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A study of the long-term and short-term efects of Snoezelen and Reminiscence therapy on patients suffering from dementia who have associated agitated behavior problems

Submission date
12/09/2003

Recruitment status
No longer recruiting

Registration date
12/09/2003

Overall study status
Completed

Last Edited
30/07/2009

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
N0081063463

Study information

Scientific Title

Study objectives
What effect does Snoezelen have on the behaviour and physiological responses of people with dementia who exhibit agitated behaviour, and how do these effects compare to those resulting from a more traditional form of therapy, such as Reminiscence?

As of 28/07/09 the target number of participants was updated from "not provided at time of registration" to 20 as detailed in 2004 results.

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
Mental and Behavioural Disorders: Dementia

Interventions
Comparative group study. Subjects randomly allocated to one of two groups.
Each group will receive an initial introductory Snoezelen session after initial baseline assessments and observations.

Group 1 will then receive three Snoezelen sessions over 2 weeks, 1 week without intervention and then three reminiscence sessions over a further 2 weeks.
Group 2 will follow the same pattern, but will have reminiscence therapy first.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Heart rate reduction
2. Frequency of observed agitated behaviour (Agitated Behaviour Mapping Instrument) after each session
3. Frequency of agitated behaviour (Cohen-Mansfield Agitation Inventory) after each intervention and at 2-week follow-up

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/02/2000

Completion date
30/09/2006

Eligibility

Key inclusion criteria
1. Subjects will have dementia and be reported by staff as exhibiting significant agitated behaviour, known to psychiatric services and either day patients or on an organic assessment ward.
2. No age limit will be applied but the range is expected to be between 55-85.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
20 (8 male, 12 female) (added 28/07/09)

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment

01/02/2000

Date of final enrolment
30/09/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Psychiatry for the Elderly
Leicester
United Kingdom
LE5 4PW

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
Hospital/treatment centre

Funder Name

Leicestershire Partnership 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2004		Yes	No