

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

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

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Faculty of Science

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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?
<a href="#">Protocol article</a>	protocol	26/08/2016		Yes	No
<a href="#">Results article</a>		04/02/2019	26/04/2021	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No