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Investigating cognitive effects of aromatherapy on people with dementia living in residential care facilities

Submission date	Recruitment status	[ ] Prospectively registered
09/06/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/09/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/11/2006	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
ECN-04-201

Study information

Scientific Title

Acronym
Aromatherapy trial

Study objectives
Twelve weeks of aromatherapy treatment with the active oil blend will show a statistically significant improvement in participants cognitive ability and behavioural characteristics compared to baseline

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at registration time

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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

Interventions
The 'active' treatment will contain 1 ml each of Cypress (Cupressus sempervirens), Lime (Citrus latifolia) and Eucalyptus (Eucalyptus globulus) essential oils, diluted in a non-fragranced aqueous cream lotion.

The 'inactive' preparation will contain 1 ml each of Ginger (Zingiber officinalis), Lemongrass (Cymbopogon citratus) and Mandarin (Citrus recticulata) essential oils, diluted in a non-fragranced aqueous cream lotion.

The placebo preparation will contain only non-fragranced aqueous cream lotion and will be used during the washout periods. An important purpose of the placebo is to control for the possible effect of touch.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Cypress (Cupressus sempervirens), Lime (Citrus latifolia) and Eucalyptus (Eucalyptus globulus)

Primary outcome measure
The primary outcome measure will be the difference in mean baseline and endpoint scores on the standardised Mini-Mental State Examination (MMSE) (Molloy et al., 1991). The MMSE is the standard scale used by aged care facilities for assessing the stage of dementia and cognitive function of their residents.

The annual rate of change on the MMSE for people with a base-line score between 7-28 is a decrease of 3.6 points per year, or about 0.9 points per 12 weeks (Swanwick et al., 1998). A typical Alzheimer's drug trial reports a mean MMSE increase over 12 weeks between 0.8 and 2.3 points for a similar population.

Secondary outcome measures
Secondary outcome measures will be:
1. Difference in baseline, repeated measures and endpoint scores on the Nurses Observation Scale for Geriatric Patients (NOSGER) (Spiegel et al. 1991)
2. Changes in the use of other medications related to cognitive and behavioural functions (for example, anti-depressants, anti-psychotics)
3. Correlation between ability to smell the treatments and end-point scores on MMSE and NOSGER

Overall study start date
01/04/2005

Completion date
30/09/2005

Eligibility

Key inclusion criteria
Residents in good health will be invited to participate in the treatment arms of the study if they also comply with the following criteria. They must:
1. Have been living in the nursing home for more than 3 months
2. Be more than 65 years old
3. Already be on an aromatherapy care plan; or deemed by the Director of Care or the care staff

to be unlikely to be disturbed by the use of the aromatherapy lotion in place of their normal skin integrity lotion
4. Have English as their first language

They must also have:
5. A Mini-Mental State Examination (MMSE) score of 10-26
6. A diagnosis of dementia, short-term memory loss or cognitive impairment that is not caused by any other diagnosis of mental illness

7. Residents with non-acute concomitant diseases may participate if their disease is medically controlled.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
100-130 people

Key exclusion criteria
1. Had a myocardial infarction or stroke in previous 3 months
2. Epilepsy
3. Current treatment with anti-cholinesterase or anti-cholinergic drugs
4. Eczema, psoriasis or dermatitis around the neck and shoulders area
5. Known allergy to Eucalyptus, Cypress, Ginger, Lemongrass, Lime or Mandarin essential oils or aqueous cream
6. An adverse reaction to treatment patch-tests given during screening process
7. Vision or hearing impairments that prevent them from undertaking the cognitive test

Date of first enrolment
01/04/2005

Date of final enrolment
30/09/2005

Locations

Countries of recruitment
Australia

Study participating centre

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Sponsor information

Organisation
Australian Centre for Complementary Medicine, Education and Research (ACCMER)

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Sponsor type
Research organisation

Funder(s)

Funder type
Research organisation

Funder Name
Post graduate funding from Australian Centre for Complementary Medicine, Education and Research (ACCMER) and the School of Natural and Complementary Medicine

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