potassium, urea, creatinine) and liver function tests (Albumin, Total Bilirubin, Alkaline Phosphatase (ALP), Alanine Transaminase (ALT))
5. Markers of chronic inflammation and adipokines [Adiponectin, leptin, IL6, high sensitivity C-reactive protein (hsCRP)]
6. Vitamin C & D
7. Genetic analysis
8. Urine sample
9. Height
10. Body weight
11. Body Mass Index (BMI)
12. Body fat percentage
13. Waist circumference
14. Arm and leg length
15. Blood pressure
16. Medication status
17. Smoking status
18. Family history of disease
19. Muscular/skeletal injury

20. Illness perceptions
21. Selfefficacy
22. Self regulation
23. Quality of life
24. Depression and anxiety
25. Diet
26. Sleep
27. Body composition [Dual-energy X-ray absorptiometry (DEXA) & Magnetic resonance imaging (MRI)]

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Age 40-74 years or 25-74 years if South Asian
2. Diagnosed with Impaired Glucose Regulation (IGR) within the last 5 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
1366

Key exclusion criteria
1. Due to the nature of the intervention those unable to undertake ambulatory based activity will be excluded
2. Those diagnosed with diabetes
3. With screen detected diabetes at baseline
4. Pregnant women
6. Those with normal glycaemia with no previous record of IGR in the previous 5 years

Date of first enrolment
01/08/2013

Date of final enrolment
30/04/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leicester Diabetes Centre
Leicester
United Kingdom
LE5 4PW

Sponsor information

Organisation
University of Leicester (UK)

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK) ref: 09/162/02

Results and Publications

Individual participant data (IPD) sharing plan
Researchers interested in accessing the data are asked to contact the principal investigator (Prof. Kamlesh Kunti; kk22@le.ac.uk). Please provide a detailed summary of the analysis planned and the data required for this.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/06/2021	04/06/2021	Yes	No

Results article		01/12/2021	10/01/2022	Yes	No
Protocol article	protocol	02/07/2015		Yes	No
Other publications	Development of support programme	15/12/2015		Yes	No
Other publications	economic evaluation	12/03/2024	13/03/2024	Yes	No
Statistical Analysis Plan		16/09/2019	04/10/2019	No	No