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Rehab Tracker: Framework for Monitoring and Enhancing NMES Patient Compliance

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Rehab Tracker: Framework for Monitoring and Enhancing NMES Patient Compliance

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Abstract

We describe the development of a cyber-physical system (Rehab Tracker) for improving patient compliance with at-home physical rehabilitation using neuromuscular electrical stimulation (NMES) therapy. Rehab Tracker consists of three components: 1) hardware modifications to sense and store use data from an FDA-approved NMES therapy device and provide Bluetooth communication capability, 2) an iOS-based smartphone/tablet application to receive and transmit NMES use data and serve as a conduit for patient-provider interactions and 3) a back-end server platform to receive device use data, display compliance data for provider review and provide automated positive and remedial push notifications to patients to improve compliance. This system allows for near real-time compliance monitoring via a secure web portal and offers a novel conduit for patient-provider communication during at-home rehabilitation to improve compliance. The system was tested in patients (n=5) who suffered anterior cruciate ligament rupture and surgical repair to provide proof-of-principal evidence for system functionality and an initial assessment of system usability. The system functioned as designed, recording 89% of rehabilitation sessions. Thus, Rehab Tracker is a functionally correct system with the potential to be used as a tool for studying NMES and mobile communication methodologies at scale and improving compliance with at-home rehabilitation programs.

Acknowledgements

First and foremost, I thank my advisor Dr. Christian Skalka and Dr. Michael Toth. Without them, I would not have had the opportunity to work on Rehab Tracker, and their support was essential throughout the writing process.

I would also like to thank Dr. Ryan McGinnis for writing subsection 3.1.1, editing help, sitting on my committee.

I thank all the people who helped develop Rehab Tracker over the past two years: Chia-Chun Chao, Xavier Stevens, Brian Colombini, Luke Trinity, Yifan Zhang, Sean Kates, Meghan Winter and Brandon Goodwin.

For their help deploying and testing Rehab Tracker, I would like to thank Stephen Goldman and Rebecca Choquette. Steve patiently worked with me get the system to comply with HIPAA. Becca coordinated our patient recruitment and helped patients sign up for Rehab Tracker.

I am grateful friends and family. In particular, I appreciate my roommates for tirelessly working to keep me humble.

Finally, I thank my parents, Holly and Brian Stevens, for a lifetime of supporting me and humoring my curiosity.

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Chapter 1

Introduction

Anterior Cruciate Ligament (ACL) ruptures are a debilitating injury with prolonged recovery periods, due in large part to injury and surgically induced muscle atrophy. The link between rehabilitation exercises and healing response of the leg is not well understood. In clinical settings, neuromuscular electrical stimulation (NMES) has shown some promise as a possible treatment for muscle atrophy in ACL rupture patients. NMES is proven to reduce muscle atrophy, measured by quadriceps cross sectional area, and muscle strength and function, following ACL repair surgery [1]. Additionally, there is preliminary evidence that earlier NMES therapy before surgery can provide more powerful benefits [2]. Unfortunately patient compliance with NMES therapy is low outside of clinical settings, and studying NMES therapy on a large scale would require working with unreliable self-reported data.

To address problems with NMES usage and rehabilitation compliance, Drs. Michael Toth and Christian Skalka proposed Rehab Tracker: a cyber-physical system aimed at improving patient compliance and patient outcomes when using portable NMES devices at home. Skalka and Toth also proposed a clinical trial of Rehab Tracker's

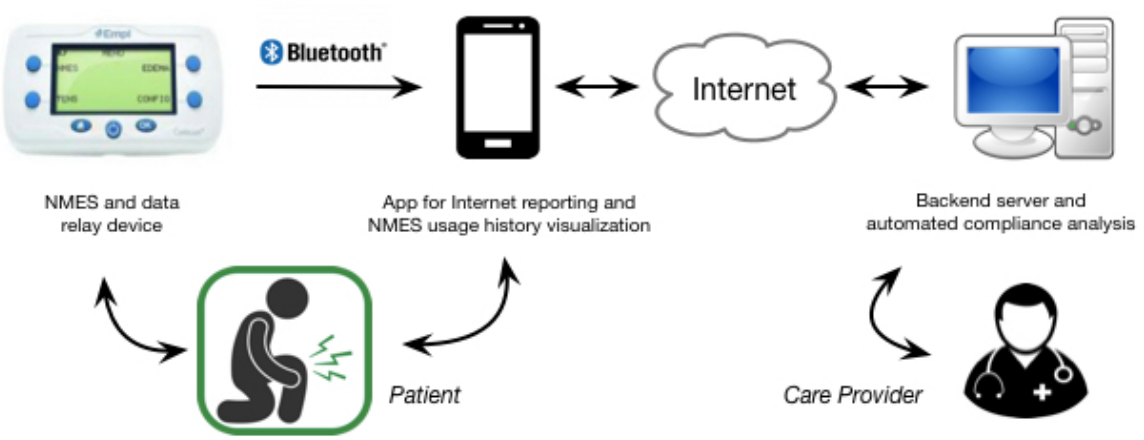

Figure 1.1: Cyber-physical system design

functionality. This trial has since been executed as part of a larger study on NMES's therapeutic benefits for ACL rupture patients taking place at the University of Vermont.

1.1 Rehab Tracker

The system (Figure 1.1) consists of four components: an embedded device on the patient's portable NMES device, a mobile app for patient use, a web interface for clinicians, and a web based back end database. The embedded device tracks patient NMES device usage through its output voltage. Then, the patient transfers the embedded systems data to the database via the mobile app. Once online, the patient's care provider can view the data and understand the patient's NMES use habits in real time. Furthermore, the system can now automatically encourage the patient to participate in NMES therapy with push notifications tailored to their specific compliance circumstances.

1.2 Clinical Trial Summary

The Rehab Tracker clinical trial was a small (n=5) single blinded, randomized control trial. The study included a 50:50 ratio of male and female patients between the ages of 18-50, with acute first time ACL ruptures in one leg, who were scheduled to undergo a BPTB autograft. All patients were recruited from the UVM Medical Center Department of Orthopedics in Dr. Slauterbeck's practice. Patients participated in the Rehab Tracker portion of the study for approximately two weeks. They used a modified NMES device for use with the Rehab Tracker system. In this study, we assessed the following criteria in Rehab Tracker. This section is repeated in subsection 4.2.6.

Functional correctness

Each feature of the system should work reliably with special attention given to critical components, for instance logging in, data transfer, and push notifications. Developers tested the system before beginning the trial, however functional correctness will continue to be evaluated throughout the trial via patient-clinician bug reports and a mock user. Patients report bugs via a Google form, which can be located from in the app or in TestFlight.

Usability

The system should be easy to use for both patients and clinicians. We hope that using Rehab Tracker integrates into a regimen of NMES therapy well, requiring minimal additional effort. Patients and clinicians submit feedback through a Google form.

Communication effectiveness

A primary goal of Rehab Tracker is to improve patient compliance through patient-clinician communication. However this is a small pilot study (n = 5), so quantitative testing for improved compliance is planned for a future study. In this trial, we would like to evaluate our cyber-physical system subjectively through patient feedback and the mock user. Collected feedback serves to improve communication methods in a future study.

Parent Study

The larger parent study strives to collect preliminary data about early NMES therapy's effect on ACL rupture patient outcomes. They assess these outcomes through bilateral assessment of skeletal muscle fiber size and function.

1.2.1 Results

As described in chapter 4, the this small clinical study demonstrated Rehab Tracker's functional correctness. 5 patients beta tested the app during the study. Most patients had every session recorded in the database. This shows that our our conduit reliably records patient use data in real life use cases. Additionally, patients generally found the app usable on top of their NMES regimens.

The study included a few functional issues, particularly with the embedded device. Intensity readings in the database are incomparable between multiple patients. Moreover, the real-time clocks in the embedded devices stopped working. This meant

that sessions are stored in the database with their sync time rather than the session time.

From a usability perspective, this clinical trial is too small for conclusive results; however many of the patients found the system intuitive and easy to use. Most difficulties were associated with downloading the app and the first login. Patients also noted that the sync feature did not inspire confidence that it was working.

1.3 Personal Contributions

While this monograph outlines the entire Rehab Tracker system and trial, the full implementation is the product of the collective effort of many students and faculty at UVM in the Computer Science department, Electrical Engineering department, and the College of Medicine. I participated in the development of Rehab Tracker in the following ways:

Management

This system was proposed by Drs. Skalka and Toth as a class project for UVM CS275: Mobile Apps and Embedded Devices project. I led the team working on this project. Our group inherited some Rehab Tracker code from a previous CS275 group. Our team worked on finishing and correcting the device-to-database sync. We also added features to this process such as support for syncing more than one NMES session's data at once and offline data storage. We also designed a new layout for the app, modified the compliance checking scheme, and restructured the database.

As the team lead, I delegated tasks throughout the team, solved implementation and architectural problems, and monitored progress. Along with Chia Chun Chao, I served as the interface between the stakeholders, Skalka and Toth, and the team. In this capacity, I also participated in solving design problems such as developing the app interface and determining the proper push notification protocol during weekly meetings with Toth and Skalka.

Technical Contributions

As a software engineer for Rehab Tracker, I worked primarily on problems concerning the mobile app and web-based components of the system. I redesigned the app authentication logic to properly enforce a data boundary when logging in and out. Additionally I designed and implemented the push notification system, which included revising the database schema, web API improvements, and implementing a scheduled push notification protocol on our server.

Collaboration with Medical Center

In order to receive internal review board approval for the clinical trial, the web-based components of Rehab Tracker had to be moved to a HIPAA compliant server owned by the College of Medicine. To achieve this transfer, I worked with Lerner College of Medicine(LCOM) Programming and Database Service Manager Stephen Goldman. This involved assisting Mr. Goldman in installing the proper libraries to the LCOM server, and collaborating to convert the system from operating on a Linux architecture to a Windows server.

Trial Support

Once the technical considerations had been taken care of, I collaborated with Rebecca Choquette, the patient coordinator for the UVM NMES study, to develop a standard operating procedure for enrolling patients and instructions for patients for downloading our app. During the trial, I was also responsible for fixing bugs and technical difficulties that patients or Becca ran into. These challenges included patients not receiving invite links to download the app, patients being enrolled with the wrong physician, or issues with the device's real time clock.

1.4 Outline of the Thesis

The remainder of this thesis describes the design and implementation of Rehab Tracker, a small pilot study to test the system, and our future intentions for the project.

Chapter 3

looks at the implementation of the system from a strictly technical perspective and describes how each piece of the system functions. It is divided up into sections based on the system components. The NMES Device section describes the hardware interface used to interact with the EMPI portable NMES Device as well as the Bluetooth Low Energy API used in transferring data to the Rehab Tracker mobile app. The iOS app section describes the user interface of the Rehab Tracker iOS app and the syncing procedure from the NMES device to the web API. Section 3.3 describes the physician portal web interface for clinicians. Section 3.4 describes all of the back end

web-based services used in the system. This includes our MySQL database, the web API used by the app, automated compliance evaluation, and the push notification infrastructure. Finally, section 3.5 underlines the security of the system.

Chapter 4

outlines the design and results of our small clinical trial. This small, single blind, randomized control trial is aimed at verifying the functional correctness of the Rehab Tracker implementation and collecting preliminary feedback on our design from a group of real patients.

Chapter 5

describes the communication with the patient used in Rehab Tracker, which were automated push notifications and patient-clinician interactions.

Chapter 6

summarizes potential directions for further research with Rehab Tracker. Because of its reliable data collection, we hope to use Rehab Tracker in a much larger study on NMES therapy for ACL rupture patients.

Chapter 2

Related Work

The following chapter summarizes research in NMES therapy for muscle atrophy, health based cyber-physical systems, and automated short message communication with patients. Medical cyber-physical systems are inherently cross disciplinary and are applicable in a broad problem space. The specific problem of NMES patient compliance has not yet been solved with a cyber-physical system, however similar systems have been used in different problem domains.

2.1 NMES therapy for muscle atrophy

The link between anterior cruciate ligament rupture (ACLr) and prolonged periods of lower extremity weakness is well known. Quadricep muscle deficits persist for years after injury and surgical intervention [3]. Additionally, many rehabilitation regimens do not recover lower extremity strength effectively [4].

Neuromuscular electrical stimulation (NMES) uses surface electrodes placed on the muscle that pass current directly through the muscle to induce contractions. Since

the late 1980s, NMES has been shown to reduce the muscle atrophy associated with lower extremity immobilization. The attenuation of muscle disuse atrophy, measured by quadriceps cross sectional area (CSA), occurred in NMES patients with distal third tibia fracture patients [5], healthy males with involuntarily immobilized knees [6], bed-ridden COPD patients [7], and patients with moderate to severe acute stroke [8]. NMES has also been applied to reducing atrophy after ACL rupture and surgical intervention.

While a number of studies show that NMES therapy reduces muscle atrophy in ACLr patients in small research studies [1], ACL patients are generally dissatisfied with their knee function two years after surgical intervention [9]. Furthermore, ACLr patients often experience bilateral strength deficits, implying that traditional measures of atrophy, strength and CSA may not be reliable metrics of NMES therapy efficacy [10].

Rehab Tracker's parent study provides insight into the ACLr research gaps outlined above. The NMES intervention provided by the parent study is the earliest intervention post injury or surgery examined (1 week post injury). Based on preliminary results, this approach is expected improve patient recovery [11]. Additionally, seeking cellular evidence of NMES's therapeutic benefits will rigorously asses the technology's efficacy and address reliability concerns seen with whole muscle tests.

2.2 At Home Patient Compliance

NMES for ACLr patients has immense potential, however research in this area must overcome the issue of variable patient compliance. Patient compliance is problem-

atic for any trial attempting to study at home treatment. In both physical therapy and antimicrobial drug regimens, compliance has been reported at below 50% with estimates in certain populations ranging from 13% to 73% [12] [13]. Any study of at home NMES therapy will likely be affected by this variable compliance.

Additionally, patient compliance data is collected through self reported surveys. There are currently no named standards for measuring adherence [14], and compliance surveys are considerably varied. Inconsistent compliance measures leads to hard to reproduce results in clinical trials. Furthermore, many studies do not use compliance measurement tools with favorable psychometric properties [14]. Inconsistent surveys yield inconsistent results in clinical trials for at home treatments such as NMES.

The Rehab Tracker cyber-physical system attempts to close that gap by automatically reporting compliance and automatically encouraging patient compliance. This innovation circumvents the inconsistent survey problem by retrieving data directly from the device. Since the system uses the same process to report data for each patient, Rehab Tracker's data is consistent, given functional correctness. Additionally, data is reported daily, which allows automatic compliance encouragement and rapid physician intervention for non compliant patients. These advancements strive to solve the at home compliance problem.

2.3 Cyber-physical systems in health applications

As of 2016, over 90% of adults in the United States own a smart phone [15]. E-health and Cyber-physical systems (CPS) have large potential in medicine due to this techno-

logical prominence. Potential uses for health CPS are wide ranging, with applications including monitoring high risk pregnancies [16], providing visiomotor balance therapy and brain imaging for stroke patients [17], and general purpose healthcare. The space of CPS in health also includes a prototype for using smart watch accelerometers to detect when a patient opens a pill bottle to take a prescribed medication [18].

While there is a wide variety of CPS in e-health, efforts have been made to implement systems for improving patient compliance similar to Rehab Tracker. WellDoc^{TM} is a system for monitoring blood sugar in type two diabetes. This system functions similarly to Rehab Tracker, with a Bluetooth enabled blood glucose monitor, a mobile phone app, and a website for physicians to access data. WellDoc^{TM} automatically reports patient use data to the physician team each month, and sends the patient diabetes management information [19]. HipGuard also uses a networked sensor to send feedback to patients and clinicians. In this case, the sensor monitors posture in patients after hip surgery, and alerts patients and clinicians when the patient has poor hip posture or dangerous loading of the hip [20].

2.4 Automated communication protocols

Short messaging service (SMS) or texting, provides a rapid and efficient way to interact with patients. Text messaging health interventions have been successfully implemented in preventative care applications [21], lifestyle applications [22], disease management and adherence [23] [24], patient education [25], and as a mechanism for data retrieval [26]. The format of text messaging as a general purpose two-way communication allows interventions of various complexities to be implemented. Re-

minding a patient to perform a task may only require sending texts, but more complex monitoring applications may need encryption to safely transfer private health information between the patient and healthcare provider, and text messaging partially handle both applications.

Much of the evidence indicating that text-based interventions can improve health outcomes are of low or medium quality [27] [28]. Often the effects of text-based interventions are evaluated using surveys and questionnaires, which are prone to the issues raised in section 2.2. Currently, there is an effort to raise the quality of evidence supporting text interventions with artificial intelligence, but has yet to begin trials on patient populations [29].

Rehab Tracker follows a simpler, one-way communication strategy where patients receive reminders, however Rehab Tracker uses push notifications rather than SMS. Our study is the first to use push notifications as adherence reminders on patients recovering after sports injuries. Moreover, Rehab Tracker reports patient compliance through a cyber-physical system. A future Rehab Tracker study has the potential to evaluate the effectiveness of push notification communication protocols, and generate higher quality evidence.

Chapter 3

Technical Summary of the System

The following chapter summarizes the Rehab Tracker cyber-physical system in terms of its four main components: the NMES embedded device, the iOS app, the Physician Portal web interface, and the back-end infrastructure. Figure 1.1 describes the flow of information through the system. First, patients perform NMES therapy, and their sessions are recorded by an embedded device. Then, patients use the RehabTracker app to transfer session data to the database. Online data is viewed by the physician, and used for compliance tracking and push notifications. Full documentation and code for the system is available in a public GitHub repository here [30].

3.1 NMES Device

We installed microcontroller onto FDA approved NMES devices to directly monitor patient sessions. The controller tracks the NMES device output voltage, and processes it into session data. Then the controller acts as a Bluetooth peripheral for sending data to the RehabTracker iOS app. Figure 3.1 describes the flow of data from the

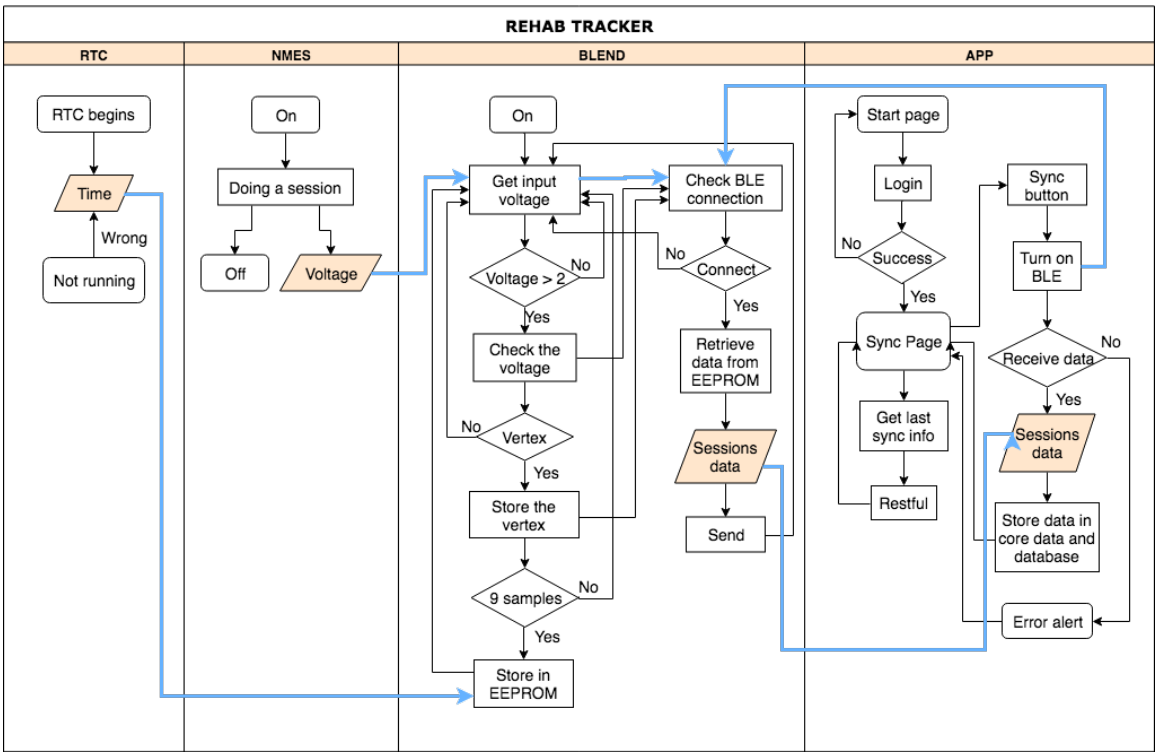

Figure 3.1: Device-app sync data flow. The columns refer to the Real-time clock (RTC), The NMES device, the microcontroller (BLEND), and the RehabTracker iOS app.

NMES controller to the iOS app during data tracking and the Bluetooth data transfer.

3.1.1 Hardware Summary

The heart of this system for tracking rehab compliance is the EMPI Continuum (Figure 3.2a), an FDA-approved multi-functional electrotherapy device that offers adjunctive rehabilitation therapies, including the NMES therapy considered herein. We integrate this proven device with instrumentation for tracking its usage and communicating that data to a companion iOS application in a small package that only slightly increases the footprint of the device (Figure 3.2). This instrumentation is

built upon the Arduino Blend (Figure 3.2c-iii), a small development board that includes an integrated microcontroller and Bluetooth 4.0 module. The four output leads of the EMPI device are passed through a custom rectifier and voltage divider circuit (Figure 3.2c-ii) and sampled through two analog inputs of the Arduino. The resulting signal provides a direct measure of device activity enabling both the duration and intensity of each session to be logged quantitatively using custom firmware on the device. The Arduino also samples a real-time clock to provide absolute timestamps for each rehabilitation session. This information is communicated to a companion mobile phone via Bluetooth as described in detail later. The Arduino-EMPI system is powered by two AA rechargeable NiMH batteries. Power delivery to the system is controlled by a master switch (Figure 3.2b-ii) to ensure that a rehabilitation session cannot be completed without also being tracked by the monitoring hardware. A step-up regulator (Figure 3.2c-i) is used to provide the requisite 2.6V to the EMPI and 5V to the Arduino. The EMPI's internal low-voltage cutoff is maintained, ensuring that the system cannot be used if the batteries are no longer capable of providing sufficient power to enable a standardized rehabilitation session. If this state is reached, an indicator LED (Figure 3.2b-iii) will not illuminate when the master power switch is engaged. The Arduino system is enclosed within a 3D-printed housing that is secured to the back of the EMPI (Figure 3.2b-iv). Batteries are housed in an external enclosure that allows for easy replacement by the user, and further acts as a convenient 'kick-stand' for the device when in use (Figure 3.2a, b-vi).

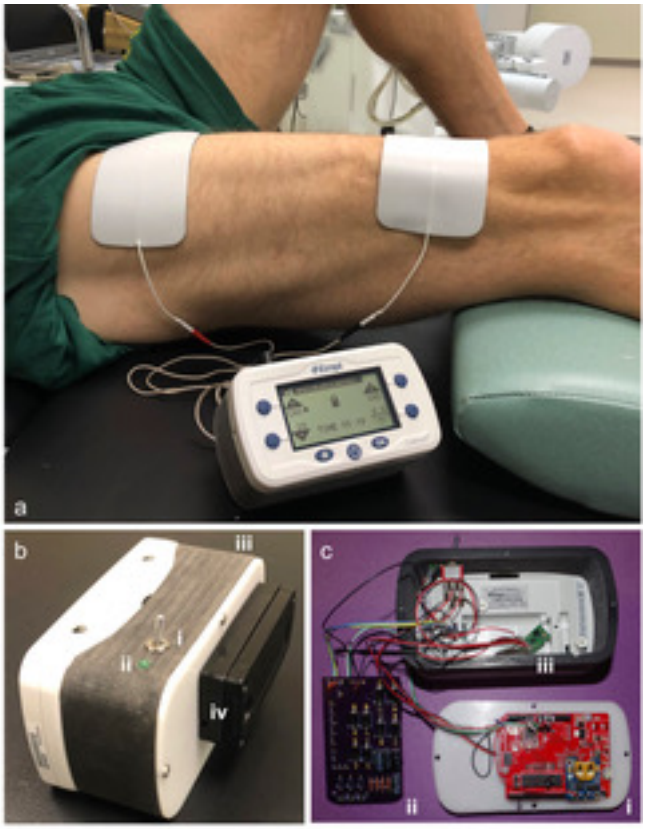

Figure 3.2: Smart EMPI system can track the duration, intensity, and timing of NMES rehabilitation sessions (a). System is composed of an Arduino (c-iii) and custom circuitry for quantifying device usage (c-ii), and is integrated within a 3D printed enclosure secured to the back of the EMPI (b-iv). Power is provided by two AA batteries secured in an external housing (b-i) and is controlled by a master switch (b-ii) and step-up regulator (c-i). An external LED (b-iii) indicates when the batteries need to be replaced.

3.1.2 NMES Device API

The software on the microcontroller processes the raw session data into a smaller more useful format for the Bluetooth transfer and functions as a Bluetooth peripheral device. The controller is arduino-like, so all the code that runs on the device is contained in one file. The file has a `setup` function that runs once, and a `loop` function that runs continuously while the device is on. This file can be found here [31].

Data Aggregation

For a patient recovering from an ACL injury, an electrical stimulation session is one hour long, however patients often end sessions early. The embedded device calculates average session intensity from the voltages every 10 contractions to accommodate sessions ended early. We have found that intensity is proportionate to the maximum voltage of each contraction. We define the array of local voltage maximums, max_volts as follows.

$$max\_volts \;=\; \{x_i \;\; x_i \in voltages, x_{i-1} < x_i, x_{i+1} < x_i\}$$

Now we calculate the average session intensity every 10 contractions with with the following formula:

$$intensity \;=\; mean(max\_volts) * c$$

where c is some constant found experimentally. With our system, we used $c = 0.1$. Finding local max voltages is implemented in Figure 3.3. The `WriteStorage()` function averages the contents of the `IntensityMap` array and saves that average

```
ant2 = next2;
next2 = analogRead(sensorPin2);
if (ant2 > next2) {
    if (maxVal2 > ant2) {
        ArrayAdd(IntensityMap(maxVal2), 2);
        maxVal2 = 0;
        delay(500);
        if (((sampleNum2 + 1) % 10) == 0) {
            WriteStorage();
            ButtonInterrupt();
        }
    }
} else {
    maxVal2 = next2;
}
```

Figure 3.3: Recording raw session data

to persistent data storage. This happens after a set of 10 maximums corresponding contractions.

Bluetooth Data Transfer

In addition to monitoring NMES device voltages, the embedded device acts as a Bluetooth low energy (BLE) peripheral to the app. Our embedded device uses the nRF8001 Bluetooth chip, and the RBL_RF8001 API. In the startup code, a call to `ble_begin()` initializes the Bluetooth environment and starts sending advertising packets. After this, the device is constantly advertising, and checking the return value of `ble_connected()` for `1`. A `1` return value indicates that the app has connected. When the app connects, the embedded device populates a custom formatted Bluetooth characteristic with the `ble_write_bytes(char * data)`. We use the following format for the characteristic.

```
start end intensity1 intensity2
start end intensity1 intensity2
start end intensity1 intensity2
...
x
```

where `start` is a session start time, `end` is a session end time, `intensity1` and `intensity2` are the calculated intensities for each device channel, and each row represents a session. The `x` delimits the end of the transfer. Finally, the device deletes all successfully transferred session data. All of the Bluetooth transfer code for the embedded device is contained in the `ButtonInterrupt()` function of `Arduino.ino`.

3.2 RehabTracker iOS app

Patients predominantly interact with the system through the iOS app. The app Figure 3.4 allows patients to sync their session data to the database and receive push notifications. The following section describes how the Rehab Tracker iOS app is implemented. The push notification system is described in section 3.4.

3.2.1 Authentication

Patients using Rehab Tracker sign in with a unique ID assigned to them by the study coordinator. Authentication relies only on a patient's username because of the small scale nature of the study. Furthermore, the registration process is done 'manually' with developers creating convoluted strings as patients' unique IDs and adding these to the database. This means the chances of a malicious party determining an ID and

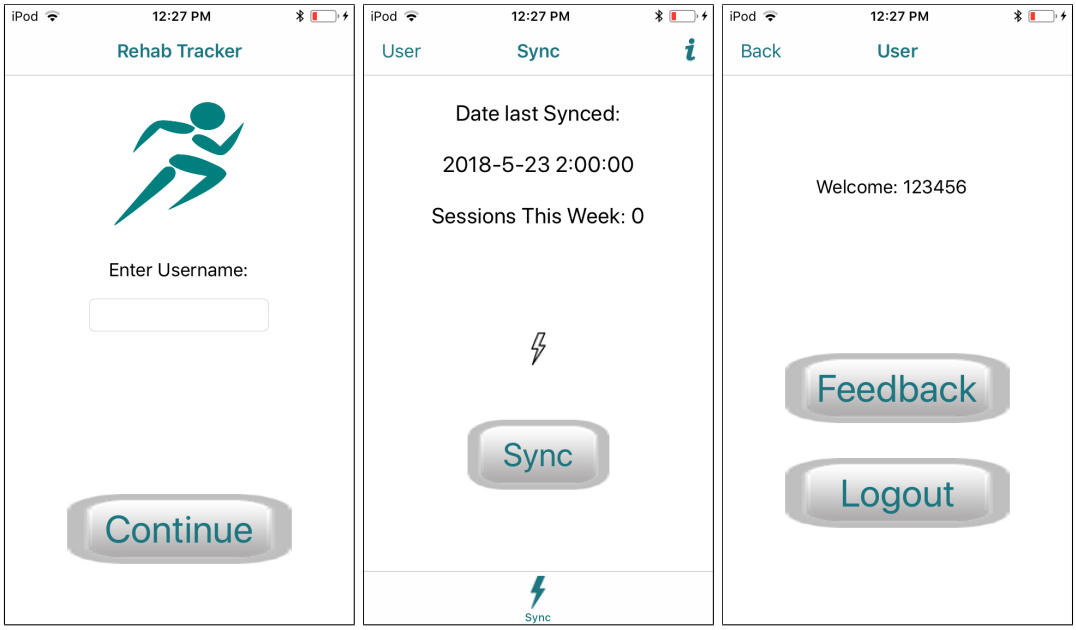

Figure 3.4: RehabTracker App interface

accessing private information is low. On the login page, displayed in the top left of Figure 3.4, the patient enters their ID number and clicks the login button. The app interfaces with the web API here to determine if the user exists in the database. If it does, the UDID of the user's phone is used to register for push notifications, and the sync page loads. When a user's ID has been verified with the database, it is also saved into core data to remember the patient on that device.

3.2.2 Sync Page

The sync page features the date of the most recent sync and a sync button. Figure 3.5 shows the flow of data through the system during the sync process. When a patient presses the sync button, the app pulls all session data from the patients NMES device, processes the data, and uploads it to the database. The code can be found here [32].

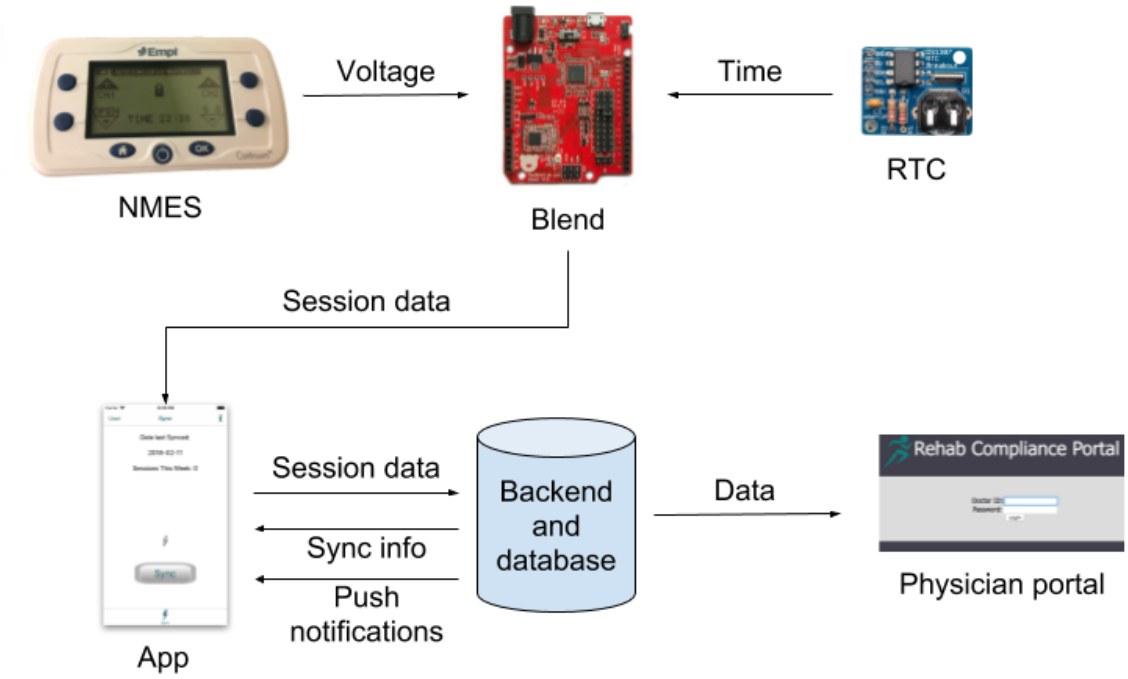

Figure 3.5: Information flow during the Sync process

Pressing the sync button initiates the Bluetooth scanning procedure by calling `centralManagerDidUpdateState(_ central: CBCentralManager)`. This function is part of the `CBCentralManagerDelegate` interface and initiates the pairing procedure. The app attempts to connect to any device named `RT`. A successful connection to the embedded device triggers the device to start populating its characteristic. The app monitors the characteristic and records its data until it receives an `x` alone on a line, or the connection times out after 30 seconds.

If the Bluetooth data transfer is successful, then the app now has a patient's session data in the format described in Figure 3.1.2. Next, the data is parsed into a list of tuples where each tuple contains the data of a single session. All data is processed into NSManagedObjects and saved to core data with the `addData()` function. Saving sessions to core data is not necessary for the system to function,

however it adds security to the system when web services are unavailable. Finally the app retrieves all not yet uploaded sessions from core data, formats them as a JSON object, and posts them to the web API at the `sync.php` endpoint.

3.2.3 About Page

The About page provides the logout button, a link to the feedback form, and some versioning information. The page is accessed by clicking the `User` in the top left of the Sync page. Clicking the feedback button opens Rehab Tracker's feedback form in a browser window. The logout button removes the current users ID from Rehab Tracker's core data and opens the login page. A screenshot of the page is in the bottom left of Figure 3.4. The about page code can be found here [33].

3.3 Physician Portal

The Physician Portal is a web interface for clinicians to view their patients session data and enroll patients for RehabTracker. This interface gives clinicians a quick and easy way to have reliable and up to date information on how their patients are handling NMES therapy. Figure 3.6 displays some screenshots of the Physician Portal

Certain clinicians are considered admins, who are allowed to enroll other clinicians for physician portal use. An enrolled clinician logs in with a username and password they receive from an admin. Once logged in, a clinician has a series of views they may use to view their patient's data. The homepage displays a table of patients who are out of compliance and a table of all patients enrolled under that clinician. This view quickly allows the clinician to make sure that each of their patients are

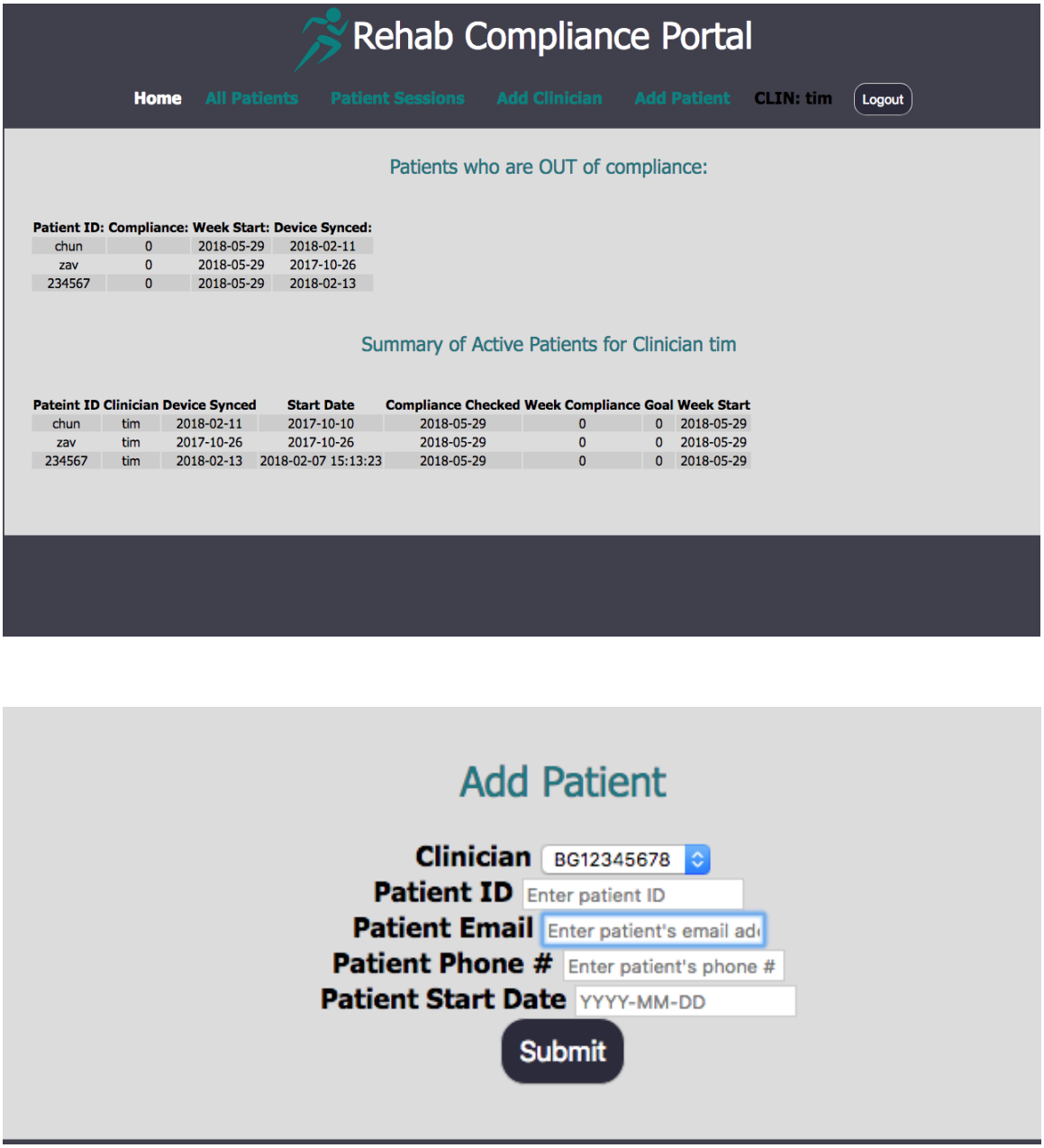

Figure 3.6: Physician Portal interface

performing their NMES sessions properly and easily points out if a patient needs intervention to improve compliance. The other two data views display data for all patients enrolled in RehabTracker, or all the session data associated with a specified patient. Finally, there is a page on the Physician Portal for clinicians to enroll patients in RehabTracker. Once this is done, the patient is able to log into the RehabTracker iOS app. Screen shots of the Physician Portal are shown in Figure 3.6. Furthermore, the code for the Physician Portal here [34].

3.4 Server Architecture

The server architecture refers to Rehab Tracker's web based back end. It includes a SQL Database, an API for use with the iOS app, compliance analysis, and an automated push notification service. All the scripts that operate over the back end are located in the `Restful` folder of our GitHub repository.

3.4.1 Database

We used a MySQL database to store data. As described by Figure 3.7, we used 5 tables to store and relate clinician, patient, session, and push notification data. The patient and clinician tables stores information about these individuals that will remain mostly constant throughout the study. When a patient completes a session, it is added to `tblsession`, and whenever a new push notification is created, it is added to the push table. The notifications table contains the notification content ordered by push notification category.

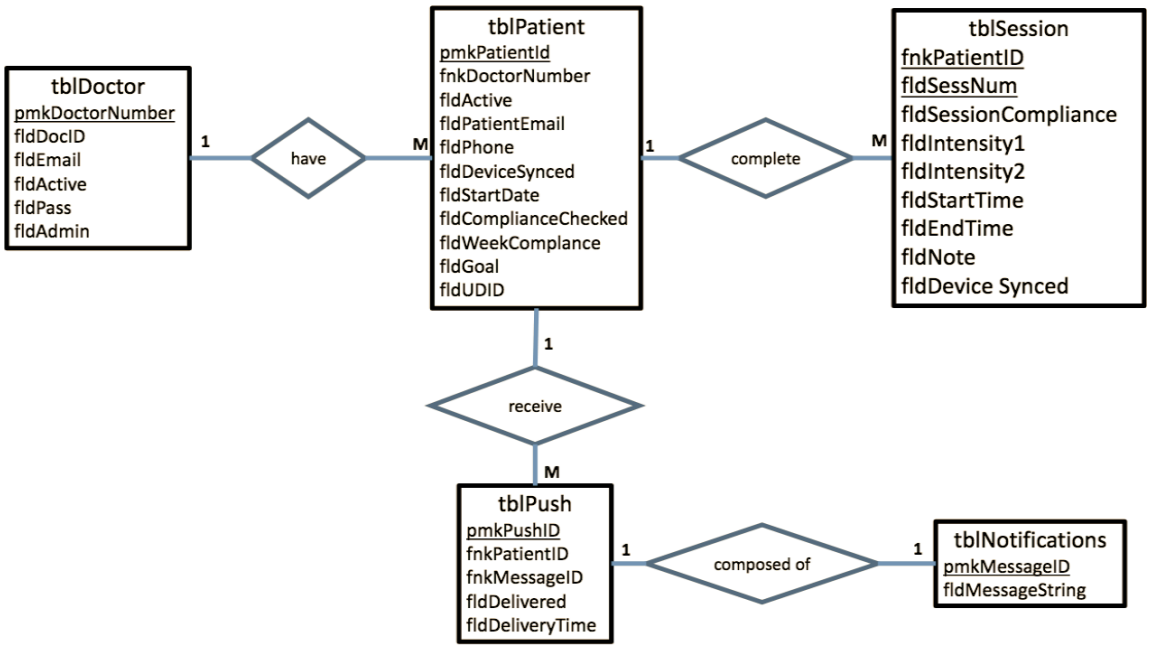

Figure 3.7: Database schema

3.4.2 Restful web API

The RehabTracker iOS app follows a three-tier client-server architecture when interacting with the database. For the middle tier, we implemented a RESTful API in php. Table 3.1 describes the all of the API function signatures. Each get request accepts arguments in the URL of the request and returns a JSON object. Every POST request accepts a JSON object in the request body and returns nothing.

The most robust feature of the API is `sync.php`. When a patient presses the sync button in the iOS app, all session data is transferred through this script to the database. It also creates a push notification for the patient for the patient when they sync, to give immediate positive feedback. Additional features of the web API include sending session data to the stats page of the iOS app and verifying that a

Script Name	**Method**	**Request Format**	**Return Type**
example.php	GET	`pmkPatientID=s`	`{"pmkPatientID":s}`
getDeviceSync.php	GET	`pmkPatientID=s`	`{"sync":d}`
getTargetIntensity.php	GET	`pmkPatientID=s`	`{"fldGoal":i}`
getUserSessionsStats.php	GET	`pmkPatientID=s`	`{"userSessions":[{ "fldSessNum":i, "fldSessionCompliance":f, "fldIntensity1":i, "fldIntensity2":i, "fldStartTime":d, "fldEndTime":d, "fldNote":s, "fldDeviceSynced":d}, ...]}`
restful.php	POST	`{ "pmkPatientID":s, "UDID":s}`	n
sync.php	GET	`pmkPatientID=s`	`{maxUserSessionNumber:i}`
sync.php	POST	`{0 : { "pmkPatientID":s, "fldSessNum":i, "fldSessionCompliance":f, "fldIntensity1":i, "fldIntensity2":i, "fldStartTime":d, "fldEndTime":d, "fldNote":s, "fldDeviceSynced":d}, 1:{...}...}`	n

Table 3.1: Web API function signatures. Actual values are replaced by characters reflecting their types. s = string, d = datetime, f = float, i = int, n = none

```
$sessionDays = array(0);
$sessionDays = array_pad($sessionDays,$dayCount + 1, 0);
foreach($sessionInformation as $session){
    $dayNum = (strtotime($session[1]) - strtotime($weekStart))/86400;
    $sessionDays[$dayNum] = 1;
}
$SessionCount = array_sum($sessionDays);
```

Figure 3.8: Counting session days

user is registered for the app authentication. Code and documentation for the web API are located here [35].

3.4.3 Checking Compliance

RehabTracker automatically checks compliance twice during the week. To implement compliance checking, we used a server scheduled job that runs each morning at 9:00am, and evaluates compliance for patients on days 3 or 7 of their weeks. According to the NMES study, compliance is defined as a one hour long sessions each day, for five days every week. In other words, the patient completes sessions every day and has two rest days.

Each day, the script selects all patients that have not had their compliance checked in the last seven days. Intuitively, this means that if patient starts Rehab Tracker on a Tuesday, then their compliance will be checked every Tuesday. For each of the selected patients, the script selects all sessions they have completed in the last week, and sorts them into seven session arrays representing the seven days of the week. The number of not empty session arrays corresponds with the number of days where a patient completed a session. Patients with five or more session days are considered

compliant, and receive a positive push notification that day congratulating them on a good week. Patients with three or four session days are considered almost compliant, and receive a notification congratulating them but encouraging them to complete the full five sessions each week. Finally, patients with two or fewer session days receives a non-compliance notification. More information on the push notification categories can be found in subsection 3.4.4.

In addition to weekly compliance, the compliance script also analyses patient activity on the third day of each week. If the patient has not completed any sessions by the third day, it sends them a push notification to remind them about NMES therapy. Code and documentation for compliance checking can be found here [36].

3.4.4 Push Notifications

The RehabTracker server uses three components to generate, store, and send Apple Push Notifications to patients using the iOS app. The compliance and API generate push notifications based on user data, the database stores notifications in `tblPush`, and `push.py`.

To generate a push notification, the compliance script and API simply need to add a row to `tblPush` containing a patients ID and the index of a push notification message in `tblNotification`. Messages are stored by category in `tblNotification`, positive sync feedback, compliant, almost compliant, not compliant, reminder. `sync.php` in the API is responsible for generating positive sync feedback notifications as encouragement for patients who do sync sessions to keep doing it. All other types of notifications are generated by `cronDatabaseCompliance.php` as weekly feedback,

or to make sure they have not forgotten about NMES. Within categories, specific message bodies are selected randomly.

In the database, `tblPush` stores patient IDs associated with message indices, and a flag for if the message has been delivered yet. `tblNotifications` stores the message strings, and `tblPatient` stores the UDID (Unique Device Identifier) associated with each patients iOS device. Together these three tables store and relate all the necessary information for sending push notifications.

`push.py` runs hourly to send any notifications in `tblPush` that have not been delivered. When it runs, it queries all undelivered push notifications from `tblPush`, all the message bodies associated with those notifications from `tblNotification`, and the UDIDs of all patients receiving notifications from `tblPatient`. Once it has all this information, it uses the PyAPNs library for sending Apple Push Notifications with Python. First it creates an `APNs` object with our certificate and key files, so Apple can verify that push notifications for Rehab Tracker are being sent by true developers. Next it loads all the notifications into a `frame` object including each message associated with a UDID. Finally, it sends the notifications with the `send_notification_multiple()` function. The `push.py` script can be found here [37].

3.5 Security and HIPAA Compliance

All patient data in Rehab Tracker is anonymous. When a patient is signed up for Rehab Tracker, they receive an anonymous user ID from the clinician with no correlation to their personal information. The patient uses this ID as their Rehab Tracker

username, and all data in the database for that patient is related this ID. Data in the database is anonymous, so it is not protected health information as defined by HIPAA. [38]

The Rehab Tracker app is not on the app store. Instead, clinical trial subjects use Apple's TestFlight platform to download the app. Since this is an invitation only download, it provides an extra layer of security to the trial. The app itself does not use passwords because users log in using their anonymous ID, and it requires a custom NMES device to give it use.

The database, web API, and physician portal are hosted on a HIPAA compliant server. The Database uses REDCap to secure permanent data storage. In order to access the data, one must use the web API or physician portal. Each of these points of access actively limits SQL injection to limit the data one may access. Additionally, the Physician Portal is username and passport protected. These security measures have allowed us to test Rehab Tracker on patients.

Chapter 4

Clinical Trial

A pilot study of Rehab Tracker was used to evaluate the systems functional correctness, usability. The study is part of a larger ACL NMES study at the University of Vermont, and much of this chapter is based on that study's grant proposal.

4.1 Introduction

Traumatic knee injuries lead to muscle atrophy and debilitation for years after injury. [39]. Because current early interventions to reduce atrophy after injury and surgery are marginally effective, we plan to define the benefit of early NMES on muscle size and function. Unfortunately, there are significant limitations of studying NMES at large scale, including variable compliance and inaccurate self reported data [40]. Therefore, there is a need for improvement in NMES data collection systems.

4.1.1 Motivation

A successful implementation of Rehab Tracker would:

Improve patient data accuracy

Patients using Rehab Tracker should have a much greater chance of reporting data accurately. The system forces patients to report data accurately by only creating session data when sessions are completed. Additionally, Rehab Tracker reports session intensities so the data can determine if the patient is receiving proper contractions from the device.

Enhance patient compliance

Patients are given positive feedback whenever they perform an NMES session and upload their data. Moreover, patients are encouraged weekly to maintain or improve their compliance based on automated compliance checking. By increasing positive patient contact, Rehab Tracker strives to enhance patient compliance.

4.2 Methods

4.2.1 Overview

The Rehab Tracker study is part of a larger study at the University of Vermont on NMES in ACLr patient popultations. The parent study is a double blinded, randomized control trial aimed at examining the effects of NMES on ACL patients within three weeks of rupture. The Rehab Tracker study examines the usability and functionality of the cyber-physical system outlined in chapter 3 on a small (n = 5) population.

For app deployment, we use Apple's TestFlight testing platform. Patients are enrolled in the system anonymously as TestFlight beta testers. The clinician creates an anonymous ID string for each patient to use and enrolls them in Rehab Tracker through the Physician Portal. Then, the developer sends a TestFlight invitation to an anonymous patient email account, generated by the clinician. Finally, the patient downloads the TestFlight app and uses their invitation to install Rehab Tracker. Sessions are performed on a modified portable NMES device, and sent through the system as described in chapter 3.

4.2.2 Recruitment

Patients are recruited through the UVMMC Department of Orthopedics and Rehabilitation Sports Medicine Service. For the parent study, we hope to recruit 24 volunteers over 16 mos to complete all 6 month follow-ups within 2 yrs, assuming an attrition rate of 20%. Within the parent study, we hoped to select 4-6 patients from the NMES treatment group to participate in testing Rehab Tracker from March 2018 to May 2018.

4.2.3 Inclusion Criteria

A 50:50 ratio of Male and Female patients were included for having the following criteria:

1. 18-50 years old
2. BMI $< 35 kg/m^2$

3. acute first time ACL rupture

4. Scheduled to undergo a BPTB autograft

Additionally, patients were specifically excluded based on the following criteria:

1. History of knee surgery or non-surgical intervention

2. Abnormal laxity of any other lower extremity besides the injured ACL

3. Signs or symptoms of arthritis, autoimmune or inflammatory disease or diabetes

4. grade IIIb or greater articular cartilage lesions (ICRS criteria)

5. women who are pregnant or plan on being pregnant.

4.2.4 Randomization

Patients will be randomized into NMES or control groups with stratification for age, sex, and injury type. Personnel who analyze tissue outcomes in the parent study are blinded to patient group assignment. Rehab Tracker developers know how many people are using the app at one time, but they do not know personal information about patients in either group.

4.2.5 Intervention

All subjects will perform NMES on the injured leg's quadriceps using a portable NMES device (Empi Continuum), starting 1 week post-injury and continuing until 3 weeks post-surgery, with NMES re-started 48 hrs post-surgery. The injured leg will be immobilized at 40°, with electrodes affixed to the anterior surface of the thigh, as

we have shown that even maximal contraction at this angle produces minimal strain on the healing ACL graft [41]. Symmetrical, biphasic pulses (400 μs duration at 50 Hz) will be used, with a duty cycle of 50% (10 s on, 10 s off) and maximal-tolerated, contractions below pain threshold using patient-selected intensity. NMES sessions will occur 5 d/week, once daily for 60 min per occasion (5 min warm-up, 50 min stimulation, 5 min cool down).

Rehab Tracker

Patients use an NMES device fitted with an embedded device to monitor the output voltage, and determine session time, intensity, and duration for approximately two weeks. This device transfers the session data it tracks to the Rehab Tracker mobile app. Then the app transfers data to our database where clinicians can view their patients data. Finally, patients will receive encouragements and reminders with apple push notification to enhance their compliance. The Rehab Tracker cyber-physical system is described in full in chapter 3.

Control

Patients will perform a microcurrent stimulation device and self report device use and simulation intensity. Self reported data will be verified by the compliance monitoring feature built into the microcurrent stimulation device. This is the control group for the parent study to show the benefits of early onset NMES intervention in an ALCr population.

4.2.6 Outcome Assessment

We would like to assess the following criteria in Rehab Tracker:

Functional correctness

Each feature of the system should work reliably as designed, especially the critical components such as logging in, data transfer, and push notifications. Developers tested the system and its components before beginning the trial, however functional correctness will continue to be evaluated throughout the trial via patient/clinician bug reports, and a mock user. Additionally, bugs will be fixed as they are reported throughout the trial.

Usability

The system should be easy to use for both patients and clinicians. We hope that using Rehab Tracker integrates into a regimen of NMES therapy well requiring minimal additional effort. Patient and clinician submit feedback through our feedback form and weekly phone communication are used to evaluate the usability of Rehab Tracker.

Communication effectiveness

A primary goal of Rehab Tracker is to improve patient compliance through patient-clinician communication. However this is a small pilot study (n = 4), so quantitative testing for improved compliance is planned for a future study. In this trial, we would like to evaluate our communication subjectively through patient feedback and the mock user. Patients, and the mock user will provide their opinions on how

the communications affected their treatment. Collected feedback serves to improve communication methods in a future study.

Parent Study

The larger parent study strives to collect preliminary data about early NMES therapy's effect on ACL rupture patient outcomes. They assess these outcomes through bilateral assessment of muscle fiber and function.

4.3 Results and Discussion

The following section describes information collected from patients during our pilot test. The pilot test took place from March 1st through June 21st 2018. Four patients used Rehab Tracker during this time.

4.3.1 Functional correctness

As a data pipeline, Rehab Tracker functioned without issue for all but one patient. While using Rehab Tracker, patients logged their sessions with the system and on device use compliance sheets. Comparing these two records shows a one to one correspondence between the hand recorded session data and Rehab Tracker data for most of the patients. With the individual who was unable to record any sessions, a hardware or device based bug is suspected. Other patients were using the system properly with the same app version at the same time. Data persistence is the most critical part of Rehab Tracker.

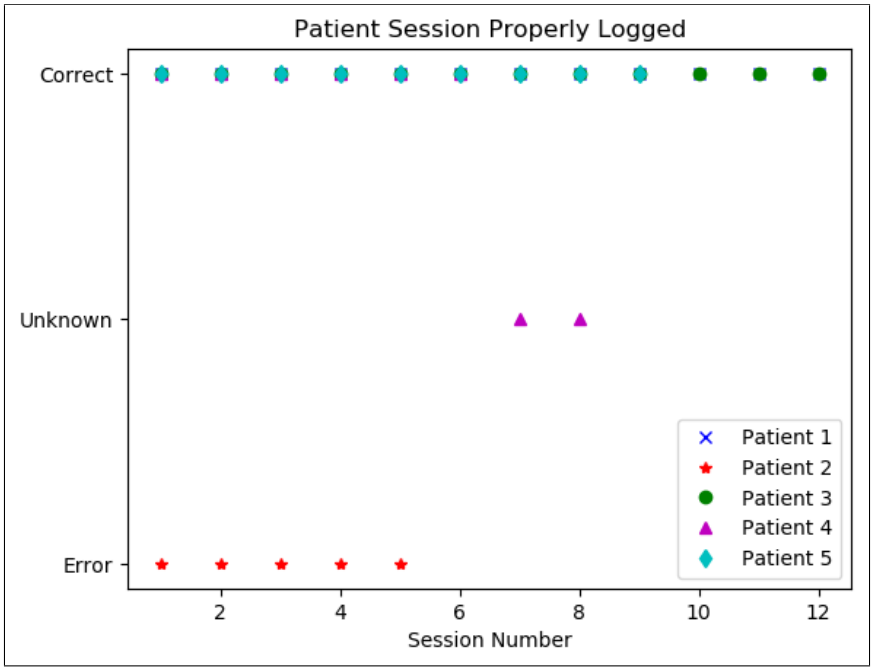

Figure 4.1: Plot of how each patient's sessions were logged in the system. Correct implies that the session is recorded in both the patient logs and the database. Unknown sessions are ones that are not in the database, but the patient log does not sufficiently note which device was used to perform the session. Error sessions are not in the database, but were explicitly attempted to be entered into the system by the patient.

While Rehab Tracker records session data properly, a few technical issues affect the quality of these records. In the study's first version of the app, a bug in the app's authentication logic prevented users from logging in. This issue was fixed days later, but it prevented patients from using the system. Additionally, the patient enrollment and app installation procedure required coordination between developers and study coordinators and several distributed steps. The added complexity of this process also delayed patients' participation in Rehab Tracker.

This pilot test has revealed that peak device voltage is not a useful predictor in session intensity between multiple patients. Within a single patient's database records, the session intensity value correlates well with the self reported patient value.

When a patient is increasing intensity session after session, the trend is reflected by the database intensity value; however, the database intensity values may differ in magnitude from the reported values. Our session data processing mechanism is the same for all patients, and related to the NMES device voltage. The patient is directly included in this circuit, and different patients affect the monitored voltage differently. Therefore, the database intensities are not useful in comparing session intensities between patients.

The NMES embedded device suffered from a hardware bug with it's real-time-clock. In the database, session time was then replaced by the sync time because the bug prohibited the NMES device from recording accurate session times. Using sync time instead of session time for recorded sessions negligibly affects patient or physician use of the system. Physicians are still given a useful view of patient compliance with sync times.

4.3.2 Usability

Patients who used Rehab Tracker were given two NMES devices: the modified Rehab Tracker device, and an unmodified backup device. The frequency that patients used the Rehab Tracker device versus the backup device provides a view of the system's usability. Two of the patients set up Rehab Tracker in a knowledgeable clinician's presence. These two patients were able to use the Rehab Tracker device for the duration of their three week trial period. On the other hand, the two patients who set up Rehab Tracker independently had significant difficulties. Both patients did successfully use the system for a brief period of time, but both stopped. One of these patients simply had their device run out of batteries, so they switched to the backup

device rather than replace the batteries. The other patient had extended difficulties with the sync procedure, and reverted to the backup device. Both patients present usability concerns for the system. In future modified NMES devices, we intend use a battery compartment that does not require a screwdriver to access. The second patient's problems primarily stemmed from issues with our enrollment process. This reduced their confidence that the app was working properly while syncing. In the future, an easier patient enrollment scheme should address this patient's issues.

Because most patients were able to successfully sync data to the database, the system appears usable, but not without possible improvements. In this trial, it appears that the enrollment process was convoluted and difficult for patients to do independently. Rehab Tracker is not available on the App Store, so patients must enroll through the apple beta testing program TestFlight. This process is much more involved than downloading a traditional IOS app. Furthermore, we received feedback from a patient that a working sync did not provide enough confidence in the systems correctness. That patient felt uneasy about their use of the system. Patients also reported a discrepancy between perceived intensity on the modified device and the backup device when using each device set at the same intensity. The backup device felt stronger than modified device, but the modified device is still usable by setting it to a higher intensity setting.

4.3.3 Parent study results

At the time of this writing, the parent study has not finished collecting results.

Chapter 5

Communication Methodologies

Rehab Tracker uses a hybrid communication protocol between patients and clinicians. Hybrid communication uses both automated push notifications and personal contact between patient and clinician. Communication with the patient happens during traditional weekly phone calls with their clinician, and through the automated push notifications. The Physician Portal also enables better clinician-patient interactions by allowing clinicians to view patient data in near real time.

Our protocol uses automated communication via push notifications. Unlike other methods of patient communication, push notifications and text messaging methodologies have little theoretical basis. Communication protocols of this nature are most mature in smoking and weight loss applications [42]. These applications often base their interventions on Social Cognitive theory, however most other mobile adherence interventions seldom apply theory. SMS and push notifications are some of the first communication media where theory must apply both to message content and timing, adding significantly to the complexity of a prospective theory [42].

A significant portion of telecommunication work has been developed and published directly in smartphone app marketplaces without the backing of academic research. Such apps may have been reviewed or developed with the help of an expert, however their methodologies lack clinical trials to prove their effectiveness [43]. These findings demonstrate a need for communications research in automated SMS and push notification adherence protocols, a potential future application for Rehab Tracker.

For the purposes of this study, we developed a protocol based on a belief in the effectiveness of positive reinforcement, and refined this protocol through alpha testing in the development team. Our protocol is explained below.

5.1 Push Notifications

For frequent patient communications, Rehab Tracker employs automated push notifications. We strive for a notification method where patients are reminded and encouraged to complete NMES sessions frequently, but not so much that non compliant patients begin to ignore the deluge of notifications. The strategy we employ has been developed though our own testing with Dr. Skalka as a mock patient, and consultation with Dr. Jean Harvey, Professor and Chair, Department of Nutrition and Food Sciences, who is a collaborator on this on-going project with Drs. Toth and Skalka. Her background includes extensive work in the utility of on-line weight loss programs and compliance monitoring. Therefore, our method was not developed through strict scientific methods. Scientifically determining an effective communication strategy is a potential area of future work described in chapter 6.

There are three different events that can occur for a push notification to be sent: a completed session, the patient's week starting with no sessions, and the end of the week. For each event, there are several different message bodies that could be sent. These are chosen at random each time the event occurs for each patient. Notification bodies are displayed in tables at the bottom of each of the following subsections. The index column represents the notification's index in `tblNotifications` in the database.

5.1.1 Completed Session

After a patient syncs session data with the system, they receive a positive reinforcement notification from the system. These notifications are intended to encourage patients to complete sessions and sync their data. Because patients should be completing five sessions every week, these notifications are the most frequent type of notification. Therefore, we have created the largest number of message bodies for completed session notifications. These messages are displayed in Table 5.1.

5.1.2 No Session Week Start

Since patient compliance is defined as completing one session a day for five days of a week, we know a patient is not compliant after three days without completing a session. This three day latency creates a problem for sending patients meaningful and appropriate reminders. We believe sending patients reminders each day that they have not completed a session would become an annoyance to patients who are still compliant, and cause them to ignore the notifications. Conversely, sending patients

Index	Notification Body
1	By completing your NMES session, you are preventing your muscles from shrinking and getting weaker.
2	Good job completing your NMES session!
3	Completing your NMES sessions is like putting money in the bank. It will pay off in larger, stronger muscles so you can get back to your activities faster.
4	The 60 min you just spent doing NMES on your leg is keeping your muscles strong.
5	The Research Team says "congrats" for finishing your NMES session.
6	By completing your NMES session, you are being proactive in preventing muscle loss and maintaining your muscle strength.
8	NMES is FDA approved to help your muscles after injury and surgery. Keep up the good work!
9	Keep up the good work on your NMES sessions!
10	Each NMES session that you complete is another step closer to getting you back on your feet.
11	Nice work on the NMES session. Contact the research team if you have any questions.
12	Nice to see that you're using up electrode pads on those NMES sessions. Contact the research team if you need more or have any questions.
13	We like to see the batteries of your NMES device drain like that! Good work finishing your session.
14	Great job finishing your NMES session!
15	Another NMES session completed. You're helping your muscles stay strong!
16	Doing NMES now is like starting the rehab on your muscles early. Good work!
17	The discipline you're showing in completing your NMES sessions will pay off in helping you maintain your muscle size and function.
18	We realize how hard it is to work the NMES sessions into your busy schedule. Great job!
19	Nice work using your NMES today. Were you able to achieve a full muscle contraction?
20	Way to go! You're on the right track! Keep it up!
21	You completed your NMES session! Congratulations! Be proud of yourself!

Table 5.1: Post-session notifications

reminders only at the end of the week to alert them of their noncompliance would make it easy for patients to forget about their NMES therapy during the week.

To strike a balance in reminding patients of their noncompliance midweek, we send a notification to patients who are beginning their week non compliant. If a patient begins their week with three consecutive days without syncing a session, then we send them the notification in Table 5.2 as a reminder inquiring if they are having any problems.

Index	Notification Body
43	We noticed you have not completed an NMES session in the last 3 days. Is there a problem? Can we help? Give us a call.

Table 5.2: Midweek noncompliance notification

5.1.3 Weekly Compliance

At the end of a patient's week, they receive a notification reporting their compliance for the week to them. We have created three subcategories for patient compliance notifications: compliant, almost compliant, and non compliant. This stratification makes sure that patients who are completing some but not all of the required sessions each week get both congratulated for the work they have done during the week, but also nudged to improve the next week. More information on how Rehab Tracker determines patient compliance can be found in subsection 3.4.3 and Figure 3.8

Compliant patients, who complete sessions on five days each week, receive any one of the notifications in Table 5.3 at the end of their week. They are intended to be positive and encouraging. Patients who complete between three and four sessions during a week receive almost or semi compliant notifications. These are intended to provide positive reinforcement to the patient for the hard work that they do, but to also make sure that they know they have the support of their physician and research team to help them be compliant if need be. By separating non compliant messages into two categories for patients who complete a different number of sessions, we deliver more targeted messages that ideally reach the patient more effectively. Semi compliant messages are displayed in Table 5.4.

Finally, patients who complete fewer than three sessions in a week are sent a non compliant notification. These messages strive not to provide negative reinforcement,

Index	Notification Body
22	Fantastic week! You met your goal for NMES sessions. Keep up the good work!
23	Nice work completing your NMES sessions for this week! Don't hesitate to call the research staff if you need anything or have any Qs.
24	You met your goal of 5 NMES sessions for the week. Great job putting in the hard work to help maintain your muscle size and strength!
25	Tremendous effort on completing your NMES sessions this week! You met your goal. Let us know if you have any Qs or we can help you with anything.
26	Successful completion of your NMES sessions this last week! The time you're putting in now will pay off in the long-term.
27	Way to go completing your e-stim sessions this week! Keep up the good work.
28	A+ on meeting your NMES prescription this week!
29	Great effort this week on completing all of your e-stim sessions!
30	You're doing awesome at achieving your rehab goals! Keep up the great work!
31	We know it's not always easy finding the extra time in your day but, YOU DID IT!! You completed your NMES sessions for the week!
32	Awesome job completing your NMES sessions this week! We like your consistency. Keep it up!
33	Congratulations! You just achieved your weekly goal of 5 NMES sessions per week!

Table 5.3: Weekly notification for compliance

but ask the patient for a reason why they didn't do an adequate number of sessions that week. These messages are displayed in Table 5.5.

5.2 Phone Calls

Each week, the patients have a phone call with the clinician to talk about how they are progressing with the treatment and address any possible issues they may have. This is standard for all patients in the NMES study regardless of their treatment plan, NMES, Rehab Tracker, or placebo.

Index	Notification Body
38	Congrats on completing 3 of your NMES sessions last week. We hope to get you up to 5 sessions per week. Is there anything we can do to help you meet that goal next week?
39	Rehab from an injury is tough. We're here to help. Let us know if there's anything we can do to help you sync 5 sessions of NMES per week.
40	We would like to see you complete 5 NMES sessions per week. You did great last week, but didn't quite sync 5 sessions. Is there anything we can do to help?
41	Stellar week of NMES! Keep up the great work and don't hesitate to contact us if there are any Qs.
42	Nice job completing 4 NMES sessions this week. We know it's hard work rehabbing from an injury like this. Is there anything we can do to help you get to 5 sessions?

Table 5.4: Weekly notification for semi compliance

Index	Notification Body
34	We noticed that you didn't sync the prescribed 5 sessions this last week. If there is a problem with the NMES unit or you need any help, please call the research staff. We're here to help.
35	Are you having problems with the NMES device or pads? We noticed you didn't sync 5 sessions this week. Call us if there's anything we can do to help.
36	We realize it's tough to fit the NMES sessions into your busy schedule. Can we help you to get to that 5 sessions per week goal?
37	Tough week? We saw that you did not sync 5 sessions of NMES. Let us know if there's anything we can do to help.

Table 5.5: Weekly notification for noncompliance

Chapter 6

Future Work

The work presented in this thesis was performed with next steps in mind. While the clinical trial tested Rehab Tracker's functional correctness, it's effect on patient outcomes is still not verified. Therefore, we would like to study Rehab Tracker in a much larger (n = 100s) randomized control trial with the intent of studying it's effects on patient compliance, patient physician interaction, and overall patient outcomes. Since the system will have more users in such a trial, some technical improvements are necessary to address scalability.

6.1 Large Scale Study

The proposed study would be a multi-site randomized control trial with the aim of evaluating patient outcomes with NMES and NMES supplemented with Rehab Tracker compared to a placebo control. This would develop statistically significant results about Rehab Tracker's correctness. This large scale study is also a future goal of Rehab Tracker's parent study.

Testing Functional Correctness

The clinical trial in this thesis did not test functional correctness against a formal definition, rather it was treated like a beta test. In a future study, functional correctness would be defined with more rigor before patient use, allowing a clear, unambiguous conclusion of the system's function. Our definition would include emphasis on more components of the system such as push notification received, proper compliance analysis, and the quality of the session data.

Augmented Patient Assessment

A larger trial would allow researchers to build stronger conclusions about Rehab Tracker's usability through patient surveys and assessments. A more formal evaluation or survey of the app conducted by each patient after the trial period would create valuable feedback for developers, as well as generate the necessary data to evaluate a usability hypothesis. Such a hypothesis could address patients' confidence in the app, how much difficulty the system adds to an NMES therapy regimen, or how beneficial the notifications are at improving compliance.

6.2 Technical Improvements

The following are ways to improve Rehab Tracker's scalability and utility for such a large study:

NMES Device

As the source of all session data, the NMES device is responsible for the most critical data processing in the system. During the trial, sessions were often recorded with inaccurate session times, and inaccurate intensities. These issues begin at the NMES device, and fixing them will be essential for large scale use.

User ID Dissemination

System use at scale would make ID dissemination manually by hand unfeasible. Additionally, patient enrollment and managing the ID dissemination was difficult for the clinicians and patients during this small study. In order to preserve researcher anonymity and address these enrollment issues,a future iteration of Rehab Tracker could work with a separate patient enrollment system. Such as system would create user IDs, communicate them to the patient and the clinician, enroll the patient in Rehab Tracker, and invite the patient to download the app. A separate system is necessary to keep the database anonymous and guarantee that researchers would not break the study blind.

Authentication

Both clinician and patient authentication will be encrypted and require passwords. Since Rehab Tracker will have far more exposure to attacks as a public app on the app store, this is a requirement. A password reset system will also be implemented instead requiring users to contact the developers.

Data Visualization

Patients and physicians will have access to bar charts of session intensity and compliance over time. Work on data visualization in the IOS app can be found here [44]. A similar visualization tool will be implemented on the Physician Portal to give clinicians an easy way to track patients' progress.

App Store Release

To accommodate significantly larger numbers of people working with Rehab Tracker at one time, the app will be released onto the App Store publicly for patients to download themselves. Furthermore, we may port Rehab Tracker to Android and the Google Play Store to our recruitment pool.

Chapter 7

Conclusion

The Rehab Tracker cyber-physical system for NMES compliance is functionally correct, and has the potential to improve patient outcomes in NMES therapy programs. Additionally, the system provides a reliable mechanism for physicians to collect data on home-based NMES interventions. This gives Rehab Tracker the potential to be a tool in studying the efficacy of different communication methodologies on improving patient compliance.

The system involves 4 components: a modified NMES device, an iOS app for patients, the server and database, and the physician portal web site. These components allow patients to efficiently and non-invasively send their NMES data to their physicians. Moreover, it strives to improve patient compliance with automatic adherence reminders. The combination of improved patient compliance and reliable data has the potential to make NMES a more effective at home therapy for orthopedic injuries.

Clinical trial results indicate that Rehab Tracker is usable and functionally correct. 4 of the 5 patients who used the system was able to perform an NMES session and log it with the system as designed. Most of the complications encountered during the

clinical trial were due to our enrollment process. In order test the ultimate research goal of improving patient compliance with a cyber-physical system, Rehab Tracker will need to be subjected to a much larger study. This preliminary trial indicates that the system is worthy of a larger study.

The field of medical cyber-physical systems is largely unexplored and full of potential future work. The concept of a cyber-physical system for improved patient compliance could be applied to a number of different areas. This is already being explored in general purpose healthcare [45], diabetes management [19], and for pill based therapies [18].

Cyber-physical systems are not without limits. While text messaging health interventions have some low quality positive results [27], interventions including both in-person and automated communications yield significantly better results [46]. This indicates that physician interaction will continue to be essential for positive patient outcomes. Even so, systems like Rehab Tracker have the potential to work with physicians to improve patient outcomes.

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