

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

Submission date 16/07/2018	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 18/07/2018	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 22/10/2020	Condition category Nutritional, Metabolic, Endocrine	☐ 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?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

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

Study type(s)

Prevention

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 or 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(s)

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

Key secondary outcome(s)

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

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 $\geq$ 18 years – 75 years
4. BMI $\geq$ 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

England

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

ROR

<https://ror.org/05p40t847>

Funder(s)

Funder type

Industry

Funder Name

Changing Health Ltd

Results and Publications

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