

CONTRACT BOOK



Children Upper Limb Support Device

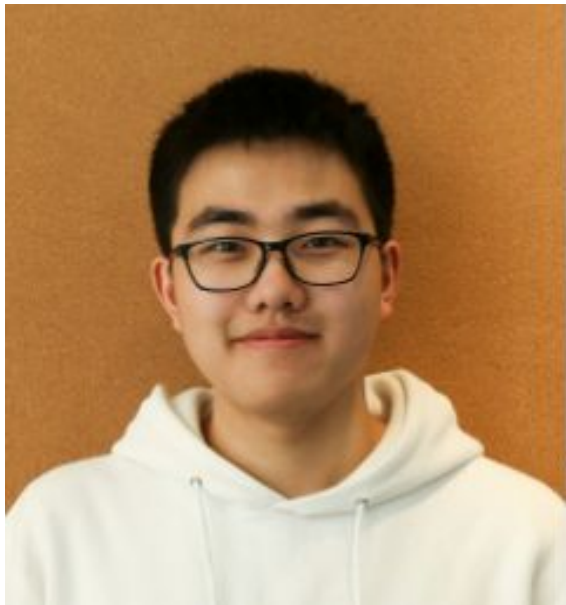
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Team Members



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Abstract

Children with upper limb muscle weakness face difficulties in performing daily activities. Some typical causes of muscle weakness in children are neuromuscular diseases, such as muscular dystrophy or spinal muscular atrophy. Duchenne muscular dystrophy, one of the most common childhood-onset forms of muscular dystrophy affects 1 in every 3,500 live male births. [1] Spinal muscular atrophy (SMA) has generally been believed to affect as many as 10,000 to 25,00 children and adults in the United States. [2]. Our Device, Happy Support, is a battery powered arm support device designed for children with upper limb muscle weakness. It provides a 3 degree of movement support with adjustable buttons to adjust height and position of the arm support device. It also includes FSR sensors with bluetooth for physical therapists to easily monitor the improvement of patients through our App.

Introduction

There exist several pediatric musculoskeletal diseases that are characterized by upper limb weakness with minimal or abnormal motor control and sensation. [3] Neuromuscular diseases, such as duchenne muscular dystrophy (DMD) or spinal muscular atrophy (SMA), are individually rare. Yet, pediatric clinicians frequently encounter children with motor delay. [4] One in 6000 to one in 10,000 children are born with this disease. [2] One in 40 to one in 50 people (approximately 6 million Americans) are carriers of the SMA gene. [2] DMD affects 1 in every 3500 live males births per year. The muscular dystrophies as a whole are estimated to affect 250,000 individuals in the United States. [1] With the cases of muscular dystrophies increasing, the marketability is also increasing dramatically. The sales of medical devices for DMD patients in the US alone in 2019 is approximately 400 million dollars, which has increased about 160% over the past 5 years. A person with one of these neuromuscular disease conditions is usually not able to be independent and requires assistance to perform daily activities. Specifically, among other gross motor challenges, these patients often are too weak to overcome the weight of their arms for daily tasks including self-feeding. Thus, it is important to design a device to help strengthen upper limb muscles or help support upper limbs for children to perform daily activities.

Field Survey

Our idea is to make the device effective for patients to do arm exercises and convenient for daily activities, especially for children. To check the practicability of our proposal and optimize our product, we contacted and visited a physical therapy center. We also had an interview with a physical therapist (Dr. Shunyong), several patients with arm weakness and their families.

The field survey provided us with guidance of what a great arm support device should have. An arm support device should include functions to replace basic human work and the ability to offer active motion guidance. The device should also focus on patients' needs, easy to operate, provide accurate data, and offer an affordable price.

We first realized that there is a huge demand for the rehabilitation equipment to replace human work. As we walked into the rehabilitation room, we saw lots of therapists helping patients to do the arm exercises. Most of them were just holding the patients' arms to repeat the same movement. Dr. Shunyong told us that this kind of therapy is called passive therapy. It gives patients the feeling of the right movement, and could completely be done by anyone else. Therefore, if including this arm pushing function, our product could free many therapists from the boring and time-consuming repetition. As a result, they could work with more patients and those who are more in need of useful guidance. According to Dr. Shunyong, one more important function that we need to consider should be active therapy guidance. When only involving the passive therapy, patients' arms would not improve quickly. But if we regulate the right arm trajectory and let patients move their arms by themselves, their arms could gain strength as expected or even at a faster speed. This is the active therapy, encouraging patients for voluntary motion. So our device should not only hold arms with a constant upward force, but also have lots of modes to exercise arms or accommodate different situations.

