

Symptom QUestionnaire to Ameliorate Symptoms of Hyperemesis (SQUASH) trial

Submission date 18/01/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 18/05/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 02/09/2016	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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