

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

☐ Prospectively registered

☐ Protocol

Registration date
08/10/2009

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
27/08/2013

Condition category
Mental and Behavioural Disorders

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

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

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 measure

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.

Secondary outcome measures

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.

Overall study start date

01/10/2009

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

64 Years

Sex

Both

Target number of participants

Phase 1: 120; Phase 2: approximately 30

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

Scotland

United Kingdom

Study participating centre

Centre for Population Health Sciences

Edinburgh

United Kingdom

EH8 9DX

Sponsor information

Organisation

University of Edinburgh (UK)

Sponsor details

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Sponsor type

University/education

Website

<http://www.ed.ac.uk/home>

ROR

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

Funder(s)

Funder type

Government

Funder Name

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	09/02/2012		Yes	No