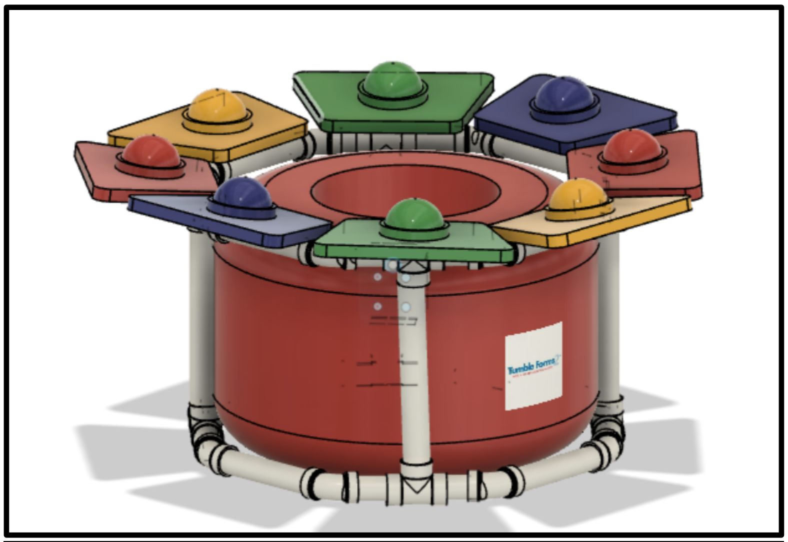

Tunnel Team Final Report

BME 460/790: Design of Medical and Assistive Devices

By: Adrianna Battle, Allan Yu, Shuming Cui, and Tong Fu

Abstract

Research shows that approximately 38% of children are born with some form of postural disorder. A common technique used to correct these types of disorders in children, comes in the form of an upright tunnel. This type of tunnel is usually referred to as a Barrel Crawl tunnel. Children with postural disorders are placed into this type of tunnel for physical therapy and encouraged to cruise around the diameter of the tunnel. This technique serves to promote straightening of the legs and spine, and ultimately corrects the overall posture of the child.

A Durham public school staff member approached our research group for assistance. They claimed that the current tunnel device did not succeed in keeping the children's attention, for the duration of their therapy. The children also frequently chose to sit down inside the tunnel, which defeated the purpose. The children in this classroom also exhibited a wide variety of intellectual disabilities. Our group was asked to make the device more captivating for the clients, so that they would be engaged for the duration of the therapy session. After much ideation and prototyping, an external device was placed on top of the current tunnel to help solve this issue. We included a motion sensor and LED lights, that would determine if the client is sitting inside the tunnel. The LED lights flashed when touched and animal sounds were activated to stimulate the clients attention. The device allows for either a simple Simon Say's game or a free play option.

Background/Introduction

Currently in the U.S., about 38% of children exhibit a postural disorder. These disorders when severe can show symptoms such as backaches, neck pain, muscle fatigue, and shortening of muscles to name a few [1]. Younger children with more severe cases often receive physical therapy. A common therapy technique for posture correction may include an upright tunnel of sorts, that aids in spinal support and provides independence for the clients. This "tunnel" commercially referred to as a barrel crawl (Fig. 1.) works best when the children cruise around the top of the tunnel. The goal of this therapy tool is to keep the child upright and aid in straightening the spine and legs. This tunnel can be a great tool to help children with disorders such as caudal regression syndrome or postural kyphosis, however, there is currently no external device or system aimed at capturing the child's attention. The tunnel is also big enough for the children to sit down inside of it, which can undo the work of therapy.

Our team was asked by the Whitted School in Durham, NC to engineer a solution to capture the attention of the special need children in their classroom. The purpose of this report is to lay out all of the decisions and steps necessary to design this novel solution and the team's planned next steps to optimize our final solution. For the purposes of this project, our team worked with two students in the classroom named Beth and Bobby. Both Bobby and Beth had both postural problems as well as mental and intellectual disabilities (i.e. cerebral palsy). Both children also have limited speech function, however, they are capable of interacting with lights and sounds. While both children face similar challenges, their abilities and limitations vary slightly. Bobby is capable of standing on his own legs and turning his body without assistance. However, he is not attracted by the tunnel and gets bored easily. He is also about to undergo back surgery. Ideally after the procedure, Bobby will be able to move more freely on his own.

Beth has caudal regression which is a rare birth defect and congenital disorder, in which the fetal development of the lower spine is irregular (Fig 2.). This disorder causes the legs to fold into themselves making walking difficult. This birth defect occurs in about 1 in 25,000 births [2]. Beth's caudal regression causes her to need assistance in straightening her legs and standing straight. Beth also has stomach problems causing her to need a gastrostomy tube (G-tube). This meant that the solution we added couldn't interfere with or touch her body or the G-tube. Our intended client for this tunnel device would be a child exhibiting postural control problems, preferably between the ages of two through five. Their heights would range between 30-45 inches and their weight would be between 25-40 pounds. The product is intended to be used in elementary school classrooms and homes for children with postural control problems. Our product would need to either be "prescribed' or recommended by a physical therapist. The tunnel would either be purchased directly by the school or by the parent for use in the home. Families with children with disabilities often have private insurance for their child. In this case they would likely be reimbursed for the tunnel cost and only pay a copay.

Description of Solution

Over the span of this course we created an external structure, equipped with a simple Simon Says like game with LED light up buttons and animal sounds to mitigate the school's problem. The external structure is placed around the current tunnel. A motion sensor was incorporated, that would detect if the child was standing upright or sitting down inside the tunnel. The base of the device was constructed using PVC pipes and pipe fittings. The colored buttons rest on wooden panels, and are attached to the base using plastic pipe straps and screws. The PCB board is attached to one of the vertical pipes via a box, and pipe straps have wires running through the pipe for concealment. Pictures of the completed device prototype can be reviewed in Appendix A (Figure 3). A detailed breakdown of the parts and budget are also identified in appendix C (Table 3).

Ideation Process

The brainstorming process began with an idea generation task. During a 10-minute period each member of the team came up with approximately 60 ideas about a device that would help with the presented problem. These ideas were generated keeping the following device functions in mind: do not tip over, direct the head up, prevent the kids from sitting, and keeping the attention of children.

Decomposition/FAST analysis

The groups ideas were then filtered based on ranking criteria and weighed using a Pugh scoring matrix. The three design categories considered were standing function, attraction, and safety. Each idea was put into their respective category, then scored based on three metrics: feasibility, effectiveness, and safety. For each category a score of 1, 3, or 9 was given, ranking from least viable, viable, to most viable, respectively. These three categories were then weighted based on what features were most relevant to the design, with effectiveness accounting for 70%, feasibility 25%, and safety 5%. The weighted average of these scores, determined the final score for each idea. Finally, the top three scores were chosen from each design category as the best ideas to continue with.

Design and Development

Prototyping

The final result of the brainstorming session was an eight-button panel Simon Says game that would surround the tunnel. These buttons would light up randomly for the child to press and then a random song/animal sound would encourage them to keep standing. Eventually the game would cause them to continually move around the tunnel, while having fun. Additionally, a sensor was placed inside the tunnel, that would shut off the game if the child sat down in the tunnel. A test video can also be seen in the group folder on Sakai. The video demonstrates how we were able to create a device using PVC and wood, to hold eight buttons in a circular pattern around the tunnel. Arduino software was utilized, randomly lighting up a button for the child to press to activate a corresponding sound. Lastly, a distance sensor was employed to keep track of the child's head. This sensor is able to turn the device off if it does not sense the head of the child at standing height. The prototype was sent back to the school for one week, in order for the team to receive feedback.

The feedback received from the prototype was that the children did show a good amount of interest in the game and did attempt to push the buttons. The music, however, did not hold their interest. They felt that there may have been too many button choices for them, and that the children probably would do better with just four buttons to push. They also felt that larger buttons would be more attractive to the kids, and that the volume should be a little louder.

Device Instructions and Use

The device has two initial switches, one for the power and one for the mode. The power switch is turned on, which lights up the device and plays its startup sequence indicating that the device is working. To change the songs, all one needs to do is eject the microSD card and upload their own .mp3 or .wav files into the music folder. The songs must be renamed to either 0001, 0002, 0003, or 0004. Depending on which mode you have the switch on (Free play or Simon Says mode) the following sequence will occur:

<u>Free play</u>

All four lights will light up and it's up to the child to press any button, and a random animal noise will play. This will continue until the device mode is switched or turned off. If the child sits down in the tunnel, then the game will pause by having all lights turn off and a message will play through the speaker for the child to stand up to continue to play.

<u>Simon Says</u>

In this mode, a random light will flash, and its corresponding animal song will play. It is up to the child to find this flashing light and push it. When a button is pushed, the animal song will play and then a new random light is chosen and the process is repeated. If the wrong button is pressed, then an error beep plays and the correct button lights up again, giving the child another chance. As with the free play mode, if the child sits down in the tunnel, then the game will pause. All the lights will turn off and a message will play through the speaker for the child to stand up to continue to play.

The device consists of 4 LED push buttons, with a speaker and distance sensor connected to an Arduino Uno breadboard. The breadboard also consists of a DF player and an amplifier to store the songs played, as well as housing resistors for the push buttons. The resistors are placed in series with the LEDs in order to ensure safety of the LEDS and the circuit. A picture of the mechanical drawings and CAD rendering can be viewed in Appendix A(Figure 4 and 5)The DF player is wired according to this diagram (Appendix C, Table 5 and 6), with its output fed through an amplifier and then through the speakers. 1.5v power and 1 ground rail are used to connect the entire circuit. Finally, the distance sensor is wired according to this diagram, which has two pins, and an echo and trigger pin. The distance sensor works by measuring the wave sent by the echo pin and when it bounces off a solid object, converting the time it took to bounce as a distance measurement.

Hazard Analysis

A detailed hazard analysis was conducted after the prototype was created. To start, any external hazards that were externally visible were considered, such as; exposed wire, exposed screws, and boards. The potential effects of the hazard were then written down and scored on three different criteria: severity, occurrence and risk. These criteria on a scale from 1 to 4 with, with 1 being frequent and 4 being negligible. Then a plan to redesign these potential hazards was formed, from the most urgent (the highest combined score) to the least urgent. Other hazards included the decomposition of the device, such as boards falling off, pipes breaking, or even the subject's emotions towards the device. Again, the same scoring and redesign plan was put in place for these as well. The full hazard analysis can be viewed in Appendix D, Table 2.

Regulatory Pathway

According to the FDA, if a product meets the definition of *Per Section 201(h) of the Food, Drug, and Cosmetic Act,* it can be considered as a medical device [3]. This product should be considered a medical device because the intention for use is to capture the attention and enhance the standing performance of the children with disabilities without achieving through a chemical action. This instrument might also be used to mitigate the pain and train and educate the children who might have intellectual disabilities to have better cognitive ability. Moreover, the device should be classified as Class I since it is a low-risk device. More detailed explanation and analysis is discussed in the Hazard Analysis section.

Devices like a medical supporting wheelchair, crutch, and cane could be considered as similar devices. The most appropriate regulatory pathway for this device is to go through the De Novo pathway. It is one of the fastest pathways to bring low-risk products without direct precedents onto the market. Since this product is considered as having low risk to children and no identified precedents in the FDA database, De Novo should be the most appropriate and efficient regulatory pathway, avoiding a more rigorous FDA route.

Three clinical trials are needed for the product [4]. The first stage including small studies on a population of 10-30 healthy and disabled children should be conducted to collect preliminary safety and performance of the device. It is also considered as the feasibility and pilot stage and should be conducted in a randomized controlled trial that will collect data from both disabled children using the device and disabled children that don't use the device. This could be done by collecting data and surveys in W.G. Pearson Elementary School. The next stage, which is the pivotal stage, will include a larger study on 150-300 children who have postural disorders and intellectual disabilities to confirm clinical efficacy and risk. Statistical analysis should also be conducted in this trial. The purpose of the pivotal study is to gain regulatory approval to market the device. Lastly, a post-market study on a much larger and more general population (thousands of children) should be run to monitor long term effectiveness and to better understand potential adverse events that may be caused by the usage of the device.

Take the first trial as an example. One of the primary endpoints can be a survey comprising behavioral or cognitive scores to evaluate the children. One of the secondary endpoints can be the average duration time (how long the children would like to stay in the tunnel) of the two groups. Trial is declared successful if having the device on the tunnel is superior to not having the device on the tunnel, which can be expressed as children playing with this device stay longer in the tunnel.

Summary of Evaluation

Based on the requirement of the tunnel, different performance criteria have been designed. In order to evaluate the performance of the tunnel, two different plans have been made: a verification plan and validation plan. The verification plan can be done in the lab, which is based on the performance of the device itself, while the validation plan is mostly based on the feedback of the clients from their experience. The purpose of the tunnel is assisting kids with postural control problems by motivating them to finish certain movements by themselves with least contact and stimulus. Based on this purpose, the requirements include seven different aspects: adjustability, duration, stability, power supply, body gesture, little contact and little stimulation. For different requirements, we designed certain verification plans and validation plans (Appendix B, Table 1).

For the verification, which is finished in the lab, the performance of the device met most of the requirements. When adding 50 pounds weight on the top, the tunnel can work without tipping over, and it can keep working for 30 minutes with a power bank. Besides, for the stability and stimulation test, the tunnel is able to stay still without tipping over with the weight added, and it shows no stimulation when working. When testing two different modes, the "free play" mode is able to play different animal noises when different buttons are tapped and the "Simon Says" mode is able to make a full turn in less than 4 minutes. For the sensor test, however, although the sensor can shut the device off when no obstacle detected in front of it, the height of the sensor is unable to adjust, which means it is hard to accommodate different clients.

The validation result is based on the feedback from teachers in school. The teacher said the light and sound of the buttons attracted the kids a lot and they are not easily getting bored anymore. The tunnel can keep staying still during the therapy time with no contact to both of the children. For Bobby, he started to get attracted by the tunnel and was able to turn his body and push the buttons all by himself. For Beth, she was able to push the buttons with the support of the tunnel by leaning on the edge of the tunnel. Besides, by changing the voice (piano, animal noise, songs, etc.), different voices could be more attractive for different kids. However, for both of the clients, they still need to be monitored and guided by the teacher in the therapy process. Sometimes they had to spend much time finding the buttons.

Discussion

Overall, it reached the purpose of gesture assistance and was proved effective for the therapy of children with postural control problems. The tunnel is adjustable and it is accommodated to clients in different heights and weights. The validation test proved the tunnel to be safe with good performance of stability and no strong stimulation to clients. Compared with the original tunnel, Bobby is not likely to get bored inside the tunnel, and Beth can straighten her legs to stand still by herself when trying to push the buttons. However, there are still certain problems that were found to be solved after testing. The sensor was proved to be effective in the lab but has not yet been put into use, and there still needs a solution for the sensor to be adjustable in height. Also, the buttons are a little bit small to attract clients' attention. The "Simon Says" game is still somehow hard for kids that they can only play the game with teacher's guidance.

Conclusion

Our team was able to successfully create a safe, effective, and fun device for both Bobby and Beth. After taking in feedback from the school we were able to optimize our final design. In order to accomplish this, we would need to conduct further testing and evaluation of the device. One caveat of the device would be that the team needs a solution for the sensor. The method of combining an adjustable distance sensor with the tunnel should be designed. Larger buttons should be used in the final design as well as more amplified speakers (noise within safety range). Nevertheless, we feel that we can reach an even larger market of children with postural problems who can potentially benefit from this therapy.

Appendices

Figure 1: Tumbleforms© Barrel Crawl

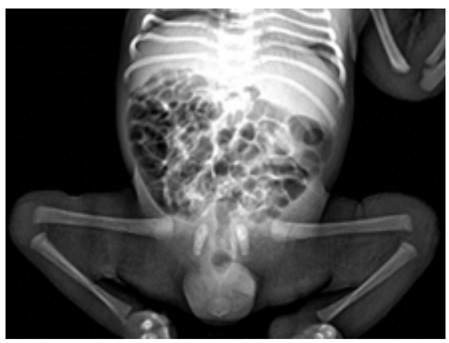

Figure 2: Spine x-ray of infant with caudal regression

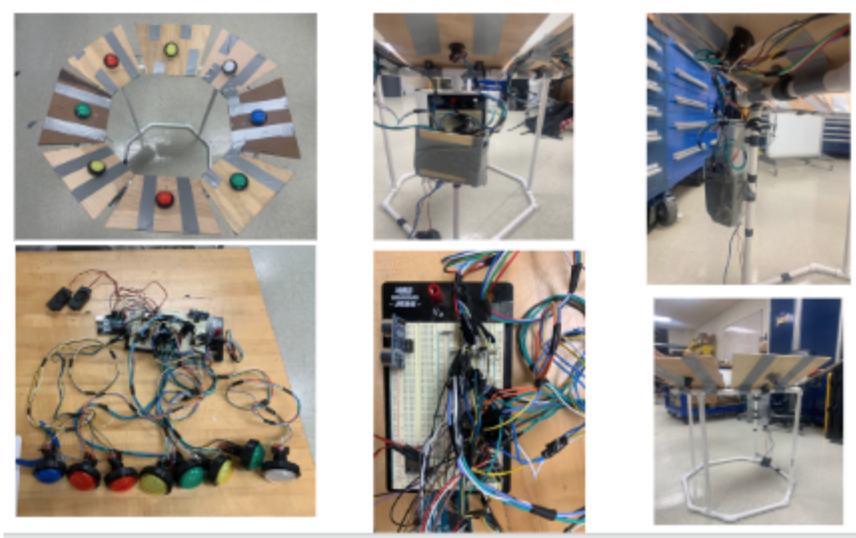

Figure 3: Pictures of Initial Prototype

***Appendix A**: Mechanical and electrical drawings*

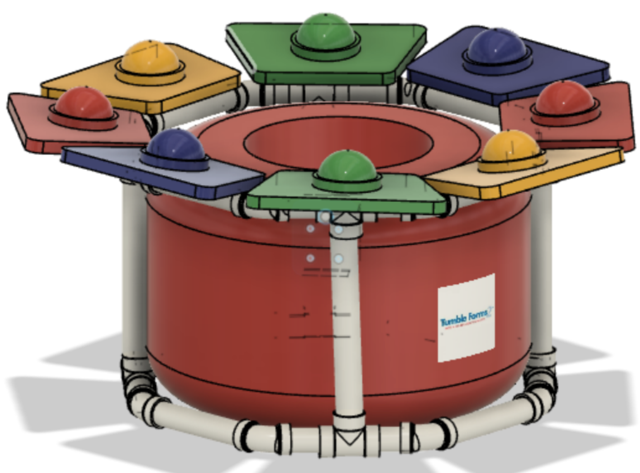

Figure 4: Tunnel external device final solution

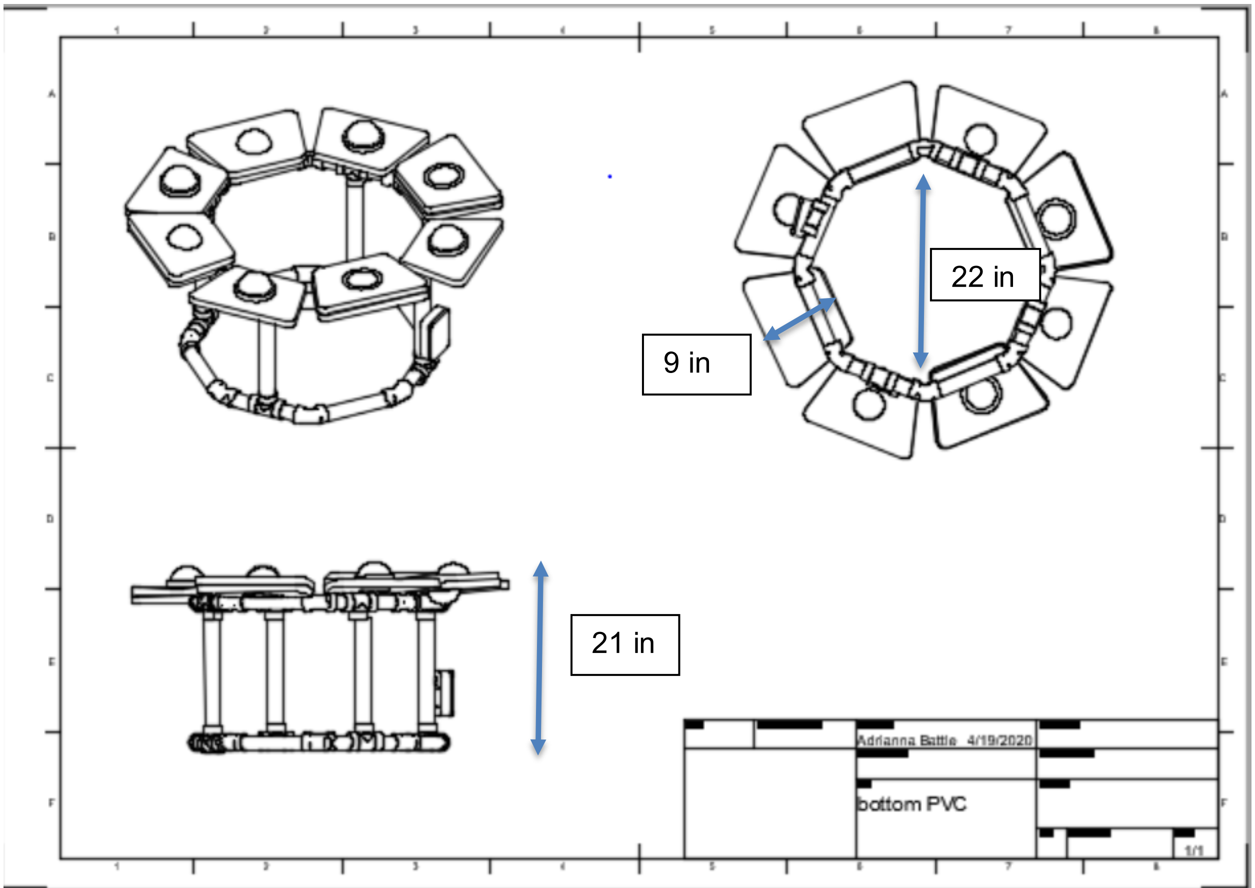

Figure 5: Mechanical Drawings of Finished Device

***Appendix B**: Detailed Device Evaluation Plan*

Table 1: Evaluation Plan

Requirement	Criteria	Verification	Validation
Adjust to accommodate a variety of clients	**Adjustable to heights between 30-45 inches and weights between 25-40 pounds**	**Height measurement (XXX) demonstrated that tunnel is able to adjust into different heights; Panels are rotatable to adjust children with different arm lengths.**	**Observed both Bobby and Beth reach the buttons and use the tunnel for 15 minutes. The tunnel is stable and adjustable for the entire time without breaking.**

Keep clients actively turning around and attracted by the game.	**Clients should actively keep playing the games and turning around to press the buttons for at least 15 minutes.**	**The game works for more than 15 minutes without unexpected shut off.; Buttons and sounds are randomly chosen at each time, meaning that each time a different sequence will be generated, decreasing the possibilities of getting bored.**	**Observed both Bobby and Beth using the tunnel for 15 minutes, with continuous interest and are attracted by the lights/animal sounds/buttons.; Count and saw both rotate around full circumference.**
Overall device stability	**The tunnel should be able to hold a client under 40 pounds without leaning or falling down.**	**Quantitative analysis demonstrated that the final assembled device exceeds anticipated load.**	**User testing demonstrated that the device did not break or deform.**
Power supply	**The tunnel should be able to work without running out of power.**	**Set up the tunnel with new batteries and portable chargers. Kept the game on for 30 minutes without power running off.**	**Observed both Bobby and Beth using the tunnel for 30 minutes without power running off.; Asked teachers to record unexpected shut offs and none was reported.; Instructions were given to teachers on how to change batteries; Observed teachers changing batteries with instructions.; Multiple charger alternatives were provided to teachers.**

Keep body straight	**During the game, both Bobby and Beth should always keep standing straight without assistance, possibly leaning on the tunnel.**	**Added obstacles of different distances in front of the sensors. ; The sensor demonstrated that the system would shut off if the distance was too far, meaning that nothing was in front of the sensor (an indication of clients probably sitting).**	**Asked teachers to count and record the times children sit, and how many times the system actually shuts down. No results from the teachers yet.; Both Bobby and Beth were observed to be actively standing and understood to stand up in order for the game to continue. This was done with help from the teachers.**
Lights and sound are safe	**The lights and sounds feedback by the tunnel should be within the range that is acceptable for children.**	**Quantitative Analysis: Measured the noise level of the sound (under 70 dB); Quantitative Analysis: Measured the light level (in the range of 100 - 300 lux)**	**Both Bobby and Beth were not scared or hurt (eg. covering their eyes with hands) when interacting with the lights and sounds.**
PVC Structure stability	**The PVC frame should be stable enough while using.**	**The maximum load-bearing of the frame tested with a result larger than 50 pounds.; The stickiness of the PVC connections was tested. Pipes were hard to pull out.; Pipes were stable after adjusting the angle of wooden platforms.**	**Observe Bobby and Beth using the tunnel without pipes breaking or falling apart.**
Buttons on the platform should be within reach	**Clients should be able to reach and push the buttons on the platform effortlessly while using it.**	**The angle of the board was adjustable.; The horizontal distance from the center of the tunnel to the button was adjustable with a minimum distance of 13 inches and maximum of 15 inches.**	**Observed both Ruth and DJ able to reach all of the buttons without putting efforts.**

