The training effect of concentrative coordination exercise on academic-related motor functions of children with ADHD

Submission date	Recruitment status	Prospectively registered	
16/01/2021	No longer recruiting	[X] Protocol	
Registration date	Overall study status Completed Condition category	Statistical analysis plan	
04/02/2021		☐ Results	
Last Edited		Individual participant data	
01/03/2021	Mental and Behavioural Disorders	Record updated in last year	

Plain English summary of protocol

Background and study aims

Attention deficit hyperactivity disorder (ADHD) is a condition that includes symptoms such as inattentiveness, hyperactivity and impulsiveness. The aim of this study is to assess the effect of an intervention program to improve concentration, executive functions and handwriting performance in children with ADHD.

Who can participate? Children with ADHD

What does the study involve?

Children will be recruited and randomly allocated to either on-site table tennis, a table tennis exergame), or a control group. The table tennis training is provided either by a coach or a ball-projection machine in the on-site group. In the exergaming table tennis group the intervention is Nintendo Wii Sport providing coordination exercise to train the concentration of the children with ADHD. The control group receives their regular treatment for the symptoms of ADHD. The intervention lasts 12 weeks with three 1-hour sessions per week.

What are the possible benefits and risks of participating?

The possible benefits of participants are the improvement of concentration level, executive functions, and handwriting. There are very few minor risks such as fatigue or soreness after exercise training.

Where is the study run from? I-Shou University (Taiwan)

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

Who is funding the study?
Ministry of Science and Technology (Taiwan)

Who is the main contact? Prof. Nan-Ying Yu ying@isu.edu.tw

Contact information

Type(s)

Scientific

Contact name

Prof Nan-Ying Yu

Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

I-Shou 1227

Study information

Scientific Title

The training effect of concentrative coordination exercise on the executive function and upper limb motor control of children with ADHD

Study objectives

Concentrative coordination training can improve executive function and handwriting performance in children with ADHD.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 17/01/2014, Institutional Review Board of the E-DA Hospital (No.6, Yida Road, Jiaosu Village, Yanchao District, Kaohsiung City 82445, Taiwan, R.O.C., +886 (0)7 6150011 ext. 5110; ed107339@edah.org.tw), ref: EMRP60102N

Study design

Single-centre randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Attention deficit hyperactivity disorder (ADHD)

Interventions

Children will be recruited and randomly assigned (using randomizer.org) to on-site table tennis (n=20), a table tennis exergame (n=20), or a control group (n=20). The table tennis training is provided either by a coach or a ball-projection machine in the on-site group. In the exergaming table tennis group the intervention is Nintendo Wii Sport providing coordination exercise to train the concentration of the children with ADHD. The control group receives their regular treatment for the symptoms of ADHD. The intervention lasts 12 weeks with three 1-hour sessions per week.

Intervention Type

Behavioural

Primary outcome measure

Handwriting performance measured using a self-developed computer program for automation level and response time at baseline and 12 weeks

Secondary outcome measures

Executive functions measured using the Stroop test and Wisconsin Card Sorting Test (WCST) at baseline and 12 weeks

Overall study start date

01/08/2015

Completion date

31/10/2017

Eligibility

Key inclusion criteria

- 1. Meet the criteria of DSM-V for ADHD
- 2. Handwriting deficits confirmed by the administration of the Chinese Handwriting Evaluation Form (CHEF). According to the test manual, the cut-off criterion for the identification of handwriting deficit was two or more of the six dimensions with a median larger than, or equal to, 3

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

60

Total final enrolment

60

Key exclusion criteria

- 1. A history of any medical, neurological, or pervasive developmental disorders, intellectual disability, oncological, musculoskeletal, sensory (hearing, vision), or skin disorders
- 2. Children with IQ score <80
- 3. Taking any medication other than methylphenidate

Date of first enrolment

10/10/2015

Date of final enrolment

30/05/2016

Locations

Countries of recruitment

Taiwan

Study participating centre I-Shou University No.8, Yida Rd. Jiaosu Village Yanchao District

Sponsor information

Organisation

I-Shou University

Sponsor details

No.8, Yida Rd Jiaosu Village Yanchao District Kaohsiung City Taiwan 82445 +886 (0)76151100 misservice@most.gov.tw

Sponsor type

University/education

Website

http://www.isu.edu.tw/en1/

ROR

https://ror.org/04d7e4m76

Funder(s)

Funder type

Government

Funder Name

Ministry of Science and Technology, Taiwan

Alternative Name(s)

Ministry of Science and Technology, R.O.C. (Taiwan), Ministry of Science and Technology of Taiwan, MOST

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Taiwan

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

05/05/2021

Individual participant data (IPD) sharing plan

The participant-level data will be available upon request from Dr Nan-Ying Yu (ying@isu.edu.tw). The data will be available for 2 years and can be provided to researchers who engage in ADHD-related researches upon request for further correlation analyses among the measured variables.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol file</u>			01/03/2021	No	No