Study Protocol

Official Title: Access-H20: Sensor driven smart faucet to enable and empower independent drinking and grooming for individuals impacted by spinal cord injury
Grant Number: 1R43HD108061-01A1
Document Date: March 2022

The study is a feasibility study aiming to determine whether or not the Nasoni Access H2O smart faucet works properly. Thus, no specific study design and statistical procedures used to determine a sample size are needed. We will recruit 20 subjects who are living with an SCI above C7. Subjects with cognitive deficits and serious mental health or medical conditions that would compromise subject safety or accurate user feedback will be excluded. Prior to data collection and study enrollment, the protocol will be explained in detail to the subjects & informed consent will be obtained. Male, female, and minority subjects will be permitted to participate. The information about the research will be provided to the subjects in written form as well as read aloud to each subject.

Study Procedures, Materials, and Potential Risks: We will provide an introduction session on the prototype. In the introduction session, Investigator Lisa Koperna will go over information with each patient, including 1) how the Nasoni Access-H2OTM 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 will be 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.

Following the introduction session, subjects will be requested to drink water & wash their face using both Access-H2O system & their existing method (which may include caregiver assistance to fill a water bottle or wash their face). Subjects will complete each activity of daily living (ADL) three times using their current method and three times using each control method with Access-H2O. e.g. voice, eye gaze, machine vision. This will create a total of 12 trials for each ADL and 24 trials total. For each trial, we will record the time it took to complete the ADL (including both subject and caregiver time), and for each of the Access-H2O trials, we will observe whether or not the system accurately turned on the water from the faucet. Subjects will also rank each of the 4 control methods for each ADL independently as to their preference and subjects will be interviewed as to why they made those selections. We expect average Likert scores >63 on the System Usability Scale (SUS). The SUS is validated, ranks scores in 1-5 responses, and integrates two factors including Usable and Learnable. All data will be acquired from the research procedures performed during usability assessments on the subjects. Data that will be collected from subjects includes performance metrics on task completion. The data will be manually recorded in a hard-copy observational coding sheet per person. The observational coding sheet is included in the IRB application

package. We will record whether they can complete, partially complete or can't complete the task by using their eyes to activate the sensor or the faucet to dispense the water, and how long it does take. Also, we will record whether they can complete, partially complete or can't complete the task by using their voices to activate the sensor of the faucet to dispense the water, and how long it does take. Each subject will be identified using a unique identifier. There is no key that will link the subject name and ID name. All data recording sheets will be stored 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.