INVESTIGATING THE SPEECH AND PSYCHOLOGICAL BENEFITS OF ADDING INTERNET ANXIETY TREATMENT TO INTENSIVE SPEECH PRACTICE FOR ADULTS WHO STUTTER

PARTICIPANT INFORMATION STATEMENT

(1) What is this study about?

You are invited to take part in a research project designed for adults who stutter and who experience social anxiety. This study is investigating whether access to an Internet Cognitive Behaviour Therapy (CBT) program immediately after completing treatment designed to reduce stuttering, improves speech and psychological outcomes.

You have been invited to participate in this study because you are an adult who stutters. This Participant Information Statement tells you about the research study. Knowing what is involved will help you decide if you want to take part in the research. Please read this information sheet carefully and ask questions about anything that you don’t understand or want to know more about.

Participation in this research study is voluntary.

By giving your consent to take part in this study you are telling us that you:
✓ Understand what you have read.
✓ Agree to take part in the research study as outlined below.
✓ Agree to the use of your personal information as described.

You will be given a copy of this Participant Information Statement to keep.

(2) Who is running the study?

The study is being carried out by the following researchers:

- Professor Mark Onslow, Director, Australian Stuttering Research Centre, The University of Sydney
- Associate Professor Ross Menzies, Australian Stuttering Research Centre, The University of Sydney
• Associate Professor Ann Packman, Senior Research Officer, Australian Stuttering Research Centre, The University of Sydney
• Dr Susan O’Brian, Senior Research Fellow, Australian Stuttering Research Centre, The University of Sydney
• Dr Robyn Lowe, Postdoctoral Research Associate, Australian Stuttering Research Centre, The University of Sydney

This study is being funded by the National Health and Medical Research Council.

(3) **What will the study involve for me?**

If you agree to participate in the study, before you start treatment and 12 months after completing the speech component of your treatment, we will collect information about you and your stuttering to determine the effectiveness of the treatments. This will involve you participating in an interview with a researcher and completing a range of questionnaires designed to assess your overall psychological functioning and well being. Participation in this study will also involve you making two 10 minute audio recordings and one 10 minute video recording of you talking before and after treatment. We will audio record your speech during a phone call while talking with a researcher. We will video record you at the Australian Stuttering Research Centre while you are talking to a researcher.

There are potentially two components to the treatment, (1) a stuttering reduction component (speech treatment) and (2) an anxiety reduction component (Internet CBT program). All participants will receive the speech treatment but only about half the participants will be offered the Internet CBT program. Neither you nor the speech pathologist will have any say about whether or not you are initially offered access to the Internet CBT program. This will be randomly decided by an independent statistician. However, if you are not offered the Internet CBT program in the first instance, you will be able to have access to the same program after all data has been collected 12 months later.

The speech treatment involves teaching you a speech technique that has been shown to assist in the reduction of stuttering. The technique is usually referred to as speech restructuring or sometimes prolonged speech or smooth speech. You will be required to attend the clinic for two hours of individual treatment and then to learn the skills required for practising the technique. Then you will be required to attend the clinic with a group of other participants for three full days of intensive speech practice within the clinic environment. During the speech practice days, there will be no opportunity to discuss (1) any anxiety you may experience associated with stuttering or (2) using your new technique in everyday environments. The focus is solely on practising your new speech technique. Student speech pathologists from the University of Sydney will assist you with your speech practice during the intensive practice days. At all times the students will be directly supervised by qualified speech pathologists.

The Internet CBT program specifically targets speech-related anxiety and will involve working through a series of graded tasks designed by a psychologist to help reduce speech-related anxiety. If you are assigned to the Internet CBT group, you will be given login details to access the program using your computer at home. This will occur after the three day speech treatment.

After the intensive speech practice component participants will receive weekly email reminders to continue practicing the speech technique. For participants in the Internet CBT group, they will receive weekly reminders to log in to the Internet program.

(4) **How much of my time will the study take?**

The diagnostic interview conducted before and after treatment will take approximately 30 minutes each time while the questionnaires may take up to 3 hours to complete each time. However, the pen and paper questionnaires can be completed at home. There will be three 10 minute recordings made
of your speech on each assessment occasion. Two of these recordings will be audio recordings and one will be a video recording.

The speech treatment will involve your attendance at the clinic for two hours of individual treatment with a speech pathologist followed by three consecutive 7-8 hour group days about a week or two later.

If you are assigned to receive the Internet CBT program, you will have up to 5 months to complete the program at home using your computer. The program can be completed at your own pace, however, it is best accessed on a regular weekly basis in order to gain the full benefit of the program.

(5) Who can take part in the study?

You will be eligible to participate in this study if you can answer “yes” to all of the following:
- Are aged 18 years or older
- Have a confirmed diagnosis of stuttering by a speech pathologist
- Experience social anxiety
- Have good spoken English as well as good skills for reading and writing English
- Have unlimited access to a computer with Internet connection

You will not be eligible to participate in this study if you respond “yes” to any of the following:
- You have received treatment for stuttering in the past 6 months
- You have received treatment for anxiety or depression from a mental health professional in the past 12 months
- You have accessed the Internet CBT program during the previous 12 months
- Your stuttering started after 12 years of age
- Your stuttering is due to a known conversion or any other psychological disorder
- You have a diagnosis of a neurological disorder (e.g. cerebral palsy, Parkinson’s disease)
- You are unable or unwilling to stabilise ‘psychological’ medication for the duration of the study

(6) Do I have to be in the study? Can I withdraw from the study once I’ve started?

Being in this study is completely voluntary and you do not have to take part. Your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at the University of Sydney, the staff or the researchers involved in the study.

If you decide to take part in the study and then change your mind later, you are free to withdraw from the study at any time. You can do this by notifying your speech pathologist.

If you decide to withdraw from the study, we will not collect any more information from you unless you give permission for us to do so. Please let us know at the time you withdraw what you would like us to do with the information we have collected about you to that point. If you wish, your information can be removed from our study records at any time until we have analysed and published the results.

You are requested to advise the research officer if:
- You elect to seek additional speech and/or psychological treatment whilst enrolled in this research.

If you do seek additional speech and/or psychological treatment while still enrolled in this research, you may no longer be eligible to continue your participation. One of the researchers will contact you to discuss.

(7) Are there any risks or costs associated with being in the study?
Aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this study.

In the unlikely event that you experience heightened psychological symptoms when responding to the assessment questionnaires or through your participation in the treatment, you are advised to contact the psychologist and chief Investigator, Ross Menzies, for information and professional guidance.

(8) Are there any benefits associated with being in the study?

We expect that your participation is this study will be of some benefit to you regardless of the group to which you are assigned, as the speech technique taught to you, is very likely to help you to control your stuttering. However, it is possible that if you are assigned to the group that receives both the speech treatment and the Internet CBT program, you may achieve an additional benefit by decreasing your anxiety. However, this benefit is likely even if you access the CBT program after the 12-month data collection period. We cannot however, guarantee that you will benefit from participating in the study.

(9) What will happen to information about me that is collected during the study?

By providing your consent, you are agreeing to us collecting personal information about you for the purposes of this research study. Your information will only be used for the purposes outlined in this Participant Information research Statement, unless you consent otherwise.

The data collected from the recordings will be analysed only by the researchers involved in this study.

Your information will be stored securely and your identity/information will be kept strictly confidential, except as required by law. Study findings may be published, but you will not be individually identifiable in these publications.

We will keep the information we collect for this study for a minimum of 20 years and we may use it in future projects. We don’t know at this stage what these other projects will involve. We will seek ethical approval before using the information in these future projects. By providing your consent you are allowing us to use your information in future projects.

(10) What will happen to my treatment when the study is finished?

At the end of the study, if you wish to receive further speech or psychological treatment the researchers can provide you with private and/or public referral details. If you were assigned to the speech treatment only group you will be granted access to the Internet CBT program when the study is finished.

Any treatment sought and received after your participation in this study will be at your own expense.

(11) Can I tell other people about the study?

Yes, you are welcome to tell other people about the study.

(12) What if I would like further information about the study?

When you have read this information, a researcher from the Australian Stuttering Research Centre will be available to discuss the details with you further and answer any questions you may have. If you would like to know more at any stage during the study, please feel free to contact Associate Professor Ross Menzies on +61 2 9351 9061, or ross.menzies@sydney.edu.au.
(13) Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. This feedback will be in the form of a one-page summary posted on the web-site of the Australian Stuttering Research Centre, the University of Sydney. You can also nominate other means for receiving feedback about the results of this study by ticking the relevant box on the consent form. This feedback will be available after the study is finished and the results analysed.

If personal feedback concerning individual results on psychological measures is considered appropriate, you will be contacted by Associate Professor Ross Menzies.

(14) What if I have a complaint or any concerns about the study?

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the University of Sydney [protocol number: 2016/393]. As part of this process, we have agreed to carry out the study according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect people who agree to take part in research studies.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number.

The Manager, Ethics Administration, University of Sydney:
- Telephone: +61 2 8627 8176
- Email: ro.humanethics@sydney.edu.au
- Fax: +61 2 8627 8177 (Facsimile)

This information sheet is for you to keep