TheraKit: A portable multi-device kit for in home neuromuscular therapy with a telemedicine approach.

Problem Statement/Research Question and Background

According to the World Health Organization (WHO) about 15% of the world's population have some form of disability. [1], The types of barriers that people with disabilities encounter are also mentioned: 1) Prohibitive costs, which involves the affordability of health services and transportation, 2) Limited availability of services, 3) Physical barriers, for example uneven access to buildings, inaccessible medical equipment or parking areas, etc…, and 4) Inadequate skills and knowledge of health workers.

According to the World Confederation of Physical Therapy [2], physical therapy provides services to individuals and populations to develop, maintain and restore maximum movement and functional ability throughout the lifespan. This includes providing services in circumstances where movement and function are threatened by ageing, injury, pain, diseases, disorders, conditions or environmental factors.

Employment of physical therapists is projected to grow 34 percent from 2014 to 2024 according to the bureau of labor statistics [3]. Demand for physical therapy services will come from the aging baby boomers, who are staying active later in life. In addition, physical therapists will be needed to treat people with mobility issues.

If the employment demand for physical therapists is not addressed, a different approach besides active health workers is needed. This approach also should consider costs of treatment and transportation, availability of services and physical barriers as mentioned before. Also the approach should consider that a health worker may not be present.

Methods/Approach/Solutions Considered

Our first approach to help patients and therapists improve the efficiency of treatment regimes by overcoming distance and transportation related difficulties was heavily inspired on our previous experience working with EMG to provide tangible feedback about the effectiveness of a given therapy when no physical response was still evident. Because of this, we considered developing a modular EMG-based rehabilitation band. This band would be configurable with different EMG and force measuring modules in a way that the therapist could easily prepare a personalized band for each patient, who could afterwards perform his or her exercises at home and, aided by the band's measurements, the therapist could remotely follow the patient's progress and provide feedback if needed.

However, this first approach was discarded after we visited "Centro de Rehabilitación Sigue" (Sigue Rehabilitation Centre). There we spoke with the centre's founders and most experienced therapists. We asked them about the most common causes a patient misses his or her

appointments and if they considered distance to be an obstacle for some patients. They told us that distance and transportation had been an obstacle that some of their former patients had encountered, however they also told us that even when transportation was not an issue, home-based therapy could be a life-changing solution for many patients experiencing chronic pain due to varied injuries. Inquiring deeper into these comments we found that for most patients the ideal home-based device should provide pain relief that would consequently improve the effectiveness of a simple exercise set. Furthermore, it would be very beneficial if the therapist could remotely adjust the device's parameters to better fit the patient's evolving needs and if the device could provide some basic information to the therapist regarding the patient's performance and habits. In this way, the patient-therapist relation could go well beyond the traditional boundaries of face-to-face appointments, to improve the patient's recovery and overall life quality.

Description of Final Approach and Design

Based on the feedback received from the therapists, we outlined the basic functionalities that our device had to offer to offer a truly meaningful impact. The device should be able to provide heat treatment, transcutaneous electric nerve stimulation (TENS) and record electromyographic activity. Besides, the treatment profile should be remotely controllable, to enable the therapist to make any necessary adjustments in between physical appointments. As a result, our design is focused on achieving the four aforementioned requirements in seamless experience for the user. This was done by developing five distinct, but interrelated elements: a EMG sensor, a TENS, a heating pad, a control and communications hub, and a mobile application for the therapist.

The EMG was built based on a common bioinstrumentation structure, comprised of amplification, electrical isolation (for safety) and filtering. The gain implemented for the circuit was of 100, done using an instrumentation amplifier (AD620). The relevant signal was extracted using a bandpass filter with cutoff frequencies of 0.5 Hz and 1 kHz. Finally the signal was sampled and processed with an ATMEGA328-PU.

The TENS circuit was implemented based on analog electronics. A timing circuit was employed to set the two selectable frequencies of operation. These frequencies are set by the ATMEGA328-PU based on the therapist's configuration, by selecting the corresponding RC circuit to drive the timer. The voltage is then amplified as a pulse using a 10:1 transformer. Finally the current is delivered to the patient using a pair of carbon electrodes.

The heating pad was adapted from an existing commercial model (Microlife: FH100, Taiwan). This decision was done to speed up the development process, and increase both user safety and comfort, since the selected pad has been extensively tested and it has been well received because of its quality. A custom interface was to be developed to control the heating pad's operation in accordance with the specifications set by the therapist, however for ease of use, this interface was reduced to visual indications through LEDs rather than a fully autonomous system.

The control and communications hub was developed with two intercommunicating microcontrollers. One of them handles data reception and controls the timing of all of the therapy's sections, as well as the settings of the heating pad and TENS. The other microcontroller handles data transmission and registers and analyzes the EMG data to extract the number of complete repetitions of a given exercise.

The therapist interacts with the device through a mobile app that was developed for Android. Through this interface, the therapist can create a patient's profile, for which the duration of heat treatment and electric stimulation, as well as the frequency of the TENS can be set. Similarly, the app displays the results of the previous session done by the patient, summarizing the results as the number of repetitions done of the desired exercise, and the duration of both the Tens and heating pad sessions. Additionally, the app presents three graphs to showcase the patient's use and progress through time; these graphs display the duration of each element of the therapy as well as its time and date, and the repetitions of any given exercise.

The system as a whole is used as follows: A person seeking physical therapy attends a personal appointment with a certified therapist. In addition to all of the usual activities done in such sessions, when the person's condition is being evaluated, the therapist also considers if TheraKit would be a good fit for this particular person's needs. If the therapists and the patient agree that it could be used, the therapist will explain how to place the device's electrodes and what exercises (if any) to perform. Once the patient gets back home, he or she will place the device as instructed (with the help of a caregiver if necessary) and plug in the device once this is done. The system will automatically search the cloud for updates to the therapy's profile, after updating any necessary values it will begin applying the designated therapy. The device will provide visual feedback through LEDs to indicate to the user in what state is the device currently operating. The EMG LED will flash to indicate that the system is registering; this is the cue for the patient to begin exercising. Once the exercise finishes after some predetermined time for the session, the device will automatically upload the results, which will be then available for inspection by the therapist to evaluate each patient's performance through time. If any adjustment is necessary at any given time, the therapist will update the desired parameters from the companion app.

Outcome (Results of any outcomes testing and/or user feedback)

Due to time constraints to obtain Institutional Review Approval (IRB), the system could not be evaluated by a person with a condition that could benefit from using our device despite the expressed interest in doing so, the time to obtain IRB approval to evaluate. However, the system was verified in a technical setting (laboratory) to evaluate its feasibility and robustness. Each element in the device was tested independently and then the system as a whole was tested.

The EMG could provide consistent results and it was safe for human interaction. Additionally, the digitization and analysis of the signal also produced the expected results throughout our

testing. As previously stated, the heating pad could not be built from the ground up, however the commercial pad employed was tested for reliability and temperature accuracy, both of which were proven to be adequate for therapeutic purposes. Similarly, verbal user feedback obtained through interviews showed that manually applying and removing the heating pad as instructed by the device presented no inconvenience at all. The TENS was tested for accuracy in the output signal using electronic equipment (oscilloscope and multimeter). The frequency and waveform were adequate, and the alternating current delivered was within acceptable limits (below 20mA) when using a load of 500 Ohms, however since we could not ensure that this element of the system was safe for human use, it could not be tested yet directly on a person. Finally, the app's design was appropriate according to feedback from the therapists consulted and its functionality in controlling the system and receiving information from it wirelessly was proven.

When assembled together (except the TENS due to safety precautions , the system as a whole performed as intended when used by a team member. The therapy's parameters could be correctly set by the user through the app, and the device could accurately keep track of the session's time and current activity (TENS, heating pad or EMG). Similarly, the device could connect to a local Wi-Fi network and upload the recorded data with no difficulties other than the whole upload process requiring about 10 seconds, and this data was correctly updated on the companion app.

Cost

Below is a table that outlines the costs of production of our device. The prototype's cost is detailed in the second column, and mass manufacturing cost estimates are provided in the third column. These costs disclosures do not include shipping, packaging and manufacturing costs. All costs are given in United States Dollars. All costs are given per unit item; when more than one item was needed (as indicated in the item table), the corresponding cost was multiplied accordingly for the total cost.

Item	Cost of device prototype ($)	Cost of production device ($)
MPS-A42 (x2)	0.35	0.076
KSP-2222A (x1)	0.21	0.041
1N4007 (x1)	0.18	0.052
1N4732A (x2)	0.26	0.073
AD620 (x1)	8.57	4.61
TL084 (x1)	0.60	0.259
NE555 (x1)	0.43	0.135

Carbon film resistor 5% (x23)	0.10	0.009
Ceramic capacitor (x8)	0.25	0.144
Electrolytic capacitor (x3)	0.45	0.14
Wirewound resistor (x1)	0.56	0.093
Transformer (x1)	9.47	6.74
ESP8266 (x1)	6.95	6.95
NTK 16Mhz (x1)	0.57	0.304
ATMEGA328-PU (x1)	1.95	0.55
Microlife Heating pad (x1)	26.19	26.19
Total	62.55	48.001

Significance

The importance of this system is to maintain the consistency and effectiveness of the patient's therapy.This system could potentially reduce recovery time of a patient because every day the patient could keep taking therapy sessions at home always keeping record of the therapy for supervision by healthcare-workers thanks to the telemedicine approach, which reduces time of therapy and transportation and also costs of transportation and medical equipment. This system is an all-in-one therapy kit and at the same time is modular which can adapt to the patient's needs. In the future other modules can be adapted to the design given.

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References

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