Furthermore, we focus on what patients need. After communicating with several children with upper limb weakness, we found that they did not like the appearance of existing devices and they would change their device during a period. The reason is that children all love something like

cartoon figures, but most devices are designed with simply single-color appearances and fail to be attractive to children. In addition, some companies only provide limited options for the size of devices. Patients may feel a little bit tight to use the small-sized one, but feel too loose to use a large size. Even if more sizes are available, children are constantly growing, which means they need to buy a new device possibly every two months. Therefore, if our product has a great appearance and an adjustable structure, young patients will not encounter problems including different appearance preferences and growing needs.

We also noticed that there are some shortcomings with current devices. First, they are hard to set up. One kind of arm support sling is attached to the wheelchair with many nodes. If patients want to install the device, their families would spend some time connecting and fixing the sling. Whenever patients want to go somewhere else, they have to uninstall the device and reconnect those nodes again. Also, some high-tech arm supports are difficult to use. We saw one very complicated orthosis, and its manual is about two hundred pages. That would be a burden for young patients and their parents. Thus we could design our product to be convenient to attach and easy to operate, making it competitive in the market.

During our conversation with therapist Shunyong, we introduced our arm support device, which could also record patients' data for the therapist to better diagnose. Shunyong mentioned some meaningful points that we should pay attention to. First is the data accuracy. He saw some patients who had spent lots of time and money taking extra physical therapy because they had been misdiagnosed due to the inaccurate test results. So we must make sure that the collected data from our device is precisely accurate. Patients can fully understand their health situation and they will not waste energy to do redundant therapies. Affordable price is also necessary. Many patients would like to choose the device with a lower price, regardless of its quality. In their opinions, all arm support devices are just tools, which are not worth much. Our product will be more popular as we intend to offer good performance and reasonable price at the same time.

We also searched for the market of arm support device for DMD and SMA patients:

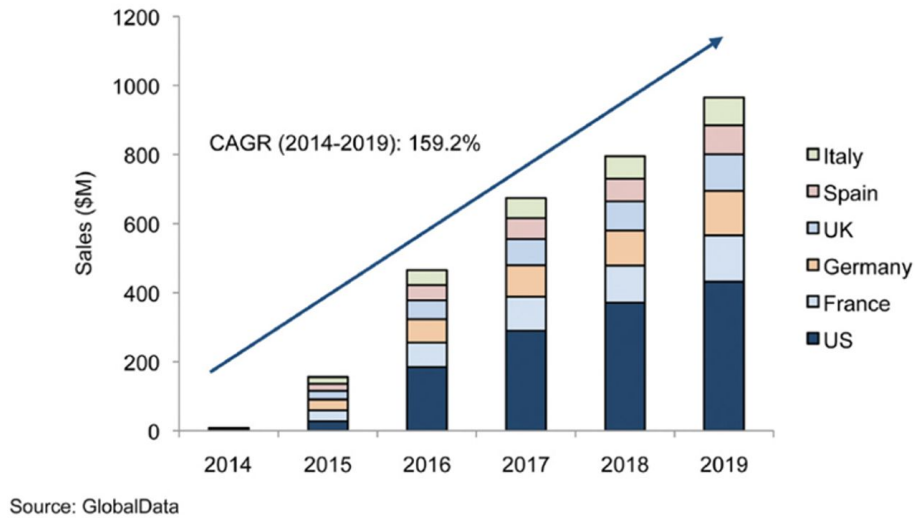


Figure 1. Sales for DMD devices by region from 2014 to 2019 [4]

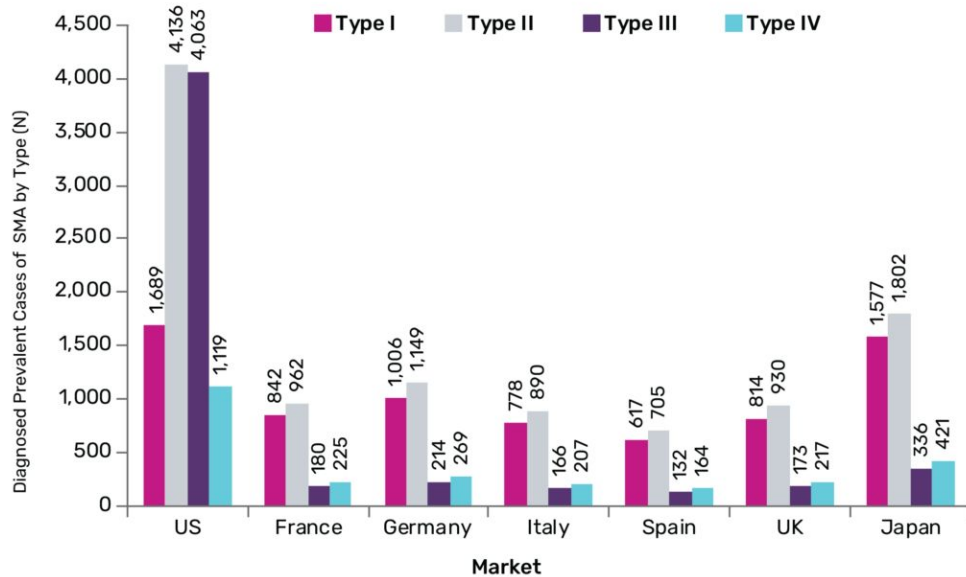


Figure 2. Sales for DMD devices by region from 2014 to 2019 [5]

We found that in the past five years, there has been an increasing trend for device sales of DMD. The huge demand not only arose in the US, but also in other countries, including France, Germany, etc. So we predict the need for arm support devices will continue to increase in the future, and there is huge demand for our products.

Patent Survey

Several extensive searches for arm support devices and existing technologies were conducted in order to find the market space for our product and compare our product with competitors. Compared to the patent search results and competitors on the market, our device is unique in that it is specifically designed for children with its detachable features. Our device also has a force resistive sensor with bluetooth that can connect to our Happy Support App, which can track and monitor patient's progress for physical therapists. We used JHU library resources and techniques provided by Dr. Sue Vazakas. The most relevant patents are listed below:

1. US10369690B2 Apparatus for human arm supporting exoskeleton
An arm supporting exoskeleton configured to be coupled to a person, comprising a shoulder base to be coupled to the trunk of the person; an arm link mechanism coupled to the upper arm; offset adjustment joint configured to adjust and fix a position of the arm link mechanism relative to the shoulder base.
2. US10561515B2 Adaptive arm support systems and methods for use
An arm support system, comprising a first link element configured to pivot about the first vertical axis; a second link element coupled to first link element; and an arm support assembly coupled to the second link element and configured to pivot and about a horizontal axis.
3. US8641782B2 Compact exoskeleton arm support device to compensate for gravity
A compact exoskeleton arm support device, comprising two joints driven by actuators and other joints driven by user force. This compact exoskeleton arm support device compensating for gravity effectively uses the actuators, thereby increasing operating efficiency and reducing production costs.
4. US102008893B2 Heavy capacity arm support systems
The arm support system comprises a harness configured to be worn on a body of a user; an arm support pivotally coupled to the harness for supporting a user's arm; a tool mount on a free end of the arm support. Which is manipulatable by user's hand and compensation elements partially offsetting a gravitational force acting on the user's arm

Pitch

Product Need

Imagine waking up one day and can not lift your arms any more. The tasks that you can perform will be very limited, even feeding yourselves would be difficult! That's the case with neuromuscular disease children and it is not a rare problem. Spinal muscular atrophy (SMA) and duchenne muscular dystrophy (DMD) are two of the most common neuromuscular diseases. SMA affects a minimum of 2500 children in the US each year while DMD affects 1 in every 3500 live males births per year. With the cases of muscular dystrophies increasing, the marketability is also increasing dramatically. The sales for DMD patients in the US alone in 2019 is approximately 400 million dollars, which has increased about 160% over the past 5 years. A child with one of these neuromuscular disease conditions is usually not able to be independent and requires assistance to perform daily activities. Specifically, these patients often are too weak to overcome the weight of their arms for daily tasks including self-feeding, writing and playing with toys. Most of the engineering devices on the market are designed for adults and are complex and at high costs. Additionally, these existing devices are used for rehabilitation purposes only.

Solution

Our company, Happy Support, seeks to create a cost-effective device (\$150-200) to help children to support elbow and wrist weight and allow 3 degrees of freedom of movement. The proposed design can be clamped on the back of a chair to allow mobility for daily use. We also incorporated a force sensitive resistor (FSR) sensor for rehabilitation purposes during physical therapies. Our market entry will be through partnership with physical therapists. There are an estimated 38,800 physical therapy clinics in the US. Physical therapists can visualize the improvement of the patient by reading the change of the amount of force generated through the FSR sensor on our device. A decreased trend of force generation indicates the gain of strength in patients. With the help of our device, the patient should be able to lift both arms to practice and improve skills during physical therapy sessions and could also use our device in performing daily activities such as writing and feeding themselves at home.

Intended Use

- The intended use of this device is mainly for children from 5 to 17 years old with upper limb muscular weakness.
- The arm support device can be used for arm rehabilitation exercise.
- It can store patients' data with owners' consent, and integrate all data into health records, which are available to therapists for better diagnosis.
- It can be also used to help patients with daily activities.
- It can be further upgraded to have a portable structure that patients could wear for outdoor activities.

Design

Our product is named “Happy Support”, and below is our logo:



Figure 3. Our company logo, Happy Support

In this logo, a happy child sitting on a strong arm represents our concept. We believe our product will help children with muscular weakness use their arms effectively just like healthy children. Also, we will guarantee our product’s quality, making it reliable for kids just like the strong arm. Our product name “Happy Support” on the bottom suggests this as well. These two words are italicized, meaning kids can lean on our dependable device. Furthermore, on the right side is not only a fist, but also, a profile of a mother looking at the kid, caring about him. And the mother represents us. We do hope that every kid could grow happily, including those with muscular weakness. So we will do our best working on our product.

Below is the model of our product. There are some cute images on the device, because it mainly aims for children. Our patients could draw whatever they like (some cartoon figures, for example) and we will print the customized drawings on demand.

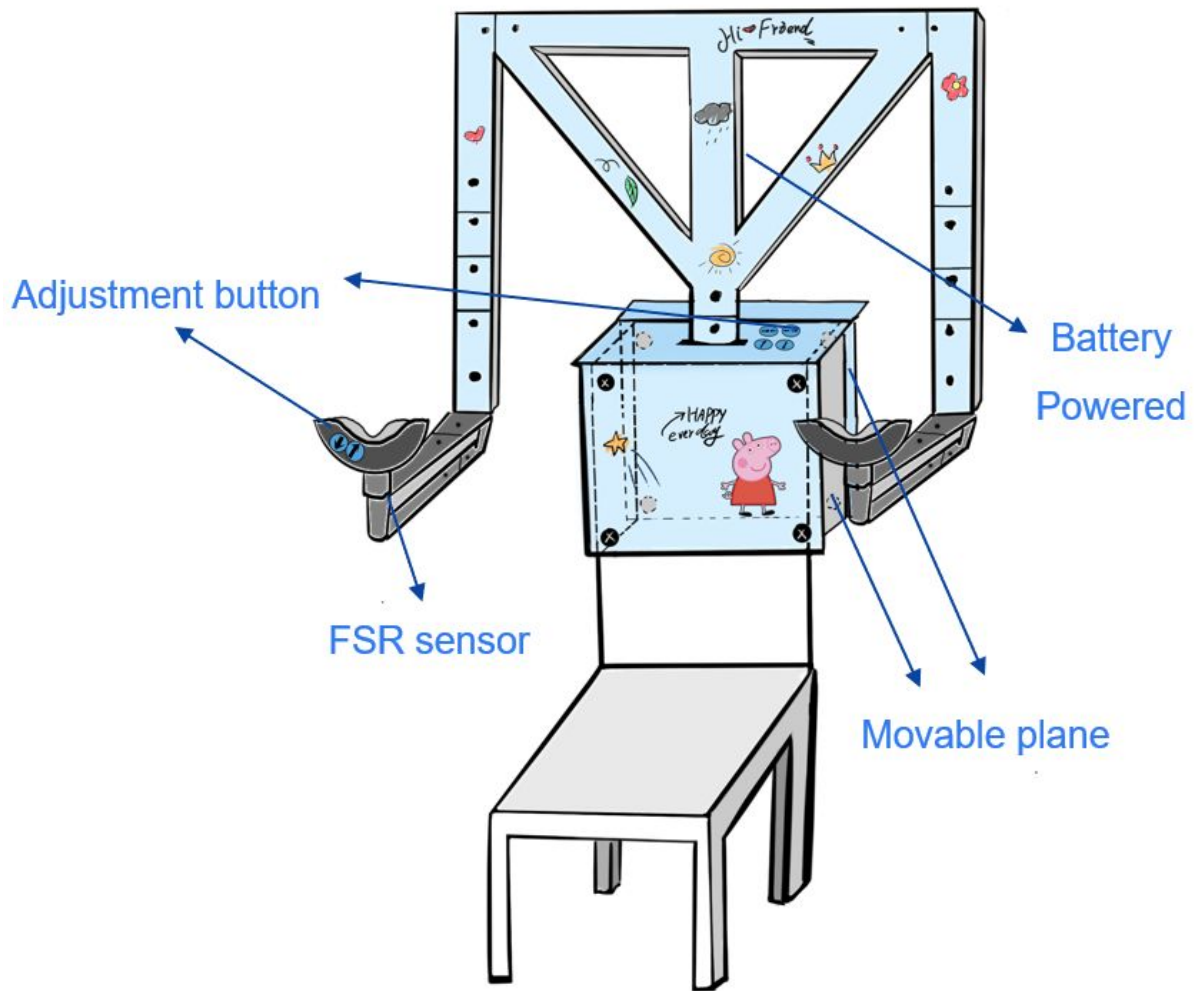


Figure 4. Final design of our product

Happy Support can be clamped on the back of a chair so that patients can easily transfer the device based on sitting positions. Those parts attached to the chair have movable lateral planes. When patients want to attach it to a chair, they can gradually push the planes and finally turn the switch to fix it. Our device can be fixed on most chairs, except those chairs with circular shapes.

Our arm support also has a reliable and adjustable structure. You can see that there are some black dots. The product is combined with several parts and we can lengthen or shorten the frame, adjust the height by simply hitting the adjustable button. Therefore, every patient will have a suitable setup as desired.

Our device is power-driven. The power source is hidden in the middle pillar. And we will develop several modes, for example the relaxing mode. We have designed an App also called Happy Support. When using our App to switch to the relaxing mode, the arm support will rotate with a certain angle, and reduce the provided force, making the patient feel comfortable.

We also incorporated a force sensitive resistor (FSR) sensor on the microcontroller to monitor the amount of force generated, through a Bluetooth module. Physical therapists can visualize the improvement of the patient through the App. The decreasing trend of the force generated by the device indicates the gain of strength in patients. With the help of our device, the patient should be able to lift both arms to practice and could also perform daily activities such as writing and eating all by themselves.

Here is the user interface of Happy Support App:

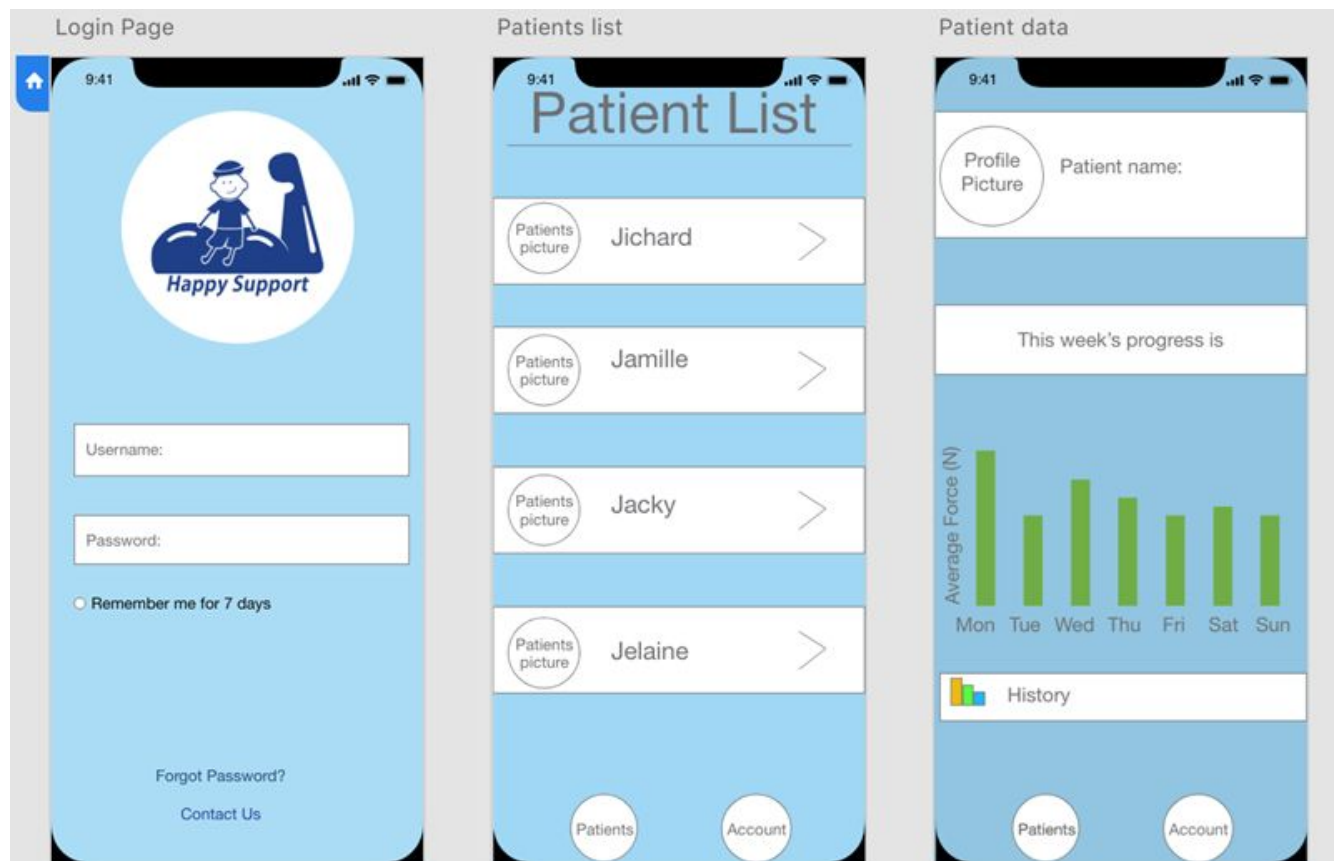


Figure 5. User interface of Happy Support App

Physical therapists could connect their phones to the device using Bluetooth by logging into their accounts. The application has an option to remember the account for a week, so that they could easily access their account in a timely manner. The application allows physical therapists to have access to all of their patients after logging in. They would have the option to click on one patient with their profile picture on it for personalization so that they could remotely monitor his or her progress for the past week. The physical therapists can also access all history of the patients such as other medical conditions etc. by clicking the history button. All the data will be automatically saved on a cloud server so that we can insure the accuracy of the progress of each patient.

Regulatory Issues

Our device, Happy Support, is an external, in contact with user, and contains force resistive sensors to monitor the amount of force generated device. The sensors need to have an insulation cover to prevent any damage of the circuitry and hence reduce the chances of patients getting electric shock. It does not need to be tested on animals due to its external use feature, thus, we need to contact the Food and Drug Administration (FDA). The device is for daily uses and rehabilitation purposes, thus, does not need to be tested on animals. The device will be a class 2 device as per the guidelines by FDA [6]. 510(k) will also be required for Happy Support device. Our mobile App, Happy Support App will be regulated by FDA and Federal Communications Commissions (FCC). Additionally, Happy Support App will take every measure required to become HIPAA compliant. Our application includes relevant patient information in 'patient profiles', 'patient weekly progress', and correspondence between patients and physical therapists. Hence, HIPAA compliance is required to ensure the security and safety of patient information.

Business Strategy

After applying for a patent of our device, we will form a close collaboration with physical therapy centers across the US. We would conduct initial clinical trials of our product with physical therapy centers to establish partnership and credibility. Currently there are over 380,000 physical therapy centers in the US that work with children for rehabilitation. For the first year, we would like to ideally target 0.1% of the physical therapy centers, which is around 380 physical therapy centers in the US. We would first give out free products for testing purposes during the first year, but would charge a small fee for application usage. For the next 5 years, we are increasing our targeting physical therapy centers at 1% rate each year. We would also start charging a fee for our product at physical therapy centers. When patients purchase our products at physical therapy centers, we would also offer a discount rate. We would not only receive revenues through direct sale of Happy Support devices, but also by putting advertisements on our Happy Support App for a fee. Below we have calculated the market volume of our product with a projection for the next 5 years. We have a total number of target centers of 380,000 in the US with a penetration rate of 1% per year. We have also started with 0.1% of centers for the first year, which is 380 centers.

Market Volume

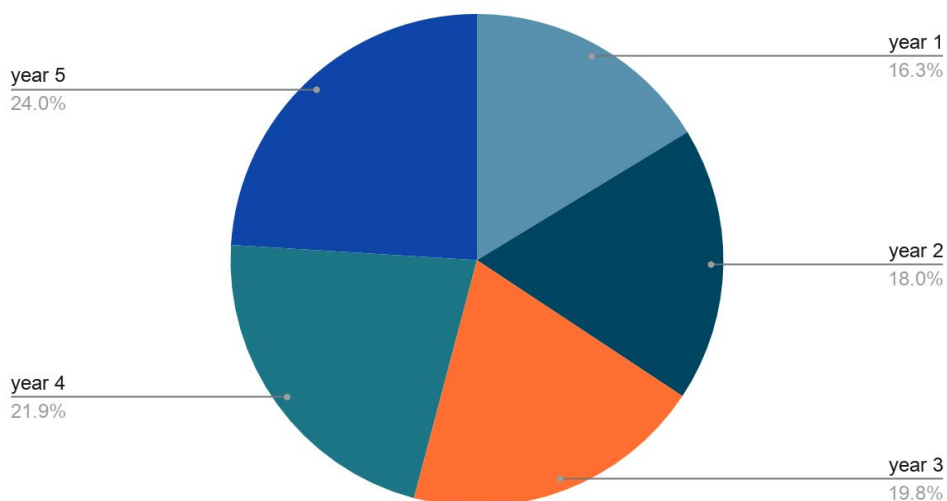


Figure 6. Market volume projection for the next five years

Financial Plan

For the development of our device and the App, we are hiring 2 other computer science engineers to help us design the mobile application and sensor part of the product. The FSR sensors that we chose are easy to purchase and cost-effective. We also use cloud servers for our patient profile data to reduce cost and increase safety in our patient information. We are also fabricating our own products by purchasing raw materials and manufacturing at our company.

Item	Cost
Engineers Salary (2 BME, 2 CS)	\$640,000 (\$80k/person per year)
Equipment	\$120,000
Raw Material (PVC, sensor, etc.)	\$15,000
Lawyer & CPA & FDA	\$40,000
Server for App data maintenance	\$5000
Renting space, stationeries, furniture	\$40,000
Product Testing	\$100,000
Research and Development	\$50,000
Patent Application	\$5000
	Total: \$975,000

Table 1. Expense sheet for the first two years

Reimbursement

Reimbursement plays an important role in future company growth and market adoption. Our company understands that in order to have a successful market growth of our product, we need to seek compliance of reimbursement with regulatory requirements. Three key factors for reimbursement are coverage, coding and payment. We will need approval from physical therapists in order to get clearance from FDA. Coverage via a National Coverage Decision (NCD) will apply to Happy Support company. Three evaluations from clinical studies will be required from insurance company coverage. In order to receive reimbursement, we must either have a valid code or we will have to create a new code. One existing code we found is HCPCS E2629 code [7] designated for arm support devices. If we can add our products to the existing code, we would be in position to receive payments from insurance companies.

Summary

Happy Support device and application have many novel features and designs that outplay the existing devices for arm support on the market. It is the only device on the market that provides multidimensional movement support while being easily transportable from chair to chair. The application would also allow physical therapists to accurately and remotely monitor and visualize the progress of their patients through the FSR sensor. Happy Support devices not only help children with muscle weakness in rehabilitation for improving muscle strength and practicing various skills, it also allows them to use it in daily life, such as playing with toys and feeding themselves. The device can also last for years without regular replacement.

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