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Cognitive therapy for sickle cell disease (SCD) pain

Submission date	Recruitment status	[_] Prospectively registered
23/01/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/07/2011	Haematological 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
REC00056

Study information

Scientific Title

Study objectives
Painful crises are the most common manifestation of sickle cell disease and accounts for the greatest number of admissions with an average length of stay of seven days. This causes severe disruption to the educational and social aspects of life for these patients. The financial implications for the health service are also considerable. A recent analysis revealed a cost of £2.5 million per annum for South East London Health Authority. Research conducted in America revealed that pain management strategies that incorporate a psychological intervention can significantly reduce casualty visits and hospital admissions. A pilot study using cognitive therapy has been carried out to assess the feasibility of using this approach in patients with Sickle Cell Disease in London. Results have shown that patients are generally very positive about this approach and consider it to be beneficial in terms of reducing psychological distress, providing emotional support and in improving confidence levels. There was a significant reduction in the duration of hospital stay when compared to the control group.

The present study seeks to extend the pilot study by evaluating of a community-based cognitive therapy intervention of the pain experience and well-being of 120 adolescents and young adults with sickle cell disease. The result of this study is likely to make significant contributions to knowledge by providing detailed information about the types of coping strategies used by patients with SCD. In addition information gained will enable us to determine whether the proposed intervention is cost effective and beneficial to a group of patients whose pain is notoriously difficult to manage.

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)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Sickle cell anaemia

Interventions
1. A cognitive behavioural therapy pain management group
2. An attention placebo group
3. Non-intervention control group

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Patient self-assessments: GHQ 30, Coping Strategies Questionnaire (CSQ), Pain Self Efficacy Questionnaire, Short Form McGill Pain Questionnaire

Secondary outcome measures
Not provided at time of registration

Overall study start date
31/12/1996

Completion date
31/12/1998

Eligibility

Key inclusion criteria
Male and female SCD patients with the SS genotype between 15 and 26 years of age, who have had three or more admissions in the previous calendar year.

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
31/12/1996

Date of final enrolment
31/12/1998

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London
London
United Kingdom
SE1 8WA

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
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Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive London (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2001		Yes	No