

Research Information Sheet [Online]

Title of Study: *Speech Fluency in Down Syndrome*

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When we say “you” in this consent form, we mean you or your child with Down Syndrome; “we” means the researchers and other staff.

KEY INFORMATION ABOUT THIS STUDY.

- This project is being conducted to learn more about the speech characteristics of people with Down Syndrome.
- This study will help us to update what we know about Down Syndrome, and what parts of speech might affect fluency (i.e. flow, or ease of talking) so we can learn how to make speaking a little easier for some.
- It is your choice whether to participate in this research project. This study is completely voluntary and you are free to withdraw at any time.
- This research involves reading through the relevant consent document(s), answering a few case-history questions, and being video-recorded while speaking for 10-20 minutes. It may take up to 30-40 minutes to complete.
- Your privacy is very important to us. The study uses encrypted servers for the videos in addition to safeguards to protect any data provided that could uniquely identify participants to be stored securely and accessed only by the lead investigators.

Purpose

You are being asked to be in a research study investigating the speech characteristics of those with Down Syndrome because you or your child has Down Syndrome. This study is being conducted at Wayne State University and will enroll approximately 200 participants who share this condition from the U.S. and other English-speaking countries. **Please read this form and ask any questions you may have before agreeing to be in the study.**

The use of new technologies allows us to connect with more people with Down Syndrome than ever before and take an in-depth look at the qualities that characterizes the speech of this population. We would like to investigate the anecdotal reports of stuttering and other fluency issues historically associated with this disorder. An international research program housed in the Department of Communication Sciences and Disorders focused on speech fluency and speech therapy wants to invest in the lives of those with Down Syndrome by taking a closer look at the speech mechanics.

Study Procedures

Please read through this document and contact the researchers with any questions you may have. You will be asked whether you consent to participate in this study via Qualtrics. If you consent you will be asked to answer some additional questions on Qualtrics, such as your age, gender, handedness, as well as any known personal and/or family history of speech and communication delays/disorders. You will then select your recording method (Zoom, WhatsApp, online video upload). A smartphone or tablet can record and upload a video that contains a casual conversation for 10 to 20 minutes, capturing the speech of the participant. A live video conference with a researcher can also be arranged via Zoom. Your participation in this study should take 30 - 40 minutes from start to finish.

The Steps

1. Read through this document and any other information sheets that may be helpful to your understanding. Please feel free to contact the researchers with any questions you may have before giving your consent to participate (10 minutes).
2. Complete the online survey hosted on Qualtrics, providing your age, gender, handedness, as well as any known personal and/or family history of communication delays/disorders (5 minutes).
3. Choose your recording method:

Option A	Option B	Option C
Live recording of online video chat with researcher.	Record a video on your smartphone or other recording device and upload file to a secure server via our website.	Record a video on your smartphone and send it to us via WhatsApp.
Requirements: <ul style="list-style-type: none"> • Home computer or other device with access to Zoom, Skype, or Microsoft Teams. • <i>You will need to provide your email address to schedule a date/time with a researcher.</i> 	Requirements: <ul style="list-style-type: none"> • Smartphone or other recording device. • <i>You will need to provide your email address to receive the web address as well as your personalized login ID.</i> 	Requirements: <ul style="list-style-type: none"> • Smartphone. • WhatsApp app. • <i>You will need to provide your phone number linked to the PI's WhatsApp account.</i>

4. While being recorded on video, take part in a casual conversation with a parent/guardian (10-20 minutes).
5. Submit your video.
6. Your video will then be transferred to an encrypted and password-protected external hard drive (under a coded file name) to protect your identity and keep your recording confidential.

Benefits

As a participant in this research study, there will be no direct benefit for you; however, information from this study may benefit other people now or in the future.

Risks

There are minimal potential health and safety risks associated with participating in this study, beyond those you encounter in daily life.

Although unlikely, by taking part in this study, you may experience the following risks:

- Possible loss of confidentiality: Signed consent/assent documents that contain participants' personal identifying information will be kept separate from the research data collected, stored in a locked cabinet in a secured laboratory on Wayne State University's main campus for data review and auditing purposes only. All video recordings will be stored under a coded filename onto an encrypted and password-protected external hard drive by the researchers. It will be stored in a separate locked cabinet in the same secured laboratory. Only the PIs will have access to these items.
- There may also be risks involved from taking part in this study that are not known to researchers at this time.

Study Costs

Participation in this study will be of no cost to you.

Compensation

You will not be paid for taking part in this study.

Confidentiality

The information collected about you or your child during the course of this study will be kept confidential to the extent permitted by law. You will be de-identified in the research records by a code name or number. If photographs, videos, or audiotape recordings of you are used for research or educational purposes (with your permission), your identity will be protected or disguised. When the results of this research are published or discussed in conferences, no information will be included that would reveal your identity. Access to the videos and all audio-visual components related to your videos will be strictly controlled by the study investigators and future project collaborators.

We will ask for your permission to use your audio recordings for future collaborative research and educational purposes within the Qualtrics survey. Nothing will be shared without your permission.

However, the study sponsor, the IRB at Wayne State University, or federal agencies with appropriate regulatory oversight [e.g., Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), Office of Civil Rights (OCR))] may review your records.

Voluntary Participation/Withdrawal

Taking part in this study is voluntary. You have the right to choose not to take part in this study. You are free to only answer questions that you want to answer. You are free to withdraw from participation in this study at any time. Your decisions will not change any present or future relationship with Wayne State University or its affiliates, or other services you are entitled to receive.

Questions

If you have any questions about this study now or in the future, you may contact Dr. Shelly Jo Kraft or Emily Lowther at the following phone number (313) 577-4047. If you have questions or concerns about your rights as a research participant, the Chair of the Institutional Review Board can be contacted at (313) 577-1628. If you are unable to contact the research staff, or if you want to talk to someone other than the research staff, you may also call the Wayne State Research Subject Advocate at (313) 577-1628 to discuss problems, obtain information, or offer input.

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APPROVAL PERIOD



**WAYNE STATE UNIVERSITY
INSTITUTIONAL REVIEW BOARD**