Improving the outcomes of NHS Health Checks in Southwark

Submission date	Recruitment status	Prospectively registered		
25/07/2014	No longer recruiting	☐ Protocol		
Registration date	Overall study status Completed Condition category	Statistical analysis plan		
15/09/2014		ResultsIndividual participant data		
Last Edited				
29/05/2020	Nutritional, Metabolic, Endocrine	Record updated in last year		

Plain English summary of protocol

Background and study aims

The aim of this study is to find out whether text messages improve engagement with a programme to prevent diabetes in Southwark. Text messages are used to give out periodic reminders, feedback on physical activity, motivational messages, and comparisons with others on the programme. The aim of these messages is to increase motivation and improve people's health. The messages are delivered by the automated IT system called Refer-All, which is already in place in Southwark (as well as other Local Authorities). There are no other differences in patient care.

Who can participate?

Participants are those patients engaged with the Walking Away from Diabetes (WAFD) service in Southwark Borough in London who have regular access to a mobile phone.

What does the study involve?

Participants are randomly allocated to the intervention or the control group. Our intervention concentrates on the Walking Away from Diabetes (WAFD) programme. This is a 12-week course that starts with a three-hour workshop that explains the benefits of physical activity and eating properly. Participants are all given a pedometer at the end of this workshop and told to record the number of steps they walk each day. They are sent text messages about physical activity and reminders. After 12 weeks participants are called in to re-check their risk of diabetes. Information on number of steps walked are gathered by a data link between participants pedometers and the IT system that issues the text messages. The control group receives usual care and does not receive any text messages.

What are the possible benefits and risks of participating?

The benefits of taking part are limited to the support provided by the SMS text messages during the 12-week programme. These include motivational, reminder and feedback information. These are designed to help participants stay motivated and engaged in sufficient physical activity and dietary changes to help reduce their risk of diabetes.

Where is the study run from?

Participants are recruited from 'Walking Away from Diabetes' session in Southwark, UK.

When is the study starting and how long is it expected to run for? July 2014 to January 2015

Who is funding the study? Public Health England (UK)

Who is the main contact? Dr Tim Chadborn

Contact information

Type(s)

Scientific

Contact name

Dr Tim Chadborn

Contact details

Skipton House 80 London Road London United Kingdom SE1 6LH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Public Health England R&D Ref:R&D 185 REC Ref 14/SC/1027

Study information

Scientific Title

Improving the outcomes of NHS Health Checks in Southwark: a randomised controlled trial

Study objectives

That SMS text messages that provide feedback on activity, general motivation, and reminders of a re-test will reduce participants' risk of diabetes (measured by HbA1C score). A secondary hypothesis is that the group receiving the messages will have a higher average steps per day, and a higher usage rate.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee South Central-Berkshire B, 29/05/2014, ref. 14/SC/1027

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Not available in web format, please email Hugo.harper@behaviouralinsights.co.uk to request a patient information sheet

Health condition(s) or problem(s) studied

Prediabetes risk

Interventions

This is a two arm trial: intervention and control:

- 1. The intervention group will receive SMS text messages that contain feedback on their performance relative to others in the programme, generic motivational messages, and reminders that they will have their risk re-assessed at the end of the 12 weeks. These messages will be received during the 12-week course. Participants will not receive more than six messages per week.
- 2. The control group will not receive these text messages they will receive usual care.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Difference in HbA1c levels after the 12-week course

Secondary outcome measures

- 1. Average steps walked per day
- 2. Usage rates of pedometer, measured by number of days have a greater than 50 step rating.

Overall study start date

26/07/2014

Completion date

Eligibility

Key inclusion criteria

- 1. Patients who are recommended to attend a 'Walking Away from Diabetes' session in Southwark. This recommendation may occur for a number of reasons and is at the discretion of clinicians and the public health team at Southwark Local Council
- 2. Completed full consent to participate in the trial
- 3. Over 35 and of both genders

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

300

Key exclusion criteria

Participants who do not have regular access to a mobile telephone are excluded as they would not be able to receive the text messages.

Date of first enrolment

26/07/2014

Date of final enrolment

01/01/2015

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Skipton House

London United Kingdom SE1 6LH

Sponsor information

Organisation

Public Health England (UK)

Sponsor details

c/o Elizabeth Coates Porton Down Salisbury United Kingdom SP5 0JG

Sponsor type

Government

Funder(s)

Funder type

Government

Funder Name

Public Health England (UK)

Alternative Name(s)

PHE

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No