

Physical activity on prescription for children with cerebral palsy: a feasibility study

Submission date 04/06/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/06/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/11/2020	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims:

Cerebral Palsy (CP) is a term for a number of conditions that affect movement and co-ordination. It occurs when there is a problem in the parts of the brain responsible for controlling muscles. This can be due to abnormal development of the brain or damage caused before, during or after birth. CP leads to a range of symptoms, including muscle stiffness or weakness, random and uncontrolled body movements and balance and coordination problems. Children with CP tend to be less physically active and more sedentary than other children which can increase risk for poor physical and mental health. Physical activity on prescription (PAP) is an effective program designed to encourage increased levels of physical activity in adults. The aim of this study is to find out whether PAP is feasible and effective in children with CP.

Who can participate?

Children with CP aged 7-11 years.

What does the study involve?

All participants take part in the PAP program. This involves children, their parents and as physiotherapist working together to create a physical activity program that the children follow for six months. At the start of the study and then after eight and 11 months, participants complete a number of questionnaires to assess their physical activity behaviours and function.

What are the possible benefits and risks of participating?

Participants could benefit from increased interest in and knowledge about physical activities. The children get attention and are able to choose physical activities which increases empowerment. There is a risk that parents may want their child to take part in a physical activity that the child is not interested in, but this risk is minimised through the discussions with the child, parents and physiotherapist towards a joint agreement.

Where is the study run from?

Lund University (Sweden)

When is study starting and how long is it expected to run for?

April 2013 to November 2014

Who is funding the study?

1. Research Platform for Disability Studies in Rehabilitation (Sweden)
2. The Promobilia foundation (Sweden)
3. Swedish National Association for Disabled Children and Young People (Sweden)

Who is the main contact?

Dr Katarina Lauruschkus
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Contact information

Type(s)

Public

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

LU-Dnr 2013/521

Study information

Scientific Title

Participation in physical activities for children with cerebral palsy: Feasibility and effectiveness of physical activity on prescription by measuring goal attainment, gross motor function and physical activity level.

Study objectives

The aim of this study was to evaluate the feasibility of PAP for children with cerebral palsy (CP) and its effectiveness on participation in physical activity and sedentary behaviour.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Regional Ethical Review Board at Lund University, 19/09/2013, ref: LU-Dnr 2013/521

Study design

Single-centre non randomised feasibility study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Home

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

Cerebral palsy

Interventions

All participants take part in the physical activity on prescription (PAP) intervention. The PAP intervention consists of a written agreement between each child, their parents and the physiotherapist and is based on Motivational Interviewing (MI), Canadian Occupational Performance Measure (COPM) and Goal Attainment Scaling (GAS).

Two months are calculated for the baseline-measurements and the discussions for reaching the agreements. The baseline-measurements involve:

1. Questionnaires regarding socioeconomic and clinical characteristics
2. Questionnaires regarding the frequency of the child's physical activities at school, leisure time and physiotherapy
3. Questionnaires regarding physical activity
4. Measurement of gross motor function and physical activity

Each child participates after that in self-selected physical activities for six months.

The first follow-up is performed at eight months involves completion of questionnaires regarding the frequency of the child's physical activities at school, leisure time and physiotherapy, questionnaires regarding physical activity and measurement of gross motor function and physical activity. The second follow-up is performed at 11 months, and involves completion of questionnaires regarding the frequency of the child's physical activities at school,

leisure time and physiotherapy, questionnaires regarding physical activity and measurement of physical activity.

The total duration of the intervention is 11 months.

Intervention Type

Behavioural

Primary outcome measure

Achievement of goals is assessed using Goal Attainment Scaling (GAS) at baseline, at 8 and 11 months.

Secondary outcome measures

1. Performance problems, concerns and issues around their physical activities are identified and the performance and satisfaction levels in self-care, productivity and leisure are assessed using the Canadian Occupational Performance Measure (COPM) at baseline, at 8 and 11 months. The performance and satisfaction levels are ranked and rated from the child's perspective on a Visual Analogue Scale (VAS) 1-10.
2. Gross motor function is assessed using The Gross Motor Function Measure 66 (GMFM-66) at baseline and at 8 months
3. Frequency of the child's physical activities at school, leisure time and physiotherapy are recorded according to the questionnaire used in the National Quality Registry and CP Follow-Up Programme at baseline, at 8 and 11 months
4. Time children spend being physically active each day with light, moderate or vigorous intensity and how much time the child spent sedentary during the last seven days is assessed using the International Physical Activity Questionnaire (IPAQ) at baseline, at 8 and 11 months
5. Physical activity is assessed using a triaxial accelerometer at baseline and 8 months
6. Activity information is assessed using time-use diaries at baseline and 8 months

Overall study start date

01/02/2013

Completion date

15/11/2014

Eligibility

Key inclusion criteria

Children:

1. Aged 7-11 years at baseline
2. Diagnosis of cerebral palsy
3. Gross and fine motor, communicative and cognitive functions
4. From both rural areas and cities in the south of Sweden

Parents:

1. Aged 36-64 years
2. Parents of participating children

Participant type(s)

Mixed

Age group

Child

Lower age limit

7 Years

Upper age limit

64 Years

Sex

Both

Target number of participants

11 children and 18 parents

Total final enrolment

11

Key exclusion criteria

Children:

1. Age younger than 7 years at baseline
2. Age older than 11 years at baseline

Date of first enrolment

20/09/2013

Date of final enrolment

30/10/2013

Locations

Countries of recruitment

Sweden

Study participating centre

Lund University

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Sponsor type

University/education

ROR

<https://ror.org/012a77v79>

Funder(s)

Funder type

Research organisation

Funder Name

Research Platform for Disability Studies in Rehabilitation

Funder Name

The Promobilia foundation (Stiftelsen Promobilia)

Funder Name

Swedish National Association for Disabled Children and Young People (Riksförbundet för Rörelsehindrade Barn och Ungdomar)

Alternative Name(s)

Swedish National Association for Disabled Children and Young People, RBU

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

Sweden

Results and Publications

Publication and dissemination plan

Planned publication of study results in a high-impact peer reviewed journal and presentation at scientific conferences.

Intention to publish date

31/12/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Katarina Lauruschkus (katarina.lauruschkus@med.lu.se)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/11/2017	26/11/2020	Yes	No