

Comparison of active treatments for impaired glucose regulation: a Salford Royal Foundation Trust and Hitachi collaboration

Submission date 23/04/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 02/07/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/04/2021	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Developing type 2 diabetes is associated with obesity and inactivity, particularly in people who are diagnosed with impaired glucose regulation (IGR), a condition where blood glucose levels are raised above normal but not high enough to warrant a diagnosis of type 2 diabetes. Changes to lifestyle can delay diabetes onset, but achieving effective lifestyle change is difficult. Health coaching might be a flexible and effective way to do this. Health coaching involves a regular series of phone calls between patient and health professional to provide support and encouragement to the patient, and promote healthy behaviours such as healthy diet, physical activity and mobility, rehabilitation, and good mental health. Salford's multidisciplinary diabetes team delivers health coaching (known as Care Call) for people with type 2 diabetes, using health advisors. The service has been adapted to meet the needs of patients with IGR and show promising results. Salford offers an existing telephone only health coaching service. There is also an enhanced version that makes greater use of web based materials which offers telephone plus web health coaching. This involves a series of short (20 minute) phone calls to patients, once a month over 6 months, with a step down call at 9 months. Patients are able to track progress using a web 'dashboard', and communicate with their health coach via the web interface. The aim of the study is to compare the existing telephone only service with the telephone plus web service.

Who can participate?

Adults diagnosed with IGR, referred to the Salford Care Call service (UK), who have access to a phone and home internet.

What does the study involve?

Participants are randomly allocated to either the telephone only or telephone plus web health coaching service. Participants are asked to fill in questionnaires about their condition and the service they receive.

What are the possible benefits and risks of participating?

No clinical benefits, side effects, disadvantages or risks are expected from taking part. However,

the information will help to show which health coaching service is preferred by patients and which health coaching service to commission in the future.

Where is the study run from?

The remote health coaching service will be delivered by health trainers from the Salford Diabetes Care Call service (UK).

When is the study starting and how long is it expected to run for?

November 2014 to August 2016

Who is funding the study?

Hitachi (UK)

Who is the main contact?

Dr Peter Coventry

Contact information

Type(s)

Scientific

Contact name

Dr Peter Coventry

Contact details

Mental Health and Addiction Research Group

Department of Health Sciences

Faculty of Science

Area 4, Room A/RC/205, ARRC Building

University of York

York

United Kingdom

YO10 5DD

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Comparison of active treatments for impaired glucose regulation: a Salford Royal Foundation Trust and Hitachi collaboration: a randomised controlled trial

Acronym

CATFISH

Study objectives

Impaired Glucose Regulation (IGR) is the name given to two conditions which can occur called Impaired Glucose Tolerance (IGT) and Impaired Fasting Glycaemia (IFG) where glucose (sugar) is not being processed efficiently in the body. This results in blood glucose levels which are above the normal range. IGR is a form of prediabetes and if no action is taken around half of patients with IGR will go on to develop type 2 diabetes within 5 to 10 years, putting them at increased risk of further health problems. Relatively modest changes to lifestyle factors such as diet and activity can delay the onset of diabetes, and lifestyle change is recommended by the National Institute for Health and Care Excellence (NICE) as critical for effective prevention.

A model of care that has potential to achieve prevention through effective behaviour change is 'health coaching'. The increasing adoption of telephone and mobile technologies among patients, and the potential to deliver care in ways that are efficient and flexible, has led to significant interest in the potential of health coaching. However, evidence of effectiveness and acceptability is mixed.

This study aims to test acceptability and efficiency of two forms of remote health coaching for people with IGR. The principal questions this study asks are:

1. In adult patients with IGR, is a web based telephone coaching intervention more acceptable than an existing telephone only coaching intervention?
2. Is the delivery of the web based intervention more efficient in terms of direct health costs attributed to delivery than the existing teleohone only service?
3. Do patients randomised to the web based service have broadly equivalent clinical outcomes to patients randomised to the existing telephone only service?

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee East of England – Norfolk Research Ethics Committee, 27/03/2015, ref: 15/EE/0117

Study design

Single-centre interventional study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Home

Study type(s)

Treatment

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

Impaired glucose regulation

Interventions

Participants are randomly allocated to either the telephone only or telephone plus web health coaching service. Participants are asked to fill in questionnaires about their condition and the service they receive.

Intervention Type

Behavioural

Primary outcome measure

Client Satisfaction Questionnaire (self-reported questionnaire) at baseline and at 9-month follow-up

Secondary outcome measures

Health outcomes:

Change in HbA1c, weight (kg), and BMI (from baseline to follow-up at 9 months), Quality of life (self reported EQ-5D), mental health (Mental Health Inventory-5)

Health experience and self-management:

Summary of Diabetes Self-Care Activities (SDSCA), Patient Activation Measure (PAM)

Direct costs of delivery of intervention

Overall study start date

20/11/2014

Completion date

31/08/2016

Eligibility

Key inclusion criteria

1. IGR confirmed by HbA1c between 42-47 mmol/ml in last 6 months
2. Access to a telephone and home internet

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

200

Total final enrolment

209

Key exclusion criteria

1. They were referred to the face-to-face group IGR education session and do not go onto receive telephone only support
2. They are already diagnosed with type 2 diabetes
3. They have gestational diabetes
4. They are aged less than 18 years old
5. They refuse consent
6. They have no English
7. Their GP considers them incapable of participating (e.g. dementia, learning difficulties, vision or motor skills limitations)

Date of first enrolment

11/05/2015

Date of final enrolment

01/06/2016

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Centre for Primary Care

Williamson Building

Manchester

United Kingdom

M13 9PL

Sponsor information

Organisation

University of Manchester

Sponsor details

Oxford Road
Manchester
England
United Kingdom
M13 9PL

Sponsor type

University/education

ROR

<https://ror.org/027m9bs27>

Funder(s)

Funder type

Industry

Funder Name

Hitachi

Alternative Name(s)

Hitachi Group

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

Japan

Funder Name

NIHR Collaboration for Leadership in Applied Health Research and Care Greater Manchester (CLAHRC)

Results and Publications

Publication and dissemination plan

Analysis of primary and secondary outcomes will be completed in summer 2017 and publication of the main trial analysis is scheduled for Jan-Feb 2018 in an high-ranking journal relevant to

primary care and diabetes prevention. Analysis of qualitative data will be concurrent with analysis of the quantitative data and publication of qualitative findings is scheduled for March 2018 in a high ranking journal relevant to patient experience of primary care interventions.

Intention to publish date

01/02/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Peter Coventry. Agreement about accessing participant level data will be made by the principal investigator in conjunction with the funder, Hitachi Europe Ltd.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	26/08/2016		Yes	No
Results article		04/02/2019	26/04/2021	Yes	No
HRA research summary			28/06/2023	No	No