Cover Page:

NCT#: NCT04665271

Title: Acceptability and Efficacy of Zemedy App versus an Education and Relaxation Training App for IBS

Date January 14, 2021

Modification

Basic Info

Confirmation Number:	**ddaedhbe**
Protocol Number:	**844160**
Created By:	**HUNT, MELISSA G**
Principal Investigator:	**HUNT, MELISSA G**
Protocol Title:	**Acceptability and Efficacy of Zemedy App versus an Education and Relaxation Training App for IBS**
Short Title:	**Zemedy App 2.0**
Protocol Description:	**The purpose of this research is to assess if a new phone app version of a self-help intervention for Irritable Bowel Syndrome (IBS), is an acceptable and effective treatment for improving the overall quality of life in patients with IBS.**
Submission Type:	**Social and Biological Sciences**
Application Type:	**EXPEDITED Category 7**

PennERA Protocol Status

Approved (No CR)

Resubmission*
No

Are you submitting a Modification to this protocol?*

Yes

Current Status of Study

Study Status

Study has not begun (no subjects entered)

If study is currently in progress, please enter the following

Number of subjects enrolled at Penn since the study was initiated

0

Actual enrollment at participating centers

0

If study is closed to further enrollment, please enter the following

Number of subjects in therapy or intervention

0

Number of subjects in long-term follow-up only

0

IRB Determination
If the change represents more than minimal risk to subjects, it must be reviewed and approved by the IRB at a convened meeting. For a modification to be considered more than minimal risk, the proposed change would increase the risk of discomfort or decrease benefit. The IRB must review and approve the proposed change at a convened meeting before the change can be implemented unless the change is necessary to eliminate an immediate hazard to the research participants. In the case of a change implemented to eliminate an immediate hazard to participants, the IRB will review the change to determine that it is consistent with ensuring the participant′s continued welfare. Examples: Convened Board Increase in target enrollment for investigator initiated research or potential Phase I research Expanding inclusion or removing exclusion criteria where the new population may be at increased risk Revised risk information with active participants Minor risk revisions that may affect a subject′s willingness to continue to participate Expedited Review Increase in target enrollment at Penn where overall enrollment target is not exceeded or potentially sponsored research Expanding inclusion or removing exclusion where the new population has the same expected risk as the previous, based on similarities of condition Revised risk information with subjects in long-term follow-up Minor risk revisions with no subjects enrolled to date Expedited Review

Modification Summary
Please describe any required modification to the protocol. If you are using this form to submit an exception or report a deviation, enter 'N/A' in the box below.
We have changed the nature of the active control condition. Rather than using an established mindfulness meditation app we are using a control app that includes links to NICE IBS treatment guidelines and multiple relaxation training videos.

Risk / Benefit
Does this amendment alter the Risk/Benefit profile of the study?
No

Change in Consent
Has there been a change in the consent documents?
Yes

If YES, please choose from the options below regarding re-consenting

Our site does not plan to obtain re-consent

Deviations

Are you reporting a deviation to this protocol?*

No

Exceptions

Are you reporting an exception to this protocol?*

No

Protocol Details

Resubmission*
Yes

Hospital Sites
Will any research activities and/or services be conducted at a Penn Medicine affiliated hospital site?
No

Study Personnel

Principal Investigator

Name:	**HUNT, MELISSA G**
Dept / School / Div:	**120 - Psychology**
Campus Address Mail Code	**6241**
Address:	**PSYCHOLOGY** **3720 WALNUT STREET**
City State Zip:	**PHILADELPHIA PA 19104-6241**
Phone:	**215-898-6103**
Fax:	**-**
Pager:	
Email:	**mhunt@psych.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	**10/04/2020**
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Study Contacts

None

Other Investigator

None

Responsible Org (Department/School/Division):

120 - Psychology

Key Study Personnel

Name:	**IPEK, SIMAY I**
Department/School/Division:	**The College**
HS Training Completed:	**Yes**

Training Expiration Date:	
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**
Name:	**MIGUEZ, SOFIA M**
Department/School/Division:	**The College**
HS Training Completed:	**Yes**
Training Expiration Date:	**09/02/2022**
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**
Name:	**DALVIE, ANIKA S**
Department/School/Division:	**The College**
HS Training Completed:	**Yes**
Training Expiration Date:	
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**
Name:	**WASMAN, BENJAMIN A**
Department/School/Division:	**The College**
HS Training Completed:	**Yes**
Training Expiration Date:	
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Disclosure of Significant Financial Interests*
Does any person who is responsible for the design, conduct, or reporting of this research protocol have a **FINANCIAL INTEREST**? No

Penn Intellectual Property*
To the best of the Principal Investigator's knowledge, does this protocol involve the testing, development or evaluation of a drug, device, product, or other type of intellectual property (IP) that is owned by or assigned to the University of Pennsylvania?
No

Certification
I have reviewed the *Financial Disclosure and Presumptively Prohibited Conflicts for Faculty Participating in Clinical Trials* and the *Financial Disclosure Policy for Research and Sponsored Projects* with all persons who are responsible for the design, conduct, or reporting of this research; and all required Disclosures have been attached to this application.
Yes

Social and Biological Sciences

Study Instruments
Discuss the particulars of the research instruments, questionnaires and other evaluation instruments in detail. Provide validation documentation and or procedures to be used to validate instruments. For well know and generally accepted test instruments the detail here can be brief. More detail may be required for a novel or new instrument. For ethnographic studies identify any study instruments to be used (i.e. for deception studies) and describe in detail where, when and how the study will be conducted and who or what are the subjects of study. Note: For more information on how to conduct ethical and valid ethnographic research, follow the link For oral histories or interviews provide the general framework for

questioning and means of data collection. If interviews or groups settings are to be audio taped or video taped describe in detail the conditions under which it will take place. Include a copy of any novel or new test instruments with the IRB submission.
Symptom Questionnaire of Rome IV Diagnostic Criteria for IBS. (Whitehead, et al.2016. Rome IV Diagnostic Questionnaires. The Rome Foundation.) Gastrointestinal Symptom Rating Scale (GSRS) (Wiklund, I. K., Fullerton, S., Hawkey, C. J., Jones, R. H., Longstreth, G. F., Mayer, E. A., . . . Naesdal, J. (2003). An irritable bowel syndrome-specific symptom questionnaire: Development and validation. Scandinavian Journal of Gastroenterology, 38(9), 947-95.) 13 items covering symptom severity in IBS. IBS Quality of Life (IBSQoL) (Patrick, D. L., Drossman, D. A., Frederick, I. O., DiCesare, J., & Puder, K. L. (1998). Quality of life in persons with irritable bowel syndrome: Development and validation of a new measure. Digestive Diseases and Sciences, 43(2), 400-411.) The standard measure of health related quality of life for people with IBS. Visceral Sensitivity Index (VSI - Aliment Pharmacol Ther. 2004 Jul 1;20(1):89-97. The Visceral Sensitivity Index: development and validation of a gastrointestinal symptom-specific anxiety scale. Labus JS, Bolus R, Chang L, Wiklund I, Naesdal J, Mayer EA, Naliboff BD.) - The Visceral Sensitivity Index (VSI) is a widely used a unidimensional 15-item scale that measures gastrointestinal symptom-specific anxiety (GSA). Preliminary and follow-up studies have found high internal consistency for the VSI, reporting a Cronbachs of about 0.93 and a mean inter-item correlation of 0.47 (26, 27). Criterion and construct validity tests showed the VSI, when compared to the ASI and the HAD, to be the strongest predictor of current IBS symptom severity (26). Studies have also shown the VSI to have good concurrent, divergent and discriminant validity (27). Gastrointestinal Cognitions Questionnaire (Hunt, M., Ertel, E., Coello, J. & Rodriguez, L. (2014). Development and validation of the GI-Cognitions Questionnaire. Cognitive Therapy and Research, 38(4), 472-482.) - The GI-Cog consists of 18 self-report items that are rated on a 5-point Likert scale, ranging from 0 (Hardly) to 4 (Very much). The questionnaire consists of three subscales. The pain/life interference subscale (e.g., When I feel my GI symptoms acting up, I'm afraid the pain will be excruciating and intolerable), the social anxiety subscale (e.g., If I have to get up and leave an event, meeting, or social gathering to go to the bathroom people will think theres something wrong with me), and the disgusts sensitivity subscale (e.g., The thought of fecal incontinence is terrifying. If it happened, it would be awful). The GI-Cog has been shown to have excellent internal consistency (= .92) and test re-test reliability (r = .87, p .001) (Hunt, Ertel, Rodriguez et al., 2012). Fear of Food Questionnare (FFQ) (Hunt, M., Zickgraf, H., Gibbons, B. & Loftus, P. (2018). Development and Validation of the Fear of Food Questionnaire (FFQ). Poster presented at the annual meeting of the Anxiety and Depression Association of America. Washington, DC.) A brief self-report instrument assessing fear of food and loss of pleasure in eating. Beck Depression Inventory-II (Beck, A. T., Steer, R. A., & Brown, G. (1996). Beck Depression InventoryII. APA PsycTests.) Mobile Application Rating Scale user version (uMARS) (Stoyanov, S. R., Hides, L., Kavanagh, D. J., & Wilson, H. (2016). Development and Validation of the User Version of the Mobile Application Rating Scale (uMARS). JMIR mHealth and uHealth, 4(2), e72.). Work productivity and activity impairment questionnaire- irritable bowel syndrome version (WPAI:IBS) (Reilly, M.C., Bracco, A., Ricci, J.F., Santoro, J. and Stevens, T. (2004), The validity and accuracy of the Work Productivity and Activity Impairment questionnaire irritable bowel syndrome version (WPAI:IBS). Alimentary Pharmacology & Therapeutics, 20: 459-467.) The Work and Social Adjustment Scale (WSAS) (Mundt JC, Marks IM, Shear MK, Greist JH.) A simple measure of impairment in functioning. Br J Psychiatry. 2002 May;180:461-4. Demographic survey- Participants will be asked to complete a survey of demographic information, that will help to determine whether the sample is representative and detect any underlying differences between the wait-list group and the intervention group. It will also aid the investigators in examining whether the effects of the intervention differ according to demographic characteristics. All questionnaires are standardized questionnaires in the literature that are readily available for use.

Group Modifications
Describe necessary changes that will or have been made to the study instruments for different groups.
NA

Method for Assigning Subjects to Groups
Describe how subjects will be randomized to groups.
Participants will be randomly assigned to either the immediate treatment group or an active control group. Random assignment will be determined using the random.org coin toss.

Administration of Surveys and/or Process

Describe the approximate time and frequency for administering surveys and/or evaluations. For surveys, questionnaires and evaluations presented to groups and in settings such as high schools, focus group sessions or community treatment centers explain how the process will be administered and who will oversee the process. For instance, discuss the potential issues of having teachers and other school personnel administer instruments to minors who are students especially if the content is sensitive in nature. Describe the procedure for audio and videotaping individual interviews and/or focus groups and the storage of the tapes. For instance, if audio tape recording is to be used in a classroom setting, describe how this will be managed if individuals in the class are not participating in the study. Explain if the research involves the review of records (including public databases or registries) with identifiable private information. If so, describe the type of information gathered from the records and if identifiers will be collected and retained with the data after it is retrieved. Describe the kinds of identifiers to be obtained, (i.e. names, social security numbers) and how long the identifiers will be retained and justification for use.

Recruitment: We will recruit study participants via online communities focused on IBS, including Reddit, Healing Well, Facebook and so on. Interested individuals will be able to click a link to the Qualtrics platform where they will first see the Explanation of Research and then will be invited to complete all the baseline measures. When they have completed the consent and initial screening questionnaires, eligible participants will be randomized as above and either given access to either the Zemedy the app or a control mindfulness meditation app. At 8 weeks after enrollment, all participants in both the control group and self-help app group will receive a battery of follow-up questionnaires (the same that they answered directly after consenting in the beginning of the study as baseline measures). After completing the 8 week questionnaires, participants in the control group will be offered access to the Zemedy app. All participants will receive 3 month post-treatment follow-up questionnaires. All questionnaires will be available through qualtrics.com. Study investigators will be responsible for sending participants the e-mails, the links to the follow up questionnaires, monitoring the questionnaires online, and answering any questions participants may have through e-mail. Questionnaires may take approximately 30-45 minutes to complete.

Data Management

Describe how and who manages confidential data, including how and where it will be stored and analyzed. For instance, describe if paper or electronic report forms will be used, how corrections to the report form will be made, how data will be entered into any database, and the person(s) responsible for creating and maintaining the research database. Describe the use of pseudonyms, code numbers and how listing of such identifiers will be kept separate from the research data.

Data from completed study questionnaires and other materials will be collected via Qualtrics secure servers. This account is password protected and only study investigators will have access to the questionnaire data. E-mails to participants will be sent from the PI's university email account. Participant identification and contact information will be stored electronically in a single spreadsheet which only study investigators will have access to. The spreadsheet will be saved on a passwordprotected computer in the PIs lab. A master database of questionnaire responses, containing no identifying participant information, will be created and maintained by the PI. This database will only reside on the PI's password protected Penn computer. All data analysis will take place either on the PIs office PC, or in the PIs lab.

Radiation Exposure*

Are research subjects receiving any radiation exposure (e.g. X-rays, CT, Fluoroscopy, DEXA, pQCT, FDG, Tc-99m, etc.) that they would not receive if they were not enrolled in this protocol?

No

Human Source Material*

Does this research include collection or use of human source material (i.e., human blood, blood products, tissues or body fluids)?

No

CACTIS and CT Studies*

Does the research involve Center for Advanced Computed Tomography Imaging Services (CACTIS) and CT studies that research subjects would not receive if they were not part of this protocol?

No

CAMRIS and MRI Studies*
Does the research involve Center for Advanced Magnetic Resonance Imaging and Spectroscopy (CAMRIS) and MRI studies that research subjects would not receive if they were not part of this protocol?
No

Cancer Related research not being conducted by an NCI cooperative group*
Does this protocol involve cancer-related studies in any of the following categories?
No

Medical Information Disclosure*
Does the research proposal involve the use and disclosure of research subject's medical information for research purposes?
No

CTRC Resources*
Does the research involve CTRC resources?
No

If the answer is YES, indicate which items is is provided with this submission:

Use of UPHS services*
Does your study require the use of University of Pennsylvania Health System (UPHS) services, tests or procedures*, whether considered routine care or strictly for research purposes?
No

Primary Focus*
Sociobehavioral (i.e. observational or interventional)

Protocol Interventions

x **Sociobehavioral (i.e. cognitive or behavioral therapy)**
Drug
Device - therapeutic
Device - diagnostic (assessing a device for sensitivity or specificity in disease diagnosis)
Surgical
Diagnostic test/procedure (research-related diagnostic test or procedure)
Obtaining human tissue for basic research or biospecimen bank
Survey instrument None of the above

The following documents are currently attached to this item:

There are no documents attached for this item.

Department budget code

None

Multi-Center Research

Penn as lead
1. Is this a multi-center study where Penn is serving as the Lead Site or the Penn PI is serving as the Lead Investigator?
No

Management of Information for Multi-Center Research

Penn irb of record
2. Is this a multi-center study where the Penn IRB will be asked to serve as the IRB of Record for other external study sites?
No

Other Sites

No other sites

Protocol

Abstract
The purpose of this research is to assess if an updated version of a self-help app for IBS is an acceptable and effective intervention for improving the overall quality of life in patients with Irritable Bowel Syndrome.

Objectives

Overall objectives
As self-help modalities are increasingly available online and through smart phone apps, it is increasingly important to test the acceptability and efficacy of those apps through rigorous, controlled research. Bold Health (https://www.bold.health/) is a company in the UK committed to developing effective digital health interventions for a number of hard to treat conditions, including IBS. They have agreed to partner with me to make their app available for free to research participants so that we can test its acceptability and efficacy.

Primary outcome variable(s)
GSRS IBSQoL ROME IV Symptoms and IBS Diagnosis GI symptom severity and overall health related quality of life are the primary outcome measures.

Secondary outcome variable(s)
VSI GICoG FFQ BDI WPAI WSAS

Background
Irritable Bowel Syndrome is a functional GI disorder that responds poorly to traditional medical management. Various psychosocial, mind/body treatments have been shown to be quite efficacious when delivered in person, in group format, via the internet with limited therapist feedback and in selfhelp book format. These interventions include cognitive-behavioral therapy, gut directed hypnotherapy, mindfulness and acceptance based interventions and interoceptive exposure therapy. With the population increasingly interested in digital, interactive interventions, the time is ripe to develop and test a digital app that can be downloaded to smart phones. Bold Health has developed such an app that combines the best of many treatment modalities. (For example, Dr. Peter Whorwell, the developer of gut directed hypnotherapy, wrote and recorded all the hypnotherapy imagery scripts for them.) They are interested in subjecting their app to rigorous testing to determine its acceptability and efficacy. an initial RCT of version 1.0 of the app was extremely promising. This is an RCT of an improved version 2.0 of the same app. They have agreed to make the app available at no cost to research participants in this trial.

Study Design

Phase*
Not applicable

Design
The aim of the current study is to test the acceptability and efficacy of an updated digital app for IBS patients. The design of the study is experimental. There will be two experimental groups, an immediate

treatment group and an active control group. Once consented and enrolled, participants will be randomly assigned to either the immediate treatment group or the active control group by the coin toss feature of random.org. Participants in the immediate treatment group will be able to download the app at no cost. Participants in the control group will be given access to a educational and relaxation training app at no cost to them. At 8 weeks after enrollment, all participants in both groups will receive a battery of follow-up questionnaires (the same that they answered directly after consenting in the beginning of the study as baseline measures). Upon receipt of the 8 week questionnaire data, participants in the control group will be given access to the Zemedy app. After having had access to the app for 8 weeks, control participants will be asked to complete another set of questionnaires. All participants will receive 3 month post-treatment follow-up questionnaires. The research method is experimental (randomized controlled trial) with a control control. Participation in the study will last approximately 4.5 months, depending on the subjects willingness to participate and rate of completion. All contact with participants will be over the Internet via e-mail and electronic questionnaires through Qualtrics. All study questionnaires and use of the app will be completed at the subjects' convenience and in their own home. All electronic questionnaire responses will be gathered via Qualtrics secure servers. Questionnaire responses will be de-identified from participants' contact information and will be assigned a code number in the main data file. Responses will be incorporated into a master database for further analysis. The master database will be password protected and only study investigators and the study PI will have access to the file.

Study duration
The study will take place over approximately 18 months, from initial approval in November 2020 to the final round of follow-up data collection in the spring of 2022. Each participant will be involved in the study for a total of 5 months (if assigned to the immediate treatment group) or 7 months if assigned to the active control group. Individuals in the immediate treatment group will be assessed at baseline, again at 8 weeks (immediately post-treatment) and again 3 months later (total 5 months). Individuals in the active control group will be assessed at baseline, again at 8 weeks at which point they will be offered cross-over to the Zemedy app and will be assessed again at 8 weeks post-treatment, and one final time 3 months later (total 7 months).

Resources necessary for human research protection
Describe research staff and justify that the staff are adequate in number and qualifications to conduct the research. Describe how you will ensure that all staff assisting with the research are adequately informed about the protocol and their research related duties. Please allow adequate time for the researchers to conduct and complete the research. Please confirm that there are adequate facilities for the research.
The PI, Dr. Melissa Hunt, is a licensed clinical psychologist who has conducted a number of such trials in the domain of chronic GI disorders.

Characteristics of the Study Population

Target population
The target population is individuals who have been diagnosed with IBS.

Subjects enrolled by Penn Researchers
300

Subjects enrolled by Collaborating Researchers
0

Accrual
Participants will consist of individuals currently suffering from IBS. There are many online forums that IBS patients frequent searching for advice, management strategies and support, including Reddit, Facebook, Healing Well and others. Participating in those forums allows researchers to recruit participants to trials like this one. Online trials like this typically have attrition rates of about 50% from the intent to treat sample. An initial enrollment of 300 would end with approximately 150 treatment completers, or 75 per group. Because we are using an active control that we expect to benefit participants to some extent, we

expect to find small to medium effect sizes in our between group differences. Given such moderate effect sizes, an N of 75 per group should allow us to detect significant effects at the level of alpha .05.

Key inclusion criteria
In order to be included in the study, subject must be at least 18 years of age or older, speak English, and have been previously diagnosed with IBS. Subjects must also own a smart phone and be willing to download either app.

Key exclusion criteria
Subjects will be excluded from the study if they are under 18 years of age, and therefore under the age of consent. However, subjects will not be excluded based on age if over 18 years old. Subjects will be excluded if they have another gastro-intestinal disorder (such as an inflammatory bowel disease.) Subjects will not be excluded based on sex, race, socioeconomic status, or religion. Participants reporting severe levels of depression, or active suicidal ideation with intent will not be included in the trial, but will be offered the Zemedy app at no cost.

Vulnerable Populations

Children Form

Pregnant women (if the study procedures may affect the condition of the pregnant woman or fetus) Form

Fetuses and/or Neonates Form

Prisoners Form

Other x **None of the above populations are included in the research study**

The following documents are currently attached to this item:

There are no documents attached for this item.

Populations vulnerable to undue influence or coercion
NA

Subject recruitment
We will recruit study participants via various online support groups and message boards. The invitational post will include a link to the study Qualtrics page which will start with the Statement of Research/Consent and then proceed to the baseline questionnaires. We will also use graphic ads on Facebook that provide the same link to the study. Upon receipt of the questionnaires and determination of eligibility, the participants will be randomized and contacted with their group assignment.

Will the recruitment plan propose to use any Penn media services (communications, marketing, etc.) for outreach via social media avenues (examples include: Facebook, Twitter, blogging, texting, etc.) or does the study team plan to directly use social media to recruit for the research?
No

The following documents are currently attached to this item:

There are no documents attached for this item.

Subject compensation*
Will subjects be financially compensated for their participation?
Yes

The following documents are currently attached to this item:

There are no documents attached for this item.

If there is subject compensation, provide the schedule for compensation per study visit or session and total amount for entire participation, either as text or separate document

If subjects are in the immediate treatment group, they will be compensated $20 for completing the posttreatment follow-up questionnaires in the week or so after they complete the program. They will be compensated a further $20 for completing the follow-up questionnaires 3 months after completing the program. Thus, their total compensation could be as much as $40. If they are in the control group, they will be compensated $20 for completing the follow-up questionnaires 8 weeks after the initial questionnaires. They will be compensated a further $20 for completing another set of follow-up questionnaires in the week or so after they complete the program. Finally, they will be compensated a further $20 for completing the follow-up questionnaires 3 months after completing the program. Thus, their total compensation could be as much as $60. People who are randomly assigned to the control group will be compensated more money to help make up for the fact that they had to wait for two months to access the app, and have to fill out the questionnaires one extra time.

Study Procedures

Suicidal Ideation and Behavior
Does this research qualify as a clinical investigation that will utilize a test article (ie- drug or biological) which may carry a potential for central nervous system (CNS) effect(s)?
No

Procedures
We will recruit study participants via online support groups, and online message boards. Interested parties will click on a link to the study Qualtrics page, which will start with the consent form/statement of research and then ask subjects to complete all the baseline questionnaires, including the Rome IV, GSRS, IBSQoL, VSI, GICoG, FFQ, uMARS, WPAI, WSAS and BDI-II. Upon receipt of the questionnaires and determination of eligibility, the participants will be randomized and contacted via email with their group assignment. Subjects will be given information about how to download either the standard mindfulness app or the Zemedy app at no cost to them. The only contact information required will be the subject's e-mail address to identify their responses. All forms of contact will be via email, as we do not have any intention of contacting participants via phone. At 4 weeks after enrollment, both groups will be provided with a check-in email to reassure them that any logistical questions can be answered by the investigators at any point in the study and to encourage them to continue using the app. At 8 weeks after enrollment, all participants in both groups will receive a battery of follow-up questionnaires (the same that they answered directly after consenting in the beginning of the study as baseline measures). Upon receipt of the 8 week data, the individuals in the control group will be given access to the Zemedy app at no cost. All groups will receive 3 month post-treatment follow-up questionnaires. All questionnaires will be available through qualtrics.com. Study investigators will be responsible for sending participants the emails, the follow up questionnaires, monitoring the questionnaires online, and answering any questions participants may have through email. Questionnaires may take approximately 30-45 minutes to complete.

The following documents are currently attached to this item:

There are no documents attached for this item.

Deception
Does your project use deception?
No

International Research
Are you conducting research outside of the United States?
No

Analysis Plan
Data will be analyzed using standard parametric procedures, including t-test, repeated measures ANOVA and simultaneous multiple regression.

The following documents are currently attached to this item:

There are no documents attached for this item.

Data confidentiality

Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study.

x **Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords.**

Prior to access to any study-related information, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information.

x **Wherever feasible, identifiers will be removed from study-related information.**

A Certificate of Confidentiality will be obtained, because the research could place the subject at risk of criminal or civil liability or cause damage to the subject's financial standing, employability, or liability.

A waiver of documentation of consent is being requested, because the only link between the subject and the study would be the consent document and the primary risk is a breach of confidentiality. (This is not an option for FDA-regulated research.)

x **Precautions are in place to ensure the data is secure by using passwords and encryption, because the research involves web-based surveys.**

Audio and/or video recordings will be transcribed and then destroyed to eliminate audible identification of subjects.

Subject Confidentiality
Subject confidentiality will be maintained throughout the study. Data from questionnaires and other completed materials will be available to download from the Qualtrics website account to a password protected, secure PC in the PIs office. Identification and contact information will be stored electronically in a spreadsheet separate from data that will reside on a password protected computer. Data will be de-identified before entry into the master spreadsheet. This will be done by assigning each subject (identified by email address) a number. The electronic document containing this information will be kept separate from the identifying data spreadsheet, but both will be in the secure, password protected PC.

Sensitive Research Information*
Does this research involve collection of sensitive information about the subjects that should be excluded from the electronic medical record?
No

Subject Privacy
Privacy refers to the person's desire to control access of others to themselves. Privacy concerns people, whereas confidentiality concerns data. Describe the strategies to protect privacy giving consideration to the following: The degree to which privacy can be expected in the proposed research and the safeguards that will be put into place to respect those boundaries. The methods used to identify and contact potential participants. The settings in which an individual will be interacting with an investigator. The privacy guidelines developed by relevant professions, professional associations and scholarly disciplines (e.g., psychiatry, genetic counseling, oral history, anthropology, psychology).
We will collect e-mail addresses so that we can be in contact with participants and can e-mail them about their group assignment and follow-up questionnaires. If a subject indicates that they are actively suicidal at any point during the study, the PI will contact them via email to inquire as to their safety and to offer referrals to local mental health services. However, no further action will be taken that might compromise the subject's privacy.

Data Disclosure
Will the data be disclosed to anyone who is not listed under Personnel?
Subjects who experience any technical difficulties with the app will be invited to contact the tech support people at Bold Health. This should not involve disclosure of any PHI, however.

*Data Protection**

Name

Street address, city, county, precinct, zip code, and equivalent geocodes

All elements of dates (except year) for dates directly related to an individual and all ages over 89

Telephone and fax number

x **Electronic mail addresses**

Social security numbers

Medical record numbers

Health plan ID numbers

Account numbers

Certificate/license numbers

Vehicle identifiers and serial numbers, including license plate numbers

Device identifiers/serial numbers

Web addresses (URLs)

Internet IP addresses

Biometric identifiers, incl. finger and voice prints

Full face photographic images and any comparable images

Any other unique identifying number, characteristic, or code

None

Does your research request both a waiver of HIPAA authorization for collection of patient information and involve providing Protected Health Information ("PHI") that is classified as a "limited data set" (city/town/state/zip code, dates except year, ages less than 90 or aggregate report for over 90) to a recipient outside of the University of Pennsylvania covered entity?
No

Tissue Specimens Obtained as Part of Research* Are
Tissue Specimens being obtained for research?
No

Tissue Specimens - Collected during regular care*
Will tissue specimens be collected during regulator clinical care (for treatment or diagnosis)?
No

Tissue Specimens - otherwise discarded*
Would specimens otherwise be discarded?
No

Tissue Specimens - publicly available* Will
tissue specimens be publicly available?
No

Tissue Specimens - Collected as part of research protocol* Will
tissue specimens be collected as part of the research protocol?
No

Tissue Specimens - Banking of blood, tissue etc. for future use* Does
research involve banking of blood, tissue, etc. for future use?
No

Genetic testing
If genetic testing is involved, describe the nature of the tests, including if the testing is predicative or exploratory in nature. If predictive, please describe plan for disclosing results to subjects and provision of

genetic counseling. Describe how subject confidentiality will be protected Note: If no genetic testing is to be obtained, write: "Not applicable."
NA

Consent

1. Consent Process

Overview
We will recruit study participants via online support groups, and online message boards. Interested parties will click on a link to the study Qualtrics page, which will start with the consent form/statement of research and only then ask subjects to complete all the baseline questionnaires. If subjects have concerns about the study they are welcome to contact the PI at any time with questions and are, of course, free to withdraw from the study at any point.

Children and Adolescents
NA

Adult Subjects Not Competent to Give Consent
NA

2. Waiver of Consent

Waiver or Alteration of Informed Consent*
Waiver of written documentation of informed consent: the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context

Minimal Risk*

Impact on Subject Rights and Welfare*

Waiver Essential to Research*

Additional Information to Subjects

Written Statement of Research*
Yes

If no written statement will be provided, please provide justificiation

The following documents are currently attached to this item:

Written Statement of Research (consentform-shamappversion.docx)

Risk / Benefit

Potential Study Risks
There are some risks to taking part in this study. Participants may find themselves more aware of physical sensations and IBS symptoms for a period of time after using the app. They will also be asked to think in new ways about problems and situations that might come up in their life, including IBS itself. Sometimes it can be uncomfortable or even scary to think about things differently, or to practice new skills. In the event that a subject indicates active suicidal ideation on the BDI-II (a score of 2 or 3 on item 9) they will

be contacted by the study PI who will conduct a risk assessment and offer referrals to local mental health resources.

Potential Study Benefits
There are a few potential benefits of participating in this research study. Subjects will have the opportunity to use an evidence based digital self-help app for IBS at no cost that incorporates elements of a number of empirically supported treatments for IBS. The treatment may help reduce levels of depression, anxiety, and symptom severity as well as increase their overall quality of life. The purpose of this study is to test the acceptability and efficacy of a novel digital self-help app. Apps like this one are proliferating in the digital space, and it is incredibly important that they be tested for actual efficacy. The results of the study will provide researchers and clinicians with better understanding of whether or not digital self-help apps can be another treatment option for those with IBS.

Alternatives to Participation (optional)
Not to partcipate.

Data and Safety Monitoring
NA

The following documents are currently attached to this item:

There are no documents attached for this item.

Risk / Benefit Assessment
There is minimal risk to subjects for participating. There are potential benefits to subjects from completing the treatment. There are also broad benefits to this population as a whole from determining whether such digital based apps can be of help in the management of IBS.

General Attachments

The following documents are currently attached to this item:

There are no documents attached for this item.