PROTOCOL TITLE: *Self-Catheterization Mirror System for Female Patients*

PRINCIPAL INVESTIGATOR:
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STUDY SUMMARY:

Investigational Agent(s) (Drugs or Devices)	Self-Catheterization Mirror
IND / IDE / HDE #	
Indicate Special Population(s)	None
Sample Size	30
Funding Source	Shirley Ryan AbilityLab
Indicate the type of consent to be obtained	Written
Site	Shirley Ryan Ability Lab
Research Related Radiation Exposure	No
DSMB / DMC / IDMC	No

OBJECTIVES:
The purpose of this study is to evaluate the usability of a modified self-catheterization mirror compared to a standard self-catheterization mirror as well as to obtain user feedback through patient experience with the use of a modified self-catheterization mirror.

BACKGROUND:
Intermittent catheterization is a procedure to empty the bladder for individuals with voiding difficulties, such as resulting from neurologic injury (e.g., spinal cord injury or multiple sclerosis) or obstruction. IC can maintain or improve urological function and to reduce the risk of bladder infections [1,2]. Self-catheterization is a standard method for managing short-term or long-term bladder dysfunction for many individuals. However, many female patients have difficulties with self-catheterization [3]. Mirrors currently used for this procedure have insufficient stability and visibility to easily view the urethral opening during catheterization, particularly for individuals with motor impairments and urinary retention related to spinal cord injury or other medical conditions. This can be especially frustrating because catheterization is performed frequently (typically every 4-6 hours) and may need to occur at home or in public facilities.

Figure 1. *The standard self-catheterization mirror for female patients. This setup poses significant challenges for female patients to catheterize themselves, with limited stability and visibility to view the urethral opening.*

This project will develop and test a portable, cost-effective product to help female patients with a range of motor abilities catheterize themselves in various postures and settings. The long-term goal is to improve the self-catheterization experience for patients during inpatient education and after hospital discharge.

STUDY ENDPOINTS:
Our primary outcome is the patient-reported usability and experience when using the mirror. Our secondary outcome is the average time needed to set up the mirror and self-catheterize. These measures will be obtained for all patients and compared between the modified mirror and the standard mirror.

We expect that participants will be in this research study during two weeks of their inpatient rehabilitation stay at the Shirley Ryan AbilityLab, spanning two phases of testing that will each last up to 1 week.

STUDY INTERVENTION(S) / INVESTIGATIONAL AGENT(S):
We have developed modifications to a standard catheter mirror, which are intended to improve stability and visibility during the self-catheterization procedure for women with motor impairments and urinary retention related to spinal cord injury or other medical conditions. The modified mirror (**Figure 2**) features the standard catheter mirror, held in a surrounding case, with adjustable straps for suspension between the legs whether the individual is in a seated position, reclined, or in a standing position. This also provides flexibility for the mirror's angle to be manipulated for better viewing. The mirror also features LED lights that can be turned on to improve visibility, so that individuals may view the urethral opening easier during catheterization.

Figure 2. *The modified self-catheterization mirror system includes the standard mirror, held in a surrounding case, with adjustable straps for suspension between the legs and LED lights that can be turned on/off.*

All modified self-catheterization mirrors will be stored in a locked area at Shirley Ryan AbilityLab and will only be accessible to immediate study team members.

PROCEDURES INVOLVED:
Screening: This study will involve recruitment of female patients participating in self-catheterization at the Shirley Ryan AbilityLab (SRAlab). Clinicians at this location will be informed of the inclusion and exclusion criteria for this study in order to refer appropriate patients to the study. Potential research subjects will be referred to authorized research personnel and will also be identified based on inclusion and exclusion criteria using the Cerner application.

Testing: There will be two phases of the testing, with each phase lasting up to 1 week. **Phase 1** will test their experience with the standard mirror, and **Phase 2** will test their experience with the modified mirror. This order is determined so that all participants attain practice with self-catheterization and study procedures with the standard mirror first, in alignment with the standard of care. The modified mirror will not be given to the participants until Phase 2 testing begins.

> **Phase 1 (Standard mirror):** Subjects will self-catheterize every 4-6 hours, depending on their physician's orders, using the standard mirror. This will allow the subjects to self-catheterize at different times of the day and in various positions. This mirror will have already been provided for self-catheterizing patients by the hospital, and patients will have been trained to self-catheterize by their standard care team.

Subjects will be given a log sheet specifying the catheterization trial number and the assigned mirror. For each catheterization, subjects will record the position used, the mirror used, and the time it took to complete mirror set up and successfully insert a catheter. They will record this information after each catheterization within the phase.

Phase 2 (Modified mirror): Upon completion of Phase 1 testing, subjects will be trained to use the features of the modified mirror in a single training session. Study staff will demonstrate the attachment of the mirror and help the subject practice the attachment and use of the mirror in any of the positions (seated, reclined in the patient's hospital bed, and standing). If a subject is unable to achieve and maintain a position independently or with minimal assistance, the training in that position will be skipped. Study staff will confirm any positions that the subject uses to self-catheterize (confirmed against the Phase 1 log sheet), and train the subject to utilize the modified mirror in those positions. Training will be considered successful if the subject can set up the modified mirror 3 times independently in all possible self-catheterization positions. At the end of the training session, the subject will be asked if they would be comfortable using the mirror independently.

A subsequent training session will be scheduled if the subject (1) cannot set up the modified mirror 3 times independently in their possible self-catheterization positions, or (2) does not feel comfortable using the mirror independently. If the subject does not meet these criteria after a second training session, they will be asked to fill out a questionnaire regarding their experience with the device (see "Questionnaires" below) and study procedures will end; patients who do not complete a successful training session will not be invited to complete Phase 2 testing.

Immediately following the completion of a successful training session, subjects will begin the Phase 2 testing, following identical procedures as in Phase 1 but asked to use the modified mirror. Subjects will record the mirror used, position, and time for self-catheterization in a new log sheet. Subjects will continue to have the standard mirror during this phase, and will be encouraged to use this standard mirror instead for any trial if needed for successful self-catheterization.

Questionnaires: Subjects will complete a questionnaire (System Usability Scale) at the end of each testing phase related to self-operation and user satisfaction with the use of the assigned mirror. They may also complete these questionnaires at the completion of the study.

DATA AND SPECIMEN BANKING

Data will be collected and kept confidential and compliant with HIPAA requirements. All personal information and study documentation that can identify participants will be kept secure to protect their privacy and will never be shared at any time with any person or entity. Data collected during the study and shared with others will reference participants only by an alphanumeric code (i.e., de-identified). The "master list" linking personal information to the alphanumeric code will not be shared. Electronic data will be stored on a secure and password-protected network and devices managed by the Shirley Ryan AbilityLab. Electronic folders will be private with limited access as determined by the PI.

De-identified data will be stored indefinitely. If participants give written consent to be contacted for future studies, this information will be kept separate from de-identified data files, in locked cabinets accessible only by authorized research personnel. All other information will be destroyed in accordance with HIPAA and IRB compliant guidelines.

SHARING RESULTS WITH PARTICIPANTS

Participants will be recording their own results in a time log, as well as providing their own experiences and satisfaction with the use of a modified mirror during self-catheterization. There is no intent to share additional information about results with participants.

STUDY TIMELINES

- Subjects will each participate in the study for two testing phases, each lasting a period of up to 1 week
- This study will enroll participants for up to 9 months.
- This study is projected to be completed by June 2023

INCLUSION AND EXCLUSION CRITERIA

Inclusion Criteria:

- Females age 13 or older
- Urinary retention related to spinal cord injury or other medical conditions resulting in need for catheterization
- Individuals with sufficient upper limb function to catheterize independently or with minimal assistance, or as deemed appropriate for the study by the Principle Investigator.

Exclusion Criteria:

- Individuals younger than 13 years old
- Individuals with cognitive deficits or visual impairments that may impact safe use of the devices used
- Severe ROM restrictions of the upper and/or lower extremities
- Pregnant

RECRUITMENT METHODS

This study will involve recruitment of individuals who require self-catheterization due to urinary retention related to spinal cord injury or other medical conditions. Clinicians at Shirley Ryan AbilityLab (18th-25th floors) will be informed of the inclusion and exclusion criteria for this study for the referral of appropriate subjects. Potential subjects will be screened and evaluated by the research team. Clinicians on the 18th-25th floors will be trained on the use of the modified mirror and will help introduce the modified mirror to eligible and willing participants.

COMPENSATION FOR PARTICIPATION IN RESEARCH ACTIVITIES

Participants will be compensated up to $20 for their participation through the ClinCard system. When a subject completes participation, funds will be approved and loaded onto the card. These funds are provided for the subject's participation in the study.

For each participant, SRAlab will issue a ClinCard, which is a specially designed debit card for clinical research. Funds will be loaded as appropriate. The funds will be available within 1 day after being loaded and can be used at the participant's discretion. Participants will be issued one card for the duration of the study. If the participant withdraws from the study early, she will be reimbursed for these expenses for the portion of the study that was completed. If the card is lost or stolen, participants may call (866) 952-3795 or ask a coordinator for a replacement ClinCard.

WITHDRAWAL OF PARTICIPANTS

If a participant has an adverse event, requiring therapeutic intervention and/or the experience interrupts usual daily activities, the subject will be withdrawn from the research study without their consent. This may include injury or impaired skin integrity due to the use of the modified mirror.

If a participant chooses to withdraw from the study, they will be thanked for their time and asked if they wish to disclose why they have decided to withdraw from the study. From that point, all data that was already collected on the participant will be retained and missing data from continued data collection will be treated as a loss to follow up.

RISKS TO PARTICIPANTS

The modified self-catheterization mirror is a prototype device with no significant risk to participants. The device utilizes a standard catheter mirror, enables it to be suspended between the legs, and improves visibility using commercially-available resources such as adjustable straps and miniaturized LED lights. The system can easily be adjusted to fit participants and adhere to different positional needs during self-catheterization. Use of the device can be stopped at any time when completing self-catheterization.

Physical risks from this study may include skin breakdown, urinary tract infection, and muscle soreness.

- Another possible risk is discomfort, skin pressure/friction, or bruising caused by the device straps, which has the potential to lead to skin breakdown or abrasions. This risk will be minimized by a thorough skin check performed by clinicians before and after device use, and application of foam dressings or bandages as needed. Use of the modified mirror will be discontinued for any participant with skin breakdown.

- Risk of a urinary tract infection due to use of the device. This risk will be minimized by emphasis of utilizing a sterile environment during self-catheterization and following hospital protocols regarding hygiene and cleanliness of devices and equipment.

- There is a risk of muscle soreness from being in a certain position for a prolonged period of time during the self-catheterization process. Clinicians will monitor subject activity and subjective reports of pain or discomfort throughout the process. Assisted repositioning and/or rest periods will be provided as needed.

- Embarrassment or discomfort discussing self-care may be associated with this study. All staff members assisting with this study are trained professionals and familiar with the intermittent catheterization process.

Clinicians will monitor device functionality and participant comfort during use and intervene if an unforeseen challenge occurs. During study procedures, a standard mirror will always be available to the patient if needed in the event that use of the modified mirror is obstructive to the self-catheterization process.

Risk of confidentiality will be minimized by not including personal identifying information on forms (Self-Catherization Log, questionnaire, etc.) and by conducting data collection in a private setting.

Some of the questions included in the questionnaire may be upsetting or uncomfortable for the participant to answer. If they do not wish to answer a question, they may skip it.

No psychological, financial, or legal risks to participants are anticipated.

POTENTIAL BENEFITS TO PARTICIPANTS

There may be no direct benefit to the participants. The main benefit of participation in this study is understanding the real-world challenges faced by patients performing self-catheterization, which may help other people through future development of devices and procedures. The modified mirror is intended to increase stability and visibility for individuals needing to self-catheterize, and ultimately, make the self-catheterization process easier for them. There is potential for participants to experience these benefits during use.

DATA MANAGEMENT AND CONFIDENTIALITY

Data will be collected and kept confidential and compliant with HIPAA requirements. All personal information and study documentation that can identify participants will be kept secure to protect their privacy and will never be shared at any time with any person or entity. Data collected during the study and shared with others will reference participants only by alphanumeric code. The “master list” linking personal information to the alphanumeric code will not be shared. Electronic data will be stored on a secure and password protected network and devices managed by the Shirley Ryan AbilityLab. Electronic folders will be private with limited access as determined by the PI.

PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF PARTICIPANTS

Data will be reviewed by researchers after each intervention session. Any and all adverse events will be documented and reported in compliance with IRB regulations. If they occur in the presence of researchers, prompt medical attention will be requested via assessment by the resident on call. Health status will be assessed at all visits to ensure participant safety. Events will be recorded in case report forms. Participants will be encouraged to contact research staff or the PI to report any changes in health status. If participants experience major changes in health status, study participation will either be suspended or terminated depending on severity.

If any new information is identified concerning the safety of the study device, participants will be notified. This available information may affect the participant’s decision to remain in the study.

PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF PARTICIPANTS

Subject records will be kept confidential. Precautions will be taken to protect the privacy interests of subjects. Participation in this study is completely voluntary. The purpose of the study and intended use of a subject′s medical information as well as precautions taken to keep the study information and data confidential will all be explained to each participant. All collected data will be kept confidential and compliant with HIPAA standards.

COMPENSATION FOR RESEARCH-RELATED INJURY

The PI of the study is required to be notified promptly in the instance of any injury or illness inflicted on the participant as a result of the study. The hospital [Researchers, Shirley Ryan AbilityLab, Northwestern University and all affiliated clinical sites] will not pay for medical care required because of a bad outcome resulting from participation in this study. However, the subject may still seek to get paid back for care required because of a bad outcome resulting from participation in this study.

ECONOMIC BURDEN TO PARTICIPANTS

Subjects will be compensated for their participation in the study.

CONSENT PROCESS

Before recruitment and enrollment onto this study, the participant will be given a full explanation of the study and will be given the opportunity to review the consent form. Each consent form must include all the relevant elements as approved by the Northwestern University Institutional Review Board.

Trained research personnel will guide the participant through consenting process. Participant will be given detailed explanation of the purpose, time line, commitment, procedures, data handling, and privacy and confidentiality of information pertaining to the study. Once this essential information has been provided to the participant and the investigator is assured that the participant understands the implications of participating in the study, the participant will be asked to give consent to participate in the study by signing an IRB approved consent form. Subjects will be consented with a new consent form if changes are made to the protocol. Prior to participation in the trial, the written informed consent form must be signed and personally dated by the participant or authorized guardian and by the person who conducted the informed consent discussion.

The consent process will take place at the Shirley Ryan AbilityLab in Room 11-1401 or on an AbilityLab floor (patient room or private meeting space).

PARTICIPANTS WHO ARE NOT YET ADULTS (infants, children, teenagers)

Participants will be asked their age upon study screen. Any child under the age of 18 years will be considered a minor. If the participant is determined a minor, every effort will be made to ensure the screening process proceeds with a parent or an authorized legal guardian present. The consent and protocol will be explained by a trained researcher to both the present parent/authorized legal guardian and the minor. The parent or authorized legal guardian will then be asked to consent on behalf of the minor, in accordance with the DHHS and the USFDA’s subpart D. The parent or authorized legal guardian will also be given the opportunity present at all training and testing sessions.

Consent will be obtained from one parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child. This will be done to ensure the protocol is carried through in a timely manner.

Permission will also be obtained from an authorized legal guardian if necessary. Efforts will be made to determine whether the guardian is in fact legally authorized by ensuring the child lives with the aforementioned guardian. Assent will be obtained from all children. Verbal assent will be obtained for children unable to give written consent. Assent will be documented in the IRB approved consent form.

NON-ENGLISH SPEAKING PARTICIPANTS

Non-English speaking subjects will be permissible for recruitment and enrollment in the study (Spanish, Arabic, and Polish).

An interpreter who speaks the participant's primary language will be scheduled through the Shirley Ryan AbilityLab Interpreter Services department to attend all research appointments during which the participant is scheduled if necessary as determined by the participant.

PROTECTED HEALTH INFORMATION (PHI AND HIPAA)

Subjects records will be kept completely confidential. Every possible precaution will be taken to protect the privacy interests of subjects. Trained research personnel will explain the purpose of the study and intended use of a subject's medical information and the precautions taken to keep the study information and data confidential. Data will be collected and kept confidential and compliant with HIPAA standards.

Participants will be assigned an alphanumeric study ID. Identifying data will be kept in locked cabinets and password protected servers completely separate from de-identified data. Research data will be de-identified and stored in locked cabinets in the lab accessible only by authorized research personnel. Electronic data will be de-identified and kept on secure, password protected servers at the Shirley Ryan Ability Lab. Only authorized research staff will be able to access any of the formerly mentioned data. De-identified data will be kept indefinitely.

Study documentation will be collected and stored and kept confidential and compliant with HIPAA requirements. Identifying data will be held for 7 years after the study is completed and published.

All personal information (names, addresses, email or phone numbers, etc.) gathered for this study that can identify participants will be kept secure to protect their privacy and will never be shared at any time with any person or entity. Data collected during the study and shared with others will reference participants only by an alphanumeric code. The "master list" linking personal information to the alphanumeric code will not be shared, and will be kept by the study PI in a secure location. All personal information linking participants to their data will be destroyed after 7 years following the completion of the study

QUALIFICATIONS TO CONDUCT RESEARCH AND RESOURCES AVAILABLE

All sessions will occur at Shirley Ryan AbilityLab (355 East Erie St. Chicago, IL 60611)

An acute inpatient rehabilitation and research hospital. Each unit is staffed with 21 full time employee nurses; with virtually no cross-over. Study procedures will occur on the inpatient floor in private, single-patient care rooms.

All study team members will be trained on the study protocol and procedures. The study team members are employees of the Shirley Ryan AbilityLab. They are familiar with the study site and are experienced with the study population. There will be medical resources including a resident on call and nursing staff available 24 hours a day if needed in case of an emergency.

REFERENCES

1. Wyndaele, J. Intermittent catheterization: which is the optimal technique? *Spinal Cord* **40,** 432–437 (2002). https://doi.org/10.1038/sj.sc.3101312
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3. Logan K, Shaw C, Webber I, Samuel S, Broome L. Patients' experiences of learning clean intermittent self-catheterization: a qualitative study. *J Adv Nurs*. 2008; **62**(1): 32- 40.