

Cognitive therapy for sickle cell disease (SCD) pain

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 25/07/2011	Condition category Haematological Disorders	<input type="checkbox"/> Individual participant data

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

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Sponsor type

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Website

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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