Treatment for preschool age children who stutter: a randomized, multicentre, non-inferiority parallel group pragmatic trial with Mini-KIDS, social cognitive behaviour treatment and the Lidcombe Program

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THE STUDY AT A GLANCE

Dear parent(s) or guardian,

Your child will begin treatment with your speech therapist who is participating in a scientific study on treatment for stuttering for preschoolers.

To treat preschoolers who stutter, one frequently uses 3 treatments in Belgium, namely Mini-KIDS, social cognitive behaviour treatment and the Lidcombe Program.

Of these well-established treatments, it has been established in daily practice but not in the scientific literature how effective they are, and which is more appropriate in which types of children and families.

Therefore, we ask your permission for your child to participate in this study.

Before you consent, we want to fully inform you about the nature of the study; practically, as well as the benefits and the unlikely but possible risks. Only by informing you fully can you give your "informed consent".

What you read here already gives you an idea of what this study entails. Nevertheless, we ask you to read everything. You can ask questions if there are any ambiguities.

This study will compare Mini-KIDS, social cognitive behavioral therapy, and the Lidcombe Program. Thus, children who stutter will receive treatment with 1 of these 3 therapies.

Mini-KIDS is a stuttering treatment for preschoolers, where stuttering is discussed, recognized and changed in a playful direct way. Daring to stutter is the basis (pseudo-stuttering).

Social cognitive behavioral therapy focuses primarily on the child's thoughts, feelings and behaviors associated with stuttering and the situations in which stuttering occurs. One attempts to modify and train the behavior, thoughts and feelings so that the stuttering is affected.

In the Lidcombe Program, the child practices speaking stutter-free during short daily practice calls. During those practice calls, the child receives compliments on stutter-free speaking and sporadic feedback on stuttering. The parents are guided and trained in this process. Mainly due to the appreciative feedback after stutter-free moments, stuttering gradually decreases.

From daily practice experiences we expect similar results for the effectiveness of these 3 treatments, namely that after 18 months there will be (almost) no more stuttering. We also expect a similar high score in terms of the well-being of the child after 18 months and further in time. However, scientific findings on this are still lacking.

Treatment often does not last 18 months. Your child will only receive treatment for as long as it is needed. However, we will ask you some questions at regular intervals, including at 18 months.

The speech-language therapists participating are trained to deliver the 3 treatments. They will be supervised by the research team for the entire duration of the study. They will treat your child with 1 of the 3 treatments. Neither you nor your speech-language therapist can choose which treatment will be started.

Part of the treatment involves working with your child at regular intervals according to the assigned treatment for stuttering. You will be supervised for this by the speech-language therapist.

The study consists of 2 parts: a treatment phase followed by a maintenance phase, where the result of the treatment is monitored.

The treatment phase will last from 3 months to 2 years, as long as needed, with treatment sessions given weekly. Afterwards, the result of the treatment will be followed up in 7 treatment sessions for about a year (maintenance phase).

After 2 and 5 years, you will be contacted again with some questions to follow up on the long-term results.

Throughout the study, depending on the duration of treatment, up to video7 recordings will be made of your child's speech at the speech-language therapist's office and 8 video recordings at your home. In this way, the decrease in stuttering can be followed up scientifically.

The sponsor, Thomas More Mechelen-Antwerp, has insurance for this study. In the execution of the study, Thomas More Mechelen-Antwerp cooperates with the participating speech therapy practices in Belgium and with the study center of the University Hospital Antwerp that will help to practically manage the study.

In this study, there are no additional treatment sessions beyond those you would receive in normal daily practice. You will have to pay for the treatment for stuttering yourself for the amount after intervention by the mutual insurance company. You will receive compensation vouchers worth 20€ for 7 times that we ask you to record a video of your child and fill out questionnaires.

The data collected during this study will be kept confidential.

We would like to emphasize that participation in the study is entirely without obligation. You are completely free to agree or not to agree to your child's participation in the study. Even if you have agreed to participate, you can at any time drop out of the study and stop. This is your right and we will always be fully understanding and continue to provide you with the best care or treatment.

This study was evaluated by an ethics committee. Just because the study was approved does not mean it should affect your free choice of participation.

If you give permission for your child to participate in this study, we will verify in advance that all conditions are met to participate. The conditions for participation are given in detail further in this document.

In order to participate in this study, we ask for your agreement not to participate concurrently in other studies for the treatment of your child's stuttering or in studies that may affect stuttering.

If you agree to have your child participate in this study, you will sign the informed consent form. The speech-language therapist will also sign and date the consent form. This signature confirms that you have been given the necessary information about the study and that your child may participate. You will also receive a signed and dated copy of the consent form.

Now that you have some idea in broad terms of what this study entails, you can read this full consent form where the study is explained in detail. It is especially important that you understand what you are reading. The research team or your speech-language therapist is available to answer any questions you may have. If you wish, you may discuss the contents of this study with other trusted persons such as your primary care physician, family or friends.

Kind regards,

Your speech-language therapist and the research team

CHAPTER I - DESCRIPTION OF THE STUDY AND YOUR RIGHTS TO PARTICIPATE

1. Why are we doing this study?

Children's stuttering can have a major impact on their emotional and social development, especially if the stuttering does not disappear or diminish as the children get older. It is very important that stuttering be treated as soon as possible at an early age before it becomes a permanent part of the child's speech.

This clinical study (further referred to as "study") is being conducted to mutually evaluate the 3 common treatments given in Belgium to young children who stutter, Mini-KIDS, social cognitive behavioral therapy and the Lidcombe Program, in their effectiveness in treating stuttering.

Through this study, a more scientifically informed decision can be made when choosing treatment for young children who stutter. Another goal of the study is to find out which stuttering treatment gives the expected results first in treating stuttering, but also has the most lasting results.

2. Why am I being asked to participate ?

Your child is being asked to participate in this study because he/she:

- is stuttering
- is between 2 and 6.5 years old
- has no hearing loss
- has a parent who speaks the language (Dutch, French or English) and can communicate clearly with the speech-language therapist
- Has a parent who is willing to be intensively involved at home in the treatment of their child's stuttering
- Has a parent who is willing to regularly videotape their child at home as part of the study and follow-up of stuttering

Participation in the study is not possible if your child was diagnosed with a syndrome such as Down syndrome.

Twins and siblings will receive the same treatment. However, only 1 child will be able to participate in the study, and the other children will receive this treatment separately from the study. This measure serves to independently examine the results of the treatment between the related children.

The speech-language therapist will discuss with you the requirements for admission to the study.

3. Should I participate in a study ?

Your participation in this study is voluntary and should not be done under pressure. This means that you have the right not to participate in the study.

You may also withdraw at any time without providing a reason, even if you previously agreed to participate.

Your decision will not affect your relationship with your speech-language therapist or the quality of any future speech therapy treatments.

4. What will happen during the study ?

4.1. Introduction

This study will involve approximately children 250 from Belgium. This number of participants is necessary to statistically differentiate between the effectiveness of one treatment compared to the other two.

This study is a multicenter, randomized, open-label non-inferiority parallel group pragmatic study.

A multicenter study takes place at different research sites such as with the different speech-language therapists who participate.

In a randomized study, from the choice of treatments as offered in the study, one treatment is randomly assigned to the study participant using a computer program so that there are approximately equal numbers of participants in each treatment offered. Thus, if you decide to have your child participate in the study, you have a 1 in 3 chance that 1 of the 3 offered treatments for stuttering will be given.

An open-label study means that you, your child and the speech-language therapist know the treatment given. Which is the case here with the treatment given for stuttering because each treatment is different from one another.

A non-inferiority study is one where it can only be statistically shown that not 1 of the 3 treatments is less effective.

In a parallel study, participants are divided into groups that will receive a different treatment in order to compare the effectiveness of the treatment between the groups. In this study, there are 3 groups each with a treatment for stuttering: Mini-KIDS, social cognitive behaviour treatment or the Lidcombe Program.

A pragmatic study seeks to examine the effectiveness of a treatment in everyday practice that serves as a study setting to arrive at a scientific answer.

4.2 How long does the study last and how often am I expected to see the speech-language therapist ?

During the first consultation as part of the study, the speech-language therapist will assess the stuttering and, if necessary, observe for 3 months how the stuttering is progressing. Based on this assessment and any observation period, the speech-language therapist will decide whether stuttering treatment is appropriate or not.

The study consists of 2 parts: a treatment phase and a maintenance phase, where the outcome of the treatment is followed-up upon.

The treatment phase will last from 3 months to 2 years depending on the time needed to treat the stuttering, with treatment sessions given weekly. Afterwards, the result of the treatment for stuttering will be followed up in 7 treatment sessions spread over about a year or more if necessary.

At certain times throughout your child's treatment, study data will be collected. This will be collected at the 1st treatment session (baseline), as well as at the 3rd, 6th, 9th, 12th and 18th month. Study data will also be collected after 2 and 5 years. Which study data will be collected can be read in the next section.

4.3 What do the visits with the speech-language therapist involve ?

Initial consultation (screening)

During the initial consultation, the speech-language therapist will determine stuttering, gather information about it from you, give advice, and decide in consultation whether treatment for stuttering is appropriate.

As mentioned before, the speech-language therapist may choose to observe how the stuttering evolves for 3 months first.

If the choice is made to observe the stuttering first (for a maximum of 3 months), a follow-up can be arranged every 4 or 6 weeks. The speech-language therapist will tell you how to help your child during that time.

If a treatment for stuttering is indicated, the speech-language therapist will explain the study, answer your questions and give you the consent form with an information letter to read at home. You can contact the speech-language therapist if you have any questions. You sign and date the consent form together with the speech-language therapist at least at the next session (baseline). If you wish to participate, please notify the speech-language therapist at least 24 hours before the next session (baseline) to make sure your child is randomised (allocated to a treatment group) and you can complete the questionnaires before the baseline session. If you do not wish to participate, please notify the speech-language therapist.

When participating in the study, you will be asked to make a video recording at home for 10 to 15 minutes with a personal smartphone, camera or tablet of a conversation with you, and with your child speaking as much as possible.

During the recording, there should be very little background noise and the room should be well lit. In addition, the front of your child's face should be sufficiently visible at close range, as shown in the image in Figure 1. Your child's full name (first name and surname) should not be mentioned in the video.

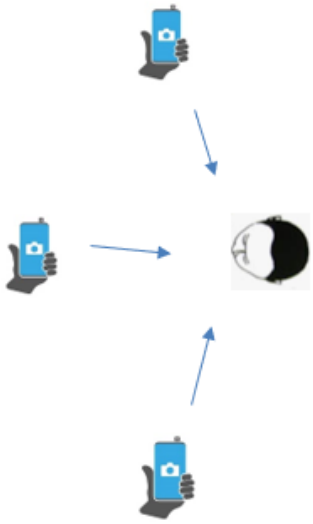

Figure 1: Recommendation arrangement of your child in the video recording

The topic of conversation can be a spontaneous conversation, a description of a picture, telling a story or explaining a game. It is important that you allow your child to speak freely. This video recording should be given to the speech therapist during the first treatment.

You will be sent questionnaires via email at home, which you will need to complete via computer or smartphone before the first treatment (baseline) below. Completing these questionnaires will take approximately 30 minutes.

First treatment session (baseline)

During this treatment, you can give the video recording you had previously recorded at home with your child to the speech therapist.

The speech therapist will give you a version of the consent form you already provided with her signature and date.

During this treatment session, the speech therapist will record a short video of your child to capture your child's speech on video.

The speech therapist will gather the necessary information about you and your child to begin treatment.

As part of the treatment, you will work with your child at home with the speech therapist. For this reason you will be guided in how to carry out the treatment at home.

During this first treatment, the speech therapist will give you more information about it, and you can ask questions. You can find more information about this in section 4.4.

Treatment sessions at 3rd, 6th, 9th, 12th, 18th and 24th month during the treatment phase and maintenance phase

During the treatment sessions in the treatment phase, and afterwards during the maintenance phase where the result of the treatment will be followed up with 7 treatment sessions spread over about a year, study data will be collected during the 3rd, 6th, 9th, 12th, 18th and 24th month.

In the process, some questionnaires will be presented to you.

You will also be asked at these times to record a short video recording at home of your child's speech as previously described, and to give the recording to the speech-language therapist during a subsequent treatment session. No stuttering treatment should be given during these video recordings.

During the treatment sessions at those time points, the speech-language therapist will record a short video of your child to capture the stuttering on video.

Follow-up of long-term results after 5 years

Five years after you started the study, you will be contacted to record one more video and answer some questions to follow up on the long-term results. The research team will contact you for this purpose.

4.4 Video recordings during treatment with the speech-language therapist

We would also like to inform you that during the 1st, 3rd, 6th and 12th month after the start of the study, video recordings will be made during the speech-language therapist's treatment(s) for 1 or 3 weeks in 20% of the participants who will be selected by chance. This can possibly happen before a treatment session with your child. You do not have to do anything for this.

These recordings serve to verify that the treatments given by the speech-language therapist are given in the manner specified in the study guidelines. Only by verifying this can the results about the effectiveness of the treatment be used statistically.

4.5 What do treatments for stuttering involve and how are parents involved ?

Depending on the assignment based on chance to one 1 of the 3 stuttering treatments offered, your child will receive treatment with Mini-KIDS, social cognitive behavioral therapy, or the Lidcombe Program.

Mini-KIDS

Mini-KIDS is a direct stuttering treatment for preschoolers that uses a playful approach to dare to stutter. For example, intentional disfluencies can be produced to show how the child can recognize and make stuttering easier.

Mini-KIDS consists of a treatment phase with 4 phases: desensitization (daring to stutter), identification (recognizing stuttering), modification (making stuttering easier) and generalization (generalizing the result), and afterwards a maintenance phase. In preschoolers between 2 and 4 years old, there is no identification phase in the treatment.

This technique of pseudo-stuttering is taught to the parent(s) individually, depending on the situation or preference. Parents also implement this treatment process at home, using pseudo-stuttering in the same way as during treatment: games to dare and be able to stutter.

During the desensitization phase, the child learns to become less sensitive to the stuttering. The idea is that stuttering is no longer a taboo subject, and the experience and feelings can be discussed so that it is no longer just a negative experience.

During the identification phase, the child learns to recognize the different types of stuttering moments in himself.

During the modification phase, the parents and the speech-language therapist help younger children to facilitate stuttering. For this, the model of the parents and the speech-language therapist is important. They demonstrate this through pseudo-stuttering. In this way, the stuttering moments change more and more in the direction of normal fluency and fluent speech. This process happens gradually and is more and more spontaneously applied by the child.

With children younger than 4 only the parents learn to recognize the stuttering, the child is too young for that. The slightly older children (from say 4 years) do learn to recognize (identify) their stuttering themselves. The skills they learn here they will use to change their stuttering more easily.

During the generalization phase, topics are often discussed with the parent(s) about which there are still questions, or for which the parents still need advice. In this way, the parent(s) feel increasingly competent to guide and support their child during and also after the treatment process.

The first 6 treatment sessions last 1 hour, thereafter 30 minutes, with weekly treatment sessions

During the maintenance phase where the result is monitored, the time between treatment sessions increases: every 2 weeks for 2 times, then to every 4 weeks for 2 times, then to every 8 weeks for 2 times and then every 16 weeks.

If necessary, additional treatment sessions will be scheduled to achieve the desired result.

<u>The social cognitive behavioral therapy</u>

Social cognitive behavioral therapy focuses primarily on the child's thoughts, feelings and behaviors associated with stuttering and the situations in which stuttering occurs. One attempts to modify and train the behavior, thoughts and feelings to affect the stuttering.

Parents are trained individually or as a group during 7 to 10 meetings in the evening that last 1 hour. During these meetings, parents learn to change their idea about stuttering so that a positive feeling and idea about it is possible. They are also taught the necessary skills to treat their child's stuttering at home. The parents are guided in this by the speech-language therapist by meeting twice a week for 30 minutes with their child.

The program consists of a treatment phase with 5 phases. These phases can run concurrently. During the 1st phase, the child is taught to like the activities that are talked about again. In addition, the conditions necessary to learn to do this are worked on with the child.

During the 2nd phase, work is done primarily through play on the self-regulation of one's own feelings that precede or arise during stuttering.

During the 3rd phase, playful work is done with thoughts and beliefs about one's self in relation to stuttering and one's own problem-solving abilities in situations when stuttering.

During the 4th phase of desensitization, attempts are made to make the child emotionally desensitized to their own stuttering so that their own negativity is no longer an obstacle. To do this, parents learn to pseudo-stutter.

During the 5th phase, the child is taught social skills and language skills that help him or her to be more self-reliant in interactions with others in a social context.

During maintenance phase where the result is monitored, the treatment sessions with the speech therapist decrease to every 2 weeks for 2 times, then to every 4 weeks for 2 times, then to every 8 weeks for 2 times and then every 16 weeks.

If necessary, additional treatment sessions will be scheduled to achieve the desired result.

The Lidcombe Program

In the Lidcombe Program, the child practices speaking stutter-free during short daily practice calls. During those practice calls, the child receives compliments on stutter-free speaking and sporadic feedback on stuttering.

