RiSolve Participant Information Leaflet

Study Number: UNI-2023-007

Study Title: A Prospective Evaluation of a Prescription Digital Therapeutic (PDTx) for Treatment of Overactive Bladder in Women: The RiSolve Trial

Principal Investigator: Professor Andrew Murphy

Introduction: You have been invited to participate in a study of an app-based treatment for Overactive Bladder. As this is an app, the study is conducted remotely. The study team is based on University Hospital Galway, supported by Primary Care Clinical Trials Network which is a collaborative research network, and is led by Professor Andrew Murphy in collaboration with Amara Therapeutics.

You may be a potentially suitable candidate for participation in this research project because you have a diagnosis of Over Active Bladder (OAB) and are currently experiencing some symptoms. Before you decide to participate in this study, it is important to understand why the research is being done and what your participation will involve. Therefore, we advise you to read this information carefully. Please take time to decide whether or not you wish to take part, and feel free to discuss it with friends or family members if you wish. This information leaflet will provide details as to the reason why the study is being done, procedures involved at each stage of the research, potential benefits as well as any risks associated with taking part in the study and further information regarding participation in this study. Participation is entirely voluntary, and your decision will not affect your future treatment in any way. You are entitled to withdraw at any stage during the study procedure.

Thank you for reading this leaflet.

What is the purpose of the study?

Individuals diagnosed with OAB may experience bothersome symptoms such as an urge to urinate that cannot be postponed, needing to urinate frequently, sleep disturbance due to needing to urinate, and urinary incontinence. More than one in six adults suffer from OAB, with increased prevalence in older ages, particularly in women. These issues can give rise to problems in daily functioning, sleep, self-esteem and quality of life.

Treatment guidelines recommend behavioural therapy as first line treatment. This includes a combination of patient education on bladder physiology, dietetics, urge suppression techniques, pelvic floor strengthening, diaphragmatic breathing, scheduled voiding, and bladder retraining exercises. There is evidence to support Cognitive Behavioural Therapy (CBT) for treating physiological conditions like OAB including preliminary data for drug-resistant OAB, but it is not considered standard therapy and most patients cannot access it. These treatments are considered more effective than medication in most cases, and come with lower risks. Behavioural therapy is generally delivered by healthcare providers through a sequence of in-person sessions that are time consuming for both the patient and healthcare provider. Unfortunately, this means that treatment is not available or affordable to those who need it.

The purpose of this study is to evaluate the effectiveness of these treatments delivered in a mobile-based app.

You have been invited to participate in this study because you have a diagnosis of Over Active Bladder (OAB) and are currently experiencing bothersome or distressing symptoms.

Do I have to take part?

Participation in the study is completely voluntary. If you decide to take part, you will be given this information leaflet to keep and will be asked to sign a consent form. Even if you decide to take part, you are still free to withdraw at any time and without giving a reason. Your decision will not affect the standard of care you receive from any medical services at any time. Consenting to take part means you are taking part in both the prescribed treatment and the study evaluating it.

Who should not take part in this study?

You should not participate in the study if any of the following is true:

- You are under 18 years of age
- You are male (the treatments being evaluated are for OAB in females only)
- You do not own or have access to a smartphone
- You are not fluent and literate in English
- You are currently using an anticholinergic/beta-agonist medications for any treatment, within the previous two weeks
- You are currently using an intermittent or indwelling catheterisation
- You are pregnant or planning pregnancy during the study period
- You currently receiving treatment for bladder/urethral, colon/anal, or cervical cancer
- You have voiding dysfunction (i.e. Yes is an answer to any of the following):

  Do you have pain in your bladder?
  OR
  Do you have to strain to urinate?
- You are currently using sacral or tibial neuromodulation.
- You are currently taking antibiotics/drugs for urinary tract infection.
- You have any contraindication to study procedures or inability to comply with protocol
- You are not willing to delay commencing pelvic floor physical therapy with a qualified physical therapist for the trial treatment period.
- You are planning surgery for pelvic organ prolapse within the trial treatment period
- You are planning to undergo pessary fitting during the study period (Note: patients with an existing pessary are eligible)

What will happen if I take part? What are the procedures involved?

If you decide to take part in this trial, the following will happen:

1. You can register your interest in participating in the study via the online form. A member of the study team will then contact you by phone to conduct a brief screening process. This is to ensure that the trial is right for you.

2. You will be asked to give consent. Once consent has been provided you will be issued a participant ID code. The information collected during your assessments will be pseudo-anonymised (meaning you will only be identified using this code and no one – apart from the study team and people authorised to see your personal data, will know who the code relates to) and entered into a study database.

3. Once informed consent has been recorded and eligibility has been formally confirmed, the app will be issued to the study participant. This app is provided for a total of 10 weeks; once started, the programme takes 8 weeks to complete.

