

ComAlong Toddler - Parental course to help the child to communicate

Submission date 09/06/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 09/08/2016	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 12/02/2021	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

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

Contact name

Mrs Anna Fäldt

ORCID ID

<https://orcid.org/0000-0001-7257-8758>

Contact details

Uppsala universitet

CHAP, Munin

Uppsala

Sweden

75185

Additional identifiers

Study information

Scientific Title

ComAlong Toddler - Early identification and randomized control trial 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

Primary study design

Interventional

Study design

Single-centre randomised controlled trial

Study type(s)

Treatment

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(s)

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)

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Upper age limit

30 Months

Sex

All

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

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

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