

A study of the long-term and short-term effects 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	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 30/07/2009	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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

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