

# Multiple Symptoms Study: a feasibility study of a GP with special interest clinic for patients with multiple medically unexplained symptoms (MMUS)

<b>Submission date</b> 01/09/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 08/10/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 27/08/2013	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Christopher Burton

**Contact details**  
Centre for Population Health Sciences  
University of Edinburgh  
20 West Richmond Street  
Edinburgh  
United Kingdom  
EH8 9DX  
[chris.burton@ed.ac.uk](mailto:chris.burton@ed.ac.uk)

## Additional identifiers

**Protocol serial number**  
2009/P/GP/10

## Study information

**Scientific Title**

Pilot randomised controlled trial of a GP with special interest clinic for patients with multiple medically unexplained symptoms (MMUS)

**Acronym**

MSS

**Study objectives**

Feasibility study of a GP with special interest clinic to test the hypothesis that this improves outcomes for patients with multiple medically unexplained symptoms (MMUS).

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Added 20/01/2010:

South East Scotland Research Ethics Committee 2 gave a favourable opinion to the study on 23 /09/2009. Amendments to the protocol were approved on the 18/11/2009.

**Study design**

Pilot randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Medically unexplained symptoms/ somatisation

**Interventions**

Phase 1 will consist of i) trial of search criteria to identify patients with MUSS, ii) a postal study using the symptoms checklist (PHQ 14). Patients who score 10 or more will be regarded as potential participants for the Phase 2 pilot clinic.

Phase 2 will pilot the Multiple Symptoms Clinic. This will consist of a baseline assessment and then randomisation to either the Symptoms Clinic or usual care. The Symptoms Clinic will consist of an initial one hour consultation followed up at fortnightly intervals by three further twenty minute consultations.

**Details of Joint Sponsor:**

NHS Lothian

Queens Medical Research Institute

Research and Development Office

47 Little France Crescent

Edinburgh

EH6 4TJ

United Kingdom

Tel: 0131 242 3300  
Fax: 0131 242 3343  
Email: R&DOffice@luht.scot.nhs.uk

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome(s)**

Assess feasibility of this approach for a larger efficacy trial. Patient outcomes to be evaluated include PHQ-14, PHQ- 9 (depression) GAD-7 (anxiety) and SF-12 (health status) and a single item self-rated improvement measure, the Patient Global Impression of Change (PGIC).

Primary outcomes will be measured 12 weeks after randomisation.

## **Key secondary outcome(s)**

Follow-up interviews. Patients who have been seen in the Symptoms Clinic will be invited to be interviewed, in a place of their choice or by telephone, by a member of the research team. The aim of the semi-structured interviews will be to elicit patients views on the identification process, the conduct of this pilot study and the content of the Symptoms Clinic.

Secondary outcomes/the follow up interviews will take place at the same time as the primary outcome measures or as soon as possible thereafter.

## **Completion date**

30/04/2010

# **Eligibility**

## **Key inclusion criteria**

Patients will be eligible for inclusion if they are aged 18-64 (both males and females) and meet all of the following four criteria:

1. They have been referred at least twice to hospital outpatients in the last three years. Where referral data is only available for shorter periods the number of referrals required may be reduced.
2. Their general practice electronic notes summary does not contain any of a list of diagnostic codes representing serious illness (coronary heart disease, stroke, cancer, severe mental illness)
3. Their general practice electronic notes summary contains one or more diagnostic codes potentially indicating an MUS disorder. These codes include both MUS syndromes (e.g. fibromyalgia, irritable bowel syndrome, tension headache) and specific codes for a negative investigation which is commonly carried out for symptoms (e.g. normal endoscopy)
4. Have a Patient Health Questionnaire-14 (PHQ-14) score of >9

## **Participant type(s)**

Patient

## **Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

64 years

**Sex**

All

**Key exclusion criteria**

1. They are unable to provide informed consent to participate
2. Their GP regards their participation as clinically inappropriate
3. In the opinion of their GP, they either have a serious illness (e.g. heart disease, cancer, serious mental illness) which was not picked up on the database search or have other medical diagnoses which can fully explain their PHQ-14 score
4. They have serious illness related disability (for instance receiving daily personal care or using a wheelchair)
5. They are likely to have difficulty communicating by telephone
6. They are likely to have difficulty completing the forms and questionnaires
7. They express significant suicidal thoughts (PHQ-9 question 9 scoring >1)
8. They are currently undergoing multidisciplinary rehabilitation or management (e.g. pain clinic)
9. They are currently undergoing specialist psychological treatment

**Date of first enrolment**

01/10/2009

**Date of final enrolment**

30/04/2010

**Locations****Countries of recruitment**

United Kingdom

Scotland

**Study participating centre**

Centre for Population Health Sciences

Edinburgh

United Kingdom

EH8 9DX

**Sponsor information**

**Organisation**

University of Edinburgh (UK)

**ROR**

<https://ror.org/01nrxf90>

## Funder(s)

**Funder type**

Government

**Funder Name**

Chief Scientist Office, the Scottish Government (UK) (ref: CZG/2/412)

## 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	09/02/2012		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes