CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Respiratory Capacity and Swallowing Function in Spinal Disorders

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Sponsor: National Institute on Deafness and Other Communication Disorders (USA)
Grant #: 2 R01 DC011020-04

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Introduction:

You are being asked to take part in a research study. Please read the information about the study presented on this form. This form includes details on study's risks and benefits that you should know before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the investigator or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish including your friends, family, and family doctor. Participation in this study is voluntary.

Background/Purpose

Swallowing is an activity that we perform many times per day, without giving it a second thought. However, approximately 8% of the world's population have difficulty swallowing due to medical conditions or injuries. At the Swallowing Rehabilitation Research Laboratory at the Toronto Rehabilitation Institute – University Health Network, we perform research to try to better understand the nature of swallowing difficulties and to determine effective treatments that will help people with swallowing difficulty to regain swallowing function.

The aim of this research study is to learn more about the relationship between respiration and swallowing for individuals with spinal disorders. Specifically, we are interested in learning how difficulties with breathing may affect a person's ability to swallow. There are 4 factors that we think may influence this relationship between respiration and swallowing:

a) The amount of air a person can breathe in and out
b) The point in the breathing cycle a person begins to swallow
c) The timing of movement of the swallowing muscles to protect the airway
d) The thickness of a liquid, which determines how fast it moves through the throat and how much time a person has to protect the airway before the liquid passes the opening to the airway

People with spinal disorders often report difficulties with breathing and swallowing. This study will help us to better understand the relationship between these two processes.

You will be one of approximately 30 participants in this study. For this experiment, we will use adults (age 18 and older) with an acquired spinal injury at the cervical or upper thoracic level and no pre-injury history of swallowing difficulties. Participants must be able to understand and follow instructions given in English. There are several medical conditions and medications that could alter the results of the study. We will ask you to review this list and tell us if any of these apply to you.Study Procedure

This study will require you to attend two 1-hour appointments, scheduled on different days:

1) Appointment #1: Intake Interview

First, we will review the research study with you and answer your questions. If you wish to proceed, we will ask you to sign the consent form. We will then ask you some brief questions about your health to make sure that there are no situations like allergies that suggest that you should not participate. During this appointment, we will also collect measurements of your tongue pressure. To do this, we will be using a tongue pressure measurement system called the Iowa Oral Performance Instrument. A small bulb will be placed just behind your front teeth, and press upwards against it with your tongue and swallow your saliva. If you have previously seen a respiratory therapist, we will also be collecting information about your breathing capacity. Respiratory measurements, such as how much air you can breathe out, will be collected from your medical chart with your consent.

2) Appointment #2: Swallowing X-ray

An appointment will be scheduled at the x-ray department of the Toronto General Hospital. During this procedure, we will collect some of the following measures:

- *X-ray Movie of your Swallowing*
  We will collect an x-ray movie of your swallowing called a Videofluoroscopy. We will ask you to take sips of 6 liquids containing barium and prepared to different consistencies (thin, slightly-thick, mildly-thick, moderately-thick and extremely-thick). The extremely-thick liquid will be about the consistency of yogurt or pudding. Barium is a safe substance that shows up dark on an x-ray

- *Nasal Airflow Measurements*
  To monitor your nasal breathing patterns while you are swallowing, we will place a flexible nasal cannula tube around your head, with soft prongs into your nostrils. This tube does not administer any air or oxygen, but measures the activity of your breathing while you swallow.

- *Spirometry (Respiration) Measurements*
  We will collect some information about your breathing capacity using a handheld spirometer. We will ask you to put your mouth around a nozzle, and take 3 relaxed (normal) breaths in and out. Then, we will ask you to inhale as much air as you can, and then exhale all of the air in your lungs. This task is often completed by respiratory therapists to better understand your respiratory capacity.
- *Tracheal Sounds and Accelerometry Measurements*
  To monitor your tracheal breathing patterns while you are swallowing, we will attach a small patch to your neck using double sided adhesive and medical tape. This wireless device does not transmit any energy to your body, but measures the sounds and movements through your skin. The patch attaches like a band-aid and is easily removed at the end of the appointment.

Potential Risks

Taking part in this study has risks. Some of these risks we know about. There is also a possibility of risks that we do not know about and have not been seen in humans to date. Please call the investigator or study staff if you have any side effects, even if you do not think it has anything to do with this study.

All the equipment that is used in this study is manufactured according to safety standards for hospital settings. There are no known risks associated with the equipment. All instruments are disinfected before use.

The risks we know of are:

a) It is possible that you might experience irritation from the adhesives used to attach the sensors for data collection. All adhesives can be readily peeled following the conclusion of data collection. If you know that you **are allergic** to latex or adhesives, we ask you to tell us this and we will suggest that you do not participate in this study. In the case that you experience an unexpected allergic reaction, standard emergency procedures will be followed. All of the staff in the lab have current CPR certification and an emergency response team is located on-site.

b) It is possible that you may dislike the taste or texture of some of the liquids that we ask you to swallow in the study. You are free to discontinue participation at any time.

c) It is possible that your tongue and swallowing muscles may become tired during data collection. Please let us know immediately if you experience any pain or discomfort. You are free to discontinue any particular session or to withdraw from the study at any time.

d) You will receive an x-ray test called a videofluoroscopy. Videofluoroscopy involves low levels of radiation exposure, which carries a risk of radiation effects (such as cancer). Radiation effects are called "stochastic effects", which means that they are effects produced at random without a threshold dose level. The probability of occurrence increases with increased radiation dose but the severity is independent of the dose. Radiation dose is measured in millisieverts (mSv). Background radiation exposure is known to occur in everyday activities such as flying in a plane (0.005 mSv per hour) or smoking cigarettes (0.18 mSv per half pack) as well as during medical tests such as a chest x-ray (0.02 mSv) or a CT scan (10 mSv). According to Health Canada, the average Canadian experiences between 2 and 4 mSv background radiation exposure each year. Health Canada recommends that occupationally exposed workers not exceed 20 mSv per year.

   Based on a previous study that we have conducted in healthy adults, the videofluoroscopy in this study is expected to involve 118+/-18 seconds of radiation exposure, with an associated dose estimate of <0.35 milliSieverts. This dose is about the same exposure as 40 hours of flying in an airplane, and about the same as the dose received from smoking a pack of cigarettes. A dose of 0.35 mSv corresponds to a risk of 1 in 39,000 of developing a radiation-induced stochastic effect from a videofluoroscopy, which is considered very rare.

e) Aspiration (entry of material into the airway) is a possible risk when you swallow. This risk is always present during swallowing. The swallowing x-ray (videofluoroscopy) is a procedure that is used in clinical practice to document the presence and severity of swallowing abnormalities, including (but not limited to aspiration). If you experience aspiration during the swallowing x-ray, we will follow standard procedures to encourage coughing and throat clearing to expel the aspirated material from your airway. If you continue to show aspiration on several sips, we will discontinue data collection immediately. If we identify that you experience aspiration, we will arrange a follow-up appointment to discuss the issue with you, and will provide you with a report to take to your family doctor identifying recommended next steps.

f) Choking is an extremely unlikely event, but is always a risk during swallowing. In the event of choking during data collection, routine emergency procedures will be followed. All study personnel carry current CPR certification.

Incidental Findings

In the unlikely event that the videofluoroscopy reveals an unexpected medical finding, the attending licensed speech-language pathologist will consult the on-call radiologist and generate a clinical report for you to take to your family doctor documenting the observation. We will

arrange a separate appointment to discuss these findings with you and will suggest appropriate resources for any further investigations that might be recommended.

Benefits

There are no anticipated benefits to you related to this study. Information learned from this study may help people with swallowing impairment in the future.

Confidentiality

You will not be named in any reports, publications or presentations that may come from this study. If you agree to participate in this study, you are consenting to allow us to collect some of your personal health information. The specific personal health information that we will collect is your:

- Name and initials;
- Year of birth;
- Sex;
- Race and ethnicity (required by the funding agency);
- Preferred contact method (your telephone number and/or your email address);
- Swallowing x-ray recording;
- Health information related to your participation in the study.
- Respiratory values, reported by Toronto Rehabilitation Institute- Lyndhurst Respiratory Therapist (session before and following appointment 2)

Some of this information may need to be collected from your active medical chart. Any information learned about you during the study will be kept confidential. Your name and any other identifying information will not be made available to anyone other than the investigators. All records will be kept securely under the supervision of Catriona M. Steele, Ph.D.

Information we collect about you through this research project, including information about your health and the care you receive, will be stored on a computer system. Some information about you may also be stored in paper form, in research or clinical hospital charts. Paper records will be kept stored in a secure locked filing cabinet in the Professor Steele's office or the Swallowing Rehabilitation Research Laboratory at Toronto Rehabilitation Institute. Computer records will be kept in a secure, password-protected drive on the Toronto Rehab research server and a back-up hard drive. All research records will be destroyed after a period of ten years.

Since the x-ray information collected in this study may be useful in supporting your current or future clinical care, this information will be included in your UHN electronic patient record. UHN also shares information with other health care organizations in order to provide patients with care. For this reason, the information related to your health or care collected for this research might also be shared with other hospitals or health care providers in Ontario who are providing you with health care or treatment. The kind of information that will be collected for this research study and could be shared include the results of the swallowing x-ray. If you have any concerns about this, or have any questions, please contact the UHN Privacy Office at 416-340-4800, x6937 (or by email at privacy@uhn.ca)

Representatives of the University Health Network Research Ethics Board and the funding sponsor may also access the data for auditing and review purposes.

Voluntary Participation

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now and then change your mind later. You may leave the study at any time.

We will give you new information that is learned during the study that might affect your decision to stay in the study.

Withdrawal from the Study

You can withdraw from this study at any time without further consequences or limitations. If you choose to leave the study, this will have no impact on any clinical services you require at the University Health Network.

If at any time during data collection the study staff become concerned that you are having difficulty tolerating the study procedures, they will discontinue data collection and withdraw you from the study.

Transportation

The second appointment is conducted at the Toronto General Hospital. Transportation to and from the Toronto General Hospital will be provided from Toronto Rehabilitation Institute-Lyndhurst for participants and accompanying attendants. The transportation cost will be covered by the research team.

Honorarium

Participants who complete the videofluoroscopy data collection session will receive a $100 honorarium as a token of appreciation for participating in the study. This will be paid at the end of your final data collection visit.

Conflicts of Interest

The National Institute on Deafness and Other Communication Disorders in the USA have funded this study and will reimburse the hospital and researcher for the costs of doing this study. All of these people have an interest in completing this study. Their interests should not influence your decision to participate in this study.

In this study, we will be asking you to swallow liquids of different thicknesses (slightly thick, mildly thick, moderately thick, and extremely thick). The definitions of these thicknesses come from a recent framework developed by the International Dysphagia Diet Standardisation Initiative (www.iddsi.org). Professor Steele, the principal investigator for this study, is a member of the board of directors for IDDSI.

The liquids for the study will be prepared with Bracco EZPaque Barium powder and with two thickening agents manufactured by Nestlé (ThickenUp™ and ThickenUp Clear™). These products have been chosen because they are readily available and approved for clinical use in Canada. Professor Steele has past and current research relationships with Bracco Canada and with Nestlé Health Science. She also serves in an advisory capacity to Nestlé Health Science on expert panels. Neither Bracco Canada nor Nestlé Health Science are involved as sponsors of this study and they will not have access to the study data. The products for this study will be purchased from the study budget. Professor Steele will not receive any payments (either personally or to the lab) from Bracco Canada or Nestlé Health Science related to the use of these products in the study.

Participant's Rights

If you are harmed as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost.

By signing this form you do not give up any of your legal rights against the investigators, sponsor or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

Questions about the Study

If you have any questions, concerns or would like to speak to the study team for any reason, please call:

Clinical Research Coordinator Teresa Valenzano
Tel: 416-597-3422, extension 7709; e-mail: tri-swallowinglab@uhn.ca

or

Principal Investigator Catriona Steele
Tel: 416-597-3422, extension 7603; e-mail: catriona.steele@uhn.ca

If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the University Health Network Research Ethics Board (UHN REB) or the Research Ethics office number at 416-581-7849. The REB is a group of people who oversee the ethical conduct of research studies. The UHN REB is not part of the study team. Everything that you discuss will be kept confidential.

You will be given a signed copy of this consent form.

Consent

This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to the use of my information as described in this form. I agree to take part in this study.

_____	_____	_____
Print Study Participant's Name	Signature	Date

My signature means that I have explained the study to the participant named above. I have answered all questions.

_____	_____	_____
Print Name of Person Obtaining Consent	Signature	Date

_____	_____	_____
Print Name of Principal Investigator	Signature	Date

Was the participant assisted during the consent process? ☐ **YES** ☐ **NO**

☐ The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to, and has had any questions answered.

_____	_____	_____
Print Name of Witness	Signature	Date

_____
Relationship to Participant