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Computer Enabled Neuroplasticity Treatment (CENT)

Submission date
19/07/2015

Recruitment status
No longer recruiting

Registration date
22/09/2015

Overall study status
Completed

Last Edited
10/10/2023

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] 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 neurobiological condition (that is, a condition affecting the nervous system caused by a biological factor, for example genetics) that results in a number of behavioural symptoms including a short attention span, restlessness and acting on impulse. It can also cause sleeping problems and anxiety. The condition is most often seen in people with learning difficulties but can affect people of any intellectual ability. It can have a considerable effect on several areas of a sufferers life, leading to a relatively poor economic and social position within their population (lower socioeconomic status), less satisfaction with their employment and marriage and conditions such as depression and addiction. It is thought that 4.4% of adults have ADHD. However the nature of the disease and the best way to treat it are still not well understood; it is thought that the efficacy of pharmacological and/or therapeutic treatments is adversely affected by people refusing or not persisting with the treatment and has not been shown to last beyond 2 years. The aim of this study is to see whether neurofeedback (NFB) will result in better treatment outcomes for adults with ADHD.

Who can participate?
Adults diagnosed with ADHD and with a IQ score of more than 80.

What does the study involve?
Participants are randomly assigned to one of two groups. Those in group 1 (intervention group) are given 40 one-hour sessions of neurofeedback. Those in group 2 (waitlist group) also receive the sessions but only after the study is complete. All participants are asked to report on their own ADHD symptoms at the start of the study, one year after treatment and then 2.5 years after treatment. Attention span is also measured, using a computer test, at the beginning of the study and after treatment.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Mental Capital Care clinic, Helsinki (Finland)

When is the study starting and how long is it expected to run for?
October 2011 to June 2016

Who is funding the study?
Finnish Funding Agency for Innovation (Tekes)

Who is the main contact?
Dr Ben Cowley
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
440078

Study information

Scientific Title
Clinical trial of neurofeedback therapy intervention for finnish adult ADHD, with waiting list control and comparison of outcomes of pre- to post-treatment improvement on self-reported symptoms and computerised attention tests

Acronym
CENT

Study objectives
Attention Deficit/Hyperactivity Disorder (ADHD) is a common psychiatric disorder, with an estimated worldwide prevalence among children of around 5% (Polanczyc et al., 2007), and persistence into adolescence and adulthood estimated between 40-60% (Faraone et al., 2006); it is associated with a variety of problems such as poor socialization and academic performance, and the efficacy of pharmacological and/or therapeutic treatments is adversely affected by non-compliance or aversion and has not been shown to last beyond 2 years.

Principal hypothesis: application of neurofeedback will result in improved scores on self-report measures of ADHD, and computerised attention tests, compared to waiting list control.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Helsingin ja Uudenmaan Sairaanhoitopiiri (english: Hospital District of Helsinki and Uusimaa), 28 /03/2012, JulkL 621/1999, 24 §

Study design
Randomized controlled single-centre trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Attention Deficit/Hyperactivity Disorder (ADHD)

Interventions
After randomisation, the treatment group will be given 40 sessions of 1 hour per session of neurofeedback at the Mental Capital Care clinic in Helsinki. Baseline, post-treatment and follow-up measurements as described.

The control group will be tested at the same times as the treatment group. They will receive a computerised attention training intervention after the follow-up measurement.

Intervention Type
Behavioural

Primary outcome(s)
1. Self-report of ADHD symptoms, using Brown Attention Deficit Disorder Scale (BADDS) to be measured at baseline, post-treatment 1 year after baseline, and follow-up 2.5 years after treatment
2. Adult ADHD Self Report Scale (ASRS) to be measured at the same timepoints as BADDS
3. Objective measure of attention, using the computerised Test Of Variables of Attention (TOVA), to be completed at baseline and post-treatment

Key secondary outcome(s))
Treatment group records of performance during neurofeedback ('learning curves').

Completion date
01/06/2016

Eligibility

Key inclusion criteria
1. Pre-existing diagnosis of ADHD
2. Nonexistence of neurological diagnoses
3. IQ score > 80 measured by a qualified psychologist using WAIS IV
4. Scores on ASRS and BADDS indicating presence of ADHD

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
54

Key exclusion criteria
Extreme outlier scores in the scales of
1. Generalized Anxiety Disorder (Spitzer et al., 2006)
2. Beck Depression Inventory (Beck et al., 1996)
3. Alcohol Use Disorders Identification Test (Saunders et al., 1993)
4. The Mood Disorder Questionnaire (Robert et al., 2000)
5. Test of prodromal symptoms of psychosis (Heinimaa et al., 2003)
6. Dissociative experiences scale (Liebowitz, 1992) for dissociative symptoms

Thresholds for exclusion were not fixed but at the discretion of the consulting psychiatrist. Use of medication for ADHD was not an exclusion criterion but participants were asked not to make changes in medication during the time of the training.

Date of first enrolment
01/04/2012

Date of final enrolment
01/08/2012

Locations

Countries of recruitment
Finland

Study participating centre
Mental Capital Care clinic
Malmi
Helsinki
Finland
00700

Sponsor information

Organisation
University of Helsinki

ROR
https://ror.org/040af2s02

Funder(s)

Funder type
Government

Funder Name
Tekes

Alternative Name(s)
Finnish Funding Agency for Innovation

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Finland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	09/05/2016		Yes	No
Other publications		29/06/2021	10/10/2023	Yes	No