STU#:

PROTOCOL TITLE: *Evaluation of a mobile health application to improve patient satisfaction and outcomes after urethroplasty: a prospective randomized controlled trial*

PRINCIPAL INVESTIGATOR:
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VERSION DATE:
1.1

STUDY SUMMARY:

Investigational Agent(s) (Drugs or Devices)	Mobile Medical App
IND / IDE / HDE #	n/a
Indicate Special Population(s)	☐ Children ☐ Children who are wards of the state ☐ Adults Unable to Consent ☐ Cognitively Impaired Adults ☐ Neonates of Uncertain Viability ☐ Pregnant Women ☐ Prisoners (or other detained/paroled individuals) ☐ Students/Employees
Sample Size	80
Funding Source	Department of Urology, Northwestern University Urology Care Foundation
Indicate the type of consent to be obtained	☒ Written ☐ Verbal/Waiver of Documentation of Informed Consent ☐ Waiver of HIPAA Authorization ☐ Waiver/Alteration of Consent Process
Site	☐ Lead Site (For A Multiple Site Research Study) ☐ Data Coordinating Center (DCC)
Research Related Radiation Exposure	☐ Yes ☒ No
DSMB / DMC / IDMC	☐ Yes ☒ No

OBJECTIVES:

Our objective is to create a custom urethroplasty specific mobile application that will guide patients through the perioperative period for urethroplasty. This application will include preoperative reminders, informational videos, postoperative instructions, and an interactive guide for common postoperative concerns such as bladder spasms, wound healing, gross hematuria, and wound and catheter issues. We will conduct a prospective, randomized controlled trial over a one-year period assessing the effectiveness of our application on perioperative outcomes and patient satisfaction for patients undergoing urethroplasty at our institution.

Aim 1: The primary study aim is to improve patient satisfaction, education, and patient reported outcome measures after urethroplasty. All enrolled patients will complete a urethroplasty specific PROM survey, the Urethral Stricture Symptom and Impact Measure (USSIM), as well as the Patient-Reported Outcomes Measurement Information System 29-item profile (PROMIS-29 v2.0) preoperatively, two weeks after catheter removal, and again at three months after surgery. Three months after surgery patients will also complete a decision regret scale. Patients enrolled with the application will complete an overall assessment of GetWell Loop at the end of the study.

Aim 2: The second aim of the study is to decrease patient phone calls and messages due to improved patient education and troubleshooting provided by the interactive guide. Prospective chart review will be conducted on all patients enrolled in the study to evaluate the number of MyChart messages and phone calls.

Aim 3: The final aim is to decrease emergency department visits and improve postoperative outcomes. Postoperative complications will be rated on the Clavien-Dindo classification. Emergency department visits will be assessed by prospective chart review and patient interviews. Overall healthcare costs will be extrapolated based on the outcomes of emergency department visits.

BACKGROUND:

Urethral stricture disease is fibrosis within the urethra that leads to significant narrowing of the urethral lumen. Strictures can occur from traumatic, iatrogenic, inflammatory, infectious, or idiopathic etiologies. Urethroplasty is the most effective and durable treatment for urethral stricture. However, perioperative care for urethroplasty is complex. Preoperative counseling can be challenging as the anatomy can be quite foreign to the layperson, thus the description of the procedure as well as the associated risks and benefits can be difficult to understand. Indeed, this appears to be a universal problem within surgery and multiple studies have highlighted poor patient comprehension and recall from standard preoperative counseling. Preoperative care can also be cumbersome, with patients in urinary retention managed with a urethral Foley requiring conversion to a suprapubic tube to allow for a period of urethral rest. Preoperative urine cultures are also required, and many patients will have a positive urine culture requiring antibiotic treatment prior to surgery.

Postoperatively, all patients will have a urethral catheter for 1-4 weeks depending on the repair. More complex strictures may require buccal mucosa graft and even local tissue flaps such as a gracilis muscle flap. At our institution, many patients undergo same-day discharge or are admitted for one night, limiting time for in person postoperative teaching. These attributes underscore the importance of patient education as they may generate patient questions and anxiety.

