# Clinical and cost-effectiveness of a cognitive behavioural intervention for improved selfmanagement in adults with psychological complications of asthma

| Submission date 23/01/2004          | <b>Recruitment status</b><br>No longer recruiting | <ul> <li>Prospectively registered</li> <li>Protocol</li> </ul>                       |
|-------------------------------------|---|--|
| <b>Registration date</b> 23/01/2004 | <b>Overall study status</b><br>Completed          | <ul> <li>Statistical analysis plan</li> <li>Results</li> </ul>                       |
| Last Edited<br>02/06/2017           | <b>Condition category</b><br>Respiratory          | <ul> <li>Individual participant data</li> <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** Prof Glenys Parry

#### **Contact details**

School of Health and Related Research Regents Court 30 Regents Street Sheffield United Kingdom S1 4DA +44 (0)114 222 0768 g.d.parry@sheffield.ac.uk

## Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

## Study information

#### Scientific Title

Clinical and cost-effectiveness of a cognitive behavioural intervention for improved selfmanagement in adults with psychological complications of asthma

#### **Study objectives**

Research evidence suggests that NHS costs of treatment of asthma in adults are associated with psychosocial factors, including for some patients, dysfunctional health beliefs and high levels of panic-fear. Clinical research and pilot work provides prima facie evidence that a brief cognitive behavioural intervention can significantly reduce levels of panic-fear, and hence service-usage. This project will estimate the proportion of a defined population who would benefit from an effective psychological intervention for improved self management of chronic asthma and compares the outcomes (clinical, psychological, economic and quality of life) for a randomly selected group of patients with psychological complications receiving a brief cognitive behavioural intervention, compared to a control group receiving standard medical treatment. The two phases of the project will yield cost-effectiveness data which can be generalised to give estimates of health gain and costs savings for a given population of known asthma and panic-fear prevalence.

#### 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 Asthma

Interventions

Patients are randomised to: 1. Cognitive behavioural therapy 2. Care as usual

**Intervention Type** Other

**Phase** Not Applicable

**Primary outcome measure** Not provided at time of registration

**Secondary outcome measures** Not provided at time of registration

Overall study start date 01/09/1997

Completion date 01/03/2001

## Eligibility

**Key inclusion criteria** Asthma patients with psychological complications

**Participant type(s)** Patient

**Age group** Not Specified

**Sex** Not Specified

**Target number of participants** Not provided at time of registration

**Key exclusion criteria** Not provided at time of registration

Date of first enrolment 01/09/1997

Date of final enrolment 01/03/2001

## Locations

**Countries of recruitment** England

United Kingdom

**Study participating centre School of Health and Related Research** Sheffield United Kingdom S1 4DA

### Sponsor information

Organisation

Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

#### **Sponsor details**

The Department of Health 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** NHS Asthma National Research and Development Programme (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