

Improving everyday doing of children with mild disabilities: a feasibility study of an occupational therapy intervention

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| Submission date 22/03/2011 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 05/05/2011 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 11/12/2013 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Not provided at time of registration

Study website

http://forsdata.unil.ch/fw_query_fors/re-result-2-det.fwx?htm.sel0=9927

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

SNF-DORE PROJEKT 113DPD6_127161/1

Study information

Scientific Title

Feasibility of a single-blind randomised controlled trial of an occupational therapy intervention with children

Acronym

Childrens ADL

Study objectives

Current hypothesis as of 11/12/2013:

How feasible is an RCT for evaluating the effectiveness of a client-centered, activity-based occupational therapy intervention with children with mild disabilities in Switzerland?

Previous hypothesis:

Does a client-centred, activity-based intervention result in enhanced objective and subjective quality of task performance in children with mild disabilities?

On 11/12/2013 the following changes were made to the trial record:

1. The public title was changed from 'Improving everyday doing of children with mild disabilities: an occupational therapy intervention study' to 'Improving everyday doing of children with mild disabilities: a feasibility study of an occupational therapy intervention '
2. The scientific title was changed from 'Effectiveness of client centered, activity based occupational therapy intervention on daily life task performance of children with mild disabilities' to 'Feasibility of a single-blind randomised controlled trial of an occupational therapy intervention with children'
3. The study design was changed from 'Randomised single-blind cross-over study' to 'Feasibility study of a multi-centre single-blind randomised controlled trial (with balanced randomisation [1:1]) with a cross-over design'
4. The anticipated end date was changed from 30/06/2012 to 28/02/2013
5. The target number of participants was changed from 100 to 20

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of Canton St.Gallen, Switzerland, 17/11/2010, EKSG 10/008

Study design

Feasibility study of a multi-centre single-blind randomised controlled trial (with balanced randomisation [1:1]) with a cross-over design

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

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

Children with mild disabilities

Interventions

1. The occupational therapy intervention is according to the Occupational Therapy Intervention Process Model (OTIPM, Fisher, 2009) i.e. a client-centred and occupation-based
2. Participating occupational therapists have received special three day training in this approach as well as monthly supervision and support by the research team
3. There will be weekly sessions of occupational therapy, during 15 weeks
4. Control-group: no treatment during a 15 weeks control phase

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

The Assessment of Motor and Process Skills (AMPS) (Fisher, 2010) is used as the objective outcome measure ["outsider" view of observed activities of daily living (ADL) performance] at baseline, three and six month.

Secondary outcome measures

As a second, subjective measure (insider view of perceived performance) the Canadian Occupational Performance Measure (COPM, Law, 2009) is used with the children and their parents, at baseline, three and six month.

Overall study start date

01/03/2011

Completion date

28/02/2013

Eligibility

Key inclusion criteria

1. Children aged 5 to 9 years, either sex
2. Who have been newly diagnosed with attention deficit hyperactivity disorder (ADHD), developmental coordination disorder (DCD) and/or learning disability, according to of Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) criteria
3. Average or above average intellectual capacity
4. Occupational therapy is prescribed

Participant type(s)

Patient

Age group

Child

Lower age limit

5 Years

Upper age limit

9 Years

Sex

Both

Target number of participants

20

Key exclusion criteria

1. Other neurological disorders, such as traumatic brain injury or cerebral palsy
2. Any other pervasive developmental disorder, including autism
3. Mental health problems, such as childhood depression
4. Mental retardation/intellectual disabilities

Date of first enrolment

01/03/2011

Date of final enrolment

28/02/2013

Locations**Countries of recruitment**

Switzerland

Study participating centre

Institute of Occupational Therapy

Winterthur

Switzerland

8401

Sponsor information

Organisation

Swiss National Science Foundation SNSF (Switzerland)

Sponsor details

Wildhainweg 3
PO Box 8232
Bern
Switzerland
3001

Sponsor type

Research organisation

Website

<http://www.snf.ch/D/Seiten/default.aspx>

ROR

<https://ror.org/00yjd3n13>

Funder(s)

Funder type

Research organisation

Funder Name

Swiss National Science Foundation (Switzerland) (ref: SNF-DORE PROJEKT 113DPD6_127161/1)

Alternative Name(s)

Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, SNF, SNSF, FNS

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Switzerland

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