Studies have shown a discordance between patient and physician perception regarding success after urethroplasty surgery. As a result, there has been growing interest in patient reported outcome measures (PROM) as a marker for success after urethroplasty. However, PROM surveys are time and resource intensive to capture.

Mobile health applications have the potential to improve patient education, quality of life, and postoperative outcomes after surgery. They are also a way to capture PROM in a more reliable and efficient manner. Within the field of urology, mobile health applications have been created for perioperative prostatectomy and cystectomy care. However, no mobile health application has been created for urethroplasty, and there has not been a randomized controlled trial regarding their efficacy within this space.

Mobile health applications are low-cost, accessible, and scalable resources that have been gaining popularity in recent years. Most patients own a smartphone regardless of socioeconomic status. Most mobile health applications are geared towards chronic illness and primary prevention, however interest in surgery specific mobile health applications is growing. A survey regarding willingness to use mobile health applications after a hypothetical surgery scenario conducted on 800 New York State residents by Abelson et al, found that 80.6% of respondents reported willingness to wear a tracker on their wrist and 74.3% were willing to fill out a daily survey after surgery. Notably, older respondents were less likely to own a smart phone but had similar willingness to participate in mobile health technologies if they did own one.

Within urology, Belarmino et al conducted a feasibility study for the use of a mobile health application after robotic assisted radical prostatectomy. 20 patients were recruited preoperatively and completed a baseline PROM survey. Their application did not include preoperative counseling but was rather focused on postoperative care including reminders to perform Kegel exercises, ambulate, and hydrate. Men were asked to complete the same PROM survey weekly after catheter removal. All respondents reported that the push reminders were useful and 93% found the app easy to use. Importantly, they also found that the PROM response rates were significantly higher than those for mail and email surveys and comparable to phone surveys.

Metcalf et al conducted a study in 2019 implementing an application for cystectomy perioperative monitoring. 20 patients were enrolled in the pilot trial and given a tablet with the preloaded application as well as a step monitor and vital sign equipment. Their study did include 14 preoperative educational videos on topics such as “Ileal conduit versus Neobladder” and “Comprehensive Care Pathway”. All participants viewed the videos and 93% averaged more than one view per video.

Notably, both these studies were feasibility studies and no study within urology thus far has evaluated the effectiveness of these mobile health applications for patient education or compared them to the standard of care.

We will conduct a prospective, randomized controlled trial assessing the effectiveness of a mobile health application on perioperative outcomes and patient satisfaction for patients undergoing urethroplasty.

STUDY ENDPOINTS:
Primary endpoint: Improve patient satisfaction, education, and patient reported outcome measures after urethroplasty.
Secondary endpoint: decrease patient phone calls, chart messages, ER visits, and improve complication rates.

STUDY INTERVENTION(S) / INVESTIGATIONAL AGENT(S):
We will conduct this study in partnership with GetWell Loop, a mobile medical application designed by GetWell Network. We plan to work with GetWell to develop a custom build plan for a urethroplasty specific perioperative patient education application. Eligible patients will be randomized to one of two arms: standard care pathway and the mobile health (mHealth) pathway.

GetWell Loop MMA details:

Purpose of the app:
The purpose of the app is to guide patients through the perioperative period surrounding urethroplasty. The application will include preoperative reminders, informational videos, postoperative instructions, and an interactive guide for common postoperative concerns such as bladder spasms, wound healing, gross hematuria, and wound and catheter issues. We will be utilizing the survey data collected from the app to determine if PROMs improved with the convenience and accessibility of this app.

The app is appropriately suited for adults 18 and older and is aesthetically easy to read/navigate and easy to understand.

App functionality:
GetWell Loop can be accessed via URL link (www.getwellnetwork.com) to their website using any computer with Internet capability. It can also be accessed in app format and can be downloaded onto iOS or Android devices via Google Play and Apple App Store. The app is free and there is no cost to the participant. Participants will use their own devices for the study. Participants without mobile phone/computer capability to utilize GetWell Loop will be excluded from the study. GetWell has technical support available on their website with Frequently Asked Questions as well as on demand technical support via a Customer Support phone number (888- 496-3375) for any participants with app related technical issues. When a device's operating system is updated, the app's functionality will not be impacted. However, GetWell Loop's mobile app does require iOS 12.4 or later or Android 5.0+. The proposed care plan will last for 90 days and patients enrolled in the care plan will automatically be removed at the end of the study. When the study is over or when a participant withdraws, we will personally contact the participant to provide instructions on removal of the application.

Participant/user support:
Participants will be trained to use the app during their initial in person visit if they choose to sign up for the study and are randomized to one of the mHealth arms. In addition, the app provides a tutorial for usage when first downloaded. Participants have access to GetWell's technical support Frequently Asked Questions on their website as well as on demand technical support via a Customer Support phone number (888-496-3375) for any participants with app related technical issues. The app will be monitored via patient feedback and data collection. Participants will be able to message providers with questions regarding the app or regarding their care through GetWell Loop and via Epic myChart. We will monitor survey data collected weekly to ensure that patients are able to complete surveys without issue.

Obtaining consent and the app's Terms of Service:
We will obtain written consent during a patient's initial urethroplasty appointment. Participants will not be consented via the app. The consent form is in-line with GetWell's Terms of Service, which are located on their website and uploaded along with this protocol. Data ownership is outlined in the Privacy Policy, which is also available on GetWell's website and attached with this protocol. All data collected and provided by participants is owned by GetWell. The Terms of Service will be summarized in the IRB consent form in a participant friendly manner. The Terms of Service are compliant with research regulations and local/state/federal law. We will plan to monitor for changes or updates to the Terms of Services by asking the GetWell developer team to email us when updates are made.

Privacy and confidentiality protections:
Research data including patient demographic, survey and medication adherence data will be collected in GetWell. All data from GetWell Loop will be stored anonymously with nonidentifiable patient identifiers in the GetWell Loop U.S. based Google Compute Cloud data center, which can be downloaded remotely by the research team. Data will then be compiled and prospectively maintained in an encrypted REDCap database through our institution. Data will be accessible only to authorized members of the study team. GetWell will have access to raw data collected from mobile surveys but will not have access to research data collected from Epic to determine qualitative/quantitative improvements in urethral stricture disease. GetWell Loop does require a username and password for everyone. Usernames are generated by the user. If a participant forgets their username and/or password, there are links on the GetWell Loop login page titled “Forgot password” and “Forgot username?” in which participants can receive a username/password reset sent to their email. Data from this study may be submitted back to the FDA in the future including patient demographic, survey and medication adherence data will be collected in GetWell.

Risks related to app use:
GetWell’s Privacy Policy is available on their website and attached with this protocol. Privacy and confidentiality risks include that while encryption is used for certain information using TLS (transport layer security), no method of transmission over the internet or electronic storage is 100% secure. If the app does not work as intended or malfunctions, participants can contact the Customer Support phone number (888-496-3375). GetWell Network has a Chief Information Security Officer who oversees the app for potential security risks. One of the lead team members of this project will monitor and receive notifications from the secure messaging portal if there are any concerns on a weekly basis. Patients will also have the option to ask care-related concerns through Epic MyChart. All information in this study is kept confidential between the study team and the participants, and no third parties will be involved.

PROCEDURES INVOLVED:
We will conduct a prospective, randomized controlled trial assessing the effectiveness of a mobile health application on perioperative outcomes and patient satisfaction for patients undergoing urethroplasty over a 12-month period. Experimental design including inclusion and exclusion criteria is outlined in **Figure 1.** Patients will undergo a two-stage consent process and a non-blinded randomization technique. Our institution performs 80-100 urethroplasty procedures a year. Our goal is to enroll 80 patients, 40 patients per arm. To reduce attrition, financial incentive will be provided after completion of the final study survey (obtained at three months postoperatively) with a $100 Amazon gift card. If enrollment is significantly lower than expected, we will have continued institutional support and funding to extend our enrollment period. We will partner with GetWell Loop, an organization that has been well established within our hospital system, to develop a custom build for our application. We will evaluate our outcomes based on an intention-to-treat and per-protocol analysis and will define statistical significance as a p-value <0.05.

