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

Submission date
01/09/2009

Recruitment status
No longer recruiting

Registration date
08/10/2009

Overall study status
Completed

Last Edited
27/08/2013

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
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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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