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'Steps to your healthy future' programme evaluation

Submission date	Recruitment status	[ ] Prospectively registered
23/01/2012	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/12/2012	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/01/2019	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims:
We would like to improve the way that people with type 2 diabetes manage their condition. Previous research has shown that people with type 2 diabetes can benefit from attending education programmes. This study will assess the benefits of a new programme called 'Steps to your healthy future' or 'Steps' for short. Steps is a group education programme which lasts for 12 months. The aim of the programme is to support patients with type 2 diabetes in their everyday lives and help them to manage their condition. The programme will help patients to learn and find out more about their whole body and what steps they can take to improve their diabetes mamangement and overall health.

Who can participate?
People who have had type 2 diabetes for between 1 and 10 years , who are aged between ages of 18 and 70 years.

What does the study involve?
To assess the Steps programme we need to compare it with normal diabetes care. This means that half of the people taking part in the study will receive the Steps programme and the other half will continue to receive their normal diabetes care. Whether participants receive the Steps programme or not will be decided randomly at the beginning of the study, the process is rather like tossing a coin.
1. If participants are randomly selected to join the intervention arm of the study they will receive the Steps programme straight away.
2. If participants are randomly selected to join the control arm of the study they will receive normal diabetes care for 12 months and then they will be invited to attend the Steps programme at the end of the study.
Taking part in the Steps programme involves attending group sessions that last for 1 hour. The programme will cover topics like nutrition, physical activity, improving posture, understanding marketing and media influences on health, understanding health habits, creating changes in behaviour and managing relationships. The Steps programme sessions will take place in small groups with a maximum of ten patients per group. Patients will be invited to bring a friend, family member or carer along to the sessions. An important factor of the Steps programme is that it is not run by medical professionals such as doctors or nurses. Instead it is delivered by

health and fitness experts. The sessions will take place once a week for the first 10 weeks and then after this initial period, there will be four follow up sessions which will be once every 10 weeks. This gives a total of 14 sessions over a period of 12 months.
Taking part in the study means that participants will be asked to attend data collection sessions at baseline when joining the study and then again after 3, 6 and 12 months. At the data collection sessions participants will be asked to fill in a questionnaire booklet and have some measurements including height, weight, waist, hip and neck circumference recorded. Selected members of the research team will look at sections of participants' medical notes to obtain recent measures of HbA1c (glucose control) and cholesterol. Participants will also be given the opportunity of taking part in two home interviews with a member of the research team.

What are the possible benefits and risks of participating?
Participants' contribution to the study will help us to improve diabetes services for people in the future, although participants may not receive any direct benefit themselves by taking part in the study. We are not aware of any risks connected with this study, but you may like to know that medical research is covered for mishaps in the same way as for patients undergoing treatment in the NHS, in that compensation is available if negligence occurs. If you have any concerns or complaints about the study or the way it has been carried out, you can contact the research team project manager: Mrs Sopna Choudhury. If you wish to complain formally, you can do this through the normal complaint mechanisms available to you through the NHS by contacting your local Patient Advice and Liaison Service (PALS).

Where is the study run from?
Birmingham and Black Country Collaboration for Leadership in Applied Health Research and Care and the University of Birmingham.

When is the study starting and how long is it expected to run for?
Recruitment for the study began in December 2012. Participants will start to receive the Steps programme in early 2013, and the study is expected to run until April 2016.

Who is funding the study?
National Institute for Health Research, UK

Who is the main contact?
Mrs Sopna Choudhury
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Contact information

Type(s)
Scientific

Contact name
Dr Shahrad Taheri

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Diabetes Centre
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Birmingham
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Additional identifiers

Study information

Scientific Title
An evaluation of a 12 month education programme 'Steps to your healthy future' for patients with type 2 diabetes mellitus

Study objectives
The aim of this study is to evaluate whether the Steps 12-month education programme delivered to a population with established T2D (>12 months <10 years duration) can yield improvements in biomedical, psychosocial and lifestyle outcome measures at 3, 6 and 12 months post baseline session. The primary outcome is a reduction in HbA1c levels of ≥ 0.6%, which represents a clinically significant change in glycaemic control.

The study will also assess the acceptability and feasibility of running this as an education programme to be rolled out for patients on a larger scale.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands - Solihull NRES Committee, 23/05/2012, ref: 12/WM/0084

Primary study design
Interventional

Study design
Single-blind randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions
T2D is a chronic and progressive disorder which affects every aspect of patients' lives. Evidence suggests that education interventions play a vital role in supporting patients to take increasing control of their diabetes and integrate self-management of the condition into daily life. However, the impact of education in self-management for patients with T2D is still not fully understood, in particular, the long term impact of self-management programmes on individuals' health behaviours has not yet been established.

A new programme entitled 'Steps to your healthy future' based on a cognitive behavioural approach has been developed and this study will assess the effectiveness and feasibility of delivering the new programme.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Evaluate whether the Steps 12-month education programme delivered to a population with established T2D (>12 months <10 years duration) can yield a reduction in HbA1c levels of ≥ 0.6%, which represents a clinically significant change in glycaemic control, at 12 months post-baseline.

Key secondary outcome(s)
Evaluate whether the Steps 12-month education programme delivered to a population with established T2D (>12 months <10 years duration) can yield improvements in biomedical measures (to include Cholesterol (Total, HDL, LDL), Blood Pressure, BMI, Weight, Waist, hip and neck circumference), psychosocial measures (to include Learning style preference, Quality of life , Diabetes-related distress, Depression presence and severity, Diabetes self efficacy, Diabetes knowledge , Perceived social support, Readiness to change), and lifestyle outcome measures (to include Smoking status, Alcohol intake, Physical activity, Dietary intake) at 3, 6 and 12 months post baseline session.

Completion date
02/04/2016

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Patients with a diagnosis of T2D for >1 year and <10 years
2. Patients between the ages of 18 and 70 years
3. Patients with an HbA1c level >7 and <11
4. Patients who commit to attend all of the programme and data collection sessions
5. Patients who are able to give informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Patients who are currently pregnant
2. Patients who cannot read and write in English
3. Patients who are not capable of moderate physical activity
4. Patients who have participated in a research study investigating medical products in the previous 6 months

Date of first enrolment
01/12/2012

Date of final enrolment
02/04/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Birmingham Heartlands Hospital
Birmingham
United Kingdom
B9 5SS

Sponsor information

Organisation
University of Birmingham (UK)

ROR
https://ror.org/03angcq70

Funder(s)

Funder type

Government

Funder Name
NIHR Collaborations for Leadership in Applied Health Research and Care (CLAHRC) - Birmingham & Black Country (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration