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The CTAR All-Star

Project Part I: Revised Concept & Project Management

Team #03

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February 8, 2019

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Abstract

The CTAR All-Star will consist of a rubber ball containing a pressure sensor and bluetooth transmitter paired with a cross-platform mobile application. The device will be used as a rehabilitation tool for people with dysphagia in a similar fashion to the traditional CTAR exercise by squeezing the ball between the chin and upper chest. The mobile device will display a real time graph showing the pressure inside the ball. The patient will be able to follow exercise routines set by medical professionals. The application will be designed to be easily modified for other rehabilitation exercises that involve pressure. This paper summarizes the revised concept and project management process for the CTAR All-Star.

Project Description

Main Goals

Dysphagia is a condition which makes it difficult or painful to swallow and is common in stroke victims and the elderly. The CTAR All-Star is intended to be used with the Chin Tuck Against Resistance (CTAR) exercise. This is a therapy exercise that strengthens the suprahyoid muscles in the neck which helps improve the symptoms of Dysphagia. The CTAR is performed by squeezing an inflatable ball between the chin and chest using either the muscles in the neck or by opening the jaw.

The CTAR All-Star will have an embedded sensor that will transmit the pressure in the ball at regular intervals. The mobile app will plot the data in real time on a mobile device. The visual feedback will allow patients to work harder at their rehabilitation and will also allow patients and medical professionals to graphically see the patient's progress over time.

Intended Users

The intended users of this product are the patients undergoing rehabilitation, however, the medical professionals who help with patient rehabilitation make up the bulk of the target market. The CTAR All-Star will benefit the intended users by speeding up and organizing the rehabilitation process. The public interest for this product will be to help the people suffering from dysphagia as well as relieving the burden on relatives and friends associated with caring for individuals with dysphagia.

Main Functionalities and Capabilities

The main functionalities that will be developed for the CTAR All-Star are the ball with imbedded microcontroller, pressure sensor, and bluetooth transmitter. The application will contain a user login, the ability to easily connect to the bluetooth device, a page for displaying the graph of the ball pressure, a page for the medical professional to create an exercise routine for the patient, and a way to store and retrieve the data from past exercises for reviewing patient progress.

Technologies

The mobile application will be built using the Xamarin.Forms framework in the Microsoft Visual Studio IDE. All of the code will be written using a combination of C# and XAML, the Plugin.BLE package will be utilized for management of bluetooth 4.0 connections, the Syncfusion plugin will be utilized for plotting the ball pressure, and the mobile app will be built for use on both iOS and Android devices.

Hardware

The team currently has a hardware prototype consisting of an Arduino Uno, HM-10 bluetooth transmitter, and a potentiometer used for transmitting digital numbers via bluetooth. This is a stand-in for the actual pressure sensor. The knob on the potentiometer can be turned to adjust the resistance and the arduino converts this analog signal into a ten bit digital number between 0 and 1023 and transmits this reading via Bluetooth 4.0 every 50ms. The final refined version of this device will likely be built by an Electrical Engineering team.

Dependability

The CTAR All-Star needs to be reliable because both the medical professionals and patients are relying on it. The CTAR All-Star is not only providing a patients' workout, but it is storing the progress of these workout over time. To ensure that this project is reliable good coding practices, testing and debugging will be done throughout the process.

For security of the user, and to stay compliant with HIPAA constraints, an EMR number will be used in place of their name and any other private information. A login screen when first accessing the application will prompt the user for their EMR number and password.

Currently there are not any safety concerns associated with the CTAR All-Star.

Significance

Worthwhile

The development of this device was requested by Kristine Galek from the Department of Speech Pathology and Audiology who believes that this will be

useful in her field. Practicing the traditional version of this exercise does not allow tracking of progress and therefore medical professionals and patients have to make subjective guesses about the type of progress they are making. This device would provide objective data which shows their improvement over time.

Professional Growth

This project will give us real world experience in software development for mobile devices as well as some hardware experience. We will organize our project using a software process model used in industry. We will gain experience working on a team of developers and improve our communication skills. We will work with a client and integrate changes as required to meet the real needs of the user. All of these are skills that will help us in our future careers.

Innovation

We have a competitive advantage over many of the current devices on the market. From our research, we found that all of the competing products are very primitive in design and do not have any way of objectively tracking user improvement or strength. There are currently no products on the market with the same level of technology as this device. Medical professionals need a device that will provide measurements in order to track patient progress.

Similar Applications

The PhagiaFlex is a similar device that targets the suprahyoid muscles underneath the chin (PhagiaFlex, website). While this device has a similar objective, it is primitive compared to the CTAR All-Star. This device fits under the chin and is held with the user's hands or a table, depending on the model. It is designed to give resistance to the user so that the muscles can be rebuilt

over time. The PhagiaFlex is a device that is targeting the same market as the CTAR All-Star. While the PhagiaFlex is a solution that strengthens the suprahyoid muscles, it is lacking real time data and statistics.

The AliMed Theraball is another device designed to strengthen the suprahyoid muscles (AliMed, website). This device's website targets elderly patients but this device can be used by anyone rehabilitating these muscles. The AliMed Theraball is also lacking any type of technology or data feedback. The CTAR All-Star will provide real time data as well as store the user's progress over time.

The IOPI PRO is a device used in alternative rehabilitation for Dysphagia that involve oral motor exercise programs. The Iowa Oral Performance Instrument objectively measures lip and tongue strength (IOPI, website). The IOPI system compares patient data with norms, sets exercise parameters and documents patient improvement. The CTAR All-Star will provide similar functions for the CTAR exercises. It will also provide a more user interactive and interesting display, a weak point with the IOPI that Dr. Galek mentioned.

Potential

Dysphagia is estimated to affect roughly 9 million adults of which approximately 37% are diagnosed with dysphagia in the US according to the Harvard Medical School Department of Otology & Laryngology. Therefore we estimate the number of people undergoing medical treatment for dysphasia to be around 3.3 million people per year. The upper limit for the number of units that could be sold in a year is close to 3 million conservatively.

Further Development

In the future, this software could be modified to be used with any other device that transmits bluetooth data. Although aimed at medical rehabilitation

exercises, it may also be useful in other fields. This specific project could also integrate a game to make rehabilitation exercises more fun and interactive.

Legal and Ethical Aspects

Potential Legal Issues or Challenges

The CTAR All-Star project is currently using Syncfusion for its real time graph. Unfortunately this software costs \$3995 for the 3 developer pack, which is out of this project's budget. An unlimited free trial is currently being used with the drawback of a pop up that has to be accepted when the user first accesses the graph. This workaround does not hinder the actual usage of the application, however it does take away from the goal of a polished and refined application.

Plans To Meet Professional Standards

As mentioned previously, The free trial issue with the graph may cause the application to feel less polished. This is a discussion that can be revisited with the client, Dr. Galek, as the project progresses. The team will provide a product that fits both the client's needs and budget.

To ensure the project meets the highest professional standards the team will use good coding practices. Additionally, the team will be transparent and realistic with the client. That way the client knows exactly what to expect and are aware of any issues that may arise. With integrity and good communication the team should have no issues meeting professional standards.

Changes and Progress

Progress

Our project has several major components working, as well as the overall framework that consists of a hamburger navigation menu and individual pages for different aspects of the application. We have a working database, animated graph, and bluetooth interface.

Major Changes

One major change that was recommended by our advisor is to keep the databases locally for now. He thought trying to create a web/server database along with all the necessary APIs would just be too much for us given our limited time.

Additionally, to appeal to a wider audience, we have decided to attempt to make our application robust and versatile enough that it can be used in the future for many different types of rehabilitation exercises.

Major Accomplishments

We have a working SQLite database that is stored locally. The database contains tables for users, patients, exercises, and pressure measurements. These are currently used in our bluetooth/graph interaction, the patient management page that the doctors will see and the initial login page for our application.

Another major working component is the graphing capability. The graph page is designed to refresh each time a new pressure measurement is added to the database. It will produce an animated line graph that the patient can look at

while performing the exercise. It has a goal line and will eventually have a timer.

The bluetooth interface is also coming along nicely. We developed an Arduino prototype to use in testing that reads an analog value from a potentiometer and converts this reading to a digital value between 0 and 1023. The HM-10 bluetooth module transmits the integer values at 50 ms intervals. The application has functionality for scanning, connecting, and receiving updates from the bluetooth device using the Plugin.BLE api.

Project Responsibilities

Security

The security subsystem will consist of a login page that consists of a username and password. We hope to integrate a fingerprint enabled login if time permits. Each user will be assigned a role, either Doctor or Patient. These roles will be used to determine what the user sees and the functions they have access to. For example, a doctor will have a list of patients and be able to assign exercises to each patient. This system will be Andrew's responsibility.

Communication

The communication subsystem will include any interface with the bluetooth device(s). It will use an Arduino device to transmit simulated data for testing. The client side of this system will use the Plugin.BLE api for Xamarin.Forms to scan, connect, and receive data from the device. This system will be Austin's responsibility.

Database Manager

The database manager subsystem will include any interface with the database. It will have a helper class to contain all the functions needed to interact with the tables stored in the database. It will also utilize the messaging center in Xamarin to update the viewmodels and ensure each page always presents the most current data. This system will be Terri's responsibility.

Patient Interface

The patient interface subsystem will include any components that the patient will interact with, such as an exercise management page, a history page, and a settings page. The patient will need to be able to pick an exercise, setup the necessary fields such as the 1 Rep Max, and perform that exercise. This system will also include a training mode if time permits. This system will be Austin's responsibility.

Doctor Interface

The doctor interface subsystem will include any components that the doctor will interact with, such as a patient management page, a create exercise page, and a patient history page. The doctor will need to be able to create and assign an exercise to their patients. They will also need to maintain their patients and monitor their progress. This system will be Terri's responsibility.

Project Monitoring and Risks

Monitoring Progress

To ensure our project is completed on time we intend to set goals and have weekly meetings to address our progress. We will break down everything that needs to be done and give each item an importance ranking.

Risks & Mitigation Strategies

Risk 1: Not Impressing Customer

Our customer really wants a game. We know there probably isn't going to be enough time. Our plan to mitigate this risk is to try to add some sort of animation that will make the patient interaction more interesting.

Risk 2: Graph Inefficiency

The graph has not been properly tested yet. We are unsure if it will be able to keep up with rate of our data stream. We plan to mitigate this by doing proper testing, restructuring our architecture, and slowing down our data stream if needed. We will also explore other graphing or animation options.

Risk 3: No EE Team To Build Hardware

There is a chance that there will be no Electrical Engineering team to build a refined CTAR All-Star ball in which case we will build a minimum viable functioning prototype that will involve very little time using a pressure sensor and some kind of inexpensive rubber ball toy.

Risk 4: Not Compatible with Apple Devices

We have not been able to test our application on an Apple device. While we have written our code with cross-platform compatibility in mind, we can't be sure it is working properly. To mitigate these doubts, we will get a testable device working.

Risk 5: Not Finishing On Time

Not finishing application by innovation day is a possible risk. Our mitigation plans will be to organize and prioritize our goals and features. We will have weekly planning meetings to stay organized and on top of our deadlines. We will also ask each other for help when we get stuck on our tasks.

Risk 6: HIPAA Privacy Violation

Maintaining security and privacy is important for HIPPA regulations. We must never identify our patients by name. To mitigate this risk, we will restrict what a user can type into our manual entry fields. The field for the EMR number that identifies the patient will only allow numerical entries.

Risk 7: Lose A Team Member

If a team member cannot work on the portion of the project for which they are responsible, the responsibility will fall on the remaining team members. Each team member will make an effort to learn about the other team members portions of the project so that knowledge of each specific component is not restricted to only one person.

Risk 8: Structure Concerns

Our team is somewhat overwhelmed with the amount of knowledge required for good coding practice using C# and Xamarin and how to use the MVVM pattern for our architecture. Getting help from someone more experienced in the field

of app development using Xamarin would be extremely helpful to give us a bit of a boost moving forward.

Risk Register

Risk Register											
Risk Id	Risks	Current Risk			Status	Owner	Raised	Mitigation Strategies	Residual Risk		
		Likelihood	Impact	Severity					Likelihood	Impact	Severity
R1	Not impressing customer	6	6	36	Open	All	7-Feb	Try to implement some sort of animation if a game is not possible	4	6	24
R2	Graph inefficiency	5	7	35	Open	Terri, Austin	7-Feb	Better architecture, slower data stream rate, explore other graphing or animation options	4	3	12
R3	No EE team to build our hardware	8	4	32	Open	Austin	7-Feb	Build our own prototype to demonstrate our application	8	1	8
R4	Not compatible with Apple devices	4	8	32	Open	Andrew	7-Feb	Get a testable device working	1	8	8
R5	Not finishing on time	2	10	20	Open	All	7-Feb	Goal organization, Prioritize functionalities, weekly meetings, asking each other for help	1	5	5
R6	HIPPA privacy violation	2	9	18	Open	Terri	7-Feb	Restrict user inputs to ensure no names are used	1	9	9
R7	Lose a team member	3	4	12	Open	All	7-Feb	Work more hours, learn other peoples parts, work from home when sick	3	2	6
R8	Structure concerns	4	3	12	Open	All	7-Feb	Get help from someone more experienced, do more research and reading	2	2	4

For this graph, we used a scale of 1 to 10 for the likelihood and impact of the risks, 1 being the lowest, 10 being the highest.

Contributions of Team Members

Terri Heglar

Terri contributed 5.5 hours to this paper. She worked on the Significance, Changes and Progress, and Project Responsibilities section. She took part in the Project Monitoring and Risks section and the Contributions Section. She

also made the Risk Register Chart with input help from the team. She also helped finalizing the paper.

Austin Yount

Austin contributed 5.5 hours to this paper. He worked on the Abstract and Project Description. Additionally, Austin contributed to the Major Accomplishments, Project Responsibilities, and the Risk Register sections. Lastly, he worked on final review, formatting, and editing.

Andrew Penrose

Andrew contributed 5.5 hours to this paper. He wrote the Legal and Ethical Aspects portion. Andrew also contributed to the project description and Risks and Mitigation Strategies. Andrew then helped review and finalize the paper.

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