INCREASING ENGAGEMENT AND DECREASING ATTRITION IN EHEALTH INTERVENTIONS

OVERSIGHT FOR MOBILE APPLICATIONS THAT ASSESS AND TREAT MENTAL ILLNESSES

A Thesis Prospectus
In STS 4500
Presented to
The Faculty of the
School of Engineering and Applied Science
University of Virginia
In Partial Fulfillment of the Requirements for the Degree
Bachelor of Science in Systems Engineering

By
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October 31, 2019

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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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The chance that you or someone you know suffers from an anxiety disorder is high. One-third of the US population will develop an anxiety disorder at some point in their lives (Beard, 2011). Anxiety causes individuals to have poorer quality of life, educational and occupational impairment, and higher suicide rates, and plagues society with lost work productivity, disability and increased healthcare utilization (Beard, 2011). An alternative treatment to taking medication is psychosocial therapy. Cognitive-behavioral therapy, referred to as CBT, is a type of psychotherapy that is meant to challenge the patient's cognitive distortions and provide coping mechanisms to them. This type of training has demonstrated efficacy in treating anxiety disorders; however, a lack of trained therapists and unwillingness to engage in exposure therapy are two initial barriers to patients seeking this kind of treatment (Beard, 2011). Online interventions are possible outlets for the dissemination of Cognitive-behavioral therapy, and in an online form they can be free and practiced wherever and whenever. However, with the Internet offering treatment to individuals that may be at a vulnerable mental state, should there be a regulatory body to create standards for apps that claim to treat or assess mental illnesses? Using Actor-Network Theory can help to examine who could provide oversight for this category of app development. This analysis will guide the STS research. The STS research project is tightly coupled with the technical project by context of the rise of health apps in the marketplace.

The team that will be working on the technical project in the Systems and Information Engineering department includes: Darby Anderson, Amanda Brownlee, Camryn Burley, Georgie Lafer, Meaghan McGowan, Judy Nguyen, William Trotter, and Halle Wine. Prof. Laura Barnes, a professor in Engineering Systems and Environment, will oversee this capstone project alongside members of the MindTrails team, working under their Director, Dr. Bethany Teachman. Anna Baglione, Ilana Ladis, and Jeremy Eberle are Ph.D. candidates in the

Psychology department that will work with the capstone team more closely. In the remainder of the first semester, the team will keep researching ways to engage the user in the MindTrails Program and will start creating Figma mock-ups. Next semester, the team will be responsible for finishing these mock-ups and turning them into ReactNative code. The STS research project will be completed alongside the technical project. This timeline is laid out in the below Figure 1, Gantt chart.

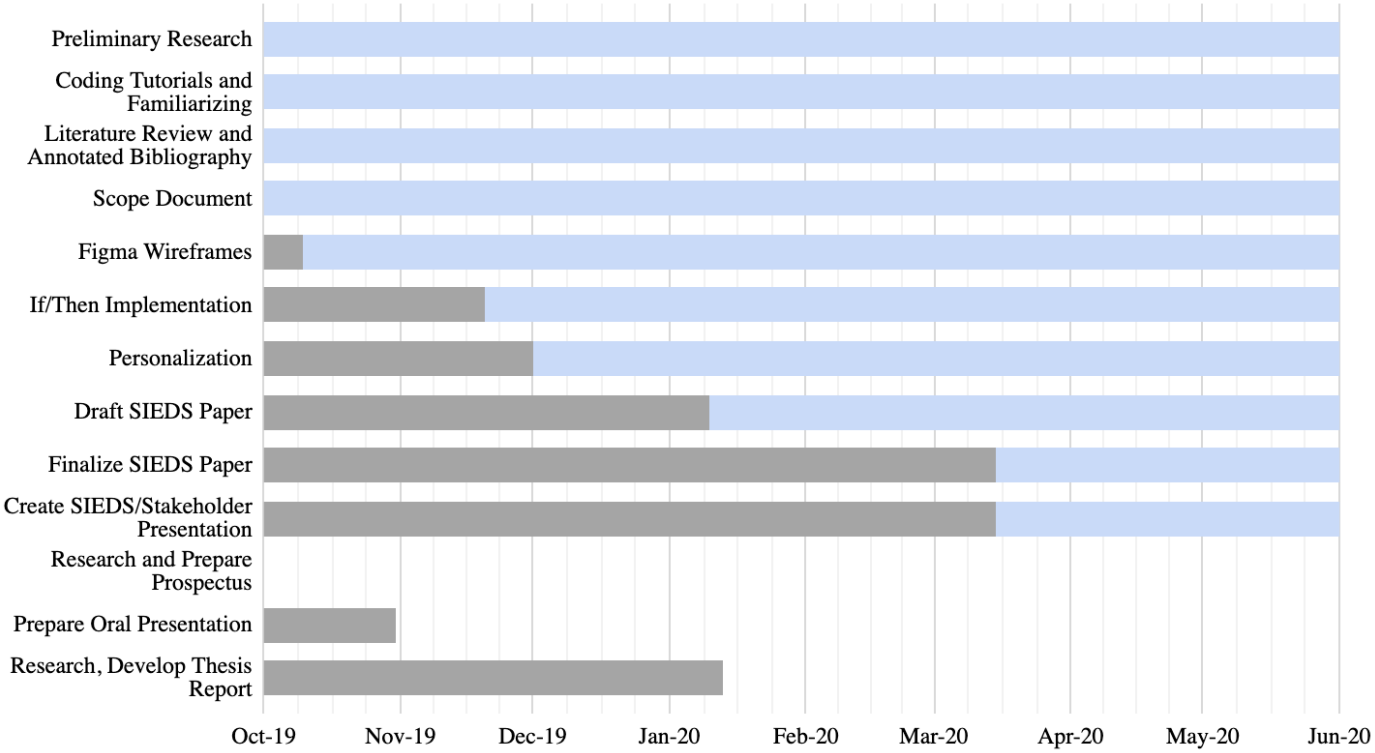

Figure 1: Gantt Chart: This graphically lays out how the team will go through the technical project alongside the STS portions (Created by Taylor Luong using scope document (Anderson et al., 2019).

INCREASING ENGAGEMENT AND DECREASING ATTRITION IN EHEALTH INTERVENTIONS

The technical capstone work aims to improve the current interface of the MindTrails Project, an online intervention for people suffering from General Anxiety Disorder. The website program offers five levels of training sessions that use cognitive bias modification for interpretation techniques often found in traditional therapies for anxiety (Beard, 2011). Cognitive bias modification treatment is a form of cognitive-behavioral therapy designed to challenge the patient's cognitive distortions and give them coping mechanisms (Beard, 2011). The MindTrails Project attempts to overcome various barriers to treatment by offering this form of therapy over the Internet, and has had success in previous studies. However, people tend to dropout without finishing all or most of the sessions offered. Between the first session and the fifth session, about 77% of participants stopped using the program (de Paiva et al., 2019). High dropout rates for self-directed online treatments are normal (Miloff, Marklund, & Calbring, 2015). The online method of delivery has the potential to help a large population that may have access to traditional in-person therapy sessions. In order for users to get the most out of this treatment, the MindTrails Project needs to implement strategies to decrease attrition.

To help the MindTrails Project, the capstone team aims to introduce personalization, implementation intentions, and goal-setting to the next iteration of the website. Additionally, the capstone team will work alongside a computer science capstone team to develop a mobile application version of the online program. According to Doherty, the leading contributors to successful treatments for mental health disorders are extremely personal; for example, supportive therapeutic relationships and networks (2012). Both attributes are difficult to automate when removing the human aspect of an intervention. From multiple publications of mental health

treatments and online interventions, Doherty has created four key design strategies that can potentially capture a similar effect of personal treatment: social, personal, interactive, and supportive (Doherty, 2012). With these strategies and the given objectives from previous iterations, the capstone team has devised two groups: one to research and address personalization and one to research and address implementation intentions and goal-setting.

A trait of anxiety is interpretation bias, which means that the person takes an ambiguous statement or situation and places negative bias, making the statement or situation catastrophic to them (Beard, 2011). An application of using cognitive bias modification for interpretation in an online environment is giving the user scenarios that are ambiguous until the last word, and then offering the user suggested letters to fill in the last word, which will be positive or neutral. An example of this exercise from the MindTrails Project intervention is depicted below in Figure 1.

Personalizing a scenario like the one described in Figure 1 to the right makes the situation more relevant to the user and provides an opportunity to introduce practices more similar to in-person therapy. A therapist knows their patients' demographics or asks questions to get a better feel for what kinds of situations they would best resonate with. Therapists can use patient feedback immediately through conversation with them. In order to automate this kind of

Figure 1: Cognitive Bias Modification for Interpretation: This exemplifies an ambiguous scenario for the user to fill in the last word (Adapted by Taylor Luong from de Paiva Azevedo et al., 2018).

interaction, data on the users' demographics and lifestyles must be collected and processed into usable information. The personalization group intends to use the information collected before the user starts their sessions to make situations reflect their life more closely.

Implementation intentions and goal-setting are closely tied together since implementation intentions can lead to better success in achieving the goals set (Gollwitzer, 1999). *"*If I encounter ___, then I will do ___,*"* is the basic structure of an implementation intention designed to create an association between anticipated events and goal-directed behaviors in response (Gollwitzer, 1999). The group working on this part will be tasked with offering the user options to set goals, and then make the implementation intentions reflect the goals specific to the user.

The two teams will initially create wireframes to incorporate the new features into the existing layout in an online wireframing tool called Figma. Professor Laura Barnes, from the Department of Engineering Systems and Environment, will oversee this capstone project alongside members of the MindTrails team, working under their Director, Dr. Bethany Teachman. Anna Baglione, Ilana Ladis, and Jeremy Eberle are Ph.D. candidates in the Psychology Department and will work closely with the capstone team. The capstone team will be able to make changes to the ReactNative code on Github, and if time permits, will be able to conduct feasibility and usability testing on participants using the new version. A Computer Science capstone team will also be working on the interface to implement these changes as they work to create a mobile application version of the MindTrails Program. The MindTrails Project is part of a broader community: Project Implicit Mental Health, where people can participate in a variety of new studies. The MindTrails Project has previously been able to successfully conduct studies to measure the effects of the program, proving their ability to do so after the capstone

team works on this iteration as well. The MindTrails Project's goals are funded by the National Institute of Health.

The technical paper will be a conference paper to present at the Systems and Information Engineering Design Symposium. The overall objective is to help the MindTrails Project impact more people suffering from General Anxiety Disorders that would seek treatment otherwise, or that would not have the opportunity to seek treatment. This paper is meant to document the methods in which an online intervention can incorporate design strategies to increase user engagement.

OVERSIGHT FOR MOBILE APPLICATIONS THAT ASSESS AND TREAT MENTAL ILLNESSES

When technology advances at a faster rate than the regulation around it, the lag time before oversight is provided can pave progress in certain ways. This time also allows regulation to form where most needed. The MindTrails Project leverages technology to lower barriers to treatment for anxiety disorders, but the regulation around mental health applications is lacking. Even with current regulations for mobile applications that treat physical illnesses, more in-depth oversight is still needed and emerging. This STS research paper will look at the current state of regulations in the mobile application health space and then use Actor-Network Theory to determine what groups would be the most influential in shaping the way health applications are released and used.

The technical project that this STS project is tightly coupled with is an example of how mobile applications can lower barriers to treatment of a health condition. The treatment for a disease or illness is to seek a trained medical professional; however, health applications are becoming an alternative when there is lack of accessibility to this traditional path. Even if a patient is able to seek a trained professional financially, there are simply not enough actively working therapists in the US to fulfill demand. The graph in Figure 3 on the following page shows the breakdown of mental health professionals practicing in the US in 2017 which totals to 577,000 (Grohol, 2019). As depicted in the graph, not all those practicing even offer counseling. In the case of anxiety disorders, the 40 million US adults suffering greatly outweighs those who could help ("Facts and Statistics," n.d.). The topic of this paper is revolved around the alternative: creating apps for that. An app could increase accessibility to treatment, but during

this transition from in-person therapy to online help over an app, oversight should be implemented to guide the standards required for this type of app before releasing it to the public.

Figure 3: Lack of Trained Therapists: This graph gives the breakdown of the types of mental health professionals practicing in the US in 2017 (Adapted by Taylor Luong from data given by the Department of Labor (Grohol, 2019)).

Regulations for mobile applications and Internet applications are continuing to emerge as technology enters the health care space. The guiding regulations currently in place for all mobile applications are: the Health Insurance Portability and Accountability Act (HIPAA), the Federal Food, Drug, and Cosmetic Act (FD&C Act) enforced by the Food and Drug Administration, the Federal Trade Commission Act (FTC Act), and the Health Breach Notification Rule enforced by the FTC ("Mobile Health Apps Interactive Tool," 2016). HIPAA is enforced by the Office for Civil Rights and is aimed at protecting the privacy and security of users' health information and also requires certain entities to notify them in the case of a breach ("Mobile Health Apps Interactive Tool," 2016). Certain businesses are also required to notify the FTC in the case of a breach under the Health Breach Notification Rule. The two acts that regulate safety and effectiveness are the FD&C Act and the FTC Act. The FD&C Act regulates the safety and effectiveness of certain apps, and the Food and Drug Administration qualifies what apps they regulate by the risk posed in the case of inaccurate results from the software. To do so, they have

developed different categories for Software as a Medical Device, or SaMD, which includes applications that are not part of a hardware medical device but are intended for a medical purpose to treat or to diagnose diseases or inform clinical management (*Software as a Medical Device: Possible Framework*, 2014). Mobile medical applications that fall into categories under FDA purview must be pre-certified before entering the market, meaning that companies are examined for quality control processes for software (Bates et al, p. 1975). The FTC Act prohibits deceptive or unfair practices that affect commerce, including false claims ("Mobile Health Apps Interactive Tool," 2016). To enforce this act, the FTC files lawsuits against false claims. These regulations are important in protecting the user in terms of data privacy and security as well as quality of care and information. However, the FD&C Act enforced by the FDA does not cover apps that treat or diagnose mental illnesses. The volume of apps suggests that the FDA has reasonably chosen to focus their review on higher risk health apps. This leaves room for another regulatory body to define standards for health apps that treat, assess, or diagnose mental health illnesses.

Although the FDA has put into place criteria for apps, there are critics that these criteria should be more rigorous. David Bates, a medical doctor at Brigham and Women's Hospital in Boston, reviewed the FDA's pre-certification program as too hands-off even (2018). He noted that the agency should not only harden the evaluation of apps, but also make them available to patients among other enhancements in reviewing for safety, privacy, and false claims (2018). This is criticism for regulations being put into place for higher risk apps dealing with physical health, which again leads into the question: what about apps that aim to treat mental illnesses? A review of health apps on the marketplace from Van Ameringen noted inconsistency among mental health apps that aimed to treat, track, or assess illnesses such as major depressive

disorder, bipolar disorder, post-traumatic stress disorder, general anxiety disorder, and combinations (Van Ameringen, 2017). Some of the apps reviewed were created based on published evidence in clinical trials, but others were created with no published evidence to justify their methods.

Through the Actor-Network Theory, a perspective outlined by Callon, Latour, and Law (1986), this problem can be processed by looking at the actors, both human and non-human, and the sociotechnical networks that they work within. Figure 4 below depicts the actors that have some sort of agency in creating oversight for mobile health applications that pertain to mental illnesses. Regulation is interesting in the actor-network theory because it must address both the human actors and how they are intertwined with materials and technology, and it ultimately paves progression of technology in desired, or indirect, paths. The agency in this network is dispersed because it relies on the relationships within the network. For example, not one entity is completely responsible for how this technology develops, but since government agencies are taking a hands-off approach to mental health apps, other organizations will start to bridge the gap in attempt to protect the

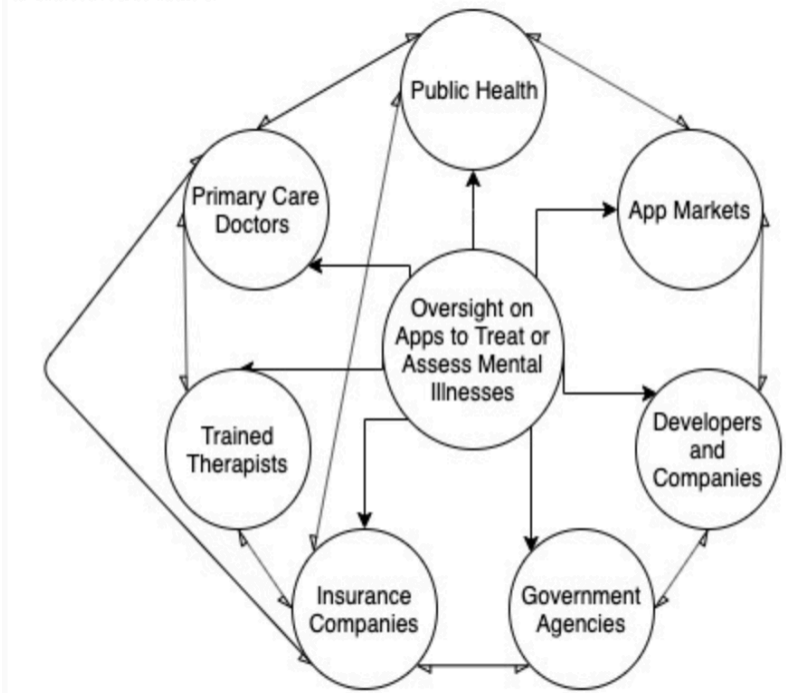

Figure 4: Network. This graphic displays the main groups that have agency in proposing regulation or oversight for mobile health applications related to mental illnesses (Created by Taylor Luong based on Actor Network Theory outlined by Callon, Latour, and Law, 1986).

public. This is the case for a website called Psyberguide.org, which is a website made and updated by licensed psychologists who review different mental health apps on the market. A user going to this website can read an expert review and look at an app's score for credibility, transparency, and usability. This type of review has potential to go further if they could require app developers reveal whether the app is based on clinical studies or backed by research, but is a start since the expert reviewers can determine whether or not the app is replicating a traditional therapy. The solution is highlighted by this perspective in giving multiple actors the potential to regulate or provide oversight before allowing the public to trust this sort of technology as a swap for traditional therapy.

Apps and online interventions can benefit users by providing ways to get treatment without high costs and without leaving the comfort of one's home; however, health care has traditionally been provided by highly trained medical doctors. This STS research aims to examine the developments in health services offered over mobile applications. The anticipated outcome of this research is to be able to compare the technological developments intertwined with general health care in terms of how society and government regard mental health and physical health treatments. The type of paper will be a scholarly article that addresses the development of mHealth alongside regulation.

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