ISRCTN61466356 https://doi.org/10.1186/ISRCTN61466356

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

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2004	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2004	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/09/2011	Mental and Behavioural Disorders	[ ] 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

Protocol serial number
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

Study type(s)
Not Specified

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(s)
1. Hospital Anxiety and Depression Scale (HADS)
2. Beck Depression Inventory (BDI)

3. Visual Analogue Scales of Mood
4. Heart Rate Monitoring

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Senior

Sex
Not Specified

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 psychotropis medication will trigger withdrawal

Date of first enrolment
01/09/2003

Date of final enrolment
01/05/2005

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Leicester
Leicester
United Kingdom
LE5 4PW

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Leicestershire Partnership NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration