# A randomised controlled trial of aromatherapy massage as a treatment for the symptoms of anxiety in clients with serious mental illness

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
29/09/2006	No longer recruiting	∐ Protocol
Registration date	Overall study status	Statistical analysis plan
29/09/2006	Completed	☐ Results
Last Edited	Condition category	Individual participant data
31/03/2020	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 Steve Moores

#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

#### Secondary identifying numbers

N0321166096

# Study information

#### Scientific Title

A randomised controlled trial of aromatherapy massage as a treatment for the symptoms of anxiety in clients with serious mental illness

#### **Study objectives**

Primary hypothesis: that aromatherapy massage will reduce anxiety in clients having serious mental disorders, as measured by standardised assessments over a six-week period. This will be tested in a randomised controlled trial against a control group who will remain untreated temporarily on a six-week waiting list.

#### 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

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

Mental and Behavioural Disorders: Anxiety

#### Interventions

- 1. Group receiving aromatherapy massage
- 2. Group temporarily not receiving aromatherapy massage

#### Intervention Type

Other

#### Phase

**Not Specified** 

#### Primary outcome measure

Trait and State anxiety assessment by self-completed, standardised inventories: Hospital Anxiety and Depression Scale (HADS), General Health Questionnaire (GHQ-30); State--Trait Anxiety Inventory (STAI-30).

Physiological measurement of blood pressure, pulse rate and breathing rate.

#### Secondary outcome measures

Not provided at time of registration

#### Overall study start date

20/09/2004

#### Completion date

24/11/2005

# **Eligibility**

#### Key inclusion criteria

Clients of community health teams in Bournemouth, Poole or Dorset who have a diagnosis of serious mental disorder of a non-psychotic nature (regarding affective disorders) and require specialist anxiety therapy for a concurrent/principal anxiety state. Clients will be referred by their care-coordinator under CPA (Care Plan Approach) on standard or enhanced care.

#### Participant type(s)

Patient

#### Age group

Adult

#### Sex

**Not Specified** 

#### Target number of participants

61

#### Kev exclusion criteria

People with psychotic disorders or drug/alcohol dependency problems.

#### Date of first enrolment

20/09/2004

#### Date of final enrolment

24/11/2005

# Locations

#### Countries of recruitment

England

#### **United Kingdom**

Study participating centre West Bournemouth CMHT Bournemouth United Kingdom BH2 5JW

# Sponsor information

#### Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

#### Sponsor details

The Department of Health, Richmond House, 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

#### Sponsor type

Government

#### Website

http://www.dh.gov.uk/Home/fs/en

# Funder(s)

## Funder type

Government

#### **Funder Name**

Dorset Healthcare NHS Trust (UK)

# **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