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: 06159946
Updated: June 30, 2025

Study Protocol

This feasibility study aims to determine whether the Access H2O™ smart faucet functions properly for SCI subjects' water access. The study can provide preliminary evidence on whether the concepts and technology are viable and suggest potential modifications for refinement. Since this is a feasibility study, a specific study design and statistical procedures for determining sample size are not required.

We recruited 18 subjects with SCI (SCI subjects) above C7 and 10 control subjects (without SCI) to ensure that the faucet operates properly. Subjects with cognitive deficits and serious mental health or medical conditions that would compromise subject safety or accurate user feedback will be excluded. We screened the subjects to determine their eligibility based on the following criteria: a) Spinal cord injury above C7; b) the participants can follow one-step verbal directions, move their eyes (to activate sensors) up, down, right and left, move their heads (to activate sensors) up, down, right, and left. The age ranges from 18 - 90 years old. The maximum age is selected because very few patients with SCI live beyond 90 years old. Male, female, and minority subjects were permitted to participate. The information about the research was provided to the subjects in written form as well as read aloud to each subject.

Prior to data collection and study enrollment, the protocol was explained in detail to the subjects & informed consent forms were obtained. We provided an introduction session on the prototype. In the introduction session, Investigator Lisa Koperna went over information with each subject, including 1) how the Access-H2O™ faucet works, 2) specific features of the faucet, 3) how to use voice to control the sensor to dispense the water, and 4) how to use eyes to activate the eye gaze sensor to control water outputs. Each patient was asked to use a speech speaker to activate the voice sensor to dispense the water and to move their eyes up, down, left, and right to activate the eye gaze sensor to control water outputs.

After the introduction session on the prototype, subjects engaged in procedures to test the functionality of the faucet. All SCI subjects who relied on 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. Sufficient space was provided to accommodate the subjects' legs under the sink, ensuring standardized data collection. The same physical therapist who conducted the interview then provided scripted instructions to each participant on how to turn the faucet on and off for different modes. During setup, the system was tested and calibrated to ensure proper operation. For example, during setup, the flow and spray angles for fountain mode and grooming mode could be customized by adjusting valve angles or water pressure to achieve the

preferred water flow trajectory.

Once the system was ready, each SCI subject was instructed to activate the water output modes for drinking, rinsing, and glooming using three different control methods: placing their hand near the motion sensor (motion control), using a speech speaker (voice control), and moving their eyes up, down, left, and right to activate the eye gaze sensor (eye gaze control). For example, to test eye gaze control, a subject looked at the right side of the eye gaze sensor to activate fountain mode for drinking and looked at the left side of the sensor to activate grooming mode for spray pattern flow to wash a quarter-sized area of soap from the left or right cheek. For each activity of daily living (drinking, rinsing, and grooming), the physical therapist rated and recorded their levels of assistance as 1) independent, 2) modified Independent, 3) assistance required, or 4) dependent. Each participant performed the same activity (drinking, rinsing, or grooming) and sensor controls (voice, motion, or eye gaze) three times. For example, a subject used the voice control to activate fountain mode for drinking and repeated the procedure three times. A total of tests was 27 (3 sensors x 3 modes x 3 repetitions).

After completing the feasibility testing procedures, each SCI subject completed the System Usability Scale (SUS) to help the investigators gain a better understanding of users' perceptions of the Access-H2O^{TM} faucet's effectiveness, efficiency, and ease of use (Bangor et al., 2008). The detailed procedures for determining a SUS score are described in Bangor et al. (2008). Briefly, each subject rated 10 survey questions on a scale from "strongly agree" to "strongly disagree." Each response was converted to a numerical value from 1 to 5, and the SUS score was calculated using the formula (X+Y) x 2.5, where X = Sum of the points for all odd-numbered questions -5, and Y = 25 - Sum of the points for all even-numbered questions.

Data collected from subjects included performance metrics on task completion. 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.

OLD DOMINION UNIVERSITY

OFFICE OF THE VICE PRESIDENT FOR RESEARCH

Physical Address
4111 Monarch Way, Suite 203
Norfolk, Virginia 23508
Mailing Address
Office of Research
1 Old Dominion University
Norfolk, Virginia 23529
Phone(757) 683-3460
Fax(757) 683-5902

DATE:	October 11, 2023
TO:	Anna Jeng, ScD
FROM:	Old Dominion University Institutional Review Board
PROJECT TITLE:	[2103206-4] 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
SUBMISSION TYPE:	New Project
ACTION:	APPROVED
APPROVAL DATE:	October 11, 2023
EXPIRATION DATE:	September 21, 2024
REVIEW TYPE:	Full Committee Review

Thank you for your submission of New Project 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.