Official Title: Sensor-driven Smart Faucet to Enable and Empower Independent Drinking and Grooming for Individuals Impacted by Spinal Cord Injury Brief Title: Access-H20 Faucet for Spinal Cord Injury
NCT number: 07062796
Unique Protocol ID: R44HD108061

Study Protocol

This feasibility study aims to evaluate the upgraded Access H2O™ smart faucet in supporting activities of daily living (ADLs) related to water access among individuals with SCI in clinical settings, as well as to assess its usability in home environments that reflect real-world conditions. The system was upgraded and refined based on findings from the SBIR Phase I study. As this is a feasibility and usability study, a formal study design and statistical power calculations for sample size determination were not required. Clinical feasibility testing of the smart faucet was conducted in Year 1 of the project (Year 1 study), while in-home feasibility and usability evaluation was conducted in Year 2 (Year 2 study).

In the Year 1 study, we recruited 18 individuals with SCI (SCI participants) and 5 control participants to ensure proper operation of the faucet. Control participants met the same recruitment criteria, except for the absence of SCI. Individuals with SCI who had cognitive deficits or serious mental health or medical conditions that could compromise safety or the accuracy of user feedback were excluded. Participants were screened for eligibility based on the following criteria: (1) diagnosis of spinal cord injury; (2) ability to follow one-step verbal directions, move the head up, down, left, and right, and use fingers to press a button on a remote control; and (3) age between 18 and 90 years. The upper age limit was selected because very few individuals with SCI live beyond 90 years. Participants of all sexes and racial/ethnic backgrounds were eligible to participate.

Information about the research was provided to participants in written form and was also read aloud. Prior to data collection and study enrollment, the study protocol was explained in detail, and written informed consent was obtained. An introductory session on the prototype was conducted for all participants. During this session, a licensed physical therapist reviewed the following with each participant: (1) how the Access H2O™ faucet operates; (2) the specific features of the faucet; (3) how to use voice commands to control the sensor and dispense water; (4) how to use motion control sensors to activate and regulate water flow; (5) how to use a remote control to activate and regulate water flow; and (6) how to use motion control sensors to adjust water temperature.

Following the introductory session, participants engaged in procedures to test the functionality of the faucet. All SCI participants who used wheelchairs remained seated in their own manual or power wheelchairs. Each wheelchair was positioned in front of a sink equipped with the Access H2O™ faucet, with sufficient space provided to accommodate the participants' legs under the sink to ensure standardized data collection.

The same physical therapist who conducted the initial session provided scripted instructions to each participant on how to turn the faucet on and off across different modes. During setup, the system was tested and calibrated to ensure proper operation. For example, the flow and spray angles for fountain mode and grooming mode were customized by adjusting valve angles or water pressure to achieve the preferred water flow trajectory.

Once the system was ready, each participant was instructed to use motion control, voice control, and remote control to activate water output modes for drinking, grooming, and washing. Specifically, participants placed their hand near the motion sensor, used voice commands through a smart speaker, or pressed a button on the remote control to operate the faucet. For example, to use voice control, the participant began by saying the wake word "Alexa," followed by a predefined command. For drinking, a command such as "Turn on Fountain Mode" activated the lower nozzle and dispensed water for hands-free drinking. Additional voice commands could be used to turn the faucet on or off and adjust the temperature (e.g., "set the faucet to hot"). Water flow continued until the participant issued a "turn off the faucet" command or used another input method.

We assessed the following: (1) whether participants could use voice, motion, or remote controls to activate the faucet for drinking (hydration); (2) whether participants could use the three control methods to rinse a quarter-sized area of soap partially or fully from the left or right cheek (grooming); and (3) whether participants could use the three control methods to wash a quarter-sized area of soap in their hair (washing). For each ADL (drinking, grooming, or washing), the physical therapist recorded performance as (1) complete, (2) partially complete, or (3) not complete. Each participant performed each activity using all three control methods (voice, motion, and wireless remote) three times. In total, 27 tests were conducted per participant (3 control methods × 3 activity modes × 3 repetitions).

In the Year 2 study, the feasibility of the smart faucet was evaluated in each participant's residential bathroom. The goal was for participants to incorporate the faucet into their daily routines in a real-world setting. A total of 10 control participants without SCI and 7 individuals with SCI met the recruitment criteria, were enrolled, and completed the testing procedures.

The inclusion criteria for participant recruitment were as follows: (1) age 18 years or older with a confirmed diagnosis of SCI; (2) residence in a home environment that can support installation of the Access H2O™ smart faucet; (3) ability to provide informed consent or have a legal guardian provide consent on their behalf; (4) stable health status, as determined by clinical evaluation; (5) ability to move the head up, down, left, and right to activate sensors; (6) ability to safely access the sink area where the Access H2O™ faucet is installed; and (7) literacy and ability to follow instructions within the Access H2O™ mobile app. The exclusion criteria were as follows: (1) severe cognitive impairment that prevents the participant from using the device as intended; (2) any medical condition that contraindicates the use of the

Access H2O™ smart faucet; and (3) participation in another clinical trial that could interfere with the outcomes of this study.

We conducted home visits for participants who met the recruitment criteria to assess whether the sink was suitable for faucet installation. If the sink was deemed suitable, written informed consent was obtained, and the faucet installation was scheduled. On the day of installation in each participant's bathroom, a licensed plumber installed the faucet. Following installation, a trained research associate performed testing and calibration of the device and provided instructions for trial preparation, including mobile app setup, usage, and operation of the faucet. The mobile app was used to automatically record user interactions and water flow settings. Each SCI participant then used the faucet for activities of daily living (ADLs) over a 14-day period, including drinking water (at least five times per day), face washing (morning and night), hand washing (morning and night), and hair washing (no set frequency). Participants were provided with a log sheet to record whether each activity was "complete" or "not complete." If an activity was skipped, participants were required to document the reason (e.g., "too difficult," "forgot," or "no need today"). On the 15th day of the trial, the plumber uninstalled the faucet, and the research associate collected the log sheet and a user-reported satisfaction survey. The data were manually recorded on a hard-copy observational coding sheet for each subject. Each subject was assigned a unique identifier, with no key linking the identifier to their name. All data recording sheets were securely stored in a locked filing cabinet throughout the study. Subject information was not used or distributed for future research studies, even if identifiers were removed. The IRB-approved letter is attached below.

Statistical Analysis Plan

The mean and standard deviations of three times on the testing variables-assistance level, completion of the activity, and time required for activity completion on three faucet modes were calculated. The feasibility testing commonly doesn't require a full statistical power analysis since it primarily focuses on gathering preliminary data used to further enhance the faucet's functionality before commercialization and does not aim to draw definitive statistical conclusions.

IRB Approval Letter

OLD DOMINION UNIVERSITY

DATE:	October 20, 2025
TO:	Anna Jeng, ScD
FROM:	Old Dominion University Institutional Review Board
PROJECT TITLE:	[2103206-12] Phase II_Access-H20: Sensor driven smart faucet to enable and empower independent drinking and grooming for individuals impacted by spinal cord injury
REFERENCE #:	23-130; 24-104; 25-130
SUBMISSION TYPE:	Continuing Review/Progress Report
ACTION:	APPROVED
APPROVAL DATE:	October 20, 2025
EXPIRATION DATE:	**September 21, 2026**
REVIEW TYPE:	Full Committee Review

Thank you for your submission of Continuing Review/Progress Report materials for this project. The Old Dominion University Institutional Review Board has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a project design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Full Committee Review based on the applicable federal regulation.

Please remember that informed consent is a process beginning with a description of the project and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the project via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All UNANTICIPATED PROBLEMS involving risks to subjects or others (UPIRSOs) and SERIOUS and UNEXPECTED adverse events must be reported promptly to this committee. Please use the appropriate reporting forms for this procedure. All FDA and sponsor reporting requirements should also be followed.

All NON-COMPLIANCE issues or COMPLAINTS regarding this project must be reported promptly to this committee.

This project has been determined to be a MINIMAL RISK project. Based on the risks, this project requires continuing review by this committee on an annual basis. Please use the appropriate forms for this procedure. **Your documentation for continuing review must be received with sufficient time for review and continued approval before the expiration date of September 21, 2026.**

Please note that all research records must be retained for a minimum of five years after the completion of the project.

If you have any questions, please contact Olivia Trumino at 7576834636 or IRB@odu.edu. Please include your project title and reference number in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within Old Dominion University Institutional Review Board's records.

Division of Research and Economic Development
4111 Monarch Way, Suite 203, Norfolk, VA 23508
Phone: 757/683-3460 • Fax: 757/683-5902

Year 1 Consent Form

INFORMED CONSENT DOCUMENT
OLD DOMINION UNIVERSITY

PROJECT TITLE
Access-H20: Sensor-driven smart faucet to enable and empower independent drinking and grooming for individuals impacted by spinal cord injury (SCI)

INTRODUCTION
The purpose of this study is to design, develop, and demonstrate the feasibility and adherence of a sensor-driven smart faucet to enable and empower independent drinking and grooming for individuals impacted by spinal cord injury (SCI).

RESEARCHERS
The responsible project investigators are:

- Anna Jeng (PI), Sc.D., Joint School of Public Health, Old Dominion University
- Lisa Koperna (Co-PI), Ph.D., Director of the Faschini Wallach Center for Restorative Therapies, School of Rehabilitation Sciences, Ellmer College of Health Sciences, Old Dominion University

DESCRIPTION OF RESEARCH STUDY

The purpose of this study is to develop and test a new faucet that could make it easier for individuals living with cervical SCI to access water for hydration and hygiene in order to live more independently. A conventional bathroom faucet makes it difficult for individuals with cervical SCI to carry out basic daily living activities, such as drinking, rinsing their mouths, and washing their faces. To address these challenges, Nasoni Inc. has developed the Nasoni Access-H2OTM faucet that includes Nasoni's dynamic fountain flow technology to allow SCI patients to access water using hands-free methods. The faucet body is controlled through a smart speaker, voice recognition using Alexa or Google Assistant, for precisely dispensing water at sensors to enable hands-free operation**.**

If you decide to participate, then you will be giving the investigators permission to collect information via surveys, observations, and/or videotaping. Surveys will include questions regarding your physical mobility related to the use of the faucet. Observational data will be collected while you are using the faucet.

If you say YES, then your participation will last for 2 to 4 hours at the ODU Faschini Wallach Center for Restorative Therapies, 1015 West 47th Street, Norfolk, VA 23529. Approximately 20 subjects will be participating in this study.

EXCLUSIONARY CRITERIA
Individuals aged 18 to 90 years old are eligible for the study. You should have been screened by a physical or occupational therapist to verify your spinal cord injury (SCI),

you are able to follow instructions, you are able to move your eyes and head up, down, and right to activate sensors, and you are able to safely access a bathroom at home. To the best of your knowledge, you do not have cognitive deficits, mental health, or medical conditions that would keep you from participating in this study.

RISKS AND BENEFITS

RISKS: If you decide to participate in this study, you may face a risk of having your information released, where other people may see it. To reduce this risk, all collected data will be de-identified, and the study team will apply all appropriate safeguards for data privacy. The Nasoni smart faucet prototype will be evaluated for safety by clinical consultants and the engineering team before you use it. The research team does not anticipate any significant risk or safety issues with the faucet. The water temperature and force of spray will be controlled, which will reduce the risk of discomfort and prevent injury if the controls do not function properly. And, as with any research, there is some possibility that you may be subject to risks that have not yet been identified.

BENEFITS

You are not anticipated to receive any direct benefit from participation in this study, as the study is for data collection only. However, your participation may lead to the commercialization of a smart faucet, which could improve access to water for activities of daily living for those living with spinal cord injury in the future.

COSTS AND PAYMENTS

The researchers want your decision about participating in this study to be absolutely voluntary. Yet they recognize that your participation may pose some inconvenience. You will receive 300 dollars to compensate your time and inconvenience. to help defray incidental expenses associated with participation.

NEW INFORMATION

If the researchers find new information during this study that would reasonably change your decision about participating, then they will give it to you.

CONFIDENTIALITY

The researchers will take reasonable steps to keep private information, such as questionnaires, medical history, and laboratory findings, confidential. The researcher will remove identifiers from all identifiable private information collected and will store information in a locked filing cabinet during the course of the study. The subject's information will not be used or distributed for future research studies, even if identifiers are removed. The results of this study may be used in reports, presentations, and publications; but the researcher will not identify you. Of course, your records may be subpoenaed by court order or inspected by government bodies with oversight authority.

WITHDRAWAL PRIVILEGE

It is OK for you to say NO. Even if you say YES now, you are free to say NO later, and walk away or withdraw from the study -- at any time. Your decision will not affect your

relationship with Old Dominion University or otherwise cause a loss of benefits to which you might otherwise be entitled.

COMPENSATION FOR ILLNESS AND INJURY

If you say YES, then your consent in this document does not waive any of your legal rights. However, in the event of injury arising from this study, neither Old Dominion University nor the researchers are able to give you any money, insurance coverage, free medical care, or any other compensation for such injury. In the event that you suffer injury as a result of participation in any research project, you may contact Principal Investigator Anna Jeng at 757-683-4594 or Dr. Tancy Vandecar-Burdin, the current IRB chair, at 757-683-3802, or the Division of Research and Economic Development at 757-683-3460, who will be glad to review the matter with you.

VOLUNTARY CONSENT

By signing this form, you are saying several things. You are saying that you have read this form or have had it read to you, that you are satisfied that you understand this form, the research study, and its risks and benefits. The researchers should have answered any questions you may have had about the research. If you have any questions later on, you may contact the responsible principal investigator, Dr. Anna Jeng, at 757-683-4594. If at any time you feel pressured to participate, or if you have any questions about your rights or this form, then you should call Dr. Tancy Vandecar-Burdin, the current IRB chair, at 757-683-3802, or the Division of Research and Economic Development at 757-683-3460.

And importantly, by signing below, you are telling the researcher YES, that you agree to participate in this study. The researcher should give you a copy of this form for your records.

Subject's Printed Name & Signature	**Date**

INVESTIGATOR'S STATEMENT

I certify that I have explained to this subject the nature and purpose of this research, including benefits, risks, costs, and any experimental procedures. I have described the rights and protections afforded to human subjects and have done nothing to pressure, coerce, or falsely entice this subject into participating. I am aware of my obligations under state and federal laws and promise compliance. I have answered the subject's questions and have encouraged him/her to ask additional questions at any time during the course of this study. I have witnessed the above signature(s) on this consent form.

Investigator's Printed Name & Signature	**Date**

Year 2 Study Consent Form

INFORMED CONSENT DOCUMENT
OLD DOMINION UNIVERSITY

PROJECT TITLE

Access-H20: Sensor-driven smart faucet to enable and empower independent drinking and grooming for individuals impacted by spinal cord injury (SCI)

INTRODUCTION

The purpose of this study is to design, develop, and demonstrate the feasibility and adherence of a sensor-driven smart faucet to enable and empower independent drinking and grooming for individuals impacted by spinal cord injury (SCI).

RESEARCHERS

The responsible project investigators are:

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DESCRIPTION OF RESEARCH STUDY

The purpose of this study is to develop and test a new faucet that could make it easier for individuals living with cervical SCI to access water for hydration and hygiene to live more independently. A conventional bathroom faucet makes it difficult for individuals with cervical SCI to carry out basic daily living activities, such as drinking, rinsing their faces, or rinsing their hair. To address these challenges, Nasoni Inc. has developed the Nasoni Access-H2OTM faucet that includes Nasoni's dynamic fountain flow technology to allow SCI patients to access water using hands-free methods of the smart faucet a home. The faucet body is controlled through a smart speaker, voice recognition using Alexa or Google Assistant, for precisely dispensing water at sensors to enable hands-free operation. Each participant needs to grant access to his or her home and install the smart faucet in the bathroom.

If you decide to participate, then you will be giving the investigators permission to collect information via surveys, observations, and/or videotaping. Surveys will include questions regarding your physical mobility related to the use of the faucet. Observational data will be collected while you are using the faucet.

If you say YES, then your participation will last for 14 days at your home. Approximately 25 subjects will be participating in this study.

EXCLUSIONARY CRITERIA

(1) age 18 years or older with a confirmed diagnosis of SCI; (2) residence in a home environment that can support installation of the Access H2O™ smart faucet; (3) ability to provide informed consent or have a legal guardian provide consent on their behalf; (4) stable health status, as determined by clinical evaluation; (5) ability to move the head up, down, left, and right to activate sensors; (6) ability to safely access the sink area where the Access H2O™ faucet is installed; and (7) literacy and ability to follow instructions within the Access H2O™ mobile app. The exclusion criteria were as follows: (1) severe cognitive impairment that prevents the participant from using the device as intended; (2) any medical condition that contraindicates the use of the Access H2O™ smart faucet; and (3) participation in another clinical trial that could interfere with the outcomes of this study.

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BENEFITS

You are not anticipated to receive any direct benefit from participation in this study, as the study is for data collection only. However, your participation may lead to the commercialization of a smart faucet, which could improve access to water for activities of daily living for those living with spinal cord injury in the future.

COSTS AND PAYMENTS

The researchers want your decision about participating in this study to be absolutely voluntary. Yet they recognize that your participation may pose some inconvenience. You will receive 500 dollars to compensate your time and inconvenience. to help defray incidental expenses associated with participation.

NEW INFORMATION

If the researchers find new information during this study that would reasonably change your decision about participating, then they will give it to you.

CONFIDENTIALITY

The researchers will take reasonable steps to keep private information, such as questionnaires, medical history, and laboratory findings, confidential. The researcher will remove identifiers from all identifiable private information collected and will store information in a locked filing cabinet during the course of the study. The subject's information will not be used or distributed for future research studies, even if identifiers are removed. The results of this study may be used in reports, presentations, and publications; but the researcher will not identify you. Of course, your records may be subpoenaed by court order or inspected by government bodies with oversight authority.

WITHDRAWAL PRIVILEGE

It is OK for you to say NO. Even if you say YES now, you are free to say NO later, and walk away or withdraw from the study -- at any time. Your decision will not affect your relationship with Old Dominion University or otherwise cause a loss of benefits to which you might otherwise be entitled.

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