

# Symptom QUestionnaire to Ameliorate Symptoms of Hyperemesis (SQUASH) trial

|                                        |                                                       |                                                      |
|----------------------------------------|-------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>18/01/2010   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered    |
|                                        |                                                       | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>18/05/2010 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                       | <input checked="" type="checkbox"/> Results          |
| <b>Last Edited</b><br>02/09/2016       | <b>Condition category</b><br>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

**Protocol serial number**  
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

**Primary study design**

Interventional

**Study design**

Randomised controlled trial

**Study type(s)**

Quality of life

**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(s)**

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.

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**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**

United Kingdom

England

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

## Sponsor information

**Organisation**  
Central Manchester University Hospitals NHS Foundation Trust (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

**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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/11/2015   |            | Yes            | No              |