

# Can the behavioural symptoms of people severely affected by dementia be effectively and safely managed without use of regular psychotropic medication?

<b>Submission date</b> 02/08/2002	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 02/08/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/08/2011	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://www.csm-oxford.org.uk/index.asp?o=1127>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

QRD/2002/01/01

## **Study information**

**Scientific Title**

**Acronym**

FITS

**Study objectives**

Many people with dementia are prescribed antidepressants and minor or major tranquillizers. This may be appropriate treatment for psychiatric symptoms such as depression, hallucinations or delusions, but use of these drugs to control behavioural symptoms that may arise out of agitation for example is controversial. Major tranquillizers are highly effective in the treatment of hallucinations and delusions, but the little evidence that we have suggests that they have only modest efficacy in improving behavioural symptoms. In contrast to the lack of evidence that these drugs are helpful in the treatment of people with dementia, there are clear costs associated with their use. All of these drugs have side-effects to which people with dementia are particularly sensitive. Further, some researchers believe that use of these drugs may be associated with an accelerated decline in dementia.

The aim of this trial is to test the effectiveness and acceptability of alternatives to regular psychotropic prescription within those people with dementia who present the most serious behavioural problems and who would thus be most likely to receive drug treatment.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

No ethics information required at time of registration.

**Study design**

Cluster 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**

Focused Intervention Training and Support (FITS) package delivered to Care staff within Continuing Care facilities versus a simple staff support group

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

1. Determine whether this approach reduces the need for neuroleptics and other sedative medications
2. To measure the safety of this intervention
3. Determine whether this improves the quality of life of those people with dementia resident in such facilities
4. To examine whether a positive intervention on residents has a beneficial effect on staff

### **Secondary outcome measures**

Not provided at time of registration

### **Overall study start date**

01/06/2003

### **Completion date**

01/02/2005

## **Eligibility**

### **Key inclusion criteria**

Being a continuing care facility providing care for people with severe dementia

### **Participant type(s)**

Patient

### **Age group**

Senior

### **Sex**

Both

### **Target number of participants**

340 (170 per arm)

### **Key exclusion criteria**

Not applicable

**Date of first enrolment**

01/06/2003

**Date of final enrolment**

01/02/2005

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Division of Psychological Medicine**

London

United Kingdom

SE5 8AF

## **Sponsor information**

**Organisation**

Alzheimer's Society (UK)

**Sponsor details**

Gordon House

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enquiries@alzheimers.org.uk

**Sponsor type**

Charity

**ROR**

<https://ror.org/0472gwq90>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

Alzheimer's Society, The Community Fund (RG 24052)

## 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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/04/2006		Yes	No