

Effectiveness of Language in Interaction Therapy in preschool children with developmental language disorders

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The research questions are:1. What is the effectiveness of Language in Interaction Therapy on the use of grammar in spoken language of children age 4 and 5 with Specific Language Impairment in comparison to usual care?2. What is the effectiveness of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON42916

Source

ToetsingOnline

Brief title

IntervenTOS

Condition

- Other condition

Synonym

Developmental Language Disorder, Specific Language Impairment

Health condition

ontwikkelingsstoornissen

Research involving

Human

Sponsors and support

Primary sponsor: Hogeschool Utrecht

Source(s) of monetary or material Support: NWO Promotiebeurs voor leraren

Intervention

Keyword: developmental language disorders speech and language therapy, efficacy, language in interaction therapy

Outcome measures

Primary outcome

Improvement in grammatical competence, measured by:

1. Change in grammatical complexity of spontaneous spoken sentences of the child.
2. Change in test score on CELF Preschool subtest Recalling Sentences (Wiig, Secord, Semel & De Jong, 2012), a sentence repetition task with an increasing score when larger proportions of the sentence are imitated correctly.

Secondary outcome

Improvement in comprehension of grammar, measured by the Coloring Booktest, where the child is asked to carry out coloring tasks on an iPad. The Coloring Booktest is developed by the Digital Humanities Lab of Utrecht University.

Study description

Background summary

Specific Language Impairment (SLI) is diagnosed when a child's language development is deficient: children experience severe difficulties in speech production and understanding of language. Grammar (complex language) is an area of language that is particularly affected. Effective intervention is important since language impairment severely hinders communication in everyday life and limits learning and school success. Intervention studies in SLI are scarce and

there is a lack of evidence for current treatment approaches.

Study objective

The research questions are:

1. What is the effectiveness of Language in Interaction Therapy on the use of grammar in spoken language of children age 4 and 5 with Specific Language Impairment in comparison to usual care?
2. What is the effectiveness of Language in Interaction Therapy on comprehension of grammar?

Study design

The study is an intervention study with an experimental single subject time series design and a non-equivalent control group. An ABA-design will be used: children will receive usual care in the first phase (A). Then the speech-language therapists (SLTs) will be coached in using Language in Interaction Therapy (LIT) after which the children will receive the intervention LIT for 12 weeks (B). Afterwards the children will receive usual care again, with the expectation that SLTs will use LIT more often than before. This usual care (A) phase is referred to as A+. The A+ phase will be followed by a phase without intervention during the summer holidays (8 weeks).

Measurements will be carried out every 4 weeks, 10 times in total. An 11th follow up measurement will be done 10 weeks after the last measurement (T11). On T1-T5 the development of the participants will be measured in the usual care condition. Subsequently the intervention group will receive LIT, resulting in a change in the way the language therapy is given, whereas other factors in the special education setting will stay the same (measurement T6 t/m T8). Measurements T9 en T10 will take place after finishing the LIT treatment, to be able to register improvement and lasting effects of CTT in the new usual care phase (A+) and in a phase without treatment.

Data of each individual participant will be analyzed separately as follows:

1. Visual analysis of the graphs with scores plotted against time. Because, at least some, improvement is expected in all phases, trends will be analyzed and compared. In case LIT is effective, the graphs will show a steeper rising line in the LIT phase than in the usual care phase.
2. Calculating the effect size by:
 - determining the Standard Mean Difference between the first usual care phase (A) and the LIT phase (B) for each participant. The same will be done for the LIT phase and the post treatment phases (usual care influenced by LIT (A+) and the control phase during the summer holidays).
 - calculating the Percentage Non-Overlapping Data (PND): the proportion of the total number of intervention points that exceeds the highest baseline point

The control group will receive usual care during the total research period and measurements will be carried out at the same moments. Although a control group is not common in a single subject design, in this study it is necessary to demonstrate that the improvements of the children are not influenced by unforeseen school matters, such as a change in education policy or a sudden intake of many new pupils.

The SLTs on every participating school will be randomly selected to give LIT or to continue usual care for the whole period. Every school will have an equal amount of SLTs in each group. The study will take place on schools for special education for children with speech, language and communication needs and will last a little more than one school year (15-08-2016 to 01-10-2017).

Intervention

Language in Interaction Therapy (LIT) and Usual Care, both administered by speech and language therapists.

Intervention LIT:

During this intervention the SLT is playing with the child with toys, real objects or craft supplies, frequently using the grammatical structures, the child has to learn. In advance, the SLT decides which grammatical structure will be the goal of the therapy session and she chooses toys and play activities that will create opportunities for using the grammatical structure. While playing, the SLT follows the child's lead in play and communication and responds to the child's utterances. Using verbal techniques that have been identified to improve the child's perception of the correct language model (emphasizing, reducing speech rate, eye contact, expressive intonation and facial expression, using contrastive sentences), the SLT stimulates the child to use the targeted grammatical structures. Grammatical rules are not explained explicitly.

The frequency of the intervention is once a week for 20 minutes. In the LIT phase of the study, the intervention will replace a regular therapy session, so the determined therapy dosage will remain unchanged.

Control condition usual care:

In the usual care phase the SLTs will administer language therapy in a regular way, designed in accordance with their own judgments. The control group will receive usual care for the total duration of the study.

Therapy goals of usual care are comparable to the goals of LIT, but there is a large variety in methods and therapy aids used. Usually both playing together and exercises are practiced. During play in usual care, elements of LIT are used, as well as broad targeted language stimulation. In exercises on the other hand, the focus of attention is often one specific sentence, for example in functional imitation with toys and work sheets. In functional imitation, a child has to imitate the SLT, while they are both performing the same action in rotation. Another exercise is the visualization of sentences to stimulate the

insight in grammatical rules.

Usual care will be administered in the dosage, determined by the school, usually twice a week for 20 minutes, individually or in a small group (3-4 children).

Study burden and risks

The burden for the children is minimal and there are no risks.

There are no adverse effects of speech and language therapy. For the participating children, Language in Interaction Therapy is in many aspects comparable to the therapy they usually receive. The intervention will be administered by the child*s own speech and language therapist, once a week. It will replace a regular therapy session, so the determined therapy dosage will remain unchanged and children will not be taken out of the classroom for extra therapy sessions.

*

Measurements consist of a play session with the research assistant and two short language tests. The tests are hardly a burden and contain the attractive element of coloring on an iPad. Children are pulled out of the classroom for only half an hour for each series of measurements.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

- Language performance at least 1,5 SD below the mean on two or more language domains
- Special educational needs
- Non-verbal intelligence within the normal range (non-verbal IQ * 85)

Exclusion criteria

- Diagnosed with Autism Spectrum Disorder
- Severe Hearing Impairment (hearing loss > 35 dB)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	25-08-2016
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date: 03-08-2016

Application type: First submission

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL58167.041.16