Impact, Feasibility, and Acceptability of a Digital Health Intervention for Healthy Children With Pediatric Lower Urinary Tract Symptoms (pLUTS)

Study Protocol

NCT05852353

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1. PURPOSE OF THE STUDY

a. Brief Summary

Pediatric lower urinary tract symptoms significantly impact children's health as well as their emotional, social, physical, and academic domains due to associated urinary symptoms, lowering their quality of life. Behavioral modifications have been identified as an effective measure to educate children and their families on strategies to rehabilitate the bladder and sphincter function to achieve more sustainable voiding habits and have been shown to reduce pLUTS in 40-70% of patients. Hence, the Bladder Basics was developed as a self-guided digital health platform to provide fun and engaging education on managing pLUTS that patients would receive in a traditional clinical encounter in an accessible manner to patients and their families.

This study is being conducted to understand the retention, engagement, knowledge, behavior change, and user experience among potential Bladder Basics stakeholders.

b. Objectives

This study aims to evaluate the impacts of Bladder Basics on knowledge improvement and clinical symptoms, as well as its acceptability and feasibility through pre-intervention, post-lesson, and post-intervention surveys.

c. Rationale for Research in Humans

This study is being conducted to understand the retention, engagement, knowledge, behavior change, and user experience of potential Bladder Basics stakeholders. We can do this by involving key stakeholders of Bladder Basics.

2. STUDY PROCEDURES

a. Procedures

This is a mixed-methods study of stakeholders such as parents of children ages 5-17. Children will not be surveyed. However, their parents will be asked about their bladder health.

Bladder Basics is designed to be a digital health education tool to improve knowledge of healthy bladder practices. It includes a set of educational videos/lessons to deliver bladder health education on various topics, such as knowing our bladder, why our bladder becomes unhappy, and how to make our bladder happy. In-video activities were also provided to increase learning engagement and facilitate learning. Participants are expected to complete the entire Bladder Basics course within 1 month.

Participants (n=1050) will be recruited using Stanford Medicine Research Office's Research Participation team's services which will include direct emailing, EPIC mychart and social media. Participants who respond to the previously mentioned recruitment methods will be navigated to an online screening survey on REDcap. This survey will assess inclusion and exclusion criteria. If they meet the inclusion criteria, they will be directed to a REDcap consent form. If they meet an exclusion criterion, they will be

informed not to proceed with the study but can leave their contact information for future study opportunities. Further questions may be asked by research personnel via email/call.

Prior to the consent meeting, the research team may reach out to participants by phone to confirm the meeting. If the participant is unable to confirm the meeting by phone, the research team may cancel the meeting and may not be able to reschedule.

After obtaining participants' consent, the virtual Zoom meeting will be recorded and they will be directed to fill out a pre-intervention survey linked to REDCap before accessing Bladder Basics. This survey will collect demographic information and other information, such as knowledge of bladder health practices, children's symptom scores, and self-efficacy as a study baseline.

Once the pre-intervention survey is completed, participants can access Bladder Basics and explore the lessons it offers. After watching each lesson, participants will fill out a post-lesson survey to assess their learning outcomes and/or their experience with Bladder Basics.

Participants will also be asked to complete post-intervention surveys at 4 weeks and 3 months.

All the surveys will be administrated in REDCap.

Section 16 attached the DRA final report, indicating that the risk of ALL the data collected in this study to the University is low.

Main points of the consent will include the following:

- Participation is voluntary
- Participation will have no effect on service/care
- Participants can end participation at any time
- Research staff will never share participants' identity with anyone else (confidentiality will be maintained).
- Patients must complete the consent and HIPAA authorization in order to proceed.

After enrollment, if participants are found to be a repeat participant, have previously enrolled in the study, or have failed to follow study procedures, we will withdraw them from the study. Furthermore, we will stop sending the 4-week and 3-month follow-up survey and will not be able to receive [redacted] Amazon gift card. If participants have already been sent the 4-week survey we will proceed with not sending them the 3-month survey and will not receive the [redacted] Amazon gift card.

Participants will be notified on their withdrawal via e-mail and access to the Bladder Basics curriculum will be removed.

b. Procedure Risks

The research team will send interested participants the RedCap consent and survey link or Bladder Basics access link. The consent process for Bladder Basics will be virtual before the participants start the course. The screening and consent language will be readable and inclusive. The surveys will be stored in a HIPAA protected Box folder within 48 hours. The notes will be de-identified. Any analysis will be performed on Stanford-compliant computers.

c. Use of Deception in the Study

Deception will not be used in this research study.

d. Use of Audio and Video Recordings

Video recording will occur during the virtual consent meeting after the consent form has been signed. The purpose of the video recording is for our team to identify repeat participants, have evidence showing reasons to pause meetings, and potential IRB review as needed.

All recordings will be stored for our record in HIPAA compliant Stanford Medicine Box. They will not be shown to anyone outside the research team and it will be deleted after the completion of the study according to IRB guidelines.

3. BACKGROUND

a. Past Experimental and/or Clinical Findings

Pediatric lower urinary tract symptoms affect 8-22% of school-age children1,2 and significantly impact their emotional, social, physical, and academic domains due to associated urinary symptoms, lowering their quality of life.3,4 The causes of pLUTS include neurogenic, anatomic, or functional abnormalities that alter typical voiding processes,5 and the current pLUTS management paradigm ranges from behavioral modifications and pharmaceutical treatment to procedural and surgical intervention.6 In particular, behavioral modifications aim to educate children and their families on strategies to rehabilitate the bladder and sphincter function to achieve more sustainable voiding habits and have been shown to reduce pLUTS in 40-70% of patients.7–10 However, most interventions occur in the clinical setting, leading to lengthy wait times and gaps in care for patients and their families given that pLUTS constitutes up to 40% of pediatric urology clinic visits.11

Because of these barriers that impact patient care and clinic resources, the Bladder Basics created through the Stanford Department of Urology in 2021. Bladder Basics is a self-guided digital health platform to increase accessibility of bladder health education to patients and their families. Given that this bladder health digital is one of the first of its kind, this project aims to evaluate the knowledge, behavior change, retention, engagement and user experience of Bladder Basics stakeholders through a mixed methods study.

b. Findings from Past Animal Experiments

None

4. PARTICIPANT POPULATION

a. Planned Enrollment

The total number of participants expected to enroll at all sites is 1050.

b. Age, Gender, and Ethnic Background

Individuals 18 years and older who are parents or guardians to children aged 5-17 years, of any gender; speaking English; will be recruited for this study.

c. Vulnerable Populations

We are enrolling parents of children aged 5-17 years. This may also include socio-economically disadvantaged individuals. Standard data protection policies will be observed for all participants and will protect these vulnerable participants: signed consent forms and all paperwork kept in locked cabinets, notes and other data will be stored on Stanford Medicine Box.

d. Rationale for Exclusion of Certain Populations

Women and minorities will be included in the research study. The study is limited to English-speaking participants due to limited study resources.

e. Stanford Populations

N/A

f. Healthy Volunteers

All participants recruited will be self-attested healthy volunteers ≥ 18 years of age involved in the care of a child 5-17 years of age.

g. Recruitment Details

We will partner with the Research Participation team for Honest Broker outreach. Potential participants are identified via STARR and invited by Research Participation team (honest broker) on behalf of study team. See Section 16 for Honest Broker study invitation letters. We will be using Direct Email and Children's Epic MyChart honest broker outreach. For Direct Email, the Research Participation team provides (via secure Box folder) contact info from interested participants to study team. For Epic MyChart, study team receives only the interested responses via Epic MyChart InBasket. Invitations will not be sent to the same individual via more than one honest broker outreach method, unless as a separate reminder. After a patient responds with interest to the honest broker invitation, the study team will respond to the patient via MyChart or Direct Email thanking them for their interest, send our screening survey link that includes a consent and HIPAA Authorization.

We will partner with the Stanford Research Registry to invite potential participants.

We will utilize the prospective tools on STARR to screen patients that meet our inclusion criteria. After generating this STARR cohort, we plan to use EPIC/EMR to further screen patient charts and determine their eligibility. Qualifying patients will be contacted via phone call to assess interest in the study.

Before contacting patients via phone, we will inform all clinicians of our study and obtain permission to cite the provider for their referral so that the patient/participant understands where we received their information from. We will inform providers that we will be screening clinic schedules and reaching out to qualifying patients to assess interest. During the phone call, we will begin by stating that we are contacting them because their doctor referred them to us that they may qualify for our study. Permission has been obtained and documented; attached in Section 16.

We also plan to use social media for study recruitment. We will turn off comments on any public social media posts. We will set up our social media (e.g., Facebook) page so that the security settings do not allow participants or others from the public to post on the wall. They will only be able to send messages via social media (e.g., Facebook). This is so that they are not posting private information or PHI on the publicly viewed wall. We may also post our screening survey on our PI's research lab website to enhance participant recruitment.

Parents may also be approached to be a part of the study at the time of referral to the clinic. Snowball sampling may also be employed. A screening survey will be conducted before selecting parents for interviews.

In addition, IRB-approved flyers will be posted in the clinic or around campus, passively in public spaces, in PCHA pediatric practices and external clinics with site permission, on our lab website, on the Stanford research websites such as those listing current research, Urology clinic website/webpage in Stanford Children's Hospital, and dispersed at health fairs/public events.

We also plan to recruit on virtual platforms, such as e-newsletters.

Lastly, we also may use the patient access service center (PASC) to recruit participants.

This study is an alternative to a clinical program that Pediatric Urology offers called Bladder Bootcamp (BBC); scheduling for BBC is done by PASC. We are interested in offering our study to patients who are waiting to be seen for their first visit at LPCH (Bladder Bootcamp or new patient visit). In terms of using PASC, we may ask PASC to direct patients to our website to learn more about our study or ask patients if it is okay for our research team to contact them about the study.