Mainly due to appreciative feedback after stutter-free moments, stuttering gradually decreases.

The Lidcombe Program consists of 2 phases. During the 1st phase, efforts are made to treat the stuttering until the stuttering (almost) disappears. During the 2nd phase, the result of the treatment is maintained.

The parents are taught during the 1st phase how to give this treatment to their child at home daily for 10 minutes. During this phase, weekly treatment sessions are scheduled with the speech therapist so that they can be guided in this process. The first 6 treatment sessions last 1 hour, afterwards 30 minutes.

During the maintenance phase, the number of treatment sessions with the speech therapist decreases to every 2 weeks for 2 times, then to every 4 weeks for 2 times, then to every 8 weeks for 2 times and then every 16 weeks.

If necessary, additional treatment sessions will be scheduled to achieve the desired result.

It is important that you, as a parent, stick to the agreements made about giving the treatment at home. For this reason the speech therapist will regularly ask you about this with a questionnaire.

5. Will I benefit from the study ?

Your child will be treated for stuttering. The speech therapists participating in the study will be supervised by experts in each treatment. So your child will be in good hands. In addition, the information obtained during the study can contribute to a better understanding of the effectiveness of the 3 treatments (Mini-KIDS, social cognitive behaviour treatment and the Lidcombe Program) that are frequently given for stuttering in Belgium, and which treatment is more appropriate for which type of children and families.

These 3 treatments offered may or may not prove to be beneficial in treating your child's stuttering. Even if the effect proves beneficial, a return or worsening of stuttering is still possible. This is also the case independently of this study. Scientific studies have already demonstrated this.

6. What are the possible risks and discomforts of participating in the study ?

Participating in this study involves particularly low risk because Mini-KIDS, social cognitive behavioral therapy, and the Lidcombe Program are commonly given to preschoolers in practice in Belgium, and participating in this study involves similar and minimal risk to other treatments for preschoolers who stutter.

It is imperative that you report any new or worsening problem or health issue of your child to the speech therapist immediately.

This applies even if you think it has nothing to do with the study (or with 1 of these 3 stuttering treatments), and even if it is already described in this document.

If, in your opinion, something has an impact on stuttering it is best to discuss this with the speech therapist.

7. What if something goes wrong during the study ?

Even if there is no fault, Thomas More Mechelen-Antwerp is liable for any harm suffered by your child that is directly or indirectly related to your child's participation in the study. Thomas More Mechelen-Antwerp has taken out insurance for this liability (with "FAULTLESS" LIABILITY) (Ref. 1). A copy of the insurance certificate can be obtained from the speech therapist.

If the speech therapist believes that a link between new or worsened health complaint(s) and the study is possible, he/she will report it to Thomas More Mechelen-Antwerp. Thomas More Mechelen-Antwerp will then immediately file a report with its insurance company. The insurance will not cover the natural evolution of stuttering or the known risks of the treatment your child would have received without participating in the study (this is your standard treatment).

8. What if other treatments become available during the study ?

During the course of the study, new important information could become available that could affect your decision to participate (further). For example, other treatments for stuttering or important new information about the treatments offered may become available. It is the duty of the speech therapist to discuss this new information with you and to give you the opportunity to reconsider your participation in the study.

If you decide to discontinue your participation in the study or if you can no longer participate, your speech therapist will ensure that you continue to receive the best possible treatment.

9. Can my participation in the study end early ?

As discussed in detail further in this section, your child's participation in the study may end early if

- You decide to withdraw your consent,
- the speech therapist decides to stop your participation in the study, or
- other agencies interrupt or terminate the study.

In any case, if your participation in the study ends early, the speech therapist will discuss with you the further treatment of stuttering with your child. Thomas More Mechelen-Antwerp may continue to retain and use data already collected prior to the termination of your participation. This is intended to avoid misinterpretation of study results (as described in section I.§ 12.4, page 18).

If you experience a new side effect after completing your participation in the study, you may contact the speech therapist and ask for follow-up.

9.1. Your decision to withdraw your consent

You have the right to withdraw your consent without giving a reason. However, we do ask that you inform the speech therapist of your decision. Even though it is not mandatory, it can be useful for the speech therapist and for Thomas More Mechelen-Antwerp to know the reason for your decision (e.g. too many trips, ...).

Withdrawing your consent means that you decide to stop all treatment sessions associated with the study.

Please discuss with the speech therapist the practicalities of discontinuing your participation (depending on your situation), including your continued follow-up.

