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Can support in time help pre-school children in developing time-processing ability?

Submission date
22/12/2015

Recruitment status
No longer recruiting

Registration date
13/01/2016

Overall study status
Completed

Last Edited
07/12/2022

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Many children who suffer from learning disabilities such as intellectual disability (ID), autism or ADHD, are reported to have problems with managing their time effectively (time-processing ability, TPA). The difference in the TPA of special needs children and that of typically developing children is thought to become more pronounced as they get older. Despite this, there is currently no real way to help improve TPA in pre-school age children. Support in Time is a programme which has been developed to help improve TPA in young children. It involves the "My Time" method, which uses techniques such as the QuaterHourWatch principle, which marks the time distance to an activity/event in dots (each representing 15 minutes). This calculates the "distance" to a certain time without the user having to work it out themselves. The aim of this study is to find out whether the Support in Time programme can help children with special needs to improve their TPA.

Who can participate?
Children aged between 5 and 6 with learning disability or developmental delay who attend a participating pre-school. Typically Developing children who attend a participating pre-school were included from 02/09/2019.

What does the study involve?
Participating pre-schools are randomly allocated to one of two groups. Children attending the pre-schools in the first group (intervention group) begin the "Support in Time" programme, which lasts for 8 weeks. This involves teaching children the "My Time" method using time aids, such as a quarter hour watch (measuring time intervals with dots), time log, memo day planner and picture schedule of the week. Children attending the pre-schools in the second group (control group) continue as normal for the first 8 weeks of the study. At the start of the study, and then again after the intervention group have completed the 8 week programme, children in both groups complete interviews and questionnaires in order to assess their time-processing ability. Following this, the control group completes the 8 week programme. These children are then assessed in order to compare their time-processing ability now to their previous result.

What are the possible benefits and risks of participating?
Children are likely to enjoy the tasks in this study and may benefit from having more control

over their time. Risks of participating are minimal; however it is possible that the study may make children more aware of their own limitations which could harm their self-esteem.

Where is the study run from?
A number of pre-schools in the Falun municipality (Sweden)

When is the study starting and how long is it expected to run for?
September 2015 to May 2020

Who is funding the study?
1. Norrbacka-Eugenia Foundation (Sweden)
2. Foundation Sunnerdahls Disability Fund (Sweden)
3. Promobilia Foundation (Sweden)
4. Center for Clinical Research in Dalarna (Sweden)

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
epn 2015/451

Study information

Scientific Title
Evaluation of a model for early intervention using remediation and time aids for pre-school children with disabilities

Acronym
SiT

Study objectives
Intervention including remediation with My Time and time aids can facilitate time-processing ability in children with disabilities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 25/05/2020:
1. Approved 09/12/2015, Regional vetting board of Uppsala (Sweden), ref: 2015/451
2. Inclusion of the additional cohort of typically developing children approved 19/08/2019, Regional vetting board of Uppsala (Sweden), ref: 2019-04301

Previous ethics approval:
Regional vetting board of Uppsala (Sweden), 09/12/2015, ref: 2015/451

Study design
Randomized controlled trial using a waiting list design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
School

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Childhood disability and developmental delay

Interventions
Each school is initially assigned as being in the control group or intervention group. After baseline assessments have been made (first two weeks of study), the children in the intervention group undergo the "My Time" intervention for 8 weeks and the children in the control group carry on as normal. After this 8 week period, full data collection will be done from both groups. The control group children now receive the intervention (as no more data collection will be made in the intervention group it is not a full randomised cross over design). The last two weeks of the study involves taking more post interventional assessments from only the children in the first control group. For the second data collection, external trained occupational therapists will be engaged to do the assessment, to obtain blinding as far as possible.(sentence added 17/05/2016)

The intervention involves the "Support in Time" model, which incorporates the "My Time" method and time aids (The Quarter-hour watch, time log, Memo day Planner and Picture schedule of the week). "My Time" is a method developed by the National Agency for Special Needs Education and Schools (Swedish SPSM), for systematic training of Time-Processing Ability (TPA) in children based on current knowledge in time-processing ability and on "the quarter-hour principle". The aim of My Time is to provide multiple options to collect experiences of duration of daily- life activities all labelled in the unity of quarter-hour dots. The method My Time includes to visualise time (using the quarter-hour watch, timelog and Memo day planner), document time (using referens shred and a timebook), process and discuss (using the activities documented in the time book as a reference, Memo day planner, picture schedule). The base to understand time starts with building a sense of duration of time in daily activities. When this is done at the child's level of abstraction it's possible to fill the reference memory with experiences of time duration in daily activities.

Intervention Type
Mixed

Primary outcome measure
Time-processing ability (TPA) is measured using the Kit for Assessment of Time-processing ability (KaTid) at baseline, after the 8 week intervention period and then a third data collection for the control group after their completion of the 8 week intervention.

Secondary outcome measures
Everyday functioning is measured using the Time-Parent scale, Autonomy scale and ABAS-II questionnaires at baseline, after the 8 week intervention period and then a third data collection for the control group after their completion of the 8 week intervention.

Overall study start date
21/09/2015

Completion date
30/05/2020

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 25/05/2020:
1. Either
1.1. Children with disabilities like CP, MMC, AST, ADHD, ID and developmental delays, or
1.2. Typically Developing children (included as of 02/09/2019)
2. Aged 5 or 6 years during the year of the intervention

Previous participant inclusion criteria:
1. Children with disabilities like CP, MMC, AST, ADHD, ID and developmental delays
2. Aged 5 or 6 years during the year of the intervention

Participant type(s)
Other

Age group
Child

Lower age limit
5 Years

Upper age limit
6 Years

Sex
Both

Target number of participants
Target enrolment of children with disabilities, n=75; Target enrolment of typically developing children, n= 76

Total final enrolment
151

Key exclusion criteria
1. Multiple disabilities
2. Severe communication problems

Date of first enrolment
15/01/2016

Date of final enrolment
30/12/2019

Locations

Countries of recruitment
Sweden

Study participating centre
Falu kommun
Barn och ungdomsförvaltningen
Egnellska huset
Myntgatan 45
Falun
Sweden
791 83

Sponsor information

Organisation
Centre for Clinical Research Dalarna

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Sponsor type
University/education

Website

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ROR
https://ror.org/03qp8ma69

Funder(s)

Funder type
Charity

Funder Name
Norrbacka-Eugenia Foundation (Norrbacka-Eugeniastiftelsen)

Alternative Name(s)
Norrbacka-Eugenia Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Sweden

Funder Name
Stiftelsen Sunnerdahls Handikappfond

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Sweden

Funder Name
Promobilia Foundation (Stiftelsen Promobilia)

Alternative Name(s)

Promobilia Foundation, Foundation Promobilia

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Sweden

Funder Name
Centrum fÖr Klinisk Forskning Dalarna

Alternative Name(s)
Center for Clinical Research Dalarna, CKF

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 25/05/2020:
Planned publication of several manuscripts in peer-reviewed journals, in addition to planned presentation of results at national and international conferences. Data from Typically developing children will be presented in one separate publication.

Previous publication and dissemination plan:
Planned publication of several manuscripts in peer-reviewed journals, in addition to planned presentation of results at national and international conferences.

Intention to publish date
01/02/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as the ethical approval does not include sharing data with external researchers. The information was not included in the informed consent signed by the participants.

IPD sharing plan summary

Not expected to be made available