4. Participants complete assessments immediately after this 8 week treatment period.

Treatment:
The treatments that feature in the app are various behavioural therapies, including: pelvic floor training, education around triggers and best practices, Pilates, journaling, urge suppression and breathing techniques, as well as brief, focused cognitive-behavioural therapy. It is estimated that participants will spend up to 2 hours a week using the app.

Assessment:
Participants are expected to complete a number of questionnaires at two time points. The first assessment is after signing up and providing consent. The second assessment is after the 8 week programme is finished. This is so that researchers can understand your level of symptoms before and after treatment.

The assessments include numerous questionnaires on Overactive Bladder, urinary incontinence, pelvic floor disorders and related issues. There will also be questionnaires asking you to evaluate your satisfaction with the app and treatment, as well as adherence to the treatment and details of any other treatments you might receive during your time in the study.

What are the potential benefits associated with participation?
It is anticipated that treatment with RiSolve will result in a reduction in the symptoms of Overactive Bladder.

What are the possible risks associated with participation?
The risks associated with treatment with the RiSolve App are similar to the risks of standard treatment. The treatment includes pelvic muscle exercises, which presents a low risk that you may experience discomfort or pain, such as pelvic pain and/or hypertonicity. The program also includes Pilates, which presents a low risk that you may experience tendonitis, shin splints, strains, sprains, bruises, abrasions and/or joint injury. Since the treatment also provides advice on dietary changes, you could have an allergic reaction/discomfort to the recommended food if you have an unknown allergy/intolerance.

Data privacy and authorisation to collect, use, and disclose personal information:
• University of Galway as a research organisation has a legitimate interest in using data relating to your health and care when you agree to take part in this research study.
• Personal data will only be processed as necessary to achieve the objective of the research, and will not be processed in a way that will cause damage or distress to you.

During your participation in this research study, the study doctor and study staff will collect or create personal health information about you using questionnaires and record it in a study database. By participating in this study, you will be asked to consent to store information relating to your investigation on a database.
Any information which is collected about you during the course of the study will be kept strictly confidential and will only be seen by staff involved in the study (which may include research staff or staff from the CRFG) and people from regulatory authorities who ensure that studies such as this are carried out correctly. All of them will have a duty of confidentiality to you as a research participant and are trained in data protection.

Pseudo-anonymisation will be assured by removing any personal or identifiable details and assigning to the data a unique patient identification number. The pseudo-anonymised data will be stored on a local server in a secure database maintained in the HRB Clinical Research Facility, Galway (CRFG) and shared amongst the study investigators, the study management team and the Sponsor.

As part of the study, data will be shared with the manufacturer of the app, Amara Therapeutics. Any data provided to the manufacturer will be pseudonymised.

Data collected as part of the study questionnaires will be linked with data collected through the RiSolve app. This is done by linking your study ID number with your RiSolve user number. Only the study site team will know which number corresponds to which.

Your GP will be notified of your participation in the study. Your GP may be contacted by the study doctor if it is deemed necessary.
Your name and personal information will not be given to anyone who is not involved in the study. Your personal information collected as part of this study, will be made available to study staff at the site. If needed, the study staff may contact your personal physician to collect additional medical information, or a personal contact in the event that you cannot be reached.

Your study information will be identified in the database by a code and not by your name. The study staff will keep record of which code belongs to you and will be kept confidential.

What rights does the General Data Protection Regulation (GDPR) provide?
Providing informed consent means that the University of Galway can process your personal data for purposes stated in the clinical trial. The written informed consent process is in line with the requirements of Good Clinical Practice, GDPR and the Data Protection Act Bill 2018 with a view to ensuring your rights are protected. The legal bases for data processing in this study are GDPR Article 6(1)(e) i.e. "*carried out in the public interest*", and 9(2)(j), i.e. special category data processing for "*scientific or historical research purposes*". The study also processes personal data under the legal basis of Article 6(1)(c) (legal obligation) and Article 9(2)(i) (safety of medical devices) as this is a regulated study. Your consent is also collected as part of the studies suitable and specific safeguards to protect the rights and freedoms of data subjects.

These include your right, at any time, to withdraw your consent from continuing in the clinical research study. Additionally, under GDPR, you have the following enhanced rights in relation to how we use your personal data:

For your data collected within the study you can apply the following privacy rights:
• Request information about the handling of your data. However, to protect the scientific integrity of the study you may not be able to receive access to some of the data before the study ends.
• Request correction of data about you if it is incorrect or incomplete. During the assessment of this request, you have the right to restrict the processing of data about you.
• Request transfer of data about you to you or someone else in a commonly used format.
• File a complaint with a data protection authority.
• Withdraw your consent at any time without giving reason. You can withdraw your consent for the study treatment and/or further follow up, without withdrawing consent for handling your data. You may also withdraw consent to the handling of your data but please note previous data processing, before this, is legally covered by your original consent. After this withdrawal no further data will be collected from you.

