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ComAlong Toddler - Parental course to help the child to communicate

Submission date	Recruitment status	[_] Prospectively registered
09/06/2016	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/08/2016	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
12/02/2021	Mental and Behavioural Disorders	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

Communication and language difficulties are often a first sign of developmental disabilities, such as delayed development, autism spectrum disorders (conditions where the sufferer has difficulty communicating and relating to others) and speech/language disorders. It is therefore very important to find ways to identify these children and help them develop their communication skills. Studies have shown that parents can help their children to communicate better. This study examines a program called “ComAlong toddler”, a course designed to help parents to support development of their child’s communication, language and play skills. The aim of this study is to find out whether attending this course can help parents to enhance their child’s communication, language and play.

Who can participate?

Children aged less than 30 months old with a communication difficulties and their parents

What does the study involve?

Parents are randomly allocated to one of two groups. Both groups receive a home visit, in which the child’s communication, play and language skills are assessed. The parents then receive individual advice on how to enhance the child's communication and play. Those in the first group then continue as normal. Those in the second group take part in the "ComAlong-toddler" parental course. This involves taking part in five two-hour sessions, during which parents receive information about normal communication development as well as how to enhance communication and how to play with their children. The parents are asked to complete “ homework” in which they practice the skills learned and record play sessions with the child on film. During the course, the recordings are used to provide individual feedback and help the rest of the parents in the group to learn. Six months later, families in both groups are visited again in order for the child’s communication, play and language skills to be reassessed. When the children are six years old, their medical records are reviewed in order to record any medical conditions and to assess their communication skills.

What are the possible benefits and risks of participating?

Children may benefit from improved communication skills. Parents may benefit by gaining more knowledge and empowerment. There are no notable risks involved with taking part in this study.

Where is the study run from?
The study is run from Uppsala University and takes place in participants homes as well as the Child Health Office in Uppsala (Sweden)

When is the study starting and how long is it expected to run for?
January 2015 to June 2022

Who is funding the study?
1. Foundation Sunnerdahls Disability Fund (Sweden)
2. The Queen Silvia Jubilee Fund (Sweden)
3. Department of Research and Development - Uppsala County Council (Sweden)
4. Uppsala University (Sweden)

Who is the main contact?
Mrs Anna Fäldt

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
ComAlong Toddler - Early identification and randomized control trail of a parental course and guidance in the home environment

Acronym
ComAlong Toddler

Study objectives
Post-intervention, the intervention group will report improvement in child communication and language and improved parental use of tools to enhance their child's communication.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional ethical committee at Uppsala University, 15/04/2015, ref: Dnr. 2015/124

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
1. Developmental delay
2. Language delay/impairment
3. Autism spectrum disorder

Interventions
Parents will be randomized to either parental course combined with home visit or home visit alone.For both groups the intervention starts with a home visit where the child's communication, play and language are assessed. The parents receive individual guidance on how to enhance the child's communication and play.

The "ComAlong-toddler" parental course is delivered as five two-hour sessions in a clinical environment. During these sessions the parents receive information about communication, typical development of communication, ways to enhance communication, how to play with the child and information about augmentative and alternative communication. The parents perform home assignments between the sessions where the methods learned are practiced at home, and

are recorded on film. During the course, the recordings are used to give individual feedback and opportunity for peer learning. The course is individualized such that the parents set their own goals for the child's further development.

Six months after the initial home visit, families in both groups receive a follow up home visit which involves an assessment of the child's development.

Intervention Type
Behavioural

Primary outcome measure
1. The child’s communication and symbolic use is measured using the Communication and Symbolic Behavior Scales Developmental Profile Infant-Toddler Checklist (ITC) and Behavioral Sample (BS) at baseline (initial home visit) and at 6 months (follow up home visit)
2. The parents’ communicative styles with the child are measured using the Responsive Augmentative and Alternative Communication Style Scale (RAACS) at baseline (initial home visit) and 6 months (follow up home visit)
3. The parental view of the child’s use and understanding of speech is measured using the SCS-18, a Swedish short version of Mac Arthur–Bates Communicative Development Inventories (CDI) at baseline (initial home visit) and 6 months (follow up home visit)

Secondary outcome measures
1. Prosocial and difficult behaviours are measured using The Strengths and Difficulties Questionnaire when the child is age three
2. Medical diagnoses are collected using information from the child’s medical records continuously, with the final collection when the child turns six
3. Information about the child’s communication, use of AAC and development is measured through developmental assessments and collected through the child’s medical records continuously, with the final collection when the child turns six
4. The number of health care visits is collected using the child’s medical records continuously, with the end point when the child turns six

Overall study start date
01/01/2015

Completion date
30/06/2022

Eligibility

Key inclusion criteria
Children:
1. Children aged <30 months
2. Children with communication disorder, identified by the Communication and Symbolic Behavior Scales Developmental Profile Infant-Toddler Checklist at the child health visit at the age of 18 months and children under 30 months of age referred to speech and language pathologist

Parents:
Parents of children with communication delay.

Participant type(s)
Patient

Age group
Child

Upper age limit
30 Months

Sex
Both

Target number of participants
750 children and between 70-150 parents.

Key exclusion criteria
1. Children whose parents can not fill in parental forms in Swedish
2. Children who live at too great a distance from the town center of Uppsala where the parental course will be offered

Date of first enrolment
01/09/2015

Date of final enrolment
30/06/2017

Locations

Countries of recruitment
Sweden

Study participating centre
Uppsala University
Uppsala
Sweden
75185

Sponsor information

Organisation
Uppsala University

Sponsor details
Uppsala universitet
Womens and childrens health

Akademiska sjukhuset
Uppsala
Sweden
75185

Sponsor type
University/education

ROR
https://ror.org/048a87296

Funder(s)

Funder type
Charity

Funder Name
Foundation Sunnerdahls Disability Fund

Funder Name
The Queen Silvia Jubilee Fund

Funder Name
Department of Research and Development - Uppsala County Council

Funder Name
Uppsala University

Results and Publications

Publication and dissemination plan
Planned publication in a peer review journal as well as presentations at academic conferences.

Intention to publish date
30/06/2019

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/06/2020	12/02/2021	Yes	No