ISRCTN17723526 https://doi.org/10.1186/ISRCTN17723526

The effectiveness and cost effectiveness of treatment by homeopaths or nutritional therapists in addition to usual care for children with attention deficit hyperactivity disorder (ADHD)

Submission date
10/04/2015

Recruitment status
No longer recruiting

Registration date
27/04/2015

Overall study status
Completed

Last Edited
26/05/2021

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Attention deficit hyperactivity disorder (ADHD) is a group of behavioural symptoms that include inattentiveness, hyperactivity and impulsiveness. ADHD has a big impact on the long term health care, education and criminality of diagnosed individuals. Children with a diagnosis of ADHD are at high risk of bad behaviour, such as early criminal behaviour, being disruptive in school and antisocial behaviour. Evidence suggests that while current treatments work well in the short term, they are not improving these long term negative behaviours. ADHD is managed mainly by health services where behavioural therapies and drug treatments are the main options offered. There are also various complementary and alternative medicine (CAM) treatments available to people affected by ADHD. Homeopathy, a 'treatment' based on the use of highly diluted substances, is a CAM sometimes sought by people to treat mental health symptoms, such as those seen in ADHD. Some parents say that using CAM treatments helps manage their children's symptoms, but there is little evidence to support these claims. Good quality evidence is needed to see whether the CAM treatments parents are trying might actually help children with ADHD. The aim of this study is to see whether treatment by homeopaths or treatment by nutritional therapists have any effect on the symptoms of ADHD when used alongside the usual treatments given to children.

Who can participate?
Children diagnosed with ADHD.

What does the study involve?
Participants are randomly allocated into one of three groups. Those in group 1 (intervention group) receive treatment by homeopaths. Those in group 2 (intervention group) receive 'treatment by nutritional therapists alongside their usual treatments. Those in group 3 (control group) receive their usual treatments. Parents and teachers of participating children are asked

to complete questionnaires relating to the child's behaviour 6 months after the start of the study.

What are the possible benefits and risks of participating?
There are no benefits or risks associated with this study.

Where is the study run from?
University of Sheffield (UK)

When is the study starting and how long is it expected to run for?
September 2015 to September 2017

Who is funding the study?
The Homeopathy Research Institute (UK)

Who is the main contact?
Mrs P Fibert (scientific)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
A pragmatic cohort randomised controlled trial of the clinical and cost effectiveness of treatment by homeopaths or nutritional therapists in addition to usual care, compared to usual care alone, for children with attention deficit hyperactivity disorder (ADHD)

Study objectives
Current hypothesis as of 05/08/2015:
The aim of this study is to see whether adjunct treatment by homeopaths or nutritional therapists is clinically- and/or cost-effective and acceptable for children with attention deficit hyperactivity disorder (ADHD). We will also assess whether the cohort multiple randomised controlled trial design is feasible to generate evidence about the acceptability, clinical and cost effectiveness of treatment by homeopaths or nutritional therapists for ADHD.

Previous hypothesis:
The aim of this study is to see whether adjunct treatment by homeopaths or polyunsaturated fatty acids is clinically- and/or cost-effective and acceptable for children with attention deficit hyperactivity disorder (ADHD). We will also assess whether the cohort multiple randomised controlled trial design is feasible to generate evidence about the acceptability, clinical and cost effectiveness of treatment by homeopaths or polyunsaturated fatty acids for ADHD.

On 05/08/2015 the following changes were made to the trial record:
1. The public title was changed; the previous public title was 'The effectiveness and cost effectiveness of treatment by homeopaths or polyunsaturated fatty acids in addition to usual care for children with attention deficit hyperactivity disorder (ADHD)'
2. The scientific title was changed; the previous scientific title was 'A pragmatic cohort randomised controlled trial of the clinical and cost effectiveness of treatment by homeopaths or polyunsaturated fatty acids in addition to usual care, compared to usual care alone, for children with attention deficit hyperactivity disorder (ADHD)'

Ethics approval required
Old ethics approval format

Ethics approval(s)
School of Health and Related Research at Sheffield University, 31/04/2015, ref: 003424, amendment sanctioned 05/08/2015

Study design
Pragmatic trial using the cohort multiple randomised controlled trial design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Attention deficit hyperactivity disorder (ADHD)

Interventions
Current interventions as of 05/08/2015:
1. Individualised treatment provided by homeopaths in addition to usual care
2. Individualised treatment by nutritional therapists in addition to usual care
3. Usual care (control)

Previous interventions:
1. Individualised treatment provided by homeopaths in addition to usual care
2. Polyunsaturated fatty acids (EPA omega-3 and GLA omega-6) in addition to usual care
3. Usual care (control)

Intervention Type
Supplement

Primary outcome measure
Conners' Global Index (CGI) psychopathology questionnaire at 6 months post-baseline (parent /teacher report).

Secondary outcome measures
1. Wellbeing: assessed using Child Health Utility (CHU-9D) index (6 months; parent questionnaire).
2. School performance: classroom disruptiveness; school attendance and school exclusion (6 months; teacher questionnaire).
3. Criminality: contact with the criminal justice system (6 months; parent questionnaire).
4. Emotional lability: 3 questions from CGI (6 months; parent questionnaire).

Overall study start date
01/09/2015

Completion date
01/02/2018

Eligibility

Key inclusion criteria
1. Parent reported clinical diagnosis of ADHD
2. CGI T-score of at least 55
3. Age 5-18

4. Able to speak and read English
5. Informed consent (parent and child)

Participant type(s)
Patient

Age group
Child

Lower age limit
5 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
134

Total final enrolment
144

Key exclusion criteria
1. Children with terminal conditions such as cancer
2. Families where English is not written or spoken
3. Children currently receiving treatment by a homeopath or taking polyunsaturated fatty acids
4. Children with CGI T-score less than 55
5. Children who are vegetarians (PUFA arm)

Date of first enrolment
01/09/2015

Date of final enrolment
01/09/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Sheffield
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S1 4DA

Sponsor information

Organisation
University of Sheffield

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Sponsor type
University/education

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

ROR
https://ror.org/05krs5044

Funder(s)

Funder type
Research organisation

Funder Name
The Homeopathy Research Institute

Results and Publications

Publication and dissemination plan
The protocol is being presented as a poster at the World Federation of ADHD Conference, Glasgow, May 28-31 2015. Feasibility results will be submitted for publication in a peer reviewed ADHD journal (e.g the journal associated with this conference) in 2018. Results will also form a component of PhD thesis submission, due for completion in 2018.

Intention to publish date

01/01/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	02/03/2018		Yes	No
Results article		01/07/2019	26/05/2021	Yes	No