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Scottish Neurological Symptoms Study 2: Symptom Management Research Trial in Neurology

Submission date	Recruitment status	[X] Prospectively registered
14/12/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
24/01/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
01/05/2014	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

MRC 68076

Study information

Scientific Title

Acronym
SNSS2: SMaRT Neurology

Study objectives
Patients with neurological symptoms that are diagnosed as 'not at all' or only 'somewhat' explained by disease who receive Cognitive Behavioural Self Help treatment in addition to Optimised Usual Care, will have a 10% greater mean improvement as measured on a five point clinical global improvement scale compared to patients receiving Optimised Usual Care alone, when measured 3 months after commencement of treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Scotland A Committee on 27/10/2005 (ref: 05/MRE00/96)

Study design
Two-arm two-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Medically unexplained symptoms

Interventions
1. Optimised usual care
2. Optimised usual care with the addition of four sessions of Cognitive Behavioural Self Help Therapy by use of a manual with the support of a treating nurse specialist

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Patients' self-rated global health improvement as measured on Clinical Global Improvement (CGI) scales at 3 months.

Secondary outcome measures
Patients' self rated improvement in decrease in total symptom burden, change in presenting symptoms, improvement in SF12 score, and change in Hospital Anxiety and Depression (HAD) score, Whitley score, illness beliefs and satisfaction with care

Overall study start date
01/02/2006

Completion date
31/05/2006

Eligibility

Key inclusion criteria
Patients aged 18 years or more who are attending Glasgow or Edinburgh Neurology Centres for the first time and who are deemed by the treating neurologist to have symptoms that are 'not at all' or only 'somewhat' explained by disease.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
130

Key exclusion criteria
1. Less than 18 years of age
2. Cognitive impairment
3. Insufficient ability to read and write English
4. Serious psychiatric illness
5. Actively suicidal
6. Receiving psychiatric or psychological treatment
7. Presenting solely with chronic daily headache
8. Neurologist/researcher considers participation inappropriate to patient's needs
9. Unable to travel to attend treatment sessions

Date of first enrolment
01/02/2006

Date of final enrolment
31/05/2006

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
University of Edinburgh Division of Psychiatry
Edinburgh
United Kingdom
EH10 5HF

Sponsor information

Organisation
Edinburgh University (UK)

Sponsor details
Queen's Medical Research Institute
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Sponsor type
University/education

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type

Research council

Funder Name
Medical Research Council (UK) (ref: 68076)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	09/08/2011		Yes	No