A comparative evaluation of Lavender (Lavendula augustifolia) and Geranium (Perlargonium species e.g. P. odoratissiumum, P. extipulatum, P. x fragrans) aromatherapy oils in participants with mild to moderate insomnia

Submission date 24/10/2005	Recruitment status No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 16/11/2005	Overall study status Completed	 Statistical analysis plan Results
Last Edited 18/10/2016	Condition category Mental and Behavioural Disorders	 Individual participant data 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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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

A comparative evaluation of Lavender (Lavendula augustifolia) and Geranium (Perlargonium species e.g. P. odoratissiumum, P. extipulatum, P. x fragrans) aromatherapy oils in participants with mild to moderate insomnia

Study objectives

To examine the credibility and effect size of lavender oil and geranium as potential treatments for mild insomnia and almond oil as a placebo.

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) Not specified

Study type(s) Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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

Interventions Aromatherapy oils - lavender oil versus geranium oil versus almond oil (placebo)

Intervention Type Other

Primary outcome measure

1. Actigraphic data obtained from wrist worn actigraphs

2. Subjective sleep status assessed with the PSQI

Secondary outcome measures

1. Leeds Sleep Evaluation Questionnaire

2. Borkovec and Nau Questionnaire

Overall study start date

01/12/2005

Completion date

30/04/2006

Eligibility

Key inclusion criteria

1. Healthy individuals

- 2. Aged 20-55 years
- Informed consent

4. Mild to moderate persistent insomnia defined as a Pittsburgh Sleep Quality Index Score within the range 5-14 assessed over the preceding month, and with a minimum of 3 weeks duration

Participant type(s)

Patient

Age group Adult

Sex

Both

Target number of participants

12

Key exclusion criteria

- 1. Anosmic
- 2. Menopausal women
- 3. Pregnancy (or planning to become pregnant during the trial period)
- 4. Children under 3 years
- 5. Acutely ill
- 6. Systemic illness affecting their sleep
- 7. Recently treated with aromatherapy
- 8. Suffering from any recognised sleep pathology other than insomnia

9. Taking long-term medication (except oral contraceptives) or any short-term medication which may affect their natural sleep patterns

10. Previous hypersensitivity or allergy to aromatherapy or related products

Date of first enrolment

01/12/2005

Date of final enrolment 30/04/2006

Locations

Countries of recruitment England

United Kingdom

Study participating centre Aldermoor Health Centre Southampton United Kingdom SO16 5ST

Sponsor information

Organisation University of the West of England (UK)

Sponsor details Coldharbour Lane Bristol England United Kingdom BS16 1QY

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Sponsor type University/education

ROR https://ror.org/02nwg5t34

Funder(s)

Funder type University/education

Funder Name

University of Southampton Fourth Year Medical Student Project

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