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Symptom QUestionnaire to Ameliorate Symptoms of Hyperemesis (SQUASH) trial

Submission date	Recruitment status	[ ] Prospectively registered
18/01/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/05/2010	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
02/09/2016	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Henry Kitchener

Contact details
Academic Unit of Obstetrics and Gynaecology
School of Cancer and Enabling Science
University of Manchester
St. Mary's Hospital, 5th Floor (Research)
Oxford Road
Manchester
United Kingdom
M13 9WL

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PB-PG-0906-11232

Study information

Scientific Title
A randomised controlled trial of the 'Hyperemesis Impact Symptom Score' for individualised assessment and management of symptoms of hyperemesis gravidarum

Acronym
SQUASH

Study objectives
The medicalised model for dealing with hyperemesis gravidarum (HG) does not address all of the needs of women affected by the condition and that assessment with the 'Hyperemesis Impact Symptom Score' (HIS) questionnaire will result in more holistic and effective care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bolton Research Ethics Committee, 28/01/2008, ref: 07/H1009/88

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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
Hyperemesis gravidarum

Interventions
Control group will receive standard care.

Intervention group will be asked to complete the HIS questionnaire and treatment will be tailored to their needs as described in the HIS handbook, according to the response to the questionnaire.

The intervention typically takes 30 - 60 minutes plus one telephone call at home and follow-up will be carried out at 2, 4 and 6 weeks after collection of baseline data. Those in the control arm are given standard care and follow up is carried out at 2, 4 and 6 weeks after collection of baseline data.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Quality of life at 2 weeks post-discharge as measured by the social functioning scale of the 36-item short form health survey (SF36) questionnaire.

Secondary outcome measures
1. Quality of life as measured by the SF36 (total and subscales) at 4 and 6 weeks following discharge
2. Nausea and vomiting as measured by the Pregnancy Unique Quantification of Emesis (PUQE) score
3. Cost effectiveness of implementing the questionnaire
4. Satisfaction with care as measured by the 8-item Client Satisfaction Questionnaire
5. Number of days spent in hospital with HG and number of admissions to hospital

Overall study start date
01/05/2008

Completion date
30/04/2011

Eligibility

Key inclusion criteria
1. Pregnant women
2. Admitted to participating hospitals with a diagnosis of HG
3. Aged 16 years and above
4. Able to give informed consent
5. HG is defined for this study as excessive vomiting in early pregnancy which results in hospital admission

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
240

Key exclusion criteria
1. Onset of first symptoms beyond 14 weeks gestation
2. Previously diagnosed mental health problems
3. Diabetes

Date of first enrolment
01/05/2008

Date of final enrolment
30/04/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Manchester
Manchester
United Kingdom
M13 9WL

Sponsor information

Organisation
Central Manchester University Hospitals NHS Foundation Trust (UK)

Sponsor details
R&D Directorate
Research and Innovation Directorate
1st Floor - Postgraduate Centre
Manchester Royal Infirmary
Oxford Road
Manchester
England
United Kingdom
M13 9WL

Sponsor type
Hospital/treatment centre

Website
http://www.cmft.nhs.uk/

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) programme (ref: PB-PG-0906-11232)

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?
Results article	results	01/11/2015		Yes	No