Once potential participants express interest from the above recruitment methods, we send them the link to a REDcap web questionnaire (screening survey) to determine their eligibility for the study. If they meet all the inclusion criteria, they can proceed to complete an electronic consent form, also through REDcap. If they meet the exclusion criteria, they will be informed not to proceed with the study but can leave their contact

information for future study opportunities. Further questions may be asked by research personnel via email/call. The consent form will be administered through REDcap as a form – participants are asked to read the form and provide an electronic signature at the end of the consent form on REDcap. Once we have their consent, we proceed with sending the REDCap pre and post survey.

h. Eligibility Criteria

i. Inclusion Criteria

- Parents or guardians >= 18 years of age
- involved in the care of a child 5-17 years old with or without bladder problems
- English speaking

ii. Exclusion Criteria

- Individuals <18 years old.
- Does not meet inclusion criteria

i. Screening Procedures

We are recruiting by advertising our flyer and recruitment messages on virtual platforms, such as e-newsletters. On these flyers, we tell interested participants to contact us at our lab email. Flyers will also be posted in the clinic or around campus, in pediatrician offices within the Stanford network, on our lab website, and on the Stanford research websites such as those listing current research and Urology clinic website/webpage in Stanford Children's Hospital.

We are also recruiting using the honest broker system at Stanford – through MyChart messages and Direct Email.

We will contact patients via phone to assess interest, with permission from their provider to cite them as a referral so that patients understand where we obtained their information.

We will use social media to recruit potential participants

Parents may also be approached to be a part of the study at the time of referral to the clinic.

Lastly, we may use the patient access service center (PASC) to recruit participants and offer our study to patients who are waiting to be seen for their first visit at LPCH (Bladder Bootcamp or new patient visit). In terms of using PASC, we may ask PASC to direct patients to our website to learn more about our study or ask patients if it is okay for our research team to contact them about the study.

Once they express interest from the above recruitment methods, we send them the link to a REDcap web questionnaire (screening survey) to determine their eligibility for the study. If they meet all the inclusion criteria, they can proceed to complete an electronic consent form, also through REDcap. If they meet the exclusion criteria, they will be informed not to proceed with the study but can leave their contact information for future

study opportunities. Further questions may be asked by research personnel via email/call. The consent form will be administered through REDcap as a form – participants are asked to read the form and provide an electronic signature at the end of the consent form on REDcap. Once we have their consent, we proceed with sending the REDCap pre and post survey.

j. Payments to Participants

Participants will receive up to [redacted] Amazon gift card via email upon completion of the study, as follows:

1) Receive [redacted] after completing the pre-intervention survey, post-lesson surveys, and post-intervention survey at ≤ 4 weeks.
2) Then receive [redacted] after completing the post-intervention survey at 3 months.

After enrollment, if participants are found to be a repeat participant, have previously enrolled in the study, or have failed to follow study procedures, we will withdraw them from the study. Furthermore, we will stop sending the 4-week and 3-month follow-up survey and will not be able to receive [redacted] Amazon gift card. If participants have already been sent the 4-week survey we will proceed with not sending them the 3-month survey and will not receive the [redacted] Amazon gift card.

Participants will be notified on their withdrawal via e-mail and access to the Bladder Basics curriculum will be removed.

k. Costs to Participants

None

l. Planned Duration of the Study

The probable duration of the study will be 5 years.
i) Participant screening will take approximately 5 minutes.
i) The total Bladder Basics viewing time is 1 hour, and participants will have 4 weeks to complete their viewing. We will provide pre-intervention and post-lesson surveys before and during the viewing. We will also provide post-intervention surveys at 4 weeks and 3 months.
iii) Data analysis will occur concurrently with data collection.

5. RISKS

a. Potential Risks

i. Physical well-being

We do not anticipate that this study will directly impact the physical well-being of study participants.

ii. Psychological well-being

We do not anticipate that this study will directly impact the psychological well-being of study participants.

iii. Economic well-being

We do not anticipate that this study will impact the economic well-being of study participants.

iv. Social well-being

We do not anticipate that this study will impact the social well-being of study participants.

v. Overall evaluation of risk

Low

b. International Research Risk Procedures

N/A

c. Procedures to Minimize Risk

The only potential risk to participants is breach of confidentiality. All Stanford data and documents will be kept in de-identified Stanford encrypted and HIPAA compliant files in password protected data bases and be transmitted with encrypted and secure servers meeting the requisite Stanford guidelines.

d. Study Conclusion

The study will end after data has been collected. We do not anticipate any adverse events related to the study.

6. BENEFITS

We do not anticipate any direct benefits to participants in this study. The study results may help improve health education experiences of other parents and their children with bladder health issues.

7. PRIVACY AND CONFIDENTIALITY

All participant information and specimens are handled in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and privacy policies of Stanford University, Stanford Health Care, and Stanford Children's Health.