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Gestational Diabetes: Things you need to know (but maybe don't) - a DVD for women with Gestational Diabetes Mellitus

Submission date
05/11/2012

Recruitment status
No longer recruiting

Registration date
08/11/2012

Overall study status
Completed

Last Edited
22/01/2019

Condition category
Pregnancy and Childbirth

[X] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims:
Every day around 84 pregnant women are diagnosed with gestational diabetes in the UK. While every woman with gestational diabetes receives care and treatment from their diabetes care team there are very few resources available to help women understand their diagnosis and inform them how best to manage their diabetes. To address this issue we have developed a DVD called: Gestational Diabetes.... what you need to know (but maybe dont!). This DVD has been designed and produced with continuous input from women with gestational diabetes and health care professionals. We do not know if this DVD will be of any additional benefit to women with gestational diabetes. Therefore the purpose of this study is to find out whether watching this DVD when diagnosed with gestational diabetes will have any effect on the understanding of the condition and how best to manage it, including the effect on blood sugar control or levels of stress and anxiety.

Who can participate?
All women who are aged 16 years or older, who recently have been diagnosed with gestational diabetes for the first time.

What does the study involve?
Participants will be asked to complete questionnaires on three separate occasions. Each visit will take place during routine antenatal clinic visits. The first visit will take place as soon as possible after diagnosis of gestational diabetes. The women will be asked to complete 6 short questionnaires about how they are feeling about their pregnancy and gestational diabetes diagnosis and about their diet. This will take 25 - 30 minutes. Half of the women taking part in the study will be given the DVD to watch at home (46 minutes long), and the other half will not be given the DVD. This is so we can compare the results of the two different groups to see if one is better. The women will be put into a group by chance (randomly), with the decision about which group randomly decided by a computer programme operated by an independent department. All women taking part in the study will receive the same care from their diabetes care team. Women who receive the DVD, will be asked to watch it as soon as you have some free time and will receive a follow-up call or text message to remind them to watch it. The second

visit takes place two weeks later during a routine clinic appointment. The women will be asked to complete the same 6 questionnaires which will take 25 - 30 minutes. The third visit will take place about 6-8 weeks after the babys delivery during a routine postnatal visit. The women will be asked to complete 3 questionnaires which will take approximately 20 minutes. As part of usual care, the diabetes care team will ask all women with gestational diabetes to monitor their blood sugar level with a blood glucose meter throughout their pregnancy. The researcher will download the readings from the meter at study visit 2 and at around 36 weeks gestation.

What are the possible benefits and risks of participating?
Taking part in this study may improve the participants knowledge of gestational diabetes and how to manage it. Those who do not receive the DVD as part of this study will receive a copy at the end of the study to keep. The content of the DVD may also be beneficial for after the delivery of the baby, and in any future pregnancies. The main disadvantage of taking part in the study is having to give up some spare time to complete the questionnaires and watch the DVD. However, to reduce this inconvenience we have scheduled the study visits to at the same as routine clinic appointments and questionnaires can be completed over the phone if preferred.

Where is the study run from?
Queens University Belfast in collaboration with The Ulster Hospital, Dundonald, The Royal Group of Hospitals, Belfast and St. Marys Hospital, Manchester.

When is the study starting and how long is it expected to for?
The study is starting in December 2012, and will run for 22 months.

Who is funding the study?
International Diabetes Federation and Lilly Diabetes.

Who is the main contact?
Dr Valerie Holmes
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
LT10-346

Study information

Scientific Title
Gestational Diabetes: Things you need to know (but maybe don't) - phase II: randomised controlled trial of a DVD for women with Gestational Diabetes Mellitus

Study objectives
An educational DVD developed in partnership with women with gestational diabetes mellitus (GDM) and healthcare professionals, will reduce maternal anxiety and improve glycaemic control in women diagnosed with GDM, will reduce pregnancy specific stress, increase knowledge and enhance self-efficacy, to impact positively on maternal and neonatal outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Office of Research Ethics Committees Northern Ireland (ORECNI), 10/10/2012, ref: 12/NI/0144

Study design
Multi-centre non-blinded randomised controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Gestational Diabetes Mellitus

Interventions
The experimental arm will receive the DVD in addition to standard/usual care.
The control arm will receive standard/usual care alone.

Intervention Type
Other

Phase
Phase II

Primary outcome(s)
1. Maternal anxiety at study visit 2 (2 weeks after randomization)
2. Mean 1 hour post-prandial glucose as part of a 7 point glucose profile in the 24 hour period prior to visit 2 (2 weeks after randomization) as measured by self blood glucose monitoring

Key secondary outcome(s))
1. Pregnancy specific stress at visit 2
2. Emotional adjustment to diabetes at visit 2
3. Self-efficacy at visit 2
4. Knowledge of gestational diabetes at visit 2 Maternal anxiety at visit 3 (6 weeks post delivery)
5. Risk Perception Survey for Developing Diabetes (RPS-DD) Visit 3

Completion date
01/09/2014

Eligibility

Key inclusion criteria
1. Age 16 or older
2. Pregnant women with a recent new diagnosis of GDM (as per IADPSG criteria) eligible if YES to one of the following criteria:
2.1. Fasting plasma glucose, HbA1C, or random plasma glucose at booking:
2.2. Fasting plasma glucose ≥ 5.1 mmol/l (92 mg/dl) but <7.0 mmol/l (126 mg/dl)
3. OGTT after 24 weeks gestation:
3.1. FPG ≥ 5.1 mmol/l (92 mg/dl)
3.2. 1-h plasma glucose ≥ 10.0 mmol/l (180 mg/dl)
3.3. 2-h plasma glucose ≥ 8.5 mmol/l (153 mg/dl)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Diagnosed with GDM in a previous pregnancy
2. Deemed inappropriate for woman to take part in the RCT by their Consultant Obstetrician / Physician, for example if a poor pregnancy outcome is anticipated.
3. Diagnosed with type 1 or type 2 diabetes during this pregnancy
4.Taking part in another research study

Date of first enrolment
01/12/2012

Date of final enrolment
01/09/2014

Locations

Countries of recruitment
United Kingdom

Northern Ireland

Study participating centre
Queen's University Belfast
Belfast
United Kingdom
BT12 6BA

Sponsor information

Organisation
Queen's University Belfast (UK)

ROR
https://ror.org/00hswnk62

Funder(s)

Funder type
Charity

Funder Name
This project is supported by a BRIDGES Grant from the International Diabetes Federation

Funder Name
BRIDGES, an International Diabetes Federation project, is supported by an educational grant from Lilly Diabetes. ref: LT10-346

Results and Publications

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?
Results article	results	01/04/2017	22/01/2019	Yes	No