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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

Registration date
02/07/2015

Overall study status
Completed

Last Edited
26/04/2021

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 heath 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

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Additional identifiers

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

Primary study design
Interventional

Study design
Single-centre interventional study

Study type(s)
Treatment

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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
Centre for Primary Care
Williamson Building
Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation
University of Manchester

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

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?
Results article		04/02/2019	26/04/2021	Yes	No
Protocol article	protocol	26/08/2016		Yes	No
HRA research summary			28/06/2023	No	No