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Development of an internet/mobile phone service pathway for pre-diabetes

Submission date
16/07/2018

Recruitment status
No longer recruiting

Registration date
18/07/2018

Overall study status
Completed

Last Edited
22/10/2020

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Weight loss is vital for the prevention and management of type 2 diabetes. Recent dietary studies have found that significant weight loss can reverse type 2 diabetes by reducing the amount of fat stored around vital organs. It is also known that exercise and physical activity are important for the prevention and management of type 2 diabetes. Although it's clear that diet and physical activity are effective weight loss tools, maintaining these lifestyle changes is difficult. The researchers have developed an internet and mobile phone supported education and coaching service targeting diet and physical activity using behaviour change techniques and personalised coaching. This study will assess the feasibility of this internet/mobile phone enhanced service pathway for weight loss and weight loss maintenance in those with pre-diabetes.

Who can participate?
Adults aged 18-75 years old with pre-diabetes

What does the study involve?
Participants are asked to join the study through their GP practice. All participants receive treatment which includes internet/mobile phone weight loss advice, education, weight and physical activity tracking, and an online coach. In Phase 1 (week 1-12) participants aim to lose at least 6% of their body weight. This is supported by a diet plan described in the mobile phone app. In Phase 2 (week 12-36) participants are asked to continue weight loss and/or remain below the 6% achieved during phase 1. Participants are asked to attend the clinical research facility for four visits (one screening visit and three metabolic assessments). Metabolic assessments include body fat measures, blood samples and fitness assessment. Throughout the programme, participants may also be asked to participate in focus groups and interviews for their views on the service.

What are the possible benefits and risks of participating?
There are a number of benefits. Weight loss and improvements in lifestyle can reduce the risk of health complications associated with diabetes, and can reduce the amount of fat stored around vital organs. Participants are supported throughout the study by an exercise physiologist and a behavioural psychologist who educates them about the effects of diet on glucose control and

encourages them to become more physically active. The disadvantages of this study are that participants are required to attend all of the study visits which takes time. In addition, some individuals may experience discomfort when blood samples are taken.

Where is the study run from?
This study is run from the Clinical Research Facility within the Royal Victoria Infirmary, Newcastle Upon Tyne. North East GP practices are recruiting participants.

When is the study starting and how long is it expected to run for?
March 2017 to December 2019

Who is funding the study?
Changing Health Ltd

Who is the main contact?
1. Dr Sophie Cassidy
Sophie.cassidy@newcastle.ac.uk
2. Dr Djordje Jakovljevic
Djordje.jakovljevic@newcastle.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Sophie Cassidy

ORCID ID
http://orcid.org/0000-0002-0228-7274

Contact details
MoveLab: Physical Activity and Exercise Research group
Institute of Cellular Medicine
4th Floor William Leech Building
Newcastle University
Newcastle Upon Tyne
United Kingdom
NE2 4HH
+44 (0)191 2088264
sophie.cassidy@ncl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
33540

Study information

Scientific Title
An open non-randomised pilot study to assess acceptability and feasibility of an internet/mobile phone enhanced service pathway for the prevention of type 2 diabetes

Study objectives
Improving diet and physical activity levels are important in the prevention and management of T2DM, and have been shown to induce weight loss. It is known however that maintaining weight loss is difficult, but using behaviour change techniques, structured education and individual coaching can help. The trialists have developed an internet and mobile phone service which bring together these components. The null hypothesis is that this service will not lead to weight loss at the end of the weight maintenance phase (6 months after baseline). This is a pilot trial to determine the feasibility of the intervention and estimate key parameters for the design of the definitive trial e.g. (SD for continuous outcomes; recruitment rates, retention rates, intervention adherence, enablers, barriers to completing the intervention).

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West-Preston Research Ethics Committee, 03/04/2017, ref: 17/NW/0130

Study design
Non-randomised; Interventional; Design type: Treatment, Prevention, Education or Self-Management, Dietary, Psychological & Behavioural, Physical, Management of Care, Active Monitoring

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Internet/virtual

Study type(s)
Prevention

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
Type 2 diabetes mellitus

Interventions

A single group design. All 40 participants with prediabetes will receive treatment, which will include internet/mobile phone weight loss advice, weight and physical activity tracker, and an online coach. Participants with prediabetes according to fasting plasma glucose (FPG) 5.6–6.9 mmol/L, and/or HbA1c 5.7–6.4% (39–47 mmol/mol), will not have changed their medication, or undergone a weight loss programme in the past year. Subjects will be aged 18-75 years, will not already take part in regular exercise, will not be undergoing any or dietary change, no history of alcohol abuse, no acute or chronic gastrointestinal conditions and must have access to the internet via a smart phone of computer.

PART 1:
All participants will receive treatment, which will include internet / mobile phone weight loss advice, education, weight and physical activity tracking, and an online coach (n = 80, treatment). In Phase 1 (week 1-12) participants will aim to lose around 6% of their baseline body weight. This will be supported by a diet plan described in the mobile phone app. In Phase 2 (week 12-36) participants will be asked to continue weight loss and/or remain below the 6% achieved during phase 1.

PART 2:
Participants will be invited to join a focus group and up to 18 individual interviews will be undertaken throughout, to identify enabling factors and barriers to completion of the programme. Part 2 will be initiated later during the programme, once recruitment is underway. The interview topic guides are currently being developed and will be ready to use 6 months after the first recruit to the study. They will be submitted as an amendment in due course.

For the duration of the programme, participants will have access to the internet/mobile phone service, to help with weight loss and maintenance. The patient service is accessed via iOS and Android version mobile apps, supplemented by a web app and telephone coaching support. Patients will use the mobile app to log their weight weekly and view graphs of their weight change over time; track their daily activity using the phone's built-in step counting function; track their food intake through a photo diary using the phone's camera; set goals related to their food and activity; and book telephone coaching appointments using a live calendar function linked to their coach's availability. The coach will have access to all data recorded by the patients using the app, and will use this to inform the structure and delivery of each telephone coaching appointment. The coach will be able to view progress and will offer up to 1x20 (first phone call) + 8x10 coaching sessions over the duration of the programme. The app also provides 6 modules of structured learning content featuring animated videos, illustrated articles, and interactives (e. g. Shopping List Switches, Carbohydrate Calculator, Action Planning demonstrations). In addition, patients can review their progress and access the learning content via the accompanying web app - providing constant access should their mobile phone become lost or inactive during the study.

Metabolic control, urine/stool samples, cardiorespiratory function, body composition, physical activity, food frequency questionnaire and wellbeing will be assessed at baseline, after weight loss (Phase 1 – week 13) and weight maintenance (Phase 2 – week 37). All measurements and interviews will be taken at the Clinical research facility, RVI, Newcastle Upon Tyne.

Intervention Type

Behavioural

Primary outcome measure

1. The feasibility of recruitment, including length of time required to complete patient recruitment and retention rates, monitored throughout the study through screening and recruitment records and follow-up contact with patients.
2. Adherence to and completion of the intervention, assessed through focus groups and individual interviews at the end of the intervention
3. Delivery of intervention components by lifestyle coaches (i.e. in accordance to the protocol), assessed through focus groups and individual interviews at the end of the intervention
4. Enabling factors and barriers to completion of the programme and effective implementation, assessed through focus groups and individual interviews at the end of the intervention

Secondary outcome measures
1. Body composition measured using BODPOD at months 0, 3 and 9
2. Metabolic control measured using fasting blood samples at months 0, 3 and 9
3. Fitness assessed using cardiopulmonary exercise testing at months 0, 3 and 9
4. Cardiac function measured using non-invasive cardiac output monitoring at months 0, 3 and 9

Overall study start date
24/03/2017

Completion date
19/10/2020

Eligibility

Key inclusion criteria
1. Prediabetes based on FPG 5.6–6.9 mmol/L and/or HbA1c 5.7–6.4% (39–47 mmol/mol)
2. No previous diagnosis of Type 2 diabetes
3. Age ≥ 18 years – 75 years
4. BMI ≥ 25
5. Weight stable for the past 6 months
6. Access to a computer, internet and smart mobile phone
7. Happy and able to use a smart mobile phone
8. Willing and able to provide written informed consent
9. Willing to wear the activity monitor for 7 days
10. Willing to undertake study activities including the BODPOD

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40

Total final enrolment
23

Key exclusion criteria
1. Inability to speak or read English
2. Insulin treated
3. Contraindications to exercise determined at the exercise screening
4. Contraindications to weight loss
5. Mental or physical incapacity which makes self management inappropriate
6. Pregnancy, planning pregnancy, or lactating
7. Unable to meaningfully participate for the full duration of the study
8. Participated in a research study within the last 6 months
9. Have any allergies which are related to any of the study procedures

Date of first enrolment
19/07/2018

Date of final enrolment
19/12/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Clinical Research Facility
Level 6
Leazes Wing
Royal Victoria Infirmary
Queen Victoria Road
Newcastle Upon Tyne
United Kingdom
NE1 4LP

Sponsor information

Organisation
The Newcastle Upon Tyne Hospitals NHS Foundation Trust

Sponsor details
c/o Ayesha Clark
Freeman Hospital

Freeman Road
High Heaton
Newcastle Upon Tyne
England
United Kingdom
NE7 7DN

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Industry

Funder Name
Changing Health Ltd

Results and Publications

Publication and dissemination plan
The trial protocol will be published in due course. Planned publication of the trial results in a high-impact peer reviewed journal.

Intention to publish date
01/04/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to lack of patient consent.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	26/11/2019	05/12/2019	Yes	No
HRA research summary			28/06/2023	No	No