

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

<b>Submission date</b> 14/12/2005	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 24/01/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 01/05/2014	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> 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

# 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

47 Little France Crescent

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Scotland

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EH16 4TJ

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**Sponsor type**

University/education

**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, 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?
<a href="#">Results article</a>	results	09/08/2011		Yes	No