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# Adjunctive Dietary Intervention study for Challenging Behaviour in people with an Intellectual Disability: a randomised double blind placebo controlled multicentre clinical trial

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 06/09/2005 | Stopped | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 07/10/2005 | Stopped | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 09/03/2015 | 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

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## Additional identifiers

**Protocol serial number**
SGUL/SWLSG 001

# Study information

### Scientific Title
Adjunctive Dietary Intervention study for Challenging Behaviour in people with an Intellectual Disability: a randomised double blind placebo controlled multicentre clinical trial

### Acronym
ADICBID

### Study objectives
Dietary intervention using multivitamins is able to reduce challenging behaviour in a learning disabled adult population.

### 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
Challenging behaviour in an intellectually disabled population

### Interventions
Active multivitamin compound versus placebo.

Please note that as of 17/09/2007 this trial was put on hold due to funding issues.

### Intervention Type
Supplement

### Primary outcome(s)
Reduction in frequency and intensity of challenging behaviours

### Key secondary outcome(s))
Improvements to quality of life and social functioning

### Completion date
01/10/2008

### Reason abandoned (if study stopped)
Lack of funding/sponsorship

# Eligibility

### Key inclusion criteria
1. People aged between 18 and 70
2. People with a learning disability able to show consent or assent to inclusion
3. Challenging behaviour with a frequency averaging at least once a month in the three months prior to admission to the study
4. Existing medication usage will be allowed during the trial. There is no need to stop or change medication that the client is already taking.
5. The person must be living in a setting where there is help to fill in diaries and someone from whom objective reports are available. This will include family, residential homes or inpatient centres

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
1. Explicit refusal to participate
2. Living independently
3. Acute Mental Illness (chronic stable mental illness is allowed)
4. Full autism diagnosis (this does not include single autistic features without the full diagnosis)
5. Vegetarian
6. Allergy to vitamins or fish oils

### Date of first enrolment
01/10/2006

### Date of final enrolment
01/10/2008

# Locations

### Countries of recruitment
United Kingdom

England

**Study participating centre**
**St George's, University of London**
London
United Kingdom
SW17 0RE

# Sponsor information

**Organisation**
St George's, University of London (UK)

**ROR**
https://ror.org/040f08y74

# Funder(s)

**Funder type**
Other

**Funder Name**
No funding as of 17/09/2007

# Results and Publications

## 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? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |