Voice Therapy for Muscle Tension Voice Disorders: Contents and Processes

THERAPIST PARTICIPANT INFORMATION STATEMENT

(1) What is this study about?

You are invited to take part in a research study about what Speech Pathologists do in voice therapy. We are interested in exploring the complexities of voice therapy by unpacking the content and interactions that occur between Speech Pathologists and their clients who have Muscle Tension Voice Disorder (MTVD). The findings of this research will help identify, quantify and characterise components of voice therapy used in current clinical practice. It is hoped that this will enhance Speech Pathologists’ efforts to systemically approach future research design and reporting standards, clinical practice, and professional training.

You have been invited to participate in this study because you are a Speech Pathologist who: 1) is a practising member of Speech Pathology Australia and 2) provides voice therapy treatment for clients who have MTVD. 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 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 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 who are all Speech pathologists:

• Clare Eastwood, PhD Student, Speech Pathologist, The University of Sydney
• Patricia McCabe, PhD Certified Practising Speech Pathologist (CPSP), Associate Professor, The University of Sydney
• Catherine Madill, PhD CPSP, Director of the Voice Research Laboratory, The University of Sydney

STUDENT DECLARATION
Clare Eastwood is conducting this study as the basis for the degree of Doctor of Philosophy at The University of Sydney. This will take place under the supervision of Patricia McCabe, Associate Professor at The University of Sydney.

(3) What will the study involve for me?

This study involves completion of short questionnaires, video recording of your voice therapy session(s) and participation in interview(s) relating to the video recorded therapy session(s).

Step 1. If you are interested in participating in the study you need to contact the nominated researcher - Clare Eastwood (see contact details below). The researchers will then send you (1) consent forms, (2) an advertisement flyer and a Participation Information Statement for your clients and (3) study instructions. We ask that you display the flyer and information statement in your client waiting area. The flyer and information statement will have contact details for the clients to use if they are interested in participating. After a client has made contact with the researchers, one of the researchers will contact you to arrange a meeting time for observation of a therapy session and following interview. Prior to observation and interview you will need to fill out two short questionnaires (see below).

Step 2. Short Questionnaires

Therapist Questionnaire: you will be asked 13 questions relating to a) demographic information, b) your clinical experience and c) professional training in the area of voice.

Client Questionnaire: you will be asked 5 questions to identify a) a consenting client who is willing to be treated by you whilst being video recorded b) the client’s assessment and diagnostic information. You will be asked to fill in this questionnaire for each client recruited into the study (you can determine the number of clients according to your own preference).

Client Criteria: Clients must have the following characteristics:

• Aged 18-60
• Fluent in the English language
• Diagnosis of MTVD (see attached description)
• No prior history of voice therapy (with the exception of any therapy provided within this voice assessment)
Step 3. Video recording of therapy session and semi-structured interview

1. You and one of the researchers will meet at your clinical practice to set up the video recording equipment.
2. We are aiming to video record the first therapy session; however, according to the preferences of you and your client, recording of any therapy session will be appreciated. The entirety of the therapy session will be video recorded. The researcher will not be present in the therapy room while your therapy sessions are being video recorded.
3. Immediately post video recording of the therapy session, you will be asked to participate in a semi-structured interview, directly relating to the session. The interview will concern what occurred during the therapy session. It will be audio recorded.
4. After the interview, you will need to confirm whether you want to further participate in the study or not. This will once again involve recording of a therapy session and immediate post interview. We aim to repeat (1) the observation and interview procedures up to 2-6 times with the same client and (2) the observation and interview procedures with up to 3 new clients. You will determine the extent of your participation (as long as consent is freely given by clients).
5. You may change your mind about the extent of your participation at any point throughout the study. If you decide you want to increase or decrease your participation please contact Clare Eastwood by calling or texting 0434894571 or email clare.eastwood@sydney.edu.au. You may also approach the attending researcher on the day of the therapy session. If you do decide to increase the extent of your participation beyond what you indicate on the initial consent form, you will be asked to sign another consent form.

**Note:** this study does not concern the effectiveness of your chosen methods of voice therapy. You will not be judged as to whether your methods are right or wrong, effective or not effective. No interpretations of this nature will be disseminated in any publication or presentation.

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

**For each client:**

- The therapist questionnaire will take approximately 5 minutes to complete. The client questionnaire per client will take approximately 5-10 minutes to complete
- Setting up recording equipment for each therapy session will take approximately 5-10 minutes
- Video recordings of each complete therapy session will depend on your own clinical practice
- Each semi-structured interview per session will take approximately 30 minutes to complete. These should be completed immediately after the video recording of the therapy session.

**Note:** The total amount of time commitment will depend on how many sessions you and your client(s) are willing to participate in. This will range from a total of 45 minutes (x1 client and x1 session) to 12 hours and 45 minutes (x3 clients and x6 sessions per client).
(5) 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.

If you decide to take part in the study and then change your mind later, you are free to withdraw at any time. You can do this by contacting Clare Eastwood by calling or texting 0434894571 or email clare.eastwood@sydney.edu.au. Your decision to no longer participate in the study will not affect your current or future relationship with the researchers or anyone else at the University of Sydney.

(6) 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.

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

We cannot guarantee that you will receive any direct benefits from being in the study.

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

- The video recordings and interviews will be transcribed and analysed by the researchers for the purposes of this project.
- The questionnaires will be de-identified and coded with participant ID numbers. The information collected through the short questionnaires will be used by the researchers to help evaluate the other data collected in this project.
- During the study, any written information collected about you will be de-identified, coded with ID numbers, scanned and stored on a password protected University owned computer server. The hard copy data will be destroyed immediately after the upload is completed.
- During the study and after its completion, all electronic data will be stored on the University of Sydney Research Drive Storage in a password protected computer.
- Only the researchers will have access to the data.
- The data will be kept for a period of 5 years after the completion of this project. At the end of this time all data will be deleted.

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. Multiple studies may be published from the data collected in this project.
By providing your consent, you are agreeing to us collecting personal information about you for the purposes of this research. This information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise.

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

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

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

When you have read this information, Clare Eastwood will be available to discuss it 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 Clare Eastwood (PhD student) at clare.eastwood@sydney.edu.au or call or text 0434894571.

(11) Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by ticking the relevant box on the consent form. This feedback will be in the form of a one page lay summary. You will receive this feedback after the study is finished.

(12) 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 2016/055. 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