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Clinical Utility of Handheld Hydrogen Breathalyzer in Identification of Food Sensitivities (AIRE Study)

Date: May 31st, 2022

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Johns Hopkins Medicine - eForm A

Clinical utility of handheld hydrogen breathalyzer in identification of non-immune mediated food sensitivities

1. Abstract

Small intestinal bacterial overgrowth (SIBO) is defined as a condition in which an abnormally high amount of coliform bacteria is present in the small bowel and results in premature anaerobic fermentation of carbohydrates before reaching the colon. Commonly recognized causes include gastric achlorhydria, post-surgical bowel stasis, gastrocolic/coloenteric fistulas, and motility disorders leading to bowel stasis. The current "gold standard" for the diagnosis of SIBO, is a breath test that measures the concentration of hydrogen in response to lactulose, a carbohydrate that is only metabolized by bacteria. However, its accuracy is only about 50% and therefore it is not a very useful test, leading most physicians to treat these patients empirically based on clinical suspicion alone. The purpose of this study is to evaluate the clinical utility of a portable medical device called AIRE, an over-the-counter, commercially available handheld breath analyzer that measures exhaled hydrogen content.

2. Objectives (include all primary and secondary objectives)

Primary objective:

To examine the correlation between the results of the AIRE hydrogen and methane breathalyzer and the lactulose hydrogen breath test (LHBT) when performed together in patients clinically suspected to have SIBO.

Secondary objectives:

1. To examine the correlation between postprandial exhaled hydrogen and methane (H_2) content as measured over a 1-week period by AIRE on the patient's usual diet at home and the results of the standardized LHBT performed in the clinic
2. To examine the correlation between AIRE results and gastrointestinal symptoms suggestive of SIBO.
3. To examine the response of hydrogen and methane breath concentrations using AIRE to antibiotic treatment (in patients undergoing antibiotic treatment).
4. To assess the reproducibility of the AIRE results over several weeks in patients not undergoing antibiotic treatment.

3. Background (briefly describe pre-clinical and clinical data, current experience with procedures, drug or device, and any other relevant information to justify the research)

Small intestinal bacterial overgrowth (SIBO) is defined as a condition in which an abnormally high amount of coliform bacteria is present in the small bowel and results in premature anaerobic fermentation of carbohydrates before reaching the colon. Commonly recognized causes include gastric achlorhydria (ie due to longstanding PPI use), post-surgical bowel stasis, and gastrointestinal motility disorders leading to bowel stasis. Although SIBO is commonly suspected, a major limitation in the field is the lack of a highly accurate test for SIBO. The current gold standard relies on the demonstration of an early rise in breath hydrogen concentration in response to an orally ingested carbohydrate (commonly, lactulose) but its accuracy is about 50%. This may be because it is a one-time snapshot with an artificial substrate. Further, it has to be performed in a clinic, takes up to 5 hours and is relatively expensive. The purpose of this study is to evaluate the clinical utility of a portable medical device called AIRE, which is a validated and commercially available handheld breathalyzer that measures hydrogen and methane content in the breath and connects via Bluetooth to an associated smartphone application to provide immediate results and

visual feedback after use. H_2 concentrations determined by the AIRE device showed significant correlation with those measured by LHBT. The AIRE device therefore provides an alternative way to measure exhaled H2 and methane that have the potential for addressing many of the limitations of the standard breath test.

Study Procedures

This pilot study will be an open-label trial in patients suspected to have SIBO (abdominal bloating, distention, discomfort, change in bowel movements) and who are being considered for diagnostic testing using the lactulose-hydrogen breath test (LHBT). 150 patients will be accrued from the gastroenterology motility clinic or the scleroderma clinic, in addition, 20 healthy volunteers will be accrued making a grand total of 120 participants. Healthy volunteers will be recruited initially at the Ross Research Building. Other alternatives provided by The Recruitment Innovation Unit (RIU) from the Institute for Clinical & Translational Research (ICTR) Johns Hopkins Medicine may be considered to make our study more visible within Hopkins community. If the subject meets eligibility criteria, and the LHBT has been scheduled, a co-investigator will contact the patient to schedule a study visit with a research coordinator and obtain a written consent. Potential subjects will be provided with a copy of the Informed Consent form prior to the remote consent meeting either via email, fax, mail or previously provided during an in person visit. Potential subjects will then be contacted by phone by a study team member who is a consent designee to review the consent form in detail. Potential subjects will be given adequate time to consider the research study and ask questions prior to signing the consent form. The potential subject will then sign and date/time the informed consent document and it will be mailed, emailed or faxed to the consent designee, who will also sign/date/time. A copy of the fully signed consent form will be returned to the volunteer. The contact and screening information of patients that are successfully recruited will be documented, placed in the participant's study folder and stored in a locked cabinet in the motility clinic at Bayview. Any information documented during the screening process for patients who do not meet basic eligibility criteria or do not wish to participate will be immediately destroyed.

The study coordinator will maintain a list of all participants, each having a unique participant code, e.g. JH-SIBO1-001, along with various personally identifiable information, e.g. email, name etc. The coordinator will instruct the participant to use the participant code to sign up for the app from FoodMarble. FoodMarble however, we would never receive participant's email address or any information (the participant code is all they would have on their servers to identify the participant).

Enrolled patients will be provided the AIRE device and will be instructed on how to use the device as well as the accompanying phone application. Participants will eat their normal, typical diets during the first week of the study. They will use the AIRE machine to measure exhaled H_2 and Methane content before and after two meals each day – the first meal of the day and the last meal of the day. They will breathe into the AIRE machine before eating to obtain a baseline value. Once they have finished eating, they will breathe into the AIRE machine 30 minutes, 60 minutes, and 90 minutes postprandially. The exhaled H_2 and Methane results will be automatically recorded in the phone application, which is connected to the AIRE machine via Bluetooth. The participants will record their food intake and symptoms directly into their smartphone via an app that comes with the AIRE device. Symptom scores will be recorded at the same time they use the AIRE machine (30 minutes, 60 minutes, and 90 minutes postprandially). Note participants will be asked to not use the AIRE device after a meal including alcohol as this will skew the device results, however patients will be asked to record all meal content (including meals with alcohol) in their food log throughout the duration of the study.

Symptomatic participants will be asked to complete the Gastrointestinal Symptom Rating Scale for Irritable Bowel Syndrome (GSRS-IBS). The GSRS IBS is a 13-item reliable, valid and user-friendly instrument with excellent psychometric properties measuring. Depicting problems with satiety, abdominal pain, diarrhea,

constipation and bloating. The internal consistency reliability was high, ranging from 0.74 (pain) to 0.85 (satiety). Takes approximately 3-5 minutes. Recall period is past week
Each item is rated on a 7-point Likert scale.
Healthy volunteers will be asked the Gastrointestinal Symptom Rating Scale (GSRS). This instrument address 15 items combined into five symptom clusters: Reflux, Abdominal pain, Indigestion, Diarrhea and Constipation. The reliability and validity of the GSRS are well-documented, and norm values for a general population are available. The original questionnaire is an interview-based rating scale but has been modified to become a self-administered questionnaire. Takes approximately 3-5 minutes
Recall period is past week. Each item is rated on a 7-point Likert scale.

Following a week of AIRE measurement, participants will then undergo the physician-ordered and clinically indicated LHBT done on the clinically scheduled day and time. They will use the AIRE device one time immediately before the LHBT begins and throughout the lactulose breath test as well, at the same intervals as the lactulose breath test (breathe into AIRE device immediately after breathing into the standard lactulose breath test tube).

Subjects will be notified of the breath test result and whether or not they will receive antibiotics. This will be the only result for disclosure to the participant. Decisions regarding treatment will be based on clinical judgment and standard of care, after taking into consideration the patient's history and test results. This decision will be made by the care provider (MD or mid-level) and will be discussed with the patient by a member of the study team.

A Lactulose challenge using the AIRE device will be repeated after 5 – 7 days of the initial LHBT if this reports negative findings for SIBO. We are testing the hypothesis that repeating the test will increase the probability of a positive response.

If subjects receive antibiotic treatment, they will be asked to use the AIRE device three days before they begin taking antibiotics, during treatment, and for four weeks after treatment ends.

One month later (if no antibiotics were prescribed) participants will repeat the 1-week use of AIRE device described above. Therefore, all participants will complete this second week of AIRE use regardless whether or not they received antibiotics. A second round of antibiotics will be prescribed if the patient does not response to the initial treatment based on the attending physician decision.

Once the second week of AIRE use is completed, participants will return the AIRE machine. Data from the app is automatically downloaded from the app to the Food Marble server.

Data analysis will be performed at Mayo Clinic Scottsdale, Arizona by Dr. Jay Pasricha, (Pasricha.Jay@mayo.edu). This site will no recruit participants.
Johns Hopkins will serve as coordinating center under supervision of Dr. Glenn Treisman, responsible for overall data management, monitoring and communication, and general oversight of the conduct of this protocol.

b. Study duration and number of study visits required of research participants.
Study duration is approximately 7 weeks with a total of 2 study visits (one initial study visit to allow for consent and to provide relevant materials, and one follow up study visit (to return materials and allow for data collection).

c. Blinding, including justification for blinding or not blinding the trial, if applicable.
N/A: no blinding indicated.

d. Justification of why participants will not receive routine care or will have current therapy stopped.

N/A: participants are not undergoing treatment related to this study.

e. Justification for inclusion of a placebo or non-treatment group.

N/A: this is not a drug study.

f. Definition of treatment failure or participant removal criteria.

Subjects can voluntarily remove themselves from a part or the entire study at any time. Subjects may also be removed from the study if:

- failure to follow instructions
- study is cancelled
- there may be other reasons to take a subject out of the study that we do not know at this time

g. Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely.

N/A; subjects are not undergoing any therapy related to this study.

4. Inclusion/Exclusion Criteria

Subjects will be recruited from the Johns Hopkins motility disorder clinic and/or the scleroderma clinic. Inclusion criteria for this study are as follows:

Inclusion:

- Adults (18 years of age or older)
- Chronic (>3 months) GI symptoms such as nausea, bloating, distention, altered bowel movements, weight loss or abdominal pain with no structural cause other than scleroderma
- Clinical diagnosis of SIBO by patient's gastroenterologist with plans to obtain a lactulose hydrogen breath test
- Ability to tolerate oral intake
- Ability to undergo the LHBT
- Access to a smartphone with Bluetooth capability

Exclusion:

- History of current or recent antibiotic use within the last 30 days
- History of inflammatory bowel disease
- Currently following a restrictive diet (for example low FODMAP diet)
- Unable to tolerate oral intake

Criteria for Healthy Volunteers.

Inclusion:

- Adults (18 years of age or older)
- Ability to tolerate oral intake.
- Access to a smartphone with Bluetooth capability
- Willingness to use the AIRE device at the first and last meal of the day for 8 weeks.
- Willingness to complete the GSRS questionnaire.

Exclusion:

- Patients with past or current medical history of gastrointestinal illnesses (Functional and motility disorders)
- Patients diagnosed with SIBO.
- Patient currently taking antireflux medications (Proton pump inhibitors, H2 antagonist, etc.)
- Patients following a restrictive, gluten free or FODMAP diet.
- Previous gastro-esophageal surgery including vagotomy, fundoplication, gastric bypass, ulcer surgery.
- Prior GI surgery except for uncomplicated appendectomy and laparoscopic cholecystectomy;
- Surgery within the past 3 months.
- Patients with BMI lower than 18.5 or higher than 29.9
- History of current or recent antibiotic use within the last 30 days.

5. Drugs/ Substances/ Devices—

The device being tested is AIRE breathalyzer which is a validated and commercially available hydrogen breathalyzer created by FoodMarble (https://foodmarble.com/).

6. Study Statistics—

This study is powered around the primary objective i.e. to examine the correlation between postprandial exhaled hydrogen (H_2) content as measured over a 1-week period by AIRE on the patient's usual diet at home and the results of the standardized lactulose hydrogen breath test (LHBT) performed in the clinic. We predict a moderate correlation between these two tests and assuming an alpha-error of 0.050 and a beta error of 0.200, 100 patients will be sufficient for an expected correlation coefficient of 0.5.

We are requesting this because although the original aim (comparison to a commercial test) has been almost completed, an initial look at the data also shows that we may be picking up additional signals from day to day breath testing that could be a biomarker for the response to antibiotics. This will however require additional patients since only about 30% of patients are responders (exemplifying the need for more accurate tests for SIBO); we estimate that by doing 70 more patients we will get about 20 more responders bringing the total number of responders to about 30, which may give us enough power to test this emerging hypothesis. We will do a formal interim analysis of this about halfway through the additional recruitment target and reassess the need to continue at that point.

In order to interpret the postprandial breath readings of SIBO patients it can only be done properly when compared to normative data. We estimate that 20 healthy volunteers with a proportion of 60% women and 80% between 18 and 40 years old will be enough to compare and interpret postprandial H2 readings.

In addition to the initial 100 patients and 20 healthy volunteers we want to accrued 50 patients to examine the correlation of pre and postprandial Methane breath using the AIRE device and compare also with a LHBT.

7. Risks

a. Medical risks, listing all procedures, their major and minor risks and expected frequency.

There are no risks to using AIRE breathalyzer when used properly.

b. Steps taken to minimize the risks.

N/A

c. Plan for reporting unanticipated problems or study deviations.

All adverse events or study deviations will be immediately reported to the IRB.

d. Legal risks such as the risks that would be associated with breach of confidentiality.

There are minimal risks as all patient information related to the study data will be de-identified.

e. Financial risks to the participants.

There are no financial risks to the participants.

8. Benefits

a. Description of the probable benefits for the participant and for society.

Participants may benefit from the study by gaining a more thorough understanding of their food tolerances and intolerances through use of the AIRE device. Society may benefit from the study through demonstration of clinical efficacy of a convenient and cost-effective device that has the potential to improve the quality of life for GI patients and reduce cost burden of traditional investigations and pharmacologic interventions for SIBO.

9. Payment and Remuneration

a. Detail compensation for participants including possible total compensation, proposed bonus, and any proposed reductions or penalties for not completing the protocol.

A $100.00 compensation gift card will be provided for Healthy Volunteers.

10. Costs

a. Detail costs of study procedure(s) or drug (s) or substance(s) to participants and identify who will pay for them.

The AIRE devices will be provided by FoodMarble at no cost. The remaining costs for symptom questionnaires/food logs are estimated to be minimal and will be accommodated by the study team.

If appropriate for this study, a scanned copy of the signed consent form should be uploaded to the participant's Epic/EMR record.

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: Clinical utility of handheld hydrogen breathalyzer in identification of non-immune mediated food sensitivities (AIRE study)

Application No.: IRB00204104

Supporter: **FoodMarble**

Principal Investigator: Pankaj (Jay) Pasricha, M.D.
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Baltimore, MD 21205
Phone: 410-550-6766
Fax: 410-550-3058
Email: ppasric1@jhmi.edu

You are being asked to join a research study. Participation in this study is voluntary. Even if you decide to join now, you can change your mind later.

1. Research Summary (Key Information):

The information in this section is intended to be an introduction to the study only. Complete details of the study are listed in the sections below. If you are considering participation in the study, the entire document should be discussed with you before you make your final decision. You can ask questions about the study now and at any time in the future.

The purpose of this study is to evaluate the clinical utility of a portable medical device called AIRE, an over-the-counter, commercially available handheld breath analyzer that measures exhaled hydrogen and methane content. By taking part in this study, you will help to determine whether the device may be useful to diagnose a condition called Small Bowel Bacterial Overgrowth (SIBO). Although SIBO is commonly suspected, a major limitation in the field is the lack of a highly accurate test. Thirty people will be recruited from the gastroenterology motility clinic or the scleroderma clinic. Study duration is about 7 weeks with two study visits: one initial study visit to allow for consent and to provide the AIRE device and instructions for using the smartphone app, and one follow up study visit to return the device and allow for data collection. After the first visit, you will be asked to breathe into the AIRE device once before and once after your first and last meals of the day for one week. You will also be asked to log your daily food intake during that week. Then, you will undergo your scheduled standard of care breath

test while also using the AIRE device. Depending on the results of your standard of care test and the decision of your treating physician, you may receive antibiotics. If you do not receive antibiotics, you will be asked to complete another week of using the AIRE device and food log one month later. If you do receive antibiotics, you will be asked to complete another week of using the AIRE device and food log 2 weeks later.

There are no physical risks from using the AIRE device, and the main risk of participation is information about you may become known to people outside of this study. There is no benefit to you from being in this study.

2. Why is this research being done?

This research is being done to evaluate the clinical utility of a portable medical device called AIRE, a handheld breath analyzer that measures the amount of exhaled hydrogen and methane in your breath. This device connects via Bluetooth to an associated smartphone application called "FoodMarble" to provide immediate results and visual feedback after use. This evaluation might help to diagnose a condition called Small Intestinal Bacterial Overgrowth (SIBO), which is a serious condition affecting the small intestine. It occurs when bacteria that normally grow in other parts of the gut start growing in the small intestine and causes pain and diarrhea..

The current gold standard is the Lactulose Hydrogen Breath Test – LHBT. The AIRE device is being compared to the current standard breath test (LHBT) as an alternative way to measure exhaled Hydrogen and Methane.

Are there any investigational drugs/devices/procedures?

The AIRE device is an over-the-counter commercially available breath analyzer.

Who can join this study?

People 18 years of age or older with a clinical diagnosis of SIBO and scheduled to undergo a lactulose hydrogen breath test may join this study.

150 participants will be accrued in this study.
20 healthy volunteers will be accrued.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

Visit 1:

The AIRE device will be provided to you. You will be instructed on how to use the device and the accompanying phone application.

For the first week after your visit, we will ask you to eat your normal, typical diet. You will use the AIRE machine to measure exhaled Hydrogen and Methane content before and after two meals each day – the first meal of the day and the last meal of the day. You will be asked to breathe into the AIRE machine before eating to obtain a baseline value. Then you will be asked to breathe into the AIRE machine 30 minutes, 60 minutes, and 90 minutes after eating. The exhaled hydrogen and methane results will be automatically recorded in the phone application.

Every week you will be asked to complete the Gastrointestinal Symptom Rating Scale in Irritable Bowel Syndrome (GSRS-IBS). This is a week recall questionnaire with 13 items to assess the severity of your gastrointestinal symptoms.

If you are a healthy volunteer, you will be asked to complete the Gastrointestinal Symptom Rating Scale (GSRS) weekly.

You will be asked to record your food intake and symptoms directly into the same smartphone app. Please **DO NOT** use the AIRE device after a meal including alcohol as this will skew the device results, however record all meal content (including meals with alcohol) into your food log during the study.

After a week of using the AIRE device, you will undergo your clinically scheduled LHBT (only the results of the clinical LHBT test will be disclosed to you). You will be asked to use the AIRE device one time immediately before the LHBT begins and throughout the lactulose breath test as well, at the same intervals as the lactulose breath test (breathe into AIRE device immediately after breathing into the standard LHBT tube). If the AIRE device report is negative, you will be asked to repeat the test using only the device to confirm the result.

You will be notified of the standard of care breath test result. Decisions regarding treatment, including receiving antibiotics, will be based on the LHBT standard test, clinical judgment and standard of care, after taking into consideration your history and test results. This decision will be made by your care provider and will be discussed with you.

If you receive antibiotic treatment, you will be asked to use the AIRE device three days before you begin taking antibiotics, during treatment, and for four weeks after treatment ends.

One month later (if no antibiotics were prescribed), you will be asked to repeat the 1-week use of AIRE device as described above. All participants will complete this second week of AIRE use the same regardless of antibiotic use.

Visit 2
Once the second week of AIRE use is completed, you will return the AIRE machine for at most a 30 minute visit. Data from the app is automatically downloaded from the app to the Food Marble server.

Will research test results be shared with you?
It is uncertain if the research tests will produce results that would be relevant for your clinical care, so we will not share these results with you.

How long will you be in the study?
You will be in this study for approximately 7 weeks with a total of 2 study visits, each less than 30 minutes.

4. What happens to data that are collected in the study?

Johns Hopkins and our research partners work to advance science and public health. The data we collect about you are important to this effort.

If you join this study, you should understand that you will not own your research data. If researchers use your data to create a new product or idea, including those that may have commercial value, you will not benefit financially from those efforts.

How will your data be shared now and in the future?
Sharing data is part of research and may increase what we can learn from each study.

Often, data sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas.

Your data may be shared:

- directly with research collaborators, other researchers, sponsors, government agencies, publishers of papers and other research partners
- through government or other databases/repositories

Data sharing could change over time, and may continue after the study ends.

We will do our best to protect and maintain your data in a safe way. Generally, if we share your data without identifiers (such as your name, address, date of birth) no further review and approval by an Institutional Review Board (IRB) is needed. If data are shared with identifiers, further IRB review and approval may be needed. The IRB will determine whether additional consent is required.

If you are not comfortable with the use of your data in future research, you may not want to participate in this study.

5. What are the risks or discomforts of the study?

There are no physical risks to using AIRE breathalyzer.

Interviews or questionnaires
You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

Identifiable private information
There is the risk that information about you may become known to people outside this study.

6. Are there benefits to being in the study?

There is no benefit to you from being in the study because the results of this study will not be used in decisions about your treatment. If you take part in this study, you may help others in the future.

7. What are your options if you do not want to be in the study?

You do not have to join this study. Other options include performing the LHBT only as indicated by your care provider or receiving a trial of antibiotic for clinically suspicious SIBO.

If you do not join, your care at Johns Hopkins will not be affected.

8. Will it cost you anything to be in this study?

You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet (Sheet). This Sheet will give you the following information:

- The procedures, tests, drugs or devices that are part of this research and that will be paid for by the study (no cost to you).
- The procedures, tests, drugs or devices that will be billed to you and/or your health insurer. If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

9. Will you be paid if you join this study?

Healthy volunteers will be compensated for time with a $100.00 gift card.

10. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or share your health information that it has already collected if the information is needed for this study or any follow-up activities.

11. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

12. How will your privacy be maintained and how will the confidentiality of your data be protected?

HIPAA Authorization for Disclosure of Protected Health Information

What information is being collected, used, or shared?

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Johns Hopkins Medicine and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?

The people who may request, receive, or use your private health information include the researchers and their staff who may be a part of Johns Hopkins Health System, Johns Hopkins University or the Johns Hopkins Applied Physics Laboratory. Additionally, we may share your information with other people at Johns Hopkins, for example if needed for your clinical care or study oversight. To improve coordination of your research and clinical care, some information about the study you join will be included in your electronic medical record.

By signing this form, you give permission to the research team to share your information with others outside of Johns Hopkins. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team.

We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

How will your information be protected?
The study coordinator will maintain a list of all participants, each having a unique participant code, along with personally identifiable information, such as your email, name etc. Your de-identified information will be stored in a locked cabinet in the motility clinic at Bayview.

The coordinator will give you instructions about using your participant code to sign up for the app from FoodMarble. FoodMarble would never receive your email address or any information (the participant code is the only way to identify you).

13. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers.

14. What other things should you know about this research study?

During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

What is the Institutional Review Board (IRB) and how does it protect you?
This study has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB at 410-502-2092 or jhmeirb@jhmi.edu.

What should you do if you have questions about the study, or are injured or ill as a result of being in this study?
Call the principal investigator, Dr. Pankaj Pasricha at 410-550-6766. If you wish, you may contact the principal investigator by letter. The address is on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-502-2092.

15. What does your signature on this consent form mean?

Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions, and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time

I have received the separate Insurance and Research Participant Financial Responsibility Information Sheet.

Signature of Participant, LAR or Parent/Guardian	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).