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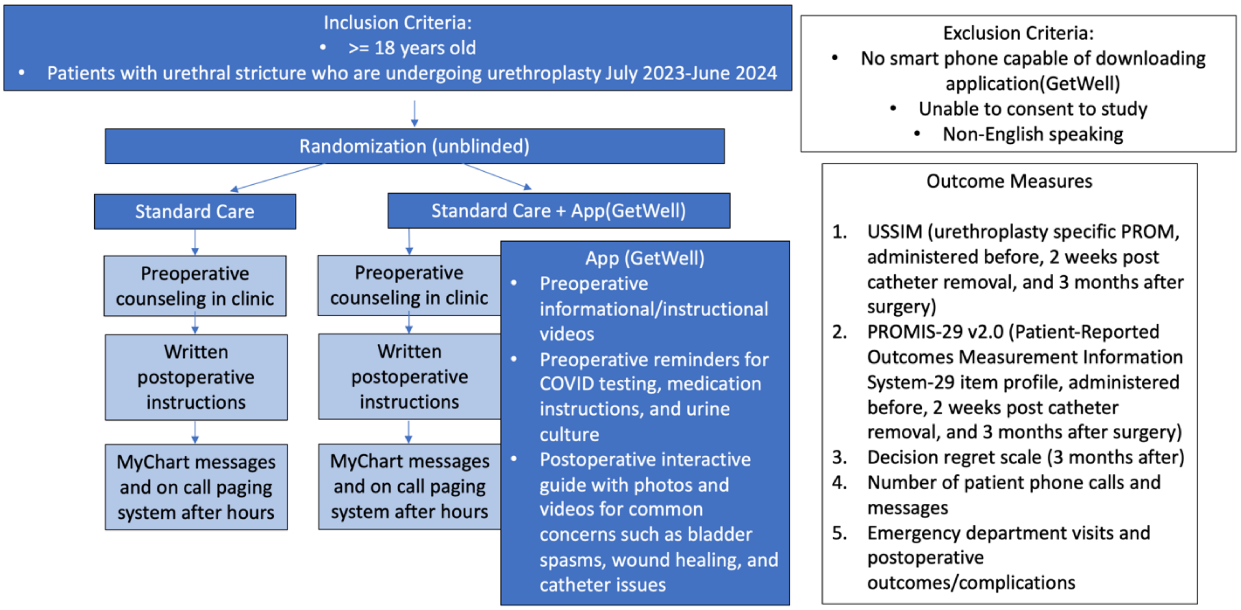

Figure 1: Experimental design

The primary study aim is to improve patient satisfaction, education, and patient reported outcome measures after urethroplasty. All enrolled patients will complete a urethroplasty specific PROM survey, the Urethral Stricture Specific PROM (USS-PROM), as well as the Patient-Reported Outcomes Measurement Information System 29-item profile (PROMIS-29 v2.0) preoperatively, two weeks after catheter removal, and again at three months after surgery. Three months after surgery patients will also complete a decision regret scale. Patients in the control arm will receive surveys at the specified timepoint via RedCap. No additional visits will be required. Patients enrolled with the application will complete an overall assessment of GetWell Loop at the end of the study. This is administered in the application.

The second aim of the study is to decrease patient phone calls and messages due to improved patient education and troubleshooting provided by the interactive guide. Prospective chart review will be conducted on all patients enrolled in the study to evaluate the number of MyChart messages and phone calls.

The final aim is to decrease emergency department visits and improve postoperative outcomes. Postoperative complications will be rated on the Clavien-Dindo classification. Emergency department visits will be assessed by prospective chart review and patient interviews. Overall healthcare costs will be extrapolated based on the outcomes of emergency department visits.

DATA AND SPECIMEN BANKING

All data from GetWell Loop will be stored anonymously with unique patient identifiers in the GetWell Loop storage cloud, which can be downloaded remotely by the research team. Data will then be compiled and prospectively maintained in an encrypted

REDCap database through our institution. Data will be accessible only to authorized members of the study team. Data will be kept indefinitely. For subjects agreeing to the future use of their data in institutionally approved studies not yet identified, data, either de-identified or identifiable, will be provided to future investigators as stipulated and approved in their IRB application and data security plan.

SHARING RESULTS WITH PARTICIPANTS

Results from the study and from the GetWell mobile health platform will be shared in person during the patient's follow-up at the completion of the study.

STUDY TIMELINES

The duration of the study is 12 months, however participation for each patient will be from time of their clinic visit where they sign up for urethroplasty and are recruited into the study to 90 days following their surgery. We plan to enroll 80 patients (40 per arm) and estimate this will take the entire year given our current clinical patient volume. We plan to start enrolling patients in August 2023 in anticipation of initiating launch of the application in August 2023. We anticipate completion of the participation in the study around July 2024.

INCLUSION AND EXCLUSION CRITERIA

Eligible patients include those over 18 years old who have a urethral stricture and are undergoing urethroplasty surgery with Dr. Ziho Lee at Northwestern Memorial Hospital. Exclusion criteria consists of patients without mobile phone capability to utilize GetWell Loop, physical or cognitive impairment precluding usage of a mobile phone or answering questionaries, and inability to consent to the study.

VULNERABLE POPULATIONS

PARTICIPANT POPULATION(S)

Accrual Number:	Category/Group: (Adults/Children Special/Vulnerable Populations)	Consented: Maximum Number to be Consented or Reviewed/Collected/Screened	Enrolled: Number to Complete the Study or Needed to Address the Research Question
Local	Adults	120	80
Study-wide		120	80
Total:		120	80

RECRUITMENT METHODS

Patients scheduled to undergo urethroplasty surgery will initially be approached in clinic and given information regarding the study design and goals. All patients regardless of race/ethnicity/gender/socio-economic status will be approached. If patients have transportation issues and cannot make it to an in-person visit, a virtual visit can be offered instead, and patients can be recruit via this approach. If interested, the patient will then sign a generalized consent form enrolling them into the study. Eligible patients will then be randomized to one of two arms: standard care pathway and mHealth pathway. We will attempt to match patients based on demographics to have even distributions between the groups. We will utilize non-blinded block randomization technique due to the nature of the intervention pathway and need for continuous enrollment.

COMPENSATION FOR PARTICIPATION IN RESEARCH ACTIVITIES

To reduce attrition, financial incentive will be provided after completion of the 3-month follow up surveys with a $100 Amazon gift card.

WITHDRAWAL OF PARTICIPANTS

Decision to participate is completely voluntary, and patients will be notified at the start of the study that if they choose not to participate, then they will continue with our standard care follow-up. Patients may drop out of the study or revert to the standard care pathway at any time.

RISKS TO PARTICIPANTS

Risks related to app use: GetWell's Privacy Policy is available on their website and attached with this protocol. Privacy and confidentiality risks include that while encryption is used for certain information using TLS (transport layer security), no method of transmission over the internet or electronic storage is 100% secure.

If the app does not work as intended or malfunctions, participants can contact the Customer Support phone number (888-496-3375). GetWell Network has a Chief Information Security Officer who oversees monitoring the app for potential security risks. One of the lead team members of this project will monitor and receive notifications from the secure messaging portal if there are any concerns on a weekly basis. Patients will also have the option to ask care-related concerns through Epic MyChart. All information in this study is kept confidential between the study team and the participants, and no third-parties will be involved. If the app fails to work as it should, there is no risk of medical harm to the patient. The app is to serve as a supplement to standard medical care. Patients will continue to receive medical recommendations at their initial medical appointments. If they choose to not answer the survey questions posed in GetWell, this will not affect their medical care. They have the option to skip any question if they are not comfortable answering.

POTENTIAL BENEFITS TO PARTICIPANTS

Patients enrolled in our GetWell Loop application will have unique access to preoperative and postoperative educational materials, preoperative reminders, as well as postoperative trouble shooting pathways. We hope that implementation of this interactive mobile health platform will improve patient education, satisfaction, and outcomes after urethroplasty.

DATA MANAGEMENT AND CONFIDENTIALITY

Statistical outcomes will be analyzed based on intention-to-treat and per-protocol analysis. We will define statistical significance as p-value <0.05. With guidance from an institutional biostatistician, we will perform statistical analysis using R (R Foundation for Statistical Computing, Vienna, Austria) comparing all two study arms. After enrollment into the study, patients will be followed for a 90-day period. Data from the standard care pathway will be collected in person or during telehealth visits. All data from GetWell Loop will be stored anonymously with unique patient identifiers in the GetWell Loop storage cloud, which can be downloaded remotely by the research team. Data will then be compiled and prospectively maintained in an encrypted REDCap database through our institution. The confidentiality and privacy rights of all subjects enrolled in the study will be fully protected and HIPAA regulations will be strictly enforced. Data resulting from this study will not be linked to subjects. Subjects will not be referred to by name or initial in any publications.

PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF PARTICIPANTS

Only members of the research team and individuals who may have access to medical records and/or informed consent documents due to their job function at the participating sites may access the records.

PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF PARTICIPANTS

No identifiable information about the patient, or provided by the patient, during the research, will be disclosed to, except:

- If necessary to protect subjects' rights or welfare (for example, if they are injured and need emergency care); or
- When the Collaborative Northwestern Institutional Review Board monitors the research or consent process; or
- When the Office for Human Research Protections (OHRP), the Office of Research Oversight (ORO), or other governmental regulatory agencies monitor the research; or if required by law.

The risk of the breach of confidentiality is possible in this study. However, all precautions will take place to make sure this issue is avoided. Data collected by study coordinators will be maintained in a secure server maintained by Northwestern University. The names of the patients will not be included on the primary database, but they will be followed by an ID number. When the results of the research are published or discussed in conferences, no information will be included that would reveal patients'

identity. Patients who are uncomfortable or embarrassed to answer questions may choose to skip them or to discontinue their participation in the study at any time.

ECONOMIC BURDEN TO PARTICIPANTS

The mobile health platform involved in this research have no cost and will not be billed to the patient or their insurance.

CONSENT PROCESS

A two-stage consent process, which has been shown in a randomized trial involving patients undergoing prostate biopsies to reduce decisional anxiety and stress related to randomization to an experimental arm, will be utilized. Patients scheduled to undergo urethroplasty will initially be approached in clinic and given information regarding the study design and goals. If interested, the patient will have time to review the consent and have any questions answered, then sign a generalized consent form enrolling them into the study.

The process to document consent and re-consent in writing will be done as follows, per Good Clinical Practice guidelines:
The consent form will be signed and personally dated by the subject and by the person who conducted the consent prior to any study procedures. A signed copy of the consent form will begiven to the subject and the original copy will be securely stored in the urology clinic. This process will be documented in the subject source documents.

NON-ENGLISH SPEAKING PARTICIPANTS

This study will provide access to participants with limited to no English proficiency and we will follow the IRB to effectively communicate the study to the participants during recruitment, consent and the duration of the study. This study will utilize the short form consenting process as described by the IRB. This short form consent will attest to the information in the informed consent and will be presented orally or by the participant's legal authorized representative. We will provide the short form to the participant or legal authorized representative. The short form will be signed and confirmation that the participant was consented in the language that is understandable by the participant, the person will be authorized by the IRB, there will be a witness to the presentation, the short form will be signed by the witness, the written summary will be signed by the witness and person obtaining consenting and finally a copy of the oral summary and short form will be given to the participant.

Once the participant is enrolled, we will adhere to the IRB standard requirements for non-English speaking participants and obtain certified translations of the documents related to the study.

PROTECTED HEALTH INFORMATION (PHI AND HIPAA)

This research study will involve the collection of Protected Health Information (PHI) from the patient's electronic medical record (EMR). PHI will also be created in this study: the

questionnaires participants will be asked to complete will collect health information which may otherwise not be captured in the EMR.

HIPAA Authorization will be obtained from all participants. The following information may be collected for each participant:

- Name
- Medical Record Number
- Telephone number
- Email address

QUALIFICATIONS TO CONDUCT RESEARCH AND RESOURCES AVAILABLE

Persons involved in this study have experience with patient care and the handling of sensitive information. Dr. Lee is an assistant professor of urology here at Northwestern who specializes in reconstructive urology. Other staff, including residents, research coordinators, medical students, and nursing will have appropriate oversight by the PI. Staff are familiar with study sites at Northwestern Memorial Hospital / Northwestern Medical Group and Northwestern University culture. Facilities for conducting this research are adequate, including clinic space, secure computer workstations, and availability of access to other Northwestern University resources including the EDW. All persons assisting with research will be adequately informed regarding the protocol and research procedures and will have access to both text of the protocol and an “open-door policy” to promote a culture of questions, transparency, and communication.