ISRCTN45577048 https://doi.org/10.1186/ISRCTN45577048

# Randomised double-blind placebo controlled trial of effect of Ginkgo biloba on cognitive function in mild-moderate dementia

**Submission date**
02/08/2002

**Registration date**
02/08/2002

**Last Edited**
11/07/2007

**Recruitment status**
No longer recruiting

**Overall study status**
Completed

**Condition category**
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**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
QRD/2001/01/07

# Study information

### Scientific Title

### Acronym
DIGGER

### Study objectives
Null Hypothesis: high purity ginkgo biloba extract does not improve cognition quality of life or carer burden in individuals with mild-moderate dementia. NB: this study will also assess the magnitude of the Hawthorne effect in dementia trials.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Received from Multi-centre Research Ethics Committee (ref: MREC/02/6/35).

### Study design
Randomised double-blind placebo controlled parallel group study

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
GP practice

### Study type(s)
Not Specified

### Participant information sheet

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

### Interventions
1. The active intervention will be concentrated, standardised Ginkgo biloba extract (25% active Ginkgo-flavoneglycosides), prepared according to accepted guidelines in a 60 mg tablet (EGB-761, Schwabe)
2. The placebo will be 60 mg of inert lactose with 2 mg quinine sulphate

### Intervention Type
Drug

### Phase
Not Specified

### Drug/device/biological/vaccine name(s)
Ginkgo extract

### Primary outcome measure
Alzheimer's Disease Assessment Scale Cognitive Subscale (ADAS-cog) at six months.

### Secondary outcome measures
All at six months:
1. Participant: Quality of Life scale in Alzheimers disease (QoL-AD), Neuropsychiatric Inventory questionnaire (NPI), Geriatric Evaluation by Relative's Rating Instrument (GERRI), adverse events
2. Carer: European Quality of life questionnaire (EQ-5D), Zarit caregiver Burden Interview (ZBI)

### Overall study start date
01/04/2003

### Completion date
31/12/2005

## Eligibility

### Key inclusion criteria
1. Aged 55 years and over
2. Clinician's diagnosis of dementia
3. Presence of a carer
4. Consent of patient and carer
5. Sufficient command of English to complete questionnaires
6. Mini Mental State Examination (MMSE-23) score of 15 - 24

### Participant type(s)
Patient

### Age group
Senior

### Sex
Both

### Target number of participants
Target: 200

### Key exclusion criteria
1. Commencement of acetylcholinesterase therapy within two months of recruitment
2. Current anticoagulant therapy
3. Abnormal clotting profile

### Date of first enrolment

01/04/2003

**Date of final enrolment**
31/12/2005

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**Senior Lecturer**
London
United Kingdom
W10 6DZ

# Sponsor information

**Organisation**
Alzheimer's Society (UK)

**Sponsor details**
Gordon House
10 Greencoat Place
London
United Kingdom
SW1P 1PH
+44 (0)20 7306 0606
enquiries@alzheimers.org.uk

**Sponsor type**
Charity

**ROR**
https://ror.org/0472gwq90

# Funder(s)

**Funder type**
Charity

**Funder Name**
Alzheimer's Society (UK)

**Alternative Name(s)**
alzheimerssoc

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Associations and societies (private and public)

**Location**
United Kingdom

# 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? |
|---|---|---|---|---|---|
| Results article | Results | 03/07/2007 | | Yes | No |