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Community-based Prevention of Diabetes (ComPoD) trial

Submission date
05/09/2014

Recruitment status
No longer recruiting

Registration date
05/09/2014

Overall study status
Completed

Last Edited
31/12/2019

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
More and more people are getting Type 2 diabetes. An increasing number of people also have blood sugar levels that are higher than normal and put them at increased risk of getting diabetes in the future - this is sometimes called pre-diabetes. The consequences of Type 2 diabetes can be serious and there are concerns that the costs of treating it may increase to a very high level unless action is taken. Fortunately, there is a strong scientific evidence that many cases of Type 2 diabetes can be prevented through weight loss and people making changes to their diet and levels of physical activity. Experts therefore recommend intensive support to help people with pre-diabetes to make healthy lifestyle changes. However, there are currently no properly evaluated real-world lifestyle programmes to prevent diabetes in the UK. Our study aims to use robust methods to find out how well a community-based diabetes prevention programme works in helping people to make healthier lifestyle choices, lose weight and reduce their risk of developing diabetes. It will also assess whether the programme is good value for money.

Who can participate?
GP practice staff will help us to identify adults with pre-diabetes and invite them to take part in the study.

What does the study involve?
After someone agrees to take part in the study a researcher will visit them in their home or another convenient location (e.g., their GP practice) to assess their weight, blood sugar and lifestyle, and ask them to wear a small device to monitor their physical activity for a week. After this we will randomly divide participants into two groups. Half will attend the diabetes prevention programme immediately (intervention group) and half will be placed on a waiting list to attend the programme after 6 months (control group). The diabetes prevention programme is called the Living Well, Taking Control programme. It is designed to help people to eat healthily, get more physically active and lose weight. To begin with, participants will be invited to attend four to six weekly sessions lasting up to two hours. These will be led by a trained lifestyle coach in a local venue and involve 10-12 people with pre-diabetes from the local community, and their partners or other supporters. After these group sessions, the lifestyle coach will provide regular support to participants, for example over the phone. Participants will then be able to choose to

attend at least five additional physical activity and healthy eating classes over the next year. The Living Well, Taking Control programme is already being provided by voluntary sector organisations in several locations in the UK and we will evaluate it at two sites. Six months after the first visit from the researcher, the researcher will visit participants again to take measures and collect information as before. Comparing the measures after 6 months for the group who attended the programme straight away with the group on the waiting list will show how good the programme is at helping people to make lifestyle changes, lose weight and reduce their risk of diabetes. After 12 months the researcher will visit those who attended the programme from the start as final time to see whether they have maintained any changes they made.

What are the possible benefits and risks of participating?
Firstly, by taking part in the study we expect that participants will find it useful to think about their diet and physical activity. We expect that those people who successfully improve their diet or increase their physical activity will lose weight. This will reduce their risk of developing diabetes, and may lower their blood pressure and cholesterol, and improve their general health and well-being. Secondly, participants may gain social benefits from taking part in the programme by meeting other people in their local area and sharing experiences of making lifestyle changes. Thirdly, by taking part in the study participants will help us to develop better services to prevent diabetes in the local areas and in the health service more widely. We do not expect participants to be harmed in any way or to experience any risks or distress from taking part in our study.

Where is the study run from?
The study will take place across two sites in the UK: Westbank Healthy Living Centre, Devon and Health Exchange, Birmingham.

When is the study starting and how long is it expected to run for?
September 2014 to March 2015.

Who is funding the study?
National Institute for Health Research (NIHR) (UK).

Who is the main contact?
Dr Jane Smith
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17309

Study information

Scientific Title
Community-based Prevention of Diabetes (ComPoD): a randomised trial with a waiting list control group to evaluate the effectiveness and cost-effectiveness of a third sector led, community-based diabetes prevention programme

Acronym
ComPoD

Study objectives
This randomised controlled trial with a 6-month waiting list control group and 12-month observational follow-up of intervention group participants aims to address the primary research question:

1. Is a community-based diabetes prevention programme delivered by voluntary sector organisations (the 'Living Well, Taking Control' programme), more effective than routine care from GP practices in modifying diabetes risk factors (weight, physical activity and blood sugar levels) amongst adults at risk of Type 2 diabetes at 6 months?

And the secondary research questions:

2. Is providing the Living Well, Taking Control programme a good use of health care resources in terms of any improvements in quality of life gained after 6 months, and when future costs and quality of life over a participant's lifetime are estimated?

3. Are any changes in weight, physical activity, blood sugar levels and self-reported quality of life and wellbeing resulting from the programme maintained up to 12 months?

4. What population, participant and provider characteristics influence the effectiveness and cost-effectiveness of the Living Well, Taking Control programme?

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West Lancaster Research Ethics Committee, 10/07/2014, 14/NW/1113

Study design
Randomised; Interventional; Design type: Prevention

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Topic: Diabetes, Primary Care; Subtopic: Type 2, Diabetes, Primary care; Disease: All Diseases, Prevention/screening

Interventions
Living Well, Taking Control: The Living Well, Taking Control programme is an existing community-based diabetes prevention programme adherent with NICE guidance that is being provided by voluntary sector organisations in Devon and the West Midlands. Participants attend 4-6 initial weekly group sessions lasting up to two hours and receive regular follow up and the opportunity to attend at least five additional physical activity and healthy eating classes over the next year to support healthy lifestyle changes.

The waiting list control group will receive the Living Well, Taking Control Programme after 6 months. During their time on the waiting list they will continue to receive routine care from their GP practice.

Follow Up Length: 6 month(s); Study Entry : Registration and One or More Randomisations

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Weight loss (kg); Timepoint(s): Baseline, 6 months, 12 months

Secondary outcome measures

1. 7-day objectively measured physical activity (i.e., accelerometry); Timepoint(s): Baseline, 6 months, 12 months
2. Blood pressure; Timepoint(s): Baseline, 6 months, 12 months
3. Dietary change (fat and fibre); Timepoint(s): Baseline, 6 months, 12 months
4. HbA1c (indicating average blood sugar levels over 3 months); Timepoint(s): Baseline, 6 months, 12 months
5. Mental health and well-being; Timepoint(s): Baseline, 6 months, 12 months
6. Other anthropometric measures (e.g., waist circumference, % body fat, muscle mass); Timepoint(s): Baseline, 6 months, 12 months
7. Perceived importance of and confidence in achieving healthy levels of activity and a healthy diet; Timepoint(s): Baseline, 6 months, 12 months
8. Quality of life (EuroQoL EQ5D); Timepoint(s): Baseline, 6 months, 12 months
9. Self-reported physical activity (NZPAQ); Timepoint(s): Baseline, 6 months, 12 months

Overall study start date
01/01/2014

Completion date
31/12/2016

Eligibility

Key inclusion criteria
As per existing programme eligibility criteria we will recruit people who:
1. Are aged 18-74 years.
2. Are considered on the basis of recent blood glucose tests to be at high risk for type 2 diabetes according to the criteria in the recent NICE diabetes prevention guidance (fasting plasma glucose level 6.1-
6.9 mmol/L, or HBA1c 42-47 mmol/l recorded at any point within the last year). A check for progression to diabetes amongst trial participants will be made at baseline using point-of-testing HbA1c assessment equipment.
3. Are resident in Exeter and Tiverton (postcodes EX1-6; EX 16) or Birmingham (postcodes B1-21).
4. Have a BMI of at least 25 (23 for certain ethnic minority populations e.g. South Asians) and less than 45 kg/m2

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
74 Years

Sex
Both

Target number of participants
Planned Sample Size: 312; UK Sample Size: 312

Total final enrolment
314

Key exclusion criteria
1. We will exclude people who have a terminal illness or do not have the mental capacity to give informed consent and understand study procedures with assistance from the researcher, an interpreter or other representative as necessary (e.g., due to dementia, severe learning disability)
2. Participants who have an HbA1c reading recorded at their baseline assessment indicating progression to Type 2 diabetes will also be excluded from the trial but will still be able to access the diabetes management component of the Living Well, Taking Control programme and will be referred accordingly

There are no other exclusion criteria as the programme providers cater for people with low literacy, needing translation services or with mental health problems, learning or physical disabilities, and will support consenting and collecting data from these groups.

Date of first enrolment
01/11/2014

Date of final enrolment
30/06/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Exeter Medical School
St Luke’s Campus
Heavitree Road
Exeter
United Kingdom
EX1 2LU

Study participating centre
Westbank Healthy Living Centre
Farm House Rise
Exminster

Exeter
United Kingdom
EX6 8AT

Study participating centre
The University of Birmingham
School of Sports, Exercise & Rehabilitation Sciences
Edgbaston
Birmingham
United Kingdom
B15 2TT

Study participating centre
Health Exchange
Avoca Court
27 Moseley Road
Digbeth
Birmingham
United Kingdom
B12 0HJ

Sponsor information

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University of Exeter (UK)

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Sponsor type
University/education

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Government

Funder Name
NIHR School for Public Health Research Public Health Practice Evaluation Scheme (UK)

Results and Publications

Publication and dissemination plan
Main results paper in preparation for submission to high impact medical journal June 2017. Further papers on modelling cost-effectiveness, process evaluation, accelerometry data to be prepared for submission late 2017.

Intention to publish date
30/06/2017

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available upon request from Dr Jane Smith, jane.smith@exeter.ac.uk

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V1.1	11/06/2014	07/06/2017	No	Yes
Results article	results	27/11/2019	31/12/2019	Yes	No
HRA research summary			28/06/2023	No	No