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An evaluation of Croí MyAction community lifestyle modification programme compared to standard care to reduce progression to diabetes /pre-diabetes in women with prior diabetes in pregnancy

Submission date
05/05/2012

Recruitment status
No longer recruiting

Registration date
28/05/2012

Overall study status
Completed

Last Edited
02/10/2014

Condition category
Pregnancy and Childbirth

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Gestational diabetes mellitus (GDM) is a type of diabetes that affects women during pregnancy. Women affected by GDM are at increased risk of developing type 2 diabetes later in life. This study will assess the effects of an intensive lifestyle intervention programme, Croí MyAction, on reducing the risks of developing type 2 diabetes amongst women with previous GDM.

Who can participate?
Women in the western regions of Ireland with previous GDM and continued risk of developing type 2 diabetes.

What does the study involve?
Participants will be randomly allocated to either the intervention group or the control group. The control group will receive usual health care, which includes standard written information on diet and lifestyle changes recommended for reducing the risk of developing type 2 diabetes, and continue with their regular health care arrangements, visiting their family doctors if required. The intervention group will receive usual health care as per the control group and will also be invited to attend the MyAction programme for 2.5 hours once per week for up to 16 weeks. Each MyAction session will include a review of individual health goals, a group exercise session and a group information session on key health topics. Weight and blood pressure will also be regularly monitored. All women will be invited back for 1-year follow-up tests to evaluate the effects of the MyAction programme. Participants will also be interviewed to find out about their experiences of MyAction.

What are the possible benefits and risks of participating?
Participants who receive the MyAction intervention will benefit from an intensive lifestyle modification and medical risk factor management programme. The early results of the MyAction

programme include improvements in physical activity levels, healthy eating, reductions in weight, BMI and waist circumference, and smoking cessation. The programme has also demonstrated improvements in blood sugar and lipid profiles and improved psychological health in terms of anxiety and depression. In turn, all of these benefits have the potential to reduce future risks of developing diabetes, stroke and heart disease. There are no foreseeable risks associated with this study; however, whenever blood samples are taken there is a low risk of pain or bruising at the site of the puncture and a possible, although low, risk of infection.

Where is the study run from?
The study is coordinated by the School of Medicine at the National University of Ireland in Galway and will be run at Croí, the West of Ireland Cardiac Foundation, University Hospital Galway.

When is the study starting and how long is it expected to run for?
The study is expected to begin in May/June 2012 and continue for 2.5 years.

Who is funding the study?
This study is funded by the Health Research Board (HRB), an Irish government agency.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
A randomised controlled trial of Croí MyAction community lifestyle modification programme compared to standard care to reduce progression to diabetes/pre-diabetes in women with prior gestational diabetes mellitus (GDM)

Study objectives
The principal question addressed by this study is:
What is the clinical impact, cost-effectiveness and psychological experience of the MyAction intensive lifestyle modification programme for women with previous gestational diabetes mellitus?

Null hypothesis: The formal null hypothesis to be tested is that there is no difference in glucose dysfunction amongst women with previous gestational diabetes mellitus following participation in an intensive lifestyle and risk factor modification programme when compared with women receiving usual health care.

On 28/11/2012 the following changes were made to the record:
1. The public title was previously "An evaluation of MyAction, a comprehensive community lifestyle intervention programme, in women with previous diabetes in pregnancy"
2. The scientific title was previously "An evaluation of MyAction, a comprehensive lifestyle and medical intervention programme, in women with previous gestational diabetes mellitus (GDM): a randomised controlled trial"

Ethics approval required
Old ethics approval format

Ethics approval(s)
Clinical Research Ethics Committee, Galway, University Hospitals, Health Service Executive of Ireland, 27/03/2012, Ref: C.A.691

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Not available in web format; please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Gestational diabetes mellitus

Interventions
The control group will receive usual health care, which includes written information on diet and lifestyle changes recommended for reducing the risk of developing type 2 diabetes and visits with general practitioners as and if required thereafter.

The intervention group will receive usual health care as per the control group in addition to attending a 12-16-week intensive lifestyle programme, MyAction. MyAction includes an initial individualised assessment by a multidisciplinary health care team followed by 2.5-hour sessions once per week (up to 16 weeks) comprising of a group exercise programme, group health promotion/education seminars and one-to-one meetings with MyAction team.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Glucose dysfunction, measured as mean reduction from baseline to 1-year follow-up by a Fasting Plasma Glucose (FPG) test and 2-hour postprandial (PP) glucose levels on a 75 g Oral Glucose Tolerance Test (OGTT).

Secondary outcome measures
1. Insulin resistance - decrease measured by HOMA analysis on insulin and glucose values on a 75 g OGTT
2. Diet adherence - measured as a combination of:
2.1. Mean improvement on the MedDietScore
2.2. Proportions achieving target fruit and vegetable consumption of >400 g/day; and
2.3. Proportions achieving oily fish intake of > once per week
3. Weight and shape - measured as:
3.1. Mean weight reduction (kg) in individuals with a Body Mass Index (BMI) of >30 kg/m2 at baseline; and
3.2. Mean reduction in waist circumference in individuals with >88 cm at baseline
4. Physical activity - measured as change in functional capacity on objective physical fitness test: Chester Step Test (CST) or 6-minute walk test
5. Lipid profile - measured as a combination of:
5.1. Proportions achieving a lipid target of total cholesterol <4.5 mmol/L, LDL<2.5 mmol/L, Tg < 1.69 mmol/L, HDL>1.29 mmol/L; and
5.2. Mean reduction in total and LDL-cholesterol
6. Positive mental health - measured on 9-items related to energy and vitality during the past month, and non-specific psychological distress (from SLÁN, the National Survey of Health and Lifestyles in Ireland, 2007)
7. General health - measured on 1-item from SLÁN, the National Survey of Health and Lifestyles in Ireland, 2007
8. Quality of life - measured on 1-item from SLÁN, the National Survey of Health and Lifestyles in

Ireland, 2007
9. Motivation to change - measured on 1-item assessing preparedness and motivation to change health-related behaviours (from the Stages of Change Model by Prochaska, DiClemente and Norcross, 1992)
10. Perceived social support - measured on 2-items from Moore et al.s research on lifestyle intervention for type 2 diabetes (2007, 2009, 2011)
11. Diabetes-related self-efficacy - measured on a 2-part exercise on confidence to engage in exercise and healthy eating under different barrier conditions (from Stanford University Patient Education Research Centre Self-efficacy for Diabetes Scale and Diabetes Empowerment Scale - Anderson, Funnell, Fitzgerald, & Marrero, 2000)
12. Economic evaluation - consists of a cost-effectiveness analysis (CEA) and cost-utility analysis (CUA). Costs of care associated with the intervention, healthcare service usage, medication usage, and private patient expenses will be estimated and aggregated. The CEA will compare the alternative programmes in terms of costs and effectiveness measured using the primary outcome in the RCT. The CUA will compare the alternative programmes in terms of costs and effectiveness measured using Quality Adjusted Life Years (QALYs). QALYs will be estimated using scores derived using the Euroqol-EQ5D instrument.

Measured at baseline and 1-year follow-up

Overall study start date
31/05/2012

Completion date
15/12/2014

Eligibility

Key inclusion criteria
1. Women of child-bearing age with a history of gestational diabetes mellitus. At recruitment, participants must also have the following risk factors for diabetes: either:
1. Impaired fasting glucose (FPG>5.6<7mmol/l) or impaired glucose tolerance (2h PG >7.8<11.1 mmol/l), or
2. Insulin resistance based on homeostasis model assessment (HOMA) analysis and the following risk factors:
2.1. Blood pressure > 130/80 mmHg
2.2. Total cholesterol > 4.5 mmol/l
2.3. Low density lipoprotein (LDL) cholesterol > 2.5 mmol/l
2.4. Triglycerides >1.69mmol/L
2.5. High density lipoprotein (HDL) cholesterol < 1.29 mmol/l
2.6. Obesity body mass index (BMI) >30
2.7. Waist circumference > 88 cm

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
114

Key exclusion criteria
1. Individuals with significant cognitive impairments or mental illness
2. Individuals with inadequate English language ability to understand the content of the intervention programme
3. Pregnant women

Date of first enrolment
31/05/2012

Date of final enrolment
15/12/2014

Locations

Countries of recruitment
Ireland

Study participating centre
School of Medicine, Clinical Sciences Institute
Galway
Ireland
N/A

Sponsor information

Organisation
Health Research Board (Ireland)

Sponsor details
73 Lower Baggot Street
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2

Sponsor type
Government

Website
http://www.hrb.ie/about/

ROR

https://ror.org/003hb2249

Funder(s)

Funder type
Government

Funder Name
Health Research Board (Ireland)

Alternative Name(s)
HRB

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Ireland

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 summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	02/05/2013		Yes	No
Results article	results	24/01/2014		Yes	No