

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

Submission date 14/12/2005	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 24/01/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 01/05/2014	Condition category 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
Prof Michael Sharpe

Contact details
University of Edinburgh Division of Psychiatry
Kennedy Tower
Royal Edinburgh Hospital
Edinburgh
United Kingdom
EH10 5HF
+44 (0)131 5376672
michael.sharpe@ed.ac.uk

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

Scotland

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

Sponsor information

Organisation
Edinburgh University (UK)

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

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, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	09/08/2011		Yes	No