

Pilot study of the short-term effects of a multi-sensory environment (MSE) on elderly patients suffering from depression.

Submission date 30/09/2004	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2004	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 28/09/2011	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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

N0081129523

Study information

Scientific Title

Study objectives

This is a pilot study. The main aim of which is to assess the appropriateness of the recruitment criteria, feasibility of the schedule of measures and the acceptability of the measures to the subjects.

A secondary aim is to identify whether there are any large effects of the interventions which may be useful in refining the methodology of the definitive study.

Multi-Sensory Environments (MSE) are widely used in paediatrics, pain clinics, maternity facilities and in the care of the elderly with dementia. Studies have shown improvements in mood, enjoyment and levels of boredom, with increased relaxation and reduced agitation. Anecdotal evidence on the benefits of MSE in depression in the elderly points to a potential benefit which should be explored.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled pilot study

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

Mental and Behavioural Disorders: Depression

Interventions

1. Intervention Group (two one-to-one sessions in the MSE over one week)
2. Control Group (two one-to-one relaxation sessions over one week)

Added 21 August 2008: This trial was stopped because the facilities required to carry out the research (i.e. the multi-sensory environment) were closed and no other alternatives were available locally.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Hospital Anxiety and Depression Scale (HADS)
2. Beck Depression Inventory (BDI)
3. Visual Analogue Scales of Mood
4. Heart Rate Monitoring

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/09/2003

Completion date

01/05/2005

Reason abandoned (if study stopped)

Lack of facilities

Eligibility**Key inclusion criteria**

12 subjects aged 65+ randomised to intervention or control, with a clinical diagnosis of depressive illness and capacity to give consent.

Participant type(s)

Patient

Age group

Senior

Sex

Not Specified

Target number of participants

12

Key exclusion criteria

1. Organic brain syndrome
2. Significant hearing impairment
3. Significant sight impairment

4. Suicidal ideation
5. Electroconvulsive therapy (ECT) during course of trial
6. Evidence of delirium or change in psychotropic medication will trigger withdrawal

Date of first enrolment

01/09/2003

Date of final enrolment

01/05/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Leicester

Leicester

United Kingdom

LE5 4PW

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

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