Simple setup	**The pipes and circuits (within the pipes) should be able to be assembled in less than 5 minutes on site without tools.**	**Designed in a way that is easy for people to detach and reconstruct all pipes.; All wires run underneath the pipes, making the system simple and clean.; Both the bottom and the top circle of the pipes were glued together. No further action required except for attaching the vertical stands to the circles.; Tested that it was possible to assemble all the parts in 5 minutes.**	**Gave detailed instructions to the teachers on how to build the device.; Asked teachers to record the time they need to build the device.**
Game is easy to understand with no bugs in the game	**The game should be functioning smoothly and correctly without bugs. All sounds, lights, and sensors work coherently.**	**Tested the code multiple times.; Made sure that different buttons were lighting up randomly enough.; Different buttons have different animal sounds corresponding to it.; The button kept lighting up until one of the buttons was pressed, giving users enough time to find the button.; If the correct button is pressed, a "correct music sequence" was played.; If the wrong button is pressed, a "wrong music sequence" was played, and the button continued to light up until the correct button was pressed.**	**Both teachers, Beth, and Bobby can easily understand the game.; Teachers were able to guard and supervise Bobby and Beth, giving them hints if they cannot find the buttons.**

Music is easy to change	**Teachers should be able to change the music based on client interests.**	**Easily uploaded the animal sounds to a SD card.; Names of the files have the format like 0001 - XXX, eg. 0001 - Cat Meow, making it easy to understand.**	**Asked the teachers what animals the children like, and observed that the music we uploaded indeed attracted clients' attention.; Asked if the teachers understand how to change the music without assistance.; A new SD card (32 GB) was given to the teachers.**

Appendix C: Hazard Analysis

Table 2: Hazard Analysis

Hazard	Potential Effect of Hazard	Severity	Occurrence	Risk Assessment	Plan (Redesign, Guard, Warn)
Exposed wires	get an electric shock if there is leakage	4	4	2	Put wires inside the pipes
Exposed wires	users tripping over, broken toe	2	2	2	Warn: Kids should stop using the tunnel if wires exposed.
Sharp edges	cuts	2	2	3	Use tapes or covers to cover the sharp edges
Exposed Screws	cuts, broken fingers	2	2	3	File down. Use tapes or covers to cover the screws
Electronic components	get an electric shock if there is leakage	3	3	2	A protection box is built for the circuit.
Boards leaning/tilting	fall out	2	2	3	Warn: Kids shouldn't lean on the edge of the tunnel. Redesign: weight added at the bottom of the tunnel.
Unstable pipes	parts falling to pieces and cause injury	2	2	3	Use glue to stick parts together.
Box falling off	broken device/exposed wires	2	3	3	Use screws and glue to stick the box from falling
Scared of the board	cry/fears	1	3	3	Decorate the boards

Scared of the sound/light	cry/fears	1	3	3	Test the levels of sound and light to make sure that they are acceptable for children before final delivery
Sticky/dirty materials	clothes get dirty	1	3	3	Sanding and cleaning device parts. Use covers on the surface of the platform
Pipes too close to the tunnel	Arms might get stuck between pipes and the tunnel	2	4	3	Leave enough space between pipes and the tunnel. Test the angle of the platform to get the best position
Pipes break	fall out when trying to reach the buttons	2	4	3	Redesign: Use pipes made from harder material
Pipes break	cuts	2	4	3	Redesign: Use pipes made from harder material
connectors between pipes detached	Someone trips on the broken parts	