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The use of alternative therapies to treat geriatric depression

Submission date	Recruitment status	[X] Prospectively registered
29/03/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/05/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/05/2008	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Evaluating the effects of music and animal-assisted therapy on depression in aged care residents

Study objectives
The primary aim of this randomised clinical study is to evaluate the efficacy of two alternative therapies, music therapy (MT) and animal-assisted therapy (AAT), to reduce depressive symptomatology in cognitively intact elderly individuals residing in aged care facilities. A secondary aim of this study is to explore neurophysiological mechanisms that may underpin any observed effects of the alternative therapy interventions. The following hypotheses have been formulated on the basis of the above aims:
1. MT and AAT will improve quality of life and reduce the physical, cognitive, affective and interpersonal deficits associated with depression in the elderly to a greater extent than the no intervention control group
2. MT and AAT will produce observable changes in electroencephalogram (EEG) indices of depression to a greater extent than the no intervention control condition
3. Changes observed in psychological indices of depression will correlate with changes observed on physiological measures of depression

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Monash University Standing Ethics Committee on Research Involving Humans (SCERH) on the 20th February 2008

Study design
A multicentre, double-blind, nested, randomised controlled trial with three independent groups

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Depression

Interventions

Experimental conditions:
Music therapy and animal-assisted therapy will each be presented by accredited therapists twice weekly to small groups (N = 5) for four weeks, yielding a total of eight therapeutic sessions. Therapy session will last approximately 45 minutes. Music therapy will comprise listening to preferred music, singing, and playing percussion instruments. Animal-assisted therapy will comprise activities with a temperament-tested dog, such as patting, grooming, playful interaction and watching the animal perform tricks. Participants assigned to either treatment will continue to receive diversional activities already in place at their respective facilities.

Control condition:
The non-intervention control group will continue to receive diversional activities already in place at the respective facilities, but will not receive an additional treatment.

Post-intervention measures will be taken the week after the interventions have been completed and post-testing will take one week to complete per facility.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Affective: symptoms of depression will be measured with the mood disorder module of the Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders IV (SCID-IV-TR) and the GDS
2. Cognitive: general cognitive status will be assessed using the SMMSE. The more specific domain of executive functioning will be assessed using the Trail Making Test Part A and B, Digit-Symbol Coding and the Controlled Oral Word Association Test (COWA).
3. General health and well-being: assessed using the Australia Quality of Life (AQoL) Scale. Pain will be assessed the Present Pain Index (PPI) and the Modified Cumulative Illness Rating Scale (MCIRS).

All outcomes will be measured over the course of four days prior to the four week intervention period and in the week following treatment.

Secondary outcome measures
Neurophysiological measures:
Two EEG components will be explored. First, previous research has indicated that depression is associated with relative left frontal asymmetry and that pharmacological and psychological treatment for depression may normalise this brain activity pattern. Second, abnormal P300 responses (such as reduced amplitude and increased latency) have also been observed in individuals with depression. Given these findings, this study will explore the effect of alternative therapies on the topographic distribution of spectral power and the amplitude and latency of the P300 evoked potential.

All outcomes will be measured over the course of four days prior to the four week intervention period and in the week following treatment.

Overall study start date
01/06/2008

Completion date
30/08/2009

Eligibility

Key inclusion criteria
1. Adults (65+ years), either sex
2. A score of at least 20 on the Standardised Mini Mental Status Examination (SMMSE)
3. A score of at least 5 on the Geriatric Depression Scale (GDS)
4. English fluency

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
150 in total

Key exclusion criteria
1. Diagnosis of dementia or delirium
2. Significant hearing or vision impairments
3. Unable to provide informed consent (due to mental status)
4. Placed in the facility within the previous three weeks

Date of first enrolment
01/06/2008

Date of final enrolment
30/08/2009

Locations

Countries of recruitment
Australia

Study participating centre
School of Psychology, Psychiatry and Psychological Medicine
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Sponsor type
University/education

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ROR
https://ror.org/02bfwt286

Funder(s)

Funder type
Charity

Funder Name
J.O. & J.R. Wicking Trust (Australia and New Zealand [ANZ] Trustees) (Australia)

Funder Name
Monash University (Australia)

Alternative Name(s)
Monash Uni | Melbourne, Monash Uni, University of Monash, Universitas Monash, MU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Australia

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