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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Reduction in frequency and intensity of challenging behaviours

Secondary outcome measures
Improvements to quality of life and social functioning

Overall study start date
01/10/2006

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200 (100 per group)

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
England

United Kingdom

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

Sponsor information

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

Sponsor details
Cranmer Terrace
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rmukherj@sgul.ac.uk

Sponsor type
University/education

Website
http://www.sgul.ac.uk

ROR

https://ror.org/040f08y74

Funder(s)

Funder type
Other

Funder Name
No funding as of 17/09/2007

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