If you wish to apply any of your data privacy rights with respect to your data, please inform your study doctor or contact University of Galway Data Protection Office at dataprotection@universityofgalway.ie

Sharing your Data:
The Sponsor, University of Galway, will keep any information they receive confidential as required by Irish and EU law. The study information will be used only for research purposes

mentioned above. If the results of this study are published or presented in a meeting, you will not be named, and it will not be possible to identify you from the information provided as having taken part in the study.

The results of the investigation will not be disclosed to any person outside of the below personnel and will not affect your diagnosis or treatment in any way.

Your encoded data will be stored for at least 15 years after the end of the study, or longer, if needed for legal requirements. During the course of the clinical trial, the data may be shared with:

- The Data Controller (University of Galway)
- Amara Therapeutics
- Individuals undertaking Controller tasks required for the conduct of the study e.g. Sponsor Auditors, Study Monitors. These people will use your personal information to check that the study is conducted correctly and to make sure the study information is accurate. These people are all required to keep the study information confidential by the nature of their work or by confidentiality agreements.
- The unit who are delegated the task of managing the data by the Controller (in the case of this study and include study researchers and Biostatistician(s) within the Data Management and Biostatistics Department of HRB Clinical Research Facility Galway, University of Galway, H91 YR71, Ireland, Tel: +353 91 494369) who are delegated the responsibility of data processing.
- Where the Sponsor uses data processors such as RedCap, they will process your data under the instructions of the Sponsor.
- The ethics committee (National Office for Research Ethics Committees).
- The Irish competent authority (HPRA) and other applicable regulatory bodies as required to facilitate audit and inspection.
- Your GP will be informed of your participation in this study.
- Transfer of encoded data to other countries: Your encoded study data may be transferred within and/or outside the EU in line with reporting requirements and as required for the operation of the study and this will be done so in line with GDPR requirements.

Where can I get further information on Data Protection and GDPR?

- If you have any questions concerning any personal data you believe or know the organisation holds about you, please contact Saravana Boominathan, by phone at 086 831 6459, or by email at risolvestudy@universityofgalway.ie. Alternatively you can contact the Principal Investigator of the study (Professor Andrew Murphy) at 091 493525.

- You can also contact the University of Galway Data Protection Officer at dataprotection@universityofgalway.ie.

• In the event that you wish to make a complaint about how your personal data is being processed by us or how your complaint has been handled, you have the right to lodge a complaint directly with the supervisory authority:

- Data Protection Commissioner: Office of the Data Protection Commissioner. Canal House, Station Road, Portarlington, Co. Laois, R32 AP23, Ireland. Phone +353 (0761) 104 800 | LoCall 1890 25 22 31 | Fax +353 57 868 4757 | email info@dataprotection.ie

For further detailed information regarding GDPR please refer to CRFG Website: http://www.nuigalway.ie/hrbcrfg

Will I get feedback on my own results?
Yes, the App provides detailed feedback on your responses. This will be provided to you at the end of the study.

What will happen to the results of the study?
The results of the study may be published in scientific or medical journals and presented at conferences. Copies of the published results will be available to you on request after the data collection is finished and the analyses have been performed. Your name will not be linked to the publications in any way.

Who is organising and funding the research?
This study is funded by the Disruptive Technology Innovation Fund from Enterprise Ireland.

The study is being carried out by researchers at the HRB Primary Care Clinical Trials Network Ireland and the HRB-Clinical Research Facility Galway, which is part of the University of Galway and is located at University Hospital Galway.

The University of Galway maintains insurance coverage for this study in accordance with Irish laws and regulations. The Principal Investigator is covered by indemnity cover from the Medical Protection Society Ltd. The app is covered by product liability insurance through Chubb.
In no way does signing this consent form waive your legal rights or relieve the study doctor, sponsor or involved institutions from their legal and professional responsibilities.

What if I have a complaint during my participation in the study?
The research team will be available for you to contact if you have any complaints during your participation in the study - see contact details below.

Who do I contact if I need further information?
If you have any questions related to your rights as a research study participant, please contact the Ethics Committee (National Office for Research Ethics Committees) on 01 234 5000.

If you have questions or concerns regarding data protection you can contact the office of the Data Protection Officer, by email at dataprotection@universityofgalway.ie, or by phone at 091 524 411.

Study team contact:
Name: Saravana Boominathan
Telephone Number: 086 831 6459
E-mail: risolvestudy@universityofgalway.ie

If you have any further questions, you can also contact the Principal Investigator on the study directly:

Name: Professor Andrew Murphy
Telephone Number: 091 493525