

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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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
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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/01nrxwf90>

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? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| Results article | results | 09/02/2012 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |