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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	Recruitment status	[X] Prospectively registered
24/10/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/11/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/10/2016	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

Contact name
Dr George Lewith

Contact details
Primary Medical Care
Aldermoor Health Centre
Aldermoor Close
Southampton
United Kingdom
SO16 5ST
+44 (0)2380 241073
gl3@soton.ac.uk

Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
1. Actigraphic data obtained from wrist worn actigraphs
2. Subjective sleep status assessed with the PSQI

Key secondary outcome(s))
1. Leeds Sleep Evaluation Questionnaire
2. Borkovec and Nau Questionnaire

Completion date
30/04/2006

Eligibility

Key inclusion criteria

1. Healthy individuals
2. Aged 20-55 years
3. 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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
University of the West of England (UK)

ROR
https://ror.org/02nwg5t34

Funder(s)

Funder type
University/education

Funder Name
University of Southampton Fourth Year Medical Student Project

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration