# To investigate the effectiveness of (manualised) reattribution therapy in the treatment of medically unexplained symptoms (MUS) within the General Hospital

Submission date	Recruitment status	Prospectively registered
12/09/2003	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
12/09/2003	Completed	Results
Last Edited	Condition category	Individual participant data
28/11/2014	Signs and Symptoms	<ul><li>Record updated in last year</li></ul>

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

#### Contact name

Mr Nigel Crompton

#### Contact details

Liaison Psychiatry, 10th Floor Royal Liverpool University Hospital Prescot Street Liverpool United Kingdom L7 8XP

#### Additional identifiers

EudraCT/CTIS number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

# Study information

#### Scientific Title

To investigate the effectiveness of (manualised) reattribution therapy in the treatment of medically unexplained symptoms (MUS) within the General Hospital

#### **Study objectives**

To determine the effectiveness of reattribution therapy for patients with medically unexplained symptoms. Previous studies in primary care have indicated that there are beneficial outcomes in training general practitioners in reattribution therapy. This study aims to establish the effectiveness of the treatment itself.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration

#### Study design

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

Signs and Symptoms: Medically unexplained symptoms (MUS)

#### **Interventions**

The research will be conducted in two phases:

Phase 1 - The development of a client manual that will be used as an adjunct to therapy. This will be achieved by running a small case series, interviewing 2-4 patients with medically unexplained symptoms undertaking four sessions of reattribution therapy. The manual will be developed by utilising current knowledge from the literature and the lessons learned from the case series.

Phase 2 - Randomised Trial. The trial will compare a group undertaking reattribution therapy with a control group receiving treatment as usual. A baseline assessment will be taken. The

treatment group will receive four sessions of reattribution therapy and will also receive an assessment 6 months after the baseline assessment.

The groups will be compared according to changes in social adjustment and symptom ratings.

#### Intervention Type

Other

#### Phase

**Not Specified** 

#### Primary outcome measure

- 1. Modified Social Adjustment Scale (primary outcome measure)
- 2. Illness Perception Questionnaire
- 3. Hospital Anxiety and Depression Scale
- 4. Economics Questionnaire
- 5. SCL-90-R (Measures psychological and somatic symptoms)
- 6. Number of contacts with primary and secondary health care services (derived from patient questionnaire and case notes)

From the study it is anticipated that the researcher will:

- 1. Devise a client centred treatment manual
- 2. Show effectiveness of reattribution therapy

#### Secondary outcome measures

Not provided at time of registration

#### Overall study start date

15/11/2000

#### Completion date

30/11/2004

## Eligibility

#### Key inclusion criteria

Four patients in initial case series and then 186 patients aged 16-64 of whom 50% (n=93) will be randomised into the treatment group and 50% into the control group (n=93).

These participants will be selected from people of this age group who are referred to the Liaison Mental Health Service with medically unexplained symptoms according to physicians or surgeons.

#### Participant type(s)

**Patient** 

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

#### Target number of participants

186

#### Key exclusion criteria

Clients presenting with Diagnostic and Statistical Manual of Mental Disorders, Fourth edition (DSM IV) organic or psychiatric mental disorders, alcohol and drug dependance or abuse, borderline personality disorder, inability to converse fluently in English will not be included in the research.

#### Date of first enrolment

15/11/2000

#### Date of final enrolment

30/11/2004

#### Locations

#### Countries of recruitment

England

United Kingdom

# Study participating centre Royal Liverpool University Hospital

Liverpool United Kingdom L7 8XP

# Sponsor information

#### Organisation

Department of Health (UK)

#### Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL

#### Sponsor type

Government

#### Website

http://www.doh.gov.uk

# Funder(s)

#### Funder type

Government

#### Funder Name

Mersey Care NHS Trust (UK)

### **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