In any case, no new data will be delivered to Thomas More Mechelen-Antwerp.

If the study data on stuttering from the video recordings or questionnaires was already used before the withdrawal of your consent, Thomas More Mechelen-Antwerp still has the right to use that study data.

Also, the study data on stuttering from the video recordings or questionnaires that were collected (but not yet processed) before the withdrawal of your consent, and the study data obtained from them, can still be used by Thomas More Mechelen-Antwerp. You can ask for these video recordings or questionnaires to be destroyed. To avoid misinterpretation of the study results, this can be postponed until the end of the study.

9.2. The speech therapist decides to stop your child's participation in the study

The speech therapist or research team may terminate your child's participation in the study because

- he/she perceives that you are not following instructions, or
- there is some other reason that will be explained to you.

9.3. Other agencies may interrupt or terminate the study

Thomas More Mechelen-Antwerp and the competent Belgian health authorities may interrupt or terminate the study,

- because the information collected shows that the treatment is not working well enough,
- for any other reason that will be explained by the relevant authority.

10. What treatment will my child receive after participating in the study ?

After your child stops treatment, the speech therapist will evaluate the stuttering. If necessary, he/she will give your child the best available standard treatment or refer you to another treating speech therapist of your choice.

11. Will my child's participation in the study incur additional costs for me ?

11.1. Examinations and treatments paid for by Thomas More Mechelen-Antwerp

The usual treatments for stuttering are to be paid for by yourself for the amount after intervention by the mutual fund. There are no additional treatment sessions for the study beyond those you would receive in usual daily practice.

In most cases, the mutual insurance company intervenes for 30-minute treatments for stuttering with the speech therapist. For the treatments with the Lidcombe Program and Mini-KIDS, it is recommended that the first 6 treatments each last 60 minutes. For that reason, the treatment for the remaining 30 minutes will be paid for by Thomas More Mechelen-Antwerp.

11.2. Other expenses paid by Thomas More Mechelen-Antwerp

You will receive a compensation voucher worth 20€ for the 7 times we ask you to record a video of your child and to fill in questionnaires. The speech therapist will inform you how this is practically arranged.

12. What data will be collected during the study and what will happen to it ?

12.1. What data will be collected and processed during the study ?

The personal data collected and processed are about your child's background information (e.g., age, gender, family history in relation to stuttering,...), the comorbidity (the occurrence of autism, ADHD, a speech disorder,...) and the results of the study tests.

12.2. How will the speech therapist handle my child's personal data ?

The speech therapist is bound by professional confidentiality when collecting and processing your or your child's data.

This means that he/she will not disclose your identity or that of your child, including in a scientific publication or lecture, and will encrypt this data (i.e., replace your identity or that of your child in the study with an identifier) before sending it to the sponsor.

As a result, the speech therapist will be the only one who will be able to link your identity or your child's identity to the data transmitted during the study, with the exceptions listed under § 12.6.

The data Thomas More Mechelen-Antwerp receives will therefore not enable it to identify you or your child.

12.3. What will happen to the information about my child collected during the study ?

Your child's participation in the study means that your child's personal data will be

- collected by the speech therapist, and
- used in coded form by the sponsor of the study.

The speech therapist and Thomas More Mechelen-Antwerp may only use the coded personal data for research purposes related to scientific publications in the context of the study in which your child is participating.

If broader use of the encrypted data is planned, it will be noted below.

In addition, Thomas More Mechelen-Antwerp may allow external researchers (not involved in this study) access to the coded data. If an external researcher wishes to use the data in research not yet described in this document, this research must be approved by an Ethics Committee. If your child's coded data is sold, you will not be compensated for it.

12.4. How will your child's data be processed ?

Your child's study data will be processed in accordance with the General Data Protection Regulation (AVG) (Ref. 2) and the Belgian Data Protection Act of 30 July 2018 (Ref. 3). Thomas More Mechelen-Antwerp is responsible for this.

The reason we may process your child's personal data is because we are conducting research and you have given permission.

The Clinical Trial Center of the University Hospital Antwerp is, at the request of Thomas More Mechelen-Antwerp, the processor of the data of the electronic case report form (eCRF - study database) and will be the location where the data will be stored electronically on a daily basis, and afterwards for 25 years.

12.5. Can I access and correct my child's data collected and processed during the study ?

You have the right to ask the speech therapist what data is collected about your child and what it is used for in this study.

You have the right to:

- access and review this data,
- receive the personal data collected,
- request correction if they are not correct,

- Withdraw your consent to the processing of personal data about you or your child. Personal data of you or your child already collected before the withdrawal will be retained to avoid misinterpretation of study results.

It is not possible to:

- to have all your records and your child's records deleted,
- Limit the processing of your or your child's data,
- To oppose the processing of your or your child's personal data.

This is not possible partly to avoid misinterpreting the results of the study.

12.6. Who other than the speech therapist has access to my personal data ?

In order to control the quality of the study, non-coded personal data about you or your child or information about you or your child relevant to this study from the speech therapy record may be inspected by people other than the study staff. This inspection is done under the supervision of the speech therapist and these individuals are bound by professional secrecy or through a confidentiality agreement. They may include:

- Thomas More Mechelen-Antwerp designated staff (MONITORS and AUDITORS) and people or organizations who provide services to or work with Thomas More Mechelen-Antwerp. However, they will never disclose your or your child's name and contact information to Thomas More Mechelen-Antwerp,
- inspectors from competent health authorities around the world,
- an independent audit group,
- persons appointed by the Ethics Committee.

If necessary for the study, coded study data may be sent to other countries within and outside the European Union (EU) and reviewed by:

- personnel (other than inspectors) of the competent health authorities of Belgium or other countries within and outside the EU,
- The Belgian Evaluating Ethics Committee(s),
- external researchers,
- Thomas More Mechelen-Antwerp, personnel designated by Thomas More Mechelen-Antwerp and people or organizations that provide services to or work with Thomas More Mechelen-Antwerp, and/or
- scientific partners from the Thomas More Mechelen-Antwerp group in Belgium and in other countries within and outside the EU.

European regulations and Belgian data protection laws impose restrictions on the transfer of data to non-EU countries. Thomas More Mechelen-Antwerp must always ensure that your or your child's encrypted study data is protected in an equivalent way when transferred to a non-EU country. If Thomas More Mechelen-Antwerp enters into a data protection agreement for this purpose, a copy of this agreement can be obtained from the speech therapist.

You can always contact your speech therapist for more information about such transfer.

12.7. What will happen to the results of the study ?

Upon completion of the study, a description and the results of the study will be published in specialized journals related to speech therapy. A copy of the scientific publication is available through the speech therapist or the research team.

A description of the study will also be available at https://www.Clinicaltrials.gov. Using the study number found on the cover page of this document, you can access this study. Within 1 year of the study's conclusion, the websites will include a summary of the results (Ref. 4).

These websites or publications will not contain information that identifies you or your child.

12.8. Will my child's data be used for purposes other than the study I am participating in ?

The results of the study will be used to answer the scientific questions of this study. In addition, Thomas More Mechelen-Antwerp could use the data obtained from this study in other research and development activities (and related scientific publications). These activities could include:

- The effectiveness of treatments for childhood stuttering in a broad sense
- other research related to stuttering

Any additional or future research beyond the study, must always be approved by a recognized Belgian Ethics Committee.

The Federal Knowledge Center for Health Care (KCE) will use anonymous data from this study for an analysis on health economics (health economics analysis).

12.9. How long will my child's data be kept ?

After the study ends, coded data from you and your child will be kept for at least 25 years (Ref. 5) to ensure the validity of the study. This will be the case even if your child stops participating in the study early.

13. Who reviewed and approved the documents regarding the study ?

The study documents were reviewed by:

- The Federal Knowledge Center for Health Care (KCE),
- An independent Belgian Ethics Committee.

The appropriate committees are responsible for protecting the individuals participating in a study. You should not interpret their approval as an incentive to participate in the study.

CHAPTER II - INFORMED CONSENT

PARTICIPANT

REQUIREMENTS FOR THE PARTICIPATION OF YOUR CHILD IN THE STUDY

- I, the parent or guardian, declare that I have been informed about the purpose of the study, its duration and consequences, possible risks and inconveniences, and what is expected of me, and that I have understood all this. My rights and the rights of my child as a participant in a study have been explained to me and I have understood them.
- I understand that as a parent or guardian I was given this document to review further at home after an initial conversation about it. I have been given the opportunity to ask any questions that come to mind by phone or email and have received satisfactory answers.
- I, as a parent or guardian , have had enough time to think about it and talk about it with a trusted person (e.g. friends, family, treating physician, ...).
- I understand that I can stop my consent for my child to participate in the study at any time.
- I understand that I voluntarily and without being compelled to do so, consent that my child will participate in this study.

  The above permission by signature was given by me at home without the presence of the speech therapist.

  I understand that I provide this consent form with a signature and date together with the speech-language therapist at least on the baseline session. I notify the speech-language therapist of my participation at least 24 hours before the baseline session to make sure my child is randomised and I can complete the questionnaires before the baseline session.
- I understand that information about me and my child will be collected and will be kept confidential.
- I agree to have my personal data or my child's personal data processed as described in Section I, § 12 page 17.
- I understand that Thomas More Mechelen-Antwerp has taken out an insurance policy in case my child suffers a disadvantage in connection with my child's participation in this study.
- I understand that if my child participates in this study, I will have no costs except those for standard treatment of stuttering.
- I agree to have my treating physician(s) informed of my child's participation in this study if appropriate.
- I agree that my child will not simultaneously participate in another study without having informed the speech therapist, and that the speech therapist could refuse such participation for good reason.
- I understand that to the extent possible and I as a parent, my child must cooperate and follow the instructions of the speech therapist and the study staff around the study.
- I understand that my child's participation in the study may be terminated without my consent if my child requires different treatment, does not follow the study schedule, has a side effect related to the study or for any other justifiable reason.

- I affirm that all of my child's information provided regarding medical and family history is correct. I understand that it may cause me harm if I fail to inform the speech therapist of or point out possible exclusion criteria.

I, as a parent or guardian, agree that my child who is between the ages of 2 and 6.5 years old may participate in the study, and I have received a copy signed and dated by the speech therapist of all pages of this document.

Name and first name of the child participating in the study:

.....

Name and first name of primary parent or guardian:

.....

Date (DD/MM/YYYY) that the first parent or guardian gives consent:

.....

Signature of first parent or guardian:

.....

_____

Name and first name of second parent or guardian (optional):

.....

Date (DD/MM/YYYY) that the second parent or guardian gives consent (optional):

.....

Signature of second parent or guardian (optional):

.....

SPEECH-LANGUAGE THERAPIST

I, the undersigned speech-language therapist, affirm

- That the participant's parent(s) or guardian(s) have been given the necessary information about the study orally, that the contents have been explained to them, and that they have been given an original signed copy of this document.
- That I have verified that the participant's parent(s) or guardian(s) have understood the study.
- That I have given the participant's parent(s) or guardian(s) adequate time to reflect on their child's participation and to ask questions.
- That no pressure was exerted on the participant's parent(s) or guardian(s) to get them to agree to their child's participation in the study.
- That I work in accordance with the ethical principles as stated in the most recent version of the "Declaration of Helsinki", the "Good Clinical Practice" and Belgian law (Ref. 6).

Date (DD/MM/YYYY) that the primary investigator (speech-language therapist) signs:

.....

Name and first name of the primary investigator (speech-language therapist):

.....

Signature of primary investigator (speech-language therapist):

.....

GLOSSARY

GBA: The Belgian Data Protection Authority ensures that personal data is carefully used and secured, and that your privacy will continue to be guaranteed in the future.

INSURANCE WITH "FAULTLESS" LIABILITY:

Thomas More Mechelen-Antwerp is liable for any injury or damage to the participant that is directly or indirectly related to the study. No fault needs to be demonstrated by you for this.

MONITOR and AUDITOR:

Both the monitor and the auditor work for Thomas More Mechelen-Antwerp.
The monitor provides continuous quality control during the course of the study. The auditor carries out an investigation after the study. They check whether the study is/was carried out according to the protocol, whether the reported data is reliable and whether the study complies with the applicable laws.

REFERENCES

[1] This is consistent with article 29 of the Belgian law of May 7, 2004 on human experimentation and the applicable royal decrees.

[2] General Data Protection Regulation No. 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC.

[3] Belgian Law of 30 July 2018 on the protection of natural persons with regard to the processing of personal data.

[4] In accordance with Chapter 4.3. of the Commission Directive : Guidelines for posting and publishing result-related information on clinical trials in relation to the implementation of Article 57(2) of Regulation (EC) No 726/2004 and Article 41(2) of Regulation (EC) No 1901/2006 - 2012/302/03.

[5] In accordance with Article 58 of the Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

[6] Belgian law of May 7, 2004 on experiments on humans and applicable royal decrees.