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# Diagnostic mHealth for Autoimmune Disorders

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# Abstract

**Many mobile applications on the market** can help patients record symptoms and progression of their illnesses, and among them, many help to document autoimmune disorders. In this article, I've used the content analysis method to analyze the existing relevant apps in the Apple App Store. My results reveal an important design gap, in that there is almost no app that allows patients to communicate with their doctors in a timely manner and accurately record their week to week, month to month medical condition. This article presents the smart phone app I developed based on the iOS operating system to fill this gap, allowing patients to journal about their pain conditions in real time, communicate with doctors online, and generate personalized custom reports. In developing this app, I designed a series of user interface prototypes as my idea evolved. I also surveyed physicians and used their feedback to modify my design and give it further theoretical support. Then I conducted usability testing with participants who have undiagnosed chronic pain or autoimmune disorders. I found that this app improved doctor/patient communication and allowed patients to be more anatomically accurate as to the source of their pain when recording their condition.

**My design strives** to make up for market vacancies and cater to user needs. Through three generations of prototyping, communicating with professionals and conducting effective user testing, I arrived at a final design prototype. This project aims to contribute to the healthcare field by bringing new design inspiration to user experience and user interface design.

# DIAGNOSTIC MHEALTH FOR AUTOIMMUNE DISORDERS

by

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Nice to meet you all!

Group Picture from Design Exhibition
From left to right:
Forough Jafari, Donald William Carr
Ran Zhang, Yumeng Yang, Yun Deng
Qingyue Song



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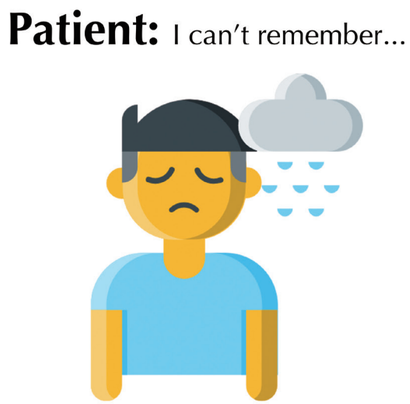
## Background

With the development of communication and network technology, smart phone apps have become popular and have penetrated people's lives. These include health management apps. **MHealth** and various other health products are starting to appear. According to previous scholars' research, risk factors for the development of chronic pain have been a major topic in pain research in the past two decades (Haefeli and Elfering, 2006). Mhealth products have many advantages, such as quick and timely recording of health information and educating users to be more self-aware about their health. Mobile phones are easy to carry, and data uploading to the cloud is secure and safe. However, mHealth products have certain defects and restrictions on their use.

With regards to patients with chronic pain, there are many needs for daily pain management, such as recording pain spots and types of pain. Timely recording of medication is an important data point for doctors to refer to in making diagnoses. However, patients often forget details about their pain when they see a doctor, which can lead to inaccurate diagnoses or complete inability to diagnose. **For patients with chronic pain or autoimmune disorders**, the existing pain recording app on the market is not mature. Some app functions are not comprehensive enough, which can lead to the loss of precious information; some apps are not guided by health care professionals during the development process, which leads to inefficiency and low availability.

In response to the above concerns, I evaluated 72 pain-related apps in the Apple Store. **New market demands and design gaps were discovered** during the analysis. Moreover, I designed a pilot study and multiple design iterations to validate my research.




Patient and physician

# Literature Review

**My literature review is focusing on four aspects: mHealth, autoimmune disorders, pain assessment, and current mHealth product review. Through these aspects, I gained a better understanding of mHealth products for autoimmune disorders.**

**1.MHealth**

The definition of mHealth can be fined by different entities. Konschak et al. (2013) defined mHealth as it stands for mobile-based or mobile-enhanced solutions that deliver health. Mobile devices can bring more opportunity for the field of healthcare through innovative information and communication technology. Voruganti et al. (2019) believe that mobile health (mHealth) tools can enable patients to communicate with their health care providers at their convenience. Web- and app-based health care tools may save more time for users than telephone and in-person services (Kummerow et al., 2015).

According to Clough and Casey (2017), “mHealth refers to the use of mobile technologies in the provision of health care. These mobile technologies typically refer to mobile, or cellular, phones, and programmable smartphones.”

**2. Autoimmune disorders**

Franz, Davidson ,and Ferguson (2016) defined autoimmune disorders as conditions in which a person's immune system attacks the body's own cells, causing tissue destruction.

According to Mifflin and Kerr (2017), "most autoimmune diseases are associated with pathological pain development. Autoimmune diseases with pathological pain include complex regional pain syndrome, rheumatoid arthritis, and Guillian-Barré syndrome to name a few” (p.2). They conduct a quick research about the autoimmune diseases listed by the National Institute of Health's National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). They discovered that a significant number of autoimmune disorders are associated with pain. According to the list provided by NIAMS, 19 of 24 of the autoimmune diseases listed (~79%) had research linking the disease to pain.



**3.Pain Assessment**

Fillingim et al. (2016) found that pain assessment is vital in terms of the classification of chronic pain condition. Moreover, pain assessment has many functions such as recording the domains of pain and sensory and affective qualities of pain. The importance of pain assessment can speak for itself. First, effective pain assessment can help to guide treatment decisions. Second, pain assessment provides a way to monitor the longitudinal course of pain.
They brought up the Patient-Reported Outcomes Measurement Information Systems (PROMIS). There is one app that is scientifically validated and available on the app store is PainOmeter, which is found to be user-friendly and include the function of multiple pain scale. At the conclusion, they summarized some important points. First, they provide four critical components for pain assessments: Pain intensity, other perceptual qualities of pain, physical distribution of pain and temporal features of pain. Also, they talked about pain assessment should be combined with other important domains, like physical and psychosocial functioning.

According to Haefeli (2006), “Pain intensity, pain-related disability, pain duration ,and pain effect are the aspects that define pain and its effects.” (p.1).

**4.Current mHealth product review**
Vega and Miró (2014) stated how mhealth product is essential with the development of technology. They also talk about pain is one of the most generalized symptoms of chronic health conditions. They reviewed 283 pain-related apps from 5 different app stores. Moreover, they found that most of the apps they reviewed are designed for patients (70%), a small portion of them are developed for healthcare providers (12.5%) or both (17.5%). They found that one significant limitation is that electronic journals are unregulated. This review indicated that patients are probably using some useless apps.

Alexander and Joshi (2016) provide a critical review of what is the current situation about smartphone applications for chronic pain. They talk about how rapidly growing of the smartphone application market, and the market of mobile health apps will keep growing. They also brought up the fact that the electronic diaries are proved to be useful; However, health care providers are rarely involved in the application building process. This will cause the content of current apps are not clinically useful.
The future of the “mobile medical apps,” which term is defined by the FDA, will have to have more valid peer-review literature and more health care professions involved.

Mantas et al. (2016 ) talk about the limitation of existing mobile application: they limited by the data they collect and the data based on self-reporting. They came up with five criteria: Existence of a pain tracking function, Ability to set goals related to improving pain and functioning, Availability of pain related education, Availability of self-care strategies and relavant skills training and Social support. They examined one application called “Fitback” which is designed perfectly fit in all five criteria.



In the discussion section, they talk about the design of a mHealth application that address chronic pain can not only depend on users’ data. They suggest three more ways to collect data: Physical activity, with the algorithm to get a high-level behavioral information. Acoustics, when people are experiencing stress, the trigger will start to analyze the talking frequencies, speaking rate ,and variability of the pitch.

Moreover, they suggest treating private information carefully because this kind of app records everything. And a number of these apps are not created with specialists.
I think the five criteria is comprehensive including the features of the current application. My criteria for the reviewed apps are more function-based. Moreover, the new ways of collecting data are compelling. If possible, I will include physical activity function in my design, because I think physical activity is important information when patients are dealing with chronic pain.

Selter et al. (2018) performed to examine a mHealth product named Limbr. This program includes three daily visual self-reports to access pain, activity level ,and medication. They adopted one program named Your Activities of Daily Living, an image-based tool for characterizing functional status. Also, their method of recording medication is an app-based medication log with visual interfaces. Limbr also provides online coaching support, which is proved as effectively improve self-management of symptoms and promote long-term behavior change retention.
They also have their plan for unproductive users, such as personalized email and encouraging messages.

**Based on my literature review, I found that mHealth product can help to journal and record pain caused by autoimmune disorders. Moreover, I found that there are abundant apps on the market for pain assessment; However, some of them are not robust enough to benefit users. Therefore, my goal is to develop a user-centered and user-friendly user interface for people that have autoimmune disorders. By documenting their pain pattern and history, it will be easier for physicians’ to diagnose their illness.**

# Methodology

**Content Analysis**

For disease management applications, I conducted a content analysis. I selected **72 apps from the Apple App Store**, all of which are about logging symptoms of chronic pain (Figure 1). Based on my observations, I categorized the features provided in these applications as follows:

- **Communication with professionals**

If this app offers the function for doctors to communicate with patients (Video chat, text message, email, voice message, etc.).

- **Anatomical Accuracy**

If this app has a body map where users can point out where is the pain spot and what is the level of accuracy.

- **Self-diagnosis of symptoms**

If the app has the function relates to self-diagnosing based on users symptoms.

- **Reporting/Journaling**

If the app provides report/ journaling function which could allow patients to record/ journaling their condition (Pain, daily exercise, diet, etc.).

- **Medication intake**

If users can input their medication through this app, such as the name of the medicine, dosage, and did it help or not.

- **Daily activity**

If the app records users daily activity, walking distance, steps, heart rate, etc.

- **Appointment scheduling**

If the app can help patients schedule appointment with the hospital.

- **Personal health data**

If the app contains users name, gender, age, weight, height, etc.

- **Self-diagnosis of autoimmune disorders**

Does this app help users diagnose their autoimmune disorders with symptoms?

- **Paid or free**

If this app is free or needs to be paid monthly or yearly.

- **For journaling pain/ chronic pain. (Pain measurement)**

If this app can help users report/ journaling their chronic pain and does the app have the pain measurement function.



| | Communicate with professionals | Anatomically Accurate | Self-diagnosis | Report/ Jounaling | Medication intaking | Daily activity | Schedule appointments | Personal health data | For undiagnosised disease | For diagnosisd disease | Graphically Beautiful | Free? | For journaling pain/ chronic | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MDlive | 5 | 3 | | | | | | | | | 5 | | | |
| TELADOC | 5 | 3 | | | | | | | | | | | | |
| dr+ on demand | 5 | 3 | | | | | | | | | | | | |
| Healthtap | 5 | 3 | | | | | | | | | | | | |
| Pingmd | 5 | 2 | | | | | | | | | | | | |
| WebMD | | 5 | 5 | | 4 | 5 | 4 | | | | | | | |
| Zocdoc | | | | | | | 5 | | | | | | | |
| PillBoxie | | | | | 5 | | | | | | | | | |
| Mango Health | | | | | 5 | 4 | | | | | | | | |
| onPatient PHR | 2 | | | 2 | 5 | 4 | 5 | 4 | 5 | | 4 | 5 | | |
| MyRa | 4 | 5 | 1 | 4 | 3 | 3 | | 3 | | 5 | 3 | 5 | | |
| Medisafe Pill Reminder & Medication Tracker | | | | | 5 | | | | | | | | | |
| Symple | | 3 | | 5 | 4 | | | | 5 | | 4 | | 5 | partial function |
| HealthSpeck | | | | 3 | | 5 | | | 5 | | 3 | 5 | | |
| Cures | | 3 | 4 | 1 | | | | | 5 | | 5 | | | |
| First Aid by American Red Cross | | 3 | 3 | | | | | | | | | | | |
| MyChart | 2 | 3 | | | 5 | 3 | 5 | 5 | | | | | | |
| Calorie Counter & Diet Tracker by MyFitnessPal | | | | | | 5 | | 5 | | | | | | |
| CareZone | | | | | 5 | | | | | | | | | |
| mySugr: Easy to use daily diabetes logbook | | | | | | 5 | | 5 | | | | | | |
| Mayo Clinic | | 1 | 1 | | | | 5 | 5 | | | 5 | 5 | | |
| AskMD | 2 | 4 | 3 | | | | 5 | 5 | | | | | | |
| Patient Journal | 4 | | | 4 | 3 | 3 | | 3 | | 5 | 2 | 5 | | |
| My Medical | | | | 4 | | | 5 | 5 | | 5 | 4 | | | |
| Oshi: IBD Tracker & Magazine | 3 | 2 | 2 | | | 4 | | | 5 | | 5 | 5 | | |
| Symptom Tracker: Pain History | 3 | 4 | | 5 | | | | | 5 | | 5 | 5 | 5 | |
| Symptom Tracker by TracknShare | | | | 5 | 4 | 4 | | | | 5 | 3 | | | |
| My Symptom Tracker (Health) | 5 | 3 | | 5 | | | | | 5 | | 3 | | 5 | partial function |
| Symple Journal | 4 | 3 | | 5 | | | | | 5 | | 3 | 5 | 5 | |
| Migraine Buddy | 5 | 5 | 3 | 5 | | | | | | 5 | 5 | 5 | | |
| My Pain Diary& Symptom Tracker | | 5 | | 5 | 5 | 4 | | | | 5 | 5 | | | |
| Smarter Symptom Tracker | 5 | 4 | | 5 | 5 | | | | | 5 | 4 | 5 | | |
| Symptom Checker- Possible Diagnosis | | 3 | 5 | | | | | | 5 | | 4 | 5 | | |
| K Health | | 3 | 4 | | | | 4 | | 5 | | 5 | 5 | | |
| Symptom Trigger Tracker | 4 | 3 | | 5 | 4 | 4 | | | 5 | | 4 | | 5 | partial function |
| Flaredown for Chronic Illness | 4 | 3 | | 5 | | 4 | | | | 5 | 5 | 5 | | |
| Smart Symptom Tracker | 4 | 3 | | 5 | 4 | | 4 | | | 5 | 4 | 5 | | |
| POTS Tracker | 4 | | | 5 | | | | 5 | | 5 | 5 | 5 | | |
| Mole Monitor | 5 | 5 | | 5 | | | | | 5 | | 4 | 5 | | |
| Tally: The anything Tracker | 3 | | | 5 | | 5 | | | 5 | | 5 | 5 | | |
| Bowelle- The IBS tracker | 3 | 4 | | 5 | | 5 | | 4 | 5 | | 5 | 5 | 5 | partial function |
| MyGiHealth GI Symptom Tracker | 3 | 4 | | 5 | | | | | | 5 | 5 | 5 | | |
| Reflux Tracker | 3 | 4 | | 5 | | 4 | | 4 | | 5 | 3 | 5 | | |
| Healthmatica | 3 | 3 | | 5 | | | | | 5 | | 4 | 5 | 5 | partial function |
| Symdir- symptom diary made easy | | 3 | | 5 | | | | | 5 | | 4 | 5 | | |
| MySymTrack | | | | 5 | | | | | | 5 | 3 | 5 | | |
| SymTrack | | 3 | | 5 | | | | 4 | | 5 | 3 | 5 | | |
| MBH Symptom Checker | | 3 | 4 | | | | | 4 | | | 2 | 5 | | |
| My Arthritis Care | 4 | 3 | | 5 | 4 | | | | | 5 | 5 | 5 | | |
| Pain Tracker- Daily Symptom Diary | | | | 5 | | 4 | | | 5 | | 3 | | 5 | |
| Pain Scored | 3 | 5 | | 5 | | 4 | | | 5 | | 5 | 5 | 5 | |
| Pain Tracker& Diary | | 5 | | 5 | | | | | 5 | | 5 | 5 | 5 | |
| PainScale Pain Diary and Coach | 4 | 5 | | 5 | | 4 | | | 5 | | 5 | 5 | 5 | |
| Chronic Pain Tracker | 3 | 5 | | 5 | 4 | 4 | | 4 | 5 | | 3 | | 5 | |
| Pain Tracker by Terry | 3 | 5 | | 5 | 3 | | | | 5 | | 4 | 5 | 5 | |
| Pain Tracker by iHealth | 3 | 3 | | 5 | | | | | 5 | | 4 | | 5 | |
| Joint Pain Tracker | | 5 | | 5 | | | | | 5 | | 3 | 5 | 5 | |
| ACPA Pain Logs | 3 | 3 | | 5 | | | | 4 | | 5 | 3 | 5 | | |
| My Pain Log | | | | 5 | | | | | 5 | | 4 | 5 | 5 | |
| Pain Diary& Community Catch | 3 | 5 | | 5 | 4 | | | | | 5 | 4 | 5 | | |
| Chronic pain diary- Ake | | 3 | 4 | 5 | | | | | | 5 | 4 | | | |
| Ouchie | | | | 5 | | 4 | | | | 5 | 5 | 5 | | |
| myPain Journal | | 3 | | 5 | | 4 | | | 5 | | 4 | | 5 | |
| VOICE Crisis Alert | | 5 | | 5 | | | | | 5 | | 3 | 5 | 5 | partial function |
| iPain Communicator | | | | 5 | 4 | 4 | | | 5 | | 3 | 5 | | |
| Pain Scale- your digital log for chronic | | 3 | | 5 | | | | | 5 | | 5 | 5 | 5 | |
| doloTrack- Migraine App | | | | 5 | 4 | | | | 5 | | 5 | 5 | 5 | |
| TRACK+REACT | | | | 4 | 4 | 5 | | | | 5 | 3 | 5 | | |
| My Lupus Log | | | | 5 | | | | | | 5 | 3 | 5 | | |
| AcroTracker | 3 | 5 | | 5 | | | | | 5 | | 3 | 5 | 5 | |
| Pain Tracking | | 1 | | 5 | | | | | 5 | | 3 | | 5 | |
| cliexa-EASE | | 5 | 5 | | | | | | 5 | | 5 | 5 | | |

Figure 1: mHealth product analysis

I gave scores to these features. On the scale of 0-5, where a score of 0 means there is no such feature, and a score of 5 represents this feature is well-designed. Then I conducted a comparative analysis of these features. All the journaling apps are useful for patients who have undiagnosed chronic pain; however, what can be journaled varies (exercise, sleep, nutrition, pain location, duration of pain, level of pain, descriptions, etc.).

# Methodology

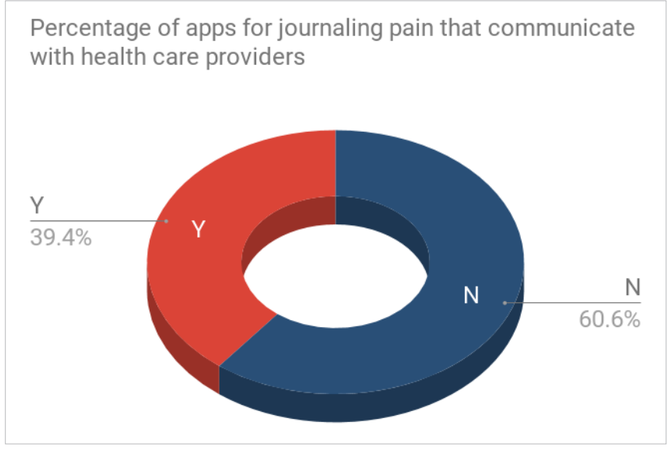



Figure 2: Percentage of apps for journaling pain that communicate with health care providers

Out of 72 mhealth apps reviewed, only 39.4% allows a person to journal/ report their chronic pain. I zoomed in to analyze only those apps for their ability to communicate with a healthcare professional and for their anatomical accuracy. I looked at these two attributes because they are essential for diagnosing many diseases that cause chronic pain (Crohn's Disease, lupus, fibromyalgia, etc.).

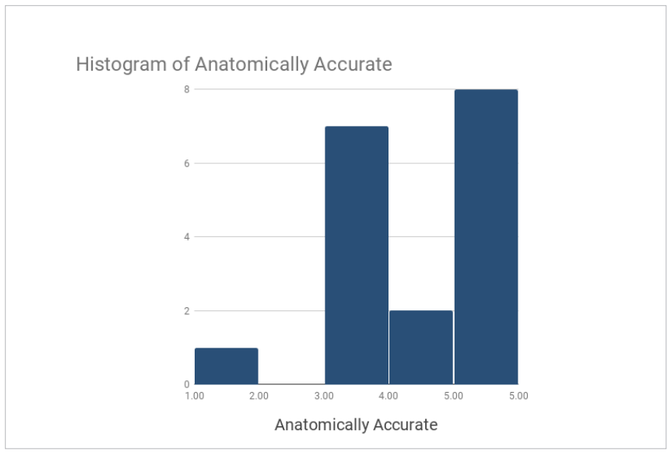



Figure 3: Histogram of anatomically accurate

This is the histogram of anatomically accurate apps. Most of the apps have a high level of anatomical accuracy. A high level of anatomical accuracy means the application contains a body map which could allow users to point out the pain spot precisely. On the contrast, a low level of anatomical accuracy indicates the app does not have the capability of recording users pain spot or the capability is limited. Among 41 apps which provides the ability of journaling chronic pain, 17 of them scored as a relatively high level of anatomically accurate.



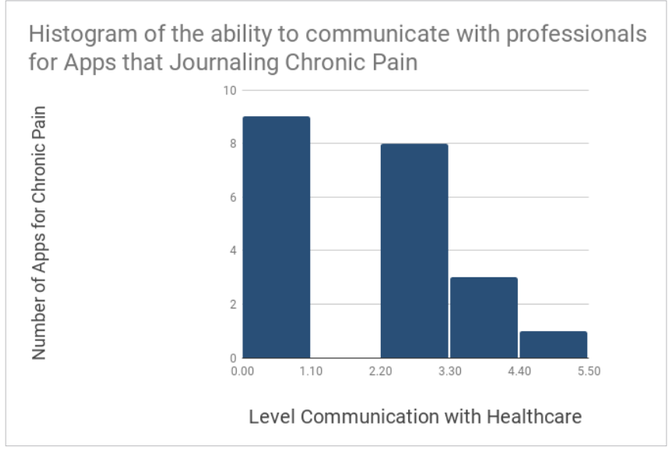



Figure 4: Histogram of the anility to communicate with professionals for apps that journaling chronic pain

In those apps with a relatively high level of anatomically accurate, only one app scored 5 for its ability to communicate with health care providers (Figure 3). However, the level of anatomical accuracy of this 5-scored app is only 3.
Moreover, most apps with a high level of anatomical accuracy are not able to assist users to connect with their physicians. This indicates that current users cannot report or share their pain progression and condition with their physicians/ health care providers.

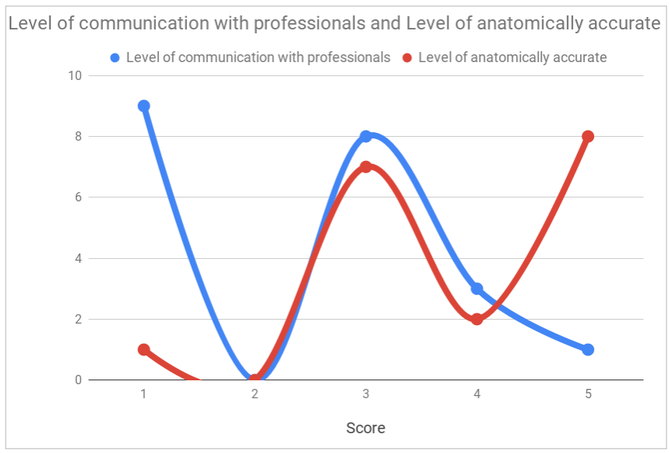



Figure 5: Level of communication with professionals and level of anatomically accurate

The line chart clearly shows a big gap: only one existing app communicates well with doctors, and it lacks anatomical accuracy. These two features are important for a pain-related app; Based on my research, there is no available app can provide these two functions at the same time. Some of the apps has a relatively high level of both features, but they are not mature enough to cater users need and not able to provide detailed ailment information for physicians.

# Methodology

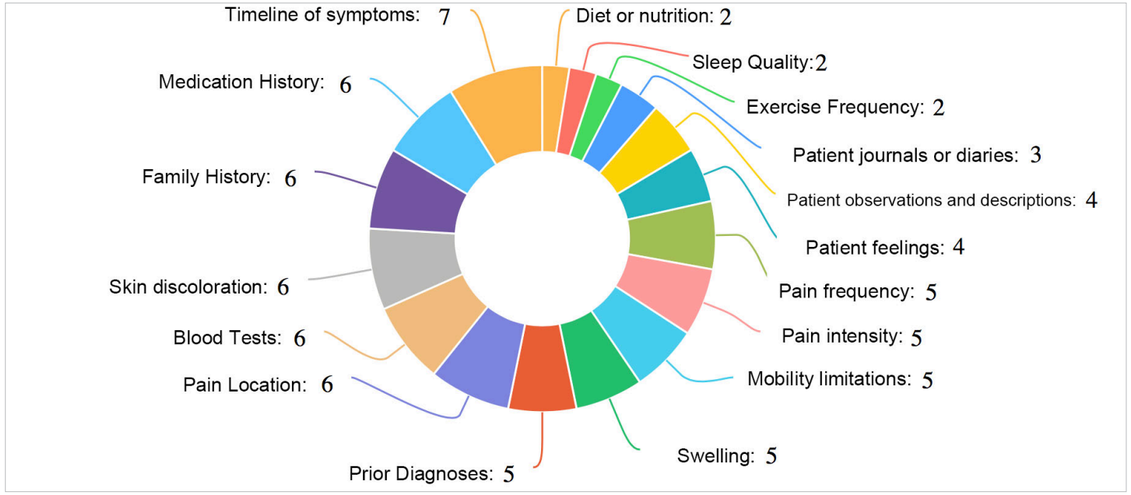



Figure 6: The results of the survey

**Survey**

I also sent out a survey to physicians addressing some questions about diagnosing autoimmune disorders while doing content analysis (See Appendix A). The results of the survey were impressive and have played a significant role in guiding my design (Figure 6). First, all of the participants think **the timeline of symptoms** is essential when they diagnose autoimmune disorders. Surprisingly, sleep quality and diet are not that important in compared with medication and family history.



The participants of the survey also gave me suggestions from their professional points of view. Most doctors said the **inaccuracy of laboratory results** was their biggest challenge in diagnosing autoimmune disorders. All of them thought lab results were insufficient for diagnosis. Depending only on the blood test results is not sufficient enough for them to diagnose autoimmune disorders. More information has to be included for a more accurate diagnosis.

The results of this survey support the following design and affirm my design approach. According to the survey, the timeline of symptoms is the most important thing when physicians are giving the diagnosis. Medication information, family history, skin discoloration, blood test ,and pain location are the second priority.

# Methodology

**Interviews with professionals**

After summarizing the content analysis and the survey, I looked for some health care providers for interviews. Some of the respondents were doctors working at the Golisano Children's Hospital, Syracuse, professors in Syracuse University, and doctors who are now running their own clinic in the Syracuse area.

I interviewed **Dr. Sgarlet** who works at Golisano Children's Hospital is responsible for diagnosing children’s autoimmune disorders. She said it is a viable project because there is currently a breakdown in communications between doctors and patients. The patient can only make an appointment by phone, and she, as a doctor, only has the opportunity to communicate with the patient face-to-face. If patients do not tell her about the details of their ailments, she has no way of knowing precious information about them.

The Electronic Medical Records (EMRs) are digital versions of the paper charts in clinician offices, clinics, and hospitals. EMRs contain notes and information collected by and for the clinicians in that office, clinic, or hospital and are mostly used by providers for diagnosis and treatment (Healthit, 2019). According to Dr. Sgarlet, the EMR system she is currently using in the hospital provides some capability for doctors to communicate with patients. However, she has hardly used this function besides giving her patients prescriptions since her patients are not actively using this function.

Currently, my project is not EMR compatible, but if approved, my long-term plan would be to implant it as a single module into the EMR system. This would greatly improve the communication efficiency between doctors and patients, and the frequency of information exchange between them.



In response to this feedback, I interviewed two of my professors who had autoimmune disorders. One of them is a patient who has been suffering from arthritis for a long time. She told me that **moderate exercise** is very beneficial for patients with autoimmune disorders. However, what should be paid attention to is the amount of exercise. Patients with arthritis can't walk a lot; otherwise, it will aggravate their pain intensity. Finding a suitable range and proper exercise intensity to benefit the body and its pain condition is essential. With her feedback, I was able to enrich my project with the function of daily exercise record. For example, with daily exercise information and in contrast with pain intensity, some conclusions about the ailment developing and the causes of the disease can be drawn.

The latter professor is a patient with rheumatism. During the interview, she told me that every time she visits the doctor, he/she asks her when she last had pain, what kind of pain, and whether she has taken any medicine. **She always has a hard time remembering**. She used to write a diary to record her condition, but she did not persist with it because it was time-consuming. She believes that the value of an electronic diary is very beneficial for such diseases. It would be a good design if there is an effective way to help her record this condition and to generate a summary report for the doctors.

Drawing from a definition by Wilde and Garvin (2007), "self-monitoring is the intentional measuring, recording, or observing of symptoms, sensations, daily activities, and thoughts and emotions." Greater awareness helps provide information to the patient and the health professional, improving the patient's ability to self-manage (Wilde & Garvin, 2007).

**Based on the feedback I got from professionals, the viability of this project has emerged. More design iterations and user testing are necessary, and further and in-depth development of this project can be done as a next step.**

# Design Gap

Combining the previous result of content analysis, and the feedback I got from the interview, I summarized the **design gap** of this project:

Currently, the mobile application market is abundant with pain-related apps. What can be journaled about and how the pain is assessed varies a lot. According to the content analysis, I have found a gap in the area of communication with health care providers and anatomical accuracy. The gap shows that there is no mobile application connecting doctors with patients and providing anatomical accuracy about the pain location at the same time. These are two primary features for users when journaling about pain.

Moreover, based on the results of the survey and interviews with professionals, the importance of a pain journal is confirmed. Other features like exercise, medication and online communication are all essential for a pain-related mobile app.

# Pilot Study

Based on the previous research, I decided to **design a prototype as my pilot study** to learn more about this gap. I adopted a software package named Invision to develop a set of interfaces for mobile application. This system allows me to connect all the pages of my app interactively. When conducting user testing, interactive pages are more intuitive for participants giving feedback.

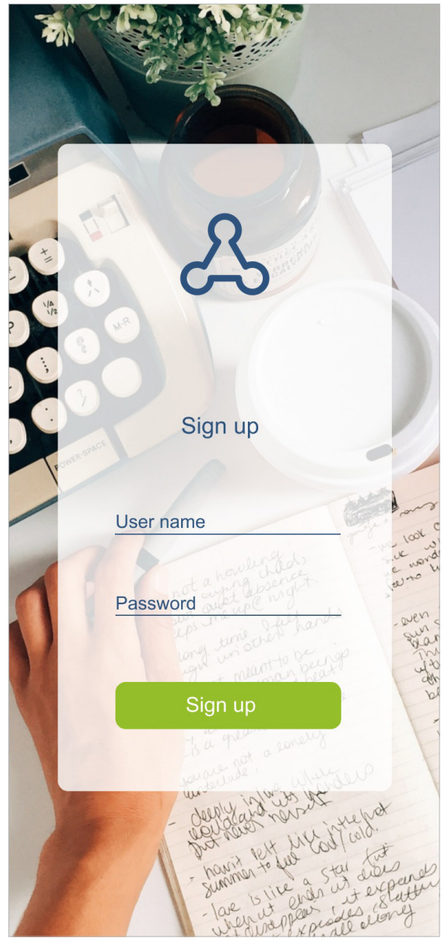



Figure 7: Landing pages from the first prototype

**Design**

Currently, I am **focusing on streamlining communication** between doctors and patients, so that doctors and patients can have a better understanding of each other and their interaction can be made more efficient. The primary function of this design will be helping patients with journaling and sending reports to their health care providers. In this application, patients are encouraged to be anatomically accurate about their pain location and to communicate with their health care providers in real time.

Based on previous research and qualitative data statistics, I conducted the first round of prototyping. I think my design should help patients record their pain in real time, give users access to their own pain history, communicate with their physicians and generate data analysis related to their pain patterns. These functions will provide better support for the patient's condition, as well as effective and accurate proofs for the doctor's diagnosis.

The first round of prototyping included four basic functions: journaling, online doctor-patient messaging, reports of pain history, and data visualization.

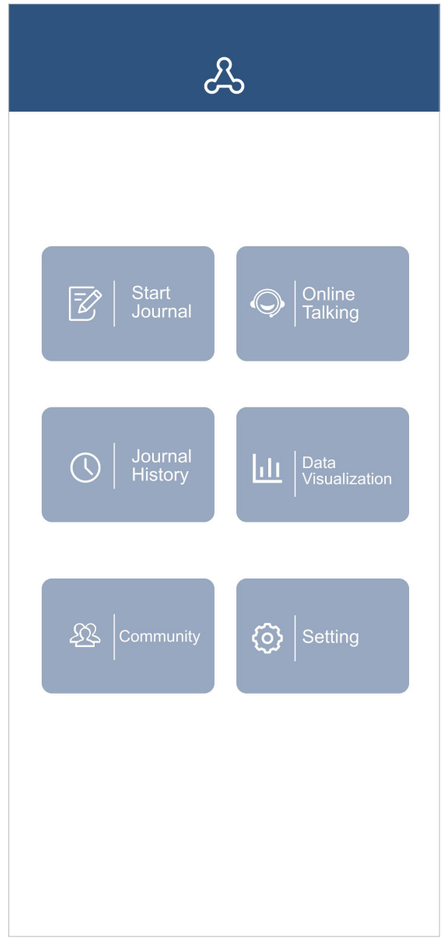



Figure 8: Main menu page

# Pilot Study

The journaling function of this first generation prototype allows users to record the location of their pain, the intensity of pain and contains various input methods (video, audio, text, etc.) which are **more comprehensive in helping patients record their symptoms.** When they finish recording, they can also choose to share these records with the doctor so that the doctor can receive information about the patient's condition immediately and give corresponding feedback.

**In 7 steps**, users can finish a pain journal. For people with undiagnosed chronic pain or autoimmune disorders, immediately and easily recording their pain should be the core value of any electronic journal.

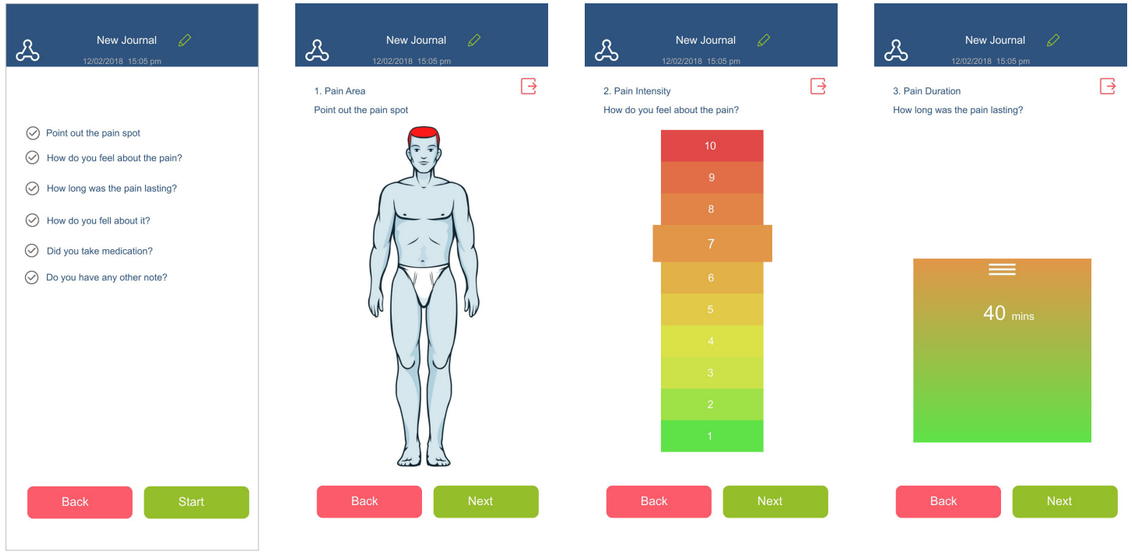



Figure 10: Starting  a new journal

# Pilot Study

The second function is to **communicate with the doctor online**. This prototype provides three different methods of communication: video chat, messages, and email. These three communication methods represent different levels of communication. If the situation is very urgent, you can choose to video chat with a nurse, as a more intuitive form of communication. If it's just daily communication, text and email will be more appropriate. Users can communicate with their doctors by choosing a communication method and then share their own journals.

This function **aims at improving the current communication level between physicians and patients**. As Dr. Sgarlet stated above, she is not able to receive important ailment information from her patients electronically; she has no other way of communicating with her patients except when they come to the hospital. Actively using this function could help strengthen the relationship between physicians and patients.

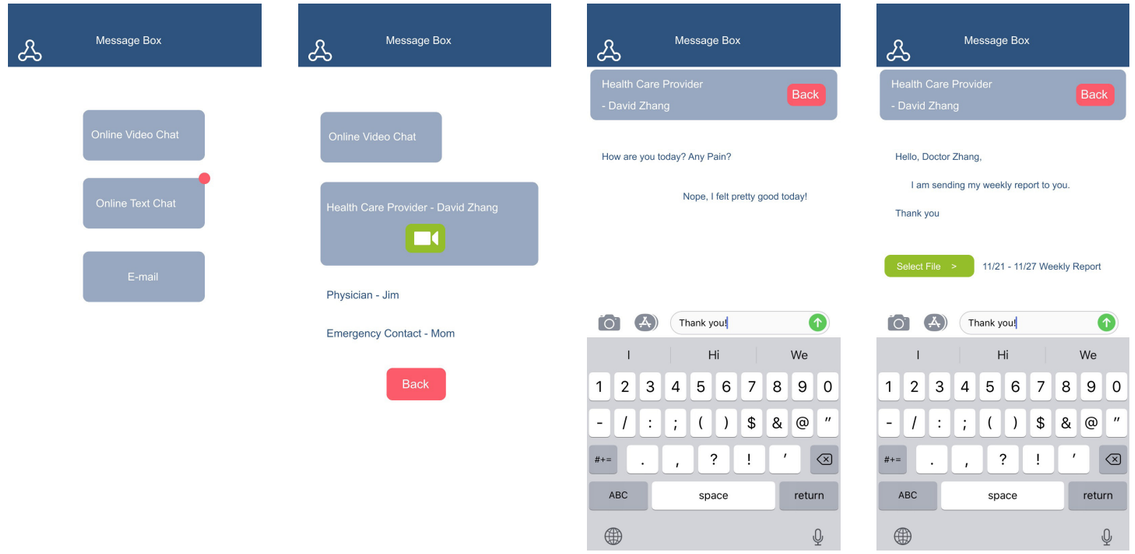



Figure 10: Message box

The third function is the **journal history.**

Users can edit previous journal entries and share their journal history with their contacts, especially with their health care providers.

Based on the results of the survey, a timeline of symptoms is the priority for an accurate diagnosis. Through analyzing patients pain history, pain triggers and patterns can be discovered. And then, this information could lead to a clear diagnosis.

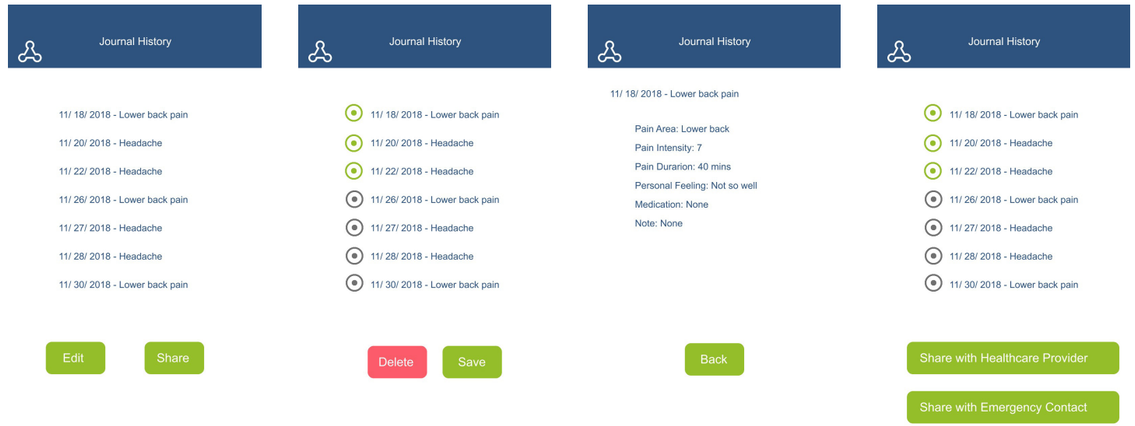



Figure 11: Journal history

The fourth function is to **generate a custom report online**. By selecting different recorded content, patients can have a daily view, a monthly view, or an annual view of their pain history. This feature provides a powerful perspective for doctors to use in their diagnoses. Documenting changes in symptoms is the key to helping doctors diagnose autoimmune diseases.

For instance, by comparing pain intensity with the amount of daily exercise, a relationship between these two factors can be seen. With the advice of health care professional, patients can adjust their exercise amounts.

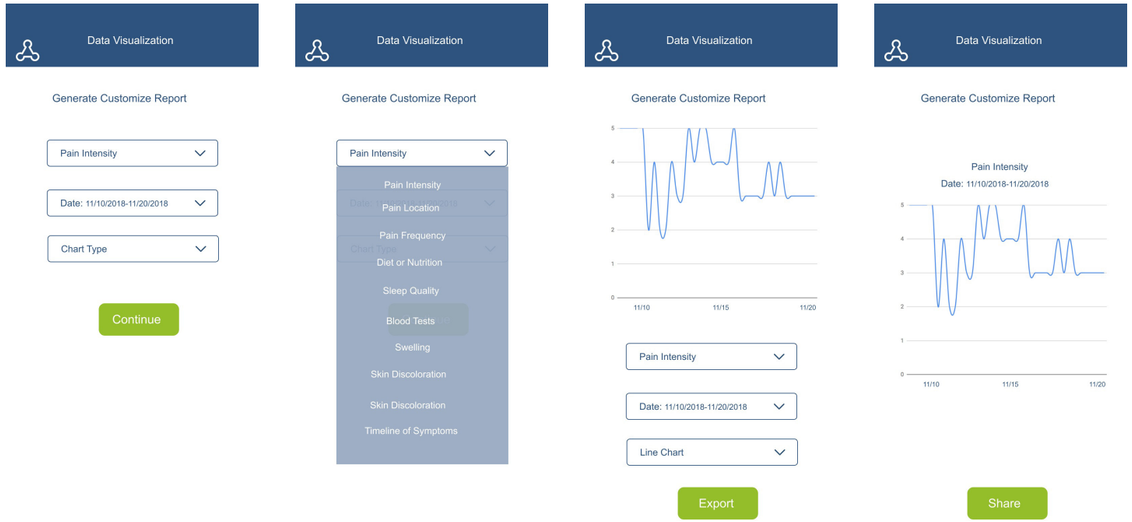



Figure 12: Data visualization

# Pilot Study

**User Testing**

For my pilot study, I worked with one volunteer who agreed to conduct **a usability test** for this prototype. She was a 44-year-old female participant who had dealt with an autoimmune disorder for the past 23 years. I used this test not to collect data but to learn how to improve my research methods and the design of this prototype.

This volunteer was given **three different tasks**. The ideal situation was to successfully complete all three tasks without anyone else's interference. The result was positive based on how much time the volunteer used to finish each task and how many errors they made.

The first task was to find how to change the language setting; the second one was to go through the whole process of starting a new journal, and the last one was to try to find how many ways you can communicate with your healthcare professionals.

Due to the limitations of Invision, some of the functions I imagined including could not be completely modeled. When discussing this app with my usability tester, I explained the situation of this semi-functional prototype beforehand. She completed all the tasks in a short amount of time, which indicates the interfaces were efficient for her.



**Summary of user's feedback**

The attitude of my usability tester in regards to this project was positive. She offered constructive suggestions from a patient point of view, which led to new insights into this project. I summarized some of her comments as shown below:

• **Add the function of "What has triggered your pain?"**
She mentioned that sometimes a rainy day could affect her knees. It would be better to have a choice to choose what kind of factor would trigger her pain.

• **Pain intensity sometimes varies, so how might users journal that accurately?**
She brought up this question since she sometimes would experience the pain with various degrees of intensity.

• **Add "When did the pain start and when it ends," instead of what is the duration of your pain.**
According to her, sometimes the pain will last up to two weeks. And it will be helpful to enter an exact time and date for the beginning of the pain and the end of the pain.

• **How to make sure my doctor is engaging with all of my journals?**
She expressed her concern about not being able to know if her physician is actively engaging with her journals.

• **Let doctors contact patients in response to their important journals.**
She hopes her physician will contact her first about her recent conditions as expressed in her journals. The communication between them has to be two-way so that she won't feel she has to continually interrupt her physician.

**The purpose of this user testing was to gain a different perspective from a real patient and to test whether the prototype is user-centered and user-friendly. Moreover, I hoped to gain a better understanding of the viability of this project.**

**IRB**

For the purpose of **valid user testing and feedback**, I got an approval letter from the **Institute of Research Integrity.** My intention was to get feedback and conduct valid user testing with real patients suffering from autoimmune disorders or undiagnosed chronic pain.

My research only asked questions regarding user interfaces. Their personal information and the details of their specific ailments was not revealed during user testing process. The data and content of the user testing will only be used to improve the usability and functionality of prototypes.

Full IRB application, please see Appendix C.



SYRACUSE UNIVERSITY

INSTITUTIONAL REVIEW BOARD
MEMORANDUM

**TO:** Jody Nyboer
**DATE:** February 26, 2019
**SUBJECT:** **Determination of Exemption from Regulations**
**IRB #:** 18-424
**TITLE:** *Diagnostic mHealth for Autoimmune Disorders*

The above referenced application, submitted for consideration as exempt from federal regulations as defined in 45 C.F.R. 46, has been evaluated by the Institutional Review Board (IRB) for the following:

1. determination that it falls within the one or more of the five exempt categories allowed by the organization;
2. determination that the research meets the organization's ethical standards.

It has been determined by the IRB this protocol qualifies for exemption and has been assigned to category **2**. This authorization will remain active for a period of five years from **February 25, 2019** until **February 24, 2024**.

**CHANGES TO PROTOCOL:** Proposed changes to this protocol during the period for which IRB authorization has already been given, cannot be initiated without additional IRB review. If there is a change in your research, you should notify the IRB immediately to determine whether your research protocol continues to qualify for exemption or if submission of an expedited or full board IRB protocol is required. Information about the University's human participants protection program can be found at: http://researchintegrity.syr.edu/human-research/ Protocol changes are requested on an amendment application available on the IRB web site; please reference your IRB number and attach any documents that are being amended.

**STUDY COMPLETION:** Study completion is when all research activities are complete or when a study is closed to enrollment and only data analysis remains on data that have been de-identified. A Study Closure Form should be completed and submitted to the IRB for review (Study Closure Form).

Thank you for your cooperation in our shared efforts to assure that the rights and welfare of people participating in research are protected.

Tracy Cromp, M.S.W.
Director

**DEPT:** VPA – School of Design, The Warehouse – 350 W. Fayette St., Syracuse, NY 13202 **STUDENT:** Yun Deng

Research Integrity and Protections | 214 Lyman Hall | Syracuse, NY 13244-1200 | 315.443.3013 | **orip.syr.edu**

Figure 13: IRB approval letter

# Design Iterations

**Iterations**

The pilot study was successful based on the feedback from user testing. After combining the feedback from one volunteer and a few health care professionals, I designed **two more generations of prototypes**.

**I adopted Adobe XD** for these two generations of the prototype. Adobe XD is a software from Adobe Creative Suite ,and it can help to build an application prototype that is more efficient and functional. Moreover, during the design process, I adopted IOS design guidelines.



**During the prototyping process**, I also interviewed a doctor. He has a clinic for medical marijuana in the Syracuse area. He interacts daily with patients who have chronic pain. He expressed his concern that video chat communication is inefficient in my prototyping. During his normal working days, doctors would not have time to take video chats with patients. He believes that if the video is a necessary means of communication, then it should be assigned to a nurse or on-call doctor. In this way, after the patient briefly introduces his or her condition, the nurse or on-call doctor can decide whether to report it or give further advice.

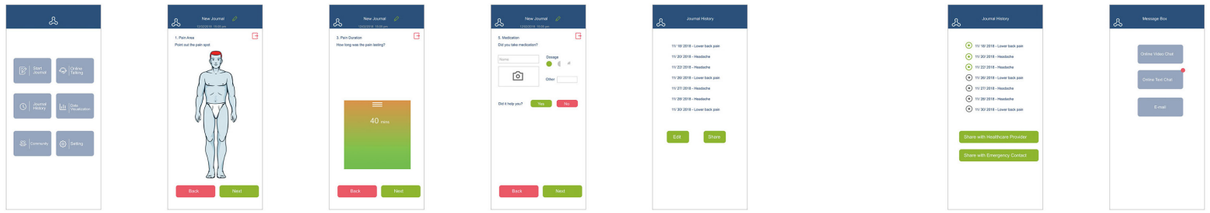
After thinking about this problem and observing other apps, I decided to **abandon the video chat function altogether**. Although the video feature was very intuitive and could provide a way to maintain regular contact with ones healthcare provider, it could cause the doctor's daily work to be interrupted. This would also infringe on the interests of other patients. In the spirit of effective time management, daily check-in with text messaging and email communication can improve communication quality and efficiency. Combining everyday communication with the content of the journal can help the doctor and the patient themselves develop a relatively comprehensive understanding of the patient's condition.

He also gave me a very interesting suggestion. He suggested that I develop a **quick start journal function**. If one user experiences long-term pain in the same area, they can simply choose to build a journal through this function quickly. Then they can create a new journal entry by making some simple modifications based on the original journal. This saves users time and eliminates the process of going through every step. I immediately took this advice. I think this suggestion will enhance the user experience. This is a more intuitive way to bring a smoother experience to the user.

# Design Iterations

## UI Development

**Prototype 1.0**



Change the style of all the icons.

Add the function of description.

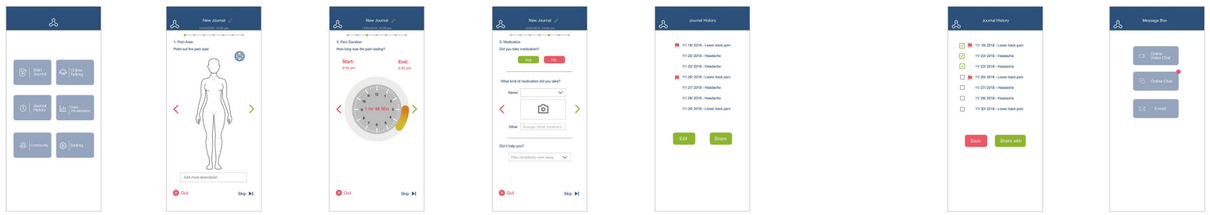
Adapt the bedtime function from iPhone, so it is more clear and easy to use.

Dropdown menu for users to choose common medicine for their condition.

Change the display of dosage.

Add the function of the flag which represents an emergency message.

**Prototype 2.0**

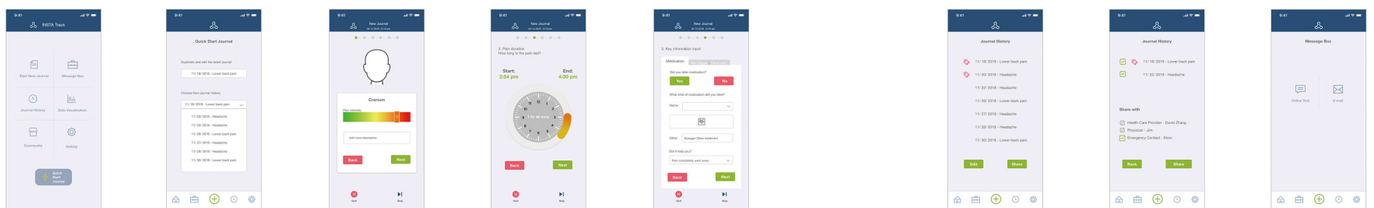


Detailing the pain area and combine the pain area with pain intensity.

Combine the vital information input and put them under three different tag.

Delete the function of video chat with health care providers.

**Prototype 3.0**



Add one important new function of quick start a new journal, which allows users to create a new journal by duplicate old ones from history.

This the user interfaces development for this project.

The first row above is the first prototype of the pilot study, and the next two rows are the two prototypes that have been modified.

There are no significant changes in the interface structure and style. After listening to the professional's opinion, I made some changes and adjustments to some features. For example, the quick start journal function is added, and the way of entering pain duration is modified.

Figure 14: Design iterations of prototypes

# Design Iterations

**User Testing**

After two generations of prototyping, I reached a point where I was ready to **conduct more user testing**. So, I started to use a convenient sample for recruitment, drawing from a network of my friends and professors.

My user testing gave each participant three tasks. Based on their level of completion and efficiency for each task, I was able to determine which functions are valid and which ones need improvement. Adobe XD provides the ability to record screen and sound at the same time. This way I can easily record the user's cursor track while also accessing their voice. This feature can help me better summarize the results of all user testing. The sound files of these tests will not be leaked and will not reveal any personal information in the following summary.

In the end, my number of usability testers reached 11. I understand that this amount of user testing is not enough for a standard app. But in the later stages of user testing, I gradually began to **notice patterns** in the responses of my subjects. Almost every participant was asking the same questions and expressing the same doubts, and there were doubts on the same pages and buttons. So, I decided to stop the user testing and start to make adjustments. After carefully summarizing the results of all user tests, I finalized my design.



The following is my **design summary** for this user test phase:

- Daily exercise is important for patients with autoimmune disorders. But be aware of finding the amount of exercise that suits patient themselves.
- The tag information added since the second generation of prototypes created some doubts with the testers.
- The quick start journal added to the third-generation prototype is very helpful for the condition record, but it needs to be more concise on the interface. The content of the interface is too long and complicated, which will reduce some of the efficiency of using.
- In the journal history function, the share button was confused in terms of its function and the location on that page. This section requires further modifications.

# Final Design

### Final Design outcome

After constant revision and comments, I finalized my design. Compared to the previous pilot study, this prototype has more function now. Because of the many effective user tests, my prototype has improved its usability and feasibility.

The following are some interface screens from the final prototype:

The link to the final prototype design, please see Appendix B.

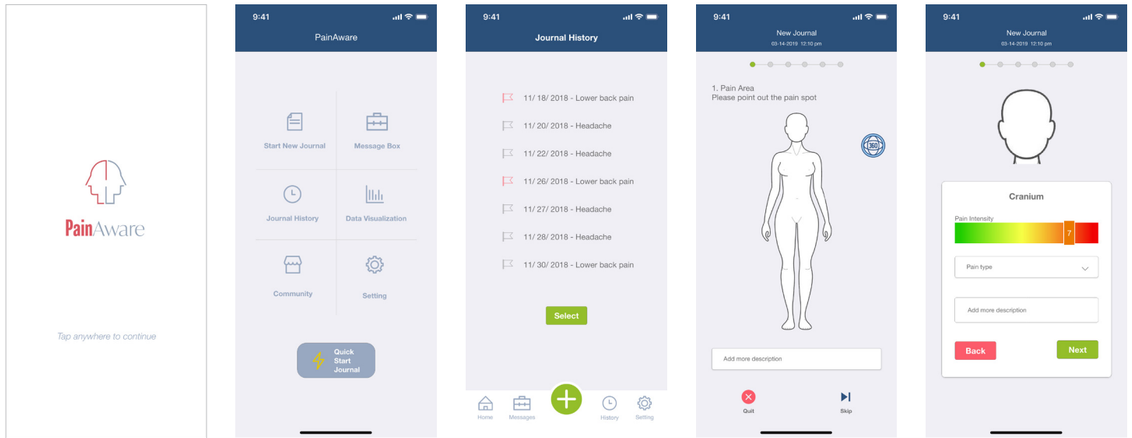



Figure 15: Final prototype design

# Design Exhibition

Figure 16: The enviornment of design exhibition at 914 Works Gallery
Photo Credit: Yumeng Yang


Figure 17: Personal exhibition spot

# Conclusions

I conducted a content analysis of the current products in the mobile app market. According to this analysis, I have found a gap in the area of communication with health care providers and anatomical accuracy. The gap shows that there is no mobile application connecting doctors with patients that provides simultaneous anatomical accuracy about pain location at the same time. These are two primary features for users when journaling about pain.

I interviewed some professionals with regard to this gap. A survey was also sent to some physicians who are responsible for diagnosing autoimmune disorders. Based on their feedback and comments, I did the first generation prototype as my pilot study. I designed the first prototype and then looked for volunteers to conduct one user testing. The results and feedback of the pilot study were very positive. Then I further deepened my design and designed the second and third generation prototype. With more user testing, I summed-up all the feedback and comments. Finally, I generated the final prototype design.



Through this project, I came to **several important conclusions:**

1. It helped me to realize the design gap and market need. It's beneficial for this project that I conducted research into the current mobile application market. In this way, I was able to summarize the disadvantage of other products and make my product more useful and efficient for the target audience. Although there are many pain-related apps on the market, the functions are not comprehensive enough and not mature enough for users.

2. Most of the available applications are not involved health care professionals during their development process. This may cause usage problem, and users are risking their personal information for potentially useless apps. Through my literature review, I found out that there is no regulation for electronic journals. This will lead to a situation that there are a variety of apps on the market, but no app is really useful or sophisticated enough for users.

3. As a designer, we should start from the needs of users when solving problems. Always put user needs as the priority. Effective user testing is an important step in the design. Only in this way will we get real user feedback. By summarizing this feedback and making changes over time, our design can be user-centered and user-friendly.

4. The final design prototype for this project is neither comprehensive or perfect. Due to the limitation of my user pool, I only asked users to test some of the core functions in this prototype. Moreover, the amount of user testing is not enough either. If there is an opportunity in the future, I will continue to deepen this project and bring this project to a higher level of usability.

# Discussion and Opportunity

While the project is trying to fill the gaps in the market and cater to the needs of users, there are still many problems that need to be solved.

First, how can I **ensure the privacy of users' information** when they use this app? The pain journal contains a portion of personal information. How to make sure the information is not going to be used by an insurance company or a malicious company is another big challenge for this project. Big data analysis is an new trend. It calculates and predicts users' behavior by obtaining their online personal information. Therefore it is important to protect personal information in this big data era. While we enjoy the convenience of the big data, we still have to be careful about the consequences of this technology.

Second, in the EMR system, there is a function that allows a doctor to communicate with patients but some doctors don't use it actively. The cause and solution should be identified so that the same problem can be avoided when promoting more apps for doctor-patient communication in the future.

Third, among patients with autoimmune disorders, some are senior citizens. And some within this population don't use smartphones on a frequent basis. Even others don't own a smartphone. Therefore, such apps are still unable to meet their usage requirements. In the future design process, we should consider **inclusive design** so that more people benefit.

Last, I have designed four generations of prototypes. Each generation contains the opinions of users and professionals. To gain access to a larger test pool, **the number of user tests is far less** than the amount that a standard app should have. Also, I only asked the user to test some of the core features. In the final design, some features have not been tested and verified by the user.

Although this project aims to improve the communication efficiency between doctors and patients, I only designed the mobile-end for patients.

My original idea was to create a system that includes the patient's mobile end and the doctor's desktop end (Figure 18). Each mobile function has a corresponding feature on the desktop. However, at this juncture, I have currently finished the prototype design of the patients' interface. In the future, if I have the opportunity, I will continue to develop the doctor's desktop system.


**Information input from patient**

**Analysis data and generate report for physician**

Figure 18: Future design concept

# Discussion and Opportunity

Based on my thesis content and my research, I believe that **artificial intelligence (AI)** technology will bring more possibilities for the future of this project. As Sannino et al. (2019) said in his paper, AI technology is changing eHealth and mHealth. He stated that more and more mobile medical technologies are now installed on patients' mobile devices and that these devices collect a large amount of patient health information and transmit it to the health care information system. Through the techniques of machine learning and data mining, many health data can be processed and analyzed. He believes that the current development of these technologies in mobile medical care is not mature enough, and the potential in the future is enormous.

Algorithmic advances in data mining and machine learning can generate a better interpretation and determination factors for health conditions and outcomes (Rehg et al., 2017).In my project, by recording and analyzing the user's pain pattern (Figure 19), this app can **prompt users with some proactive prevention before the pain occurs**. Moreover, by analyzing user's personal information and health data, this app can remind users to avoid some behaviors that may cause pain. Especially for those patients with undiagnosed chronic pain, AI can analyze from a large amount of user data and conclude some possible ailment. This will be of great help to the diagnosis of the physician.

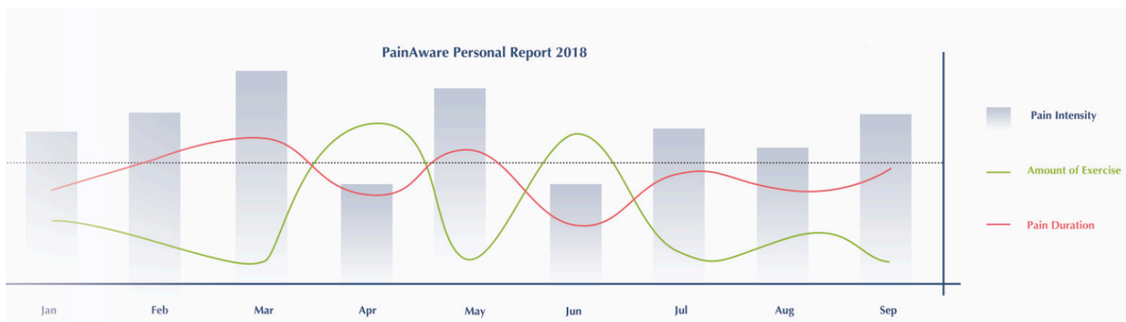



Figure 19: The concept of personal data analysis

As previously stated in this article, originally video chat was a very intuitive communication method with a healthcare provider in my project. However, this method is likely to take up too much time for the doctor, and it will hurt the interests of other patients, I chose to give up this function in my app. However, if we can use AI technology, patients can communicate with virtual doctors or nurses online. By analyzing and processing the user's previous health data, these virtual characters can know the specific situation and illness of the user. **Depending on the severity of the patient's condition, these virtual characters can give patients different levels of advice**.

# Appendix

## Appendix A:
## A Survey about Diagnosing Autoimmune Disorders



### Diagnosing Autoimmune Disorders

The goal of this anonymous survey is to gather your insight about autoimmune disorders, especially those that are particularly difficult to diagnose. As a medical professional, you have unique insight about this topic. Your responses will be used to support my graduate thesis work at School of Design at Syracuse University. If you agree to participate, you'll be directed to four questions which will take you less than 5 minutes to complete. If you have any questions, you can contact the supervising faculty at jlnyboer@syr.edu. Thank you for your time!

* Required

1. **Do you agree to participate?** *
   *Mark only one oval.*
   - ◯ Yes
   - ◯ No *Stop filling out this form.*

### Question 1

2. **Are you a doctor who diagnoses autoimmune disorders?** *
   *Mark only one oval.*
   - ◯ Yes
   - ◯ No
   - ◯ Other: _____

### Question 2

3. **In your professional opinion, what are the biggest challenges to diagnosing autoimmune disorders?** *

_____

_____

_____

_____

_____

### Question 3





4. **What information is useful for diagnosing autoimmune disorders that are particularly DIFFICULT to diagnose?** *
   *Check all that apply.*
   - ☐ Pain location
   - ☐ Pain frequency
   - ☐ Pain intensity
   - ☐ Diet or nutrition
   - ☐ Sleep quality
   - ☐ Mobility limitations
   - ☐ Exercise frequency
   - ☐ Blood tests
   - ☐ Swelling
   - ☐ Skin discoloration
   - ☐ Patient observations and descriptions
   - ☐ Patient feelings
   - ☐ Family history
   - ☐ Prior diagnoses
   - ☐ Timeline of symptoms
   - ☐ Medication history
   - ☐ Patient journals or diaries
   - ☐ Other: _____

### Question 4

5. **What are your thoughts about a phone app that streamlines communication between doctors and patients about the items you selected above (question #3)?** *

_____

_____

_____

_____

_____

Powered by Google Forms

# Appendix

## Appendix B:
## Link to the final prototype in Adobe XD

https://xd.adobe.com/view/7b79eb3e-6303-4e30-49be-c6cb4a8e82af-0d48/

## Appendix C:
## IRB application

IRB#: _____
DATE REC'D
*(For IRB Use Only)*

SYRACUSE UNIVERSITY
Institutional Review Board

**APPLICATION FOR DESIGNATION AS RESEARCH EXEMPT FROM IRB REVIEW**

Initial review generally requires 5-7 business days from the date an exempt application is received by the IRB Office. Should modifications and/or clarifications be requested by the IRB, additional review time may be required.

On average the IRB advises it may take 4 weeks for the IRB exempt review process. (This includes the investigators response time.)

***NOTE*: The Principal Investigator (PI) must be a person who holds a faculty appointment or other administrative position of Director or higher. If you have any questions regarding this IRB requirement call the IRB office at 315.443.3013 for guidance.**

**Principal Investigator/Faculty Member Information**

| | | | |
|---|---|---|---|
| First Name: Jody | Middle Initial: L | Last Name: Nyboer | |
| Position: Assistant Professor | | | |
| Department: VPA, School of Design | College: Syracuse University | | |
| Campus Address: 350 W Fayette St, Syracuse, NY 13202 | | | |
| Campus Phone: 315 443-2455 | | Fax : | |
| Email: jlnyboer@syr.edu | | Cell Phone (optional): 505-350-4612 | |

**Student/Research Staff Information** ☐ ☐NA

| | | |
|---|---|---|
| First Name: Yun | Last Name: Deng | |
| ☒ Graduate Student ☐ Undergraduate Student ☐ Other: | | |
| Department: VPA, School of Design | College: Syracuse University | |
| Local/Campus Address: 350 W Fayette St, Syracuse, NY 13202 | | |
| Local/Campus Phone: 315 443-2455 | Fax: | |
| Email: ydeng21@syr.edu | Cell Phone (optional): | |

**TITLE OF PROPOSAL:** Diagnostic mHealth for Autoimmune Disorders

**1A. IS IT RESEARCH?**

The definition of research as defined by the Department of Health and Human Services (DHHS) regulations: "Research means a ***systematic investigation***, including research development, testing and evaluation, designed to develop or contribute to ***generalizable knowledge***." 45 CFR 46.102 (d)

To be considered a "systematic investigation", the concept of a research project must:

- Attempt to answer research questions (in some research, this would be a hypothesis).
- Be methodologically driven, that is, it collects data or information in an organized and consistent way.
- Analyze data or information in some way, be it quantitative or qualitative data.
- Draw conclusions from the results.

A. **Is your project a systematic investigation?** ☒ Yes ☐ No

B. **Provide an explanation for your response:**
ABSTRACT: This design research aims to develop a mobile health application (mHealth) streamlining communication between health care providers and patients who are suffering from undiagnosed chronic pain. The method of approach to develop an interface design is to interview people (in a product design setting) to learn about their perceptions of clarity and usability of the mHealth interface. The information they share will be treated as descriptive and quantitative data that will inform and guide a design intervention. Participants will test the interface design to provide feedback about its effectiveness as a journaling / reporting tool. This knowledge is expected to have important applications to several disciplines including user experience and interface design for healthcare. The final results will be presented as a thesis exhibit and published to complete the MFA Design degree.

"Generalizable knowledge" would include one or more of the following concepts:

- The knowledge contributes to a theoretical framework of an established body of knowledge.
- The primary beneficiaries of the research are other researchers, scholars and practitioners in the field of study.
- Publication, presentation or other distribution of the results is intended to inform the field of study.
- The results are expected to be generalized to a larger population beyond the site of data collection.
- The results are intended to be replicated in other settings.
- Web based publication for professional purposes.

C. **Will your project contribute to generalizable knowledge?** ☒ Yes ☐ No

D. **Provide an explanation for your response:**
ABSTRACT: This design research aims to develop a mobile health application (mHealth) streamlining communication between health care providers and patients who are suffering from undiagnosed chronic pain. The method of approach to develop an interface design is to interview people (in a product design setting) to learn about their perceptions of clarity and usability of the mHealth interface. The information they share will be treated as descriptive and quantitative data that will inform and guide a design intervention. Participants will test the interface design to provide feedback about its effectiveness as a journaling / reporting tool. This knowledge is expected to have important applications to several disciplines including user experience and interface design for healthcare. The final results will be presented as a thesis exhibit and published to complete the MFA Design degree.





**NOTE:** Collaborative Institutional Training Initiative (CITI) is ***not*** required for research determined to be exempt. CITI is required for researchers involved in expedited or full board studies.

*If "yes" to question A, **AND** C above the activity is considered research. Continue completing the application.*

**1B. IS IT HUMAN SUBJECTS RESEARCH?**

A. Is the data that is being obtained about living individuals? ☒ Yes ☐ No
B. Are data collected through interaction or intervention with individuals (e.g., interviews, surveys, or any direct contact)? ☒ Yes ☐ No
C. Is identifiable individual private information being obtained (e.g., chart reviews, information from data or tissue repositories)? ☐ Yes ☒ No
D. Are data or specimens received by the investigator with identifiable private information? ☐ Yes ☒ No
E. Are the data/specimens coded with a link back to the individual? ☒ Yes ☐ No

*If "yes" to question A. above **AND** "yes" to one or more questions from B-E in section 1B, the activity is considered human research. Continue completing the application.*

Protocols that do not meet the criteria for *research **AND** human subjects research* need not be submitted to the IRB for review or for a determination that the project falls into an exempt category.

**Additional guidance for publically available data**:
Some research involves the analysis of data about humans for which the regulatory definition of "human subject" is not met. One example is research that involves only the analysis of de-identified data contained within publicly available datasets (available to any one regardless of occupation, purpose, or affiliation, and those individuals who are responsible for posting the dataset had legitimate access to the data and have employed the necessary mechanisms to ensure the privacy and confidentiality of the individuals about whom the data were collected).

While the activity described above meets the regulatory definition of research, the definition of human subject is not met because data about a living person is not obtained through interaction or intervention, and no private, identifiable information about a living individual is obtained.

**2. CATEGORIES FOR EXEMPTION**

I/We certify that the above research project involves human subjects only in one or more of the following categories, and will be carried out using standard methods. Please check the number next to category(ies) pertinent to the research.

☐ **1.** Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
(a) research on regular and special education instructional strategies, or
(b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods, and
(c) the research must not involve prisoners as participants

[1] *The Federal Regulations also include a sixth category for exempt research, the Institutional Review Board has the discretion to determine what categories to recognize and does not recognize research under category 6 as qualifying for exemption. If you have questions, please contact the IRB at 315.443.3013 or orip@syr.edu.*

6. Taste and food quality evaluation and consumer acceptance studies a) if wholesome foods without additives are consumed or (b) if food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration or approved by the Environment Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.





☒ **2.** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior unless:
(a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
(b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
(c) If the research involves children, the procedures must be limited to educational tests and observation of public behavior where the investigators do not participate in the activities being observed.
(d) The research must not involve prisoners as participants.

☐ **3.** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if:
(a) the human subjects are elected or appointed public officials or candidates for public office; or
(b) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
(c) The research must not involve prisoners as participants.

☐ **4.** Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. [Note: *To qualify for this exemption ALL of the data, documents, records, or specimens must be in existence **before** the project begins.]*
(a) The research must not involve prisoners as participants.

☐ **5.** Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
(a) public benefit or service programs;
(b) procedures of obtaining benefits or services under those programs;
(c) possible changes in or alternatives to those programs or procedures; or
(d) possible changes in methods or levels of payment for benefits or services under those programs.
(e) The protocol must be conducted pursuant to specific federal statutory authority.
(f) The protocol must have no statutory requirements for IRB review.
(g) The protocol must not involve significant physical invasions or intrusions upon the privacy interests of the participants.
(h) The protocol must have authorization or concurrence by the funding agency.
(i) The research must not involve prisoners as participants.

**3. SCREENING QUESTIONS**

A. Does any part of the research require that subjects be deceived? ☐Yes ☒ No
B. Will research expose human subjects to discomfort or harassment beyond levels encountered in daily life? ☐Yes ☒ No
C. Could disclosure of the subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation? ☐Yes ☒ No
D. Will individuals involuntarily confined or detained in penal institutions be subjects of the study? ☐Yes ☒ No

# Appendix

## Appendix C:
## IRB application

E. For research proposed under category 2, will research involve surveys, interview procedures, or observation of public behavior with children where the researcher will interact with the children? ☐Yes ☒ No

F. For research proposed under category 4, will any of the data, documents, records, pathological specimens, or diagnostic specimens be collected or come into existence after the date you apply for exemption? ☐Yes ☒ No

G. For research proposed under category 4, will any of the information obtained from data, documents, records, pathological specimens, or diagnostic specimens that come from private sources be recorded by the investigator in such a manner that subjects can be identified directly or through identifiers linked to the subjects? ☐Yes ☒ No

*If you checked **YES** to **ANY** of the questions above, your research is **NOT EXEMPT.** Do not complete this application. Submit an **Application for Expedited or Full Board Review**.*
*If you have checked **NO** to **ALL** of the questions above, your research may be exempt. Please complete the remainder of the exempt application.*

**4. RATIONALE FOR EXEMPTION**

Please briefly describe the proposed research and explain in clear language why you believe this research should be exempted from IRB review.

This study collects and analyzes the experiences of human subjects. This study is exempt because the data is generated by interacting with participants who are 18 years or older, and the information collected is not of sensitive nature. There are minimal to no risks associated with participating. All information collected from the interviews and data used in reports will not reveal the identity of participants.

**5. RECRUITMENT**

**Please submit all recruitment materials including but not limited to: recruitment flyers, e-mails, letters and/or scripts.**

Describe plans for recruitment and how contact will be made:

Participants of this study are a convenience sample of people who are well known to the primary investigator and graduate researcher. Because the relationships are existing, this research is based on existing knowledge that the participants have a medical condition that causes them chronic pain. Therefore, their condition is ***already open knowledge to the researcher***. For this study, it is not required that the researcher gains in-depth knowledge of the participants specific condition. Only that they experience pain and that we are attempting to track their pain history.

The participants are knowledgeable about the topic area and are aware of the nature of this project and the research questions. Once they are recruited, participants don't have to reveal any detail about their condition to the primary investigator and graduate researcher.

***See attached A for invitation letter.***

Provide a detailed description of what participants will be required to do.



**All research measures which will be used during this study including sample questions, questionnaires, recruitment scripts, etc. must be included with the application.**

This study uses a mixed-method approach to developing a design interface for journaling undiagnosed chronic pain. The research design asks participants to interact with a set of design interfaces and provide their *opinion* about it.

Participants are asked to engage in an activity designed to test out the usability of a prototype. Through this testing, participants can interact with the prototype while taking through their thoughts. Participants will be given three tasks and the process and their talking will be recorded (no faces). The three tasks focus on the functionality of this prototype. How well participants complete each task (finish time, errors, confusing parts) provides information about the effectiveness and ease of use of the prototype. Base on this testing, new prototypes can be developed and the procedures repeated.

**Devices used for testing:**
Audio and video recording device, laptop with Invision (Software) installed to present visuals to participants.

**Procedure:**

- Introduce the basic information about the prototype design.
- Present participants with the first task card that says: **Find how to change the language setting**.
- Video and audio record their performance and what they are saying during the task. Do this without interrupting the participant and do not aid them. Write down their questions as they have them.
- Repeat these procedures for the additional task cards / prompts:
  - **Try to begin a new journal**.
  - **Try to find all of the ways that you can communicate with your healthcare provider**.
- When the three tasks are complete, ask the participants if there there any additional thoughts and suggestions about this prototype design. Record their suggestions using the audio device and by taking notes..
- Analyze the information to develop multiple generations of prototypes, repeating as necessary until a final prototype design is completed.

Will this research be conducted by SU investigators in foreign countries?
☒ No.
☐ Yes. If yes, an additional form related to international research must be completed and submitted with this application: International Research Appendix.

**7. INFORMED CONSENT REQUIREMENT**
*(This is **not** required for Category 4)*

**Please provide a copy of the written or electronic informed consent document or oral consent script you will use in your study. Please note this document must include the following minimum required elements:**

1. A statement that clearly explains that the study is research. The purpose of the research should be described in lay language, avoiding the use of technical terms and using language appropriate to the targeted subject group.
2. A statement that describes what procedures will be followed, clearly explaining what participation in the study will involve.



Participants are asked to engage in an activity designed to test out the usability of a prototype. Through this testing, participants can interact with the prototype while taking through their thoughts. Participants will be given three tasks and the process and their talking will be recorded (no faces). The three tasks focus on the functionality of this prototype. How well participants complete each task (finish time, errors, confusing parts) provides information about the effectiveness and ease of use of the prototype. Base on this testing, new prototypes can be developed and the procedures repeated.

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- Repeat these procedures for the additional task cards:
  - **Try to begin a new journal.**
  - **Try to find all of the ways that you can communicate with your healthcare provider.**
- When the three tasks are complete, ask the participants if there there any additional thoughts and suggestions about this prototype design. Record their suggestions using the audio device and by taking notes..
- Analyze the information to develop multiple generations of prototypes, repeating as necessary until a final prototype design is completed.

Will you be contacting participants through a contact list or list servor provided by a department, organization, company or school? If yes, provide a letter of support from the individual authorized to provide you with this information. More than one letter may be required.
☒ Does not apply
☐ Letter(s) attached
Comments:

Will you require support from the University for selection or contact information of participants? If the answer is yes, you will be required to obtain a letter of cooperation from the Office of Institutional Research and Assessment (OIRA).
☒ Does not apply
☐ Letter attached

Will this research be conducted in a school or is it funded by the US Department of Education?
☒ No. **(Skip to Section 6)** ☐Yes. If yes, complete the form found at:
http://researchintegrity.syr.edu/wp-content/uploads/2016/10/Department-of-Education-Schools-Form.docx

**6. METHODS**



3. It must be clear that participation is voluntary and participants can withdraw from the study at any time without penalty.
4. Contact information for the investigator.
5. For adult participants, a statement that the subject is 18 years or older must appear as part of the consent.
6. For internet research add the following statement:

Whenever one works with email or the internet there is always the risk of compromising privacy, confidentiality, and/or anonymity. Your confidentiality will be maintained to the degree permitted by the technology being used. It is important for you to understand that no guarantees can be made regarding the interception of data sent via the internet by third parties.

***See attachment B for consent form.***

**8. SIGNATURES**

This is to acknowledge that I take full responsibility for the conduct of the research. **Investigators of studies exempt from IRB review are responsible for the ethical conduct of research and obtaining informed consent when appropriate.** (If this study is being conducted by a student, a faculty member must sign in the space provided). Electronic and /or faxed signatures are acceptable.

Signed: _____ (Faculty member) Date: Feb 25, 2019

Name (printed): Jody Nyboer, PhD

Signed: Yun Deng (Student, if applicable) Date: Feb 25, 2019

Name (printed): Yun Deng

Graduate ☒ Undergraduate ☐

***All notifications will be sent via email. Hard copies will be only be provided upon request.***

**RETURN ONE COPY OF THE COMPLETED APPLICATION TO:**

**SYRACUSE UNIVERSITY**
**INSTITUTIONAL REVIEW BOARD**
**Office of Research Integrity and Protections**
214 Lyman Hall
Syracuse, New York, 13244-1200
Phone: 443-3013
orip@syr.edu



**Attachment A : Invitation Letter**

Hello!

My name is Yun Deng, and I am a School of Design student in the MFA Design program. Currently, I am working on my thesis which is a smart phone application for streamlining the communication between health care provider and the patients who have autoimmune disorders. This study uses a mixed-method approach to developing a design interface for journaling undiagnosed chronic pain.

As a participant, you'll be asked to ensure that you are 18 years of age, to read and sign the following consent form, and to engage in activities designed to test out the usability of a prototype. I am interested in your *opinion* about the clarity of the interface and the features of the app. The method for gaining your opinion will involve interacting with a design prototype while talking through your thoughts. Your will be given three tasks to perform with the prototype, be asked to talk through your process, and your voice will be recorded (no faces). The three tasks focus on the functionality of this prototype. How well you complete each task (finish time, errors, confusing parts) provides information about the effectiveness and ease of use of the prototype.

You are invited to be a participant in this study. Your experience will be used to develop a set of design prototype. The final design will support the MFA Design thesis work at Syracuse University. Please read and sign the following consent form carefully.

This study will not reveal any detail of your ailments or personal information you may provide during this study.

Yun Deng
MFA Design Graduate Student
School of Design,
Syracuse University



**Attachment B: Consent Form**

Thank you for your interest in this this design research which aims to develop a mobile health application (mHealth) that aims to streamline communication between healthcare providers and patients who are suffer from chronic pain. Your insight about the design of the app is invaluable to designing an interface that will enhance the lives of people such as yourself.

As a participant, you'll be asked to ensure that you are 18 years of age, to read and sign this consent form, and to engage in activities designed to test out the usability of a prototype. I am interested in your *opinion* about the clarity of the interface and the features of the app. The method for gaining your opinion will involve interacting with a design prototype while talking through your thoughts. Your will be given three tasks to perform with the prototype, be asked to talk through your process, and your voice will be recorded (no faces). The three tasks focus on the functionality of this prototype. How well you complete each task (finish time, errors, confusing parts) provides information about the effectiveness and ease of use of the prototype.

The final design will support MFA Design thesis work at Syracuse University. Please read the following consent form carefully.

**Risks and Benefits of Participating in the Study** - The study poses minimal risks. You may refuse to participant in any activities or to answer any questions interviews at any time if you feel uncomfortable.

**Compensation** - No compensation is provided for participating in this study.

**Confidentiality** - The data, observations, notes, and digital documentation of this study will be kept confidential and will be securely stored in a locked office at Syracuse University or password protected on a computer. All data, reports and presentations that emerge will be scrubbed to remove individual names.

**Voluntary Nature of the Study** - Participation in this study is *voluntary*. The decision of whether or not to participate will not affect your relationship with Syracuse University. If you decide to participate, you are welcome to refuse any answer or withdraw your participation at any time without affecting the aforementioned relationship.

**Contacts and Questions** - Contact Yun Deng (MFA Design graduate student) at ydeng21@syr.edu or Jody Nyboer, PhD (the primary researcher) at jlnyboer@syr.edu if you have questions about this study. Questions can also be directed to the Office of Research Integrity and Protections at orip@syr.edu, or (315) 443.3013.

**Please indicate your consent to the following by initialing your choice.**
____ I consent to participating in this study, allowing the researcher the authorship to use the information collected to support the development of a design product.

**Participant Info**

Name _____
*First* *Last*

Signature _____ Date _____

E-mail _____

## Bibliography


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# Vita

## Yun Deng

**Education**

Syracuse University, Syracuse, NY — May 2019
*Master of Fine Arts in Design*

Capital University of Economics and Business, Beijing, China — July 2014
*Bachelor of Arts in Advertising*

**Award**

Syracuse University., Syracuse, NY
*M.F.A. Design Award*
*Master's Prize*

**Experience**

Syracuse University, Syracuse, NY — September, 2018-Present
*Plot-lab Technician*

- Run plotter to help students print large format visual design.
- Use laser cutter to create students projects.

Beijing eLicht Information Technology Co., Ltd.  Beijing, China — March 2015—December 2015
*Graphic Designer*

- Poster designer for social media platform
- Initial user interface design for websites.

Beijing R.T.B.W. Advertising Co., Ltd. Beijing, China — June 2013—March 2014
*Project Management Intern*

- Coordinated competition event for teenagers hosted by China Central Television.
- Participated and held event for the Association of Accredited Advertising Agencies of China (4A) “JinYin” Award.
- Managed the Germany MAN Truck& Car company’s official Sina Micro-blog account operating and daily update.