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Evaluation of the parenting support group intervention "Everyday life and parenting" for parents of preschool children with neurodevelopmental difficulties

Submission date
16/08/2024

Recruitment status
No longer recruiting

Registration date
08/10/2024

Overall study status
Ongoing

Last Edited
06/03/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Background and study aims
Young children with subclinical neurodevelopmental disorders (NDDs) and concurrent emotional and behavioral problems (EBP) are at significant risk of negative consequences in the short and long term. Early parenting support interventions are recommended and requested. However, there is a lack of interventions specifically designed for this group and adapted to a Swedish context. Based on this gap, a parenting support intervention for parents with children 2 - 6 years of age with subclinical NDD and EBP has been co-created with clinicians and parents. The current project aims to evaluate the clinical- and cost-effectiveness of this parenting support group intervention.

Who can participate?
Parents of children aged 2 - 6 years old with subclinical levels of NDD and behavioral problems. The children have been referred to child health psychologists at the Child Pediatric Outpatient Clinic in Uppsala Region. Children aged 4 – 6 years old whose parents consented to participate in the project, will be invited to participate themselves.

What does the study involve?
Parents offered the parenting support group intervention Everyday life and parenting will be included in the baseline (4, 7 or 10 weeks) and they will thus start the intervention after the baseline period. They will answer 25 questions every week during the baseline, the intervention and four weeks after the intervention. The questions are about their child's behavior, their own self-efficacy as parents and stress. They will also answer questionnaires at the start of baseline, when the intervention is finished and three months after the intervention.
Children aged 4 - 6 years old will answer 5 questions weekly during the same time period as their parent.

What are the possible benefits and risks of participating?
The potential benefit of participating in the research project is that parents are given the

opportunity to reflect on their parenting and thus gain a greater awareness of the family's challenges. Based on this, it can be easier for parents to recognise what support they and their children need. It can also be meaningful to share your own experiences and perspectives and through this contribute to knowledge that can be used to help other parents and children in similar situations.
Children may enjoy answering a questionnaire that asks about their experiences in the family. This can make them feel that their opinions are important. It is rare for children of pre-school age to be involved in similar studies and this project gives them the opportunity to make their voices heard and thus fulfil a human right.

Where is the study run from?
The Child Health and Parenting (CHAP) research group at Uppsala University (Sweden) together with the Child Pediatric Outpatient Clinic in Uppsala Region.

When is the study starting and how long is it expected to run for?
January 2024 to December 2026

Who is funding the study?
Swedish Research Council for Health, Working Life and Welfare
Foundation Sunnerdahls Disability Fund (Sweden)

Who is the main contact?
Dr Karin Fängström, karin.fangstrom@uu.se

Contact information

Type(s)
Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
The clinical- and cost-effectiveness of a parenting support group intervention for parents of preschool children with subclinical neurodevelopmental disorders and mental health problems

Study objectives
Children's behavioral problems, reported by parents, will decrease as an effect of the intervention, that parent's self-efficacy will increase and their stress will decrease

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 05/06/2024, The Swedish Ethical Review Authority (Box 2110, Uppsala, 750 02, Sweden; +46 10-475 08 00; registrator@etikprovning.se), ref: 2024-03064-01

Study design
Multiple-baseline single-case experimental design (SCED) across participants with pre- and post-measures and a 3-month follow-up

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Subclinical neurodevelopmental disorders and mental health problems

Interventions

Current interventions as of 08/11/2024:
The parenting support group intervention "Everyday life and parenting" consist of four modules. The intervention is theoretically based in social-learning theory and it uses methods from applied behavior analysis, e.g., functional behavior assessment, as well as structured teaching. Three of the intervention modules includes key components from the most effective parenting programs targeting behavior problems in children. Parenting techniques taught during the intervention includes positive parenting skills such as positive reinforcement techniques, relationship enhancement techniques and reframing unhelpful cognitive perceptions about the child. The fourth intervention module is based on theories and knowledge from treatment provided to children with autism and/or intellectual disabilities as well as the ICF framework. Important elements in this module are teaching parents how to organize the physical environment, create activity schedules, visual schedules and/or cues, establish routines with flexibility, and use visually structured activities. These elements create clarity and predictability in everyday life. Furthermore, the module includes teaching parents general analytical and learning principles for teaching new skills or dealing with problem behaviors. In addition, parents are thought how to adapt activities and demands on the individual child based on his/her cognitive and adaptive abilities.
The delivery format of our intervention is also based on well researched components and includes providing psychoeducation; discussions; homework assignments and peer support. Each module last 3 hours and the intervention is given every other week for 8 weeks.

Previous interventions:
The parenting support group intervention "Everyday life and parenting" consist of four modules. The intervention is theoretically based in social-learning theory and it uses methods from applied behavior analysis, e.g., functional behavior assessment, as well as structured teaching. Three of the intervention modules includes key components from the most effective parenting programs targeting behavior problems in children. Parenting techniques taught during the intervention includes positive parenting skills such as positive reinforcement techniques, relationship enhancement techniques and reframing unhelpful cognitive perceptions about the child. The fourth intervention module is based on theories and knowledge from treatment provided to children with autism and/or intellectual disabilities as well as the ICF framework. Important elements in this module are teaching parents how to organize the physical environment, create activity schedules, visual schedules and/or cues, establish routines with flexibility, and use visually structured activities. These elements create clarity and predictability in everyday life. Furthermore, the module includes teaching parents general analytical and learning principles for teaching new skills or dealing with problem behaviors. In addition, parents are thought how to adapt activities and demands on the individual child based on his/her cognitive and adaptive abilities.
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A computer-generated randomization sequence will be used to assign the participants to a 4-, 7- or 10-week baseline in a 1:1:1 ratio. Block randomization of block sizes 3 or 6 will be generated in a computerized randomization scheme.

Intervention Type
Behavioural

Primary outcome(s)

Current primary outcome measure as of 08/11/2024:
Questionnaire distributed to parents every week for 15, 18 or 21 weeks, i.e. during baseline phase, intervention and four weeks post intervention:
1. Child behavior problems, questions based on the Eyberg Child Behavior Inventory
2. Parental self-efficacy, the Me As a Parent questionnaire
3. Parents' perceived stress, the Parental Stress Scale

Previous primary outcome measure:
Questionnaire distributed to parents every week for 16, 19 or 22 weeks, i.e. during baseline phase, intervention and four weeks post intervention:
1. Child behavior problems, questions based on the Eyberg Child Behavior Inventory
2. Parental self-efficacy, the Me As a Parent questionnaire
3. Parents' perceived stress, the Parental Stress Scale

Key secondary outcome(s))
Current secondary outcome measure as of 08/11/2024:
Measured at pre-, post and 3-month follow-up, parent's ratings:
1. Child mental health problems, using Strength and Difficulties Questionnaire
2. Parental self-efficacy, using Me As a Parent
3. Parental stress using the Parental Stress Scale
4. Parent's mental health using General health questionnaire, GHQ-12
5. Quality of Life, using Assessing Quality of Life 8 Dimensions (AQOL-8D)
6. Costs related to consumption of societal resources, Trimbos/iMTA questionnaire (TIC-P)
7. Costs related to healthcare consumption using data from child medical records on the number of healthcare visits, prescribed drugs, referrals etc.

Measured weekly during 15, 18 or 21 weeks:
8. Children's positive and negative experiences of family life using 5 questions developed for this study

Previous secondary outcome measure:
Measured at pre-, post and 3-month follow-up, parent's ratings:
1. Child mental health problems, using Strength and Difficulties Questionnaire
2. Parental self-efficacy, using Me As a Parent
3. Parental stress using the Parental Stress Scale
4. Parent's mental health using General health questionnaire, GHQ-12
5. Quality of Life, using Assessing Quality of Life 8 Dimensions (AQOL-8D)
6. Costs related to consumption of societal resources, Trimbos/iMTA questionnaire (TIC-P)
7. Costs related to healthcare consumption using data from child medical records on the number of healthcare visits, prescribed drugs, referrals etc.

Measured weekly during 16, 19 or 22 weeks:
8. Children's positive and negative experiences of family life using 5 questions developed for this study

Completion date
31/12/2026

Eligibility

Key inclusion criteria

1. Parents of children aged 2 - 6 years old with subclinical levels of NDD and behavioral problems (as assessed by a clinical psychologist) who have been offered and accepted to participate in the parenting intervention Everyday Life and Parenting
2. Parents need to be able to answer questionnaires in Swedish
3. Only one parent from each family will be included (i.e., the father as fathers often are underrepresented and therefore will contribute to a gender balance in the sample)
4. Children aged 4 - 6 years old, who's parent/parents participate in Everyday life and parenting

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
4 years

Upper age limit
99 years

Sex
All

Key exclusion criteria
1. Parents who cannot answer the questionnaires in Swedish
2. Parents who don't understand the study information or informed consent
3. Children whose parents are excluded based on the above criteria
4. Children below 4 years of age

Date of first enrolment
16/08/2024

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
Sweden

Study participating centre
Child Pediatric Outpatient Clinic in Uppsala Region
Islandsgatan 2
Uppsala
Sweden
75308

Sponsor information

Organisation
Uppsala University

ROR
https://ror.org/048a87296

Organisation
Akademiska Children's Hospital/Region Uppsala

Funder(s)

Funder type
Research council

Funder Name
Forskningsrådet om Hälsa, Arbetsliv och Välfärd

Alternative Name(s)
Swedish Research Council for Health, Working Life and Welfare, Forskningsrådet om Hälsa, Arbetsliv och Välfärd, FORTE

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Funder Name
Foundation Sunnerdahls Disability Fund

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from dr Karin Fängström (karin.fangstrom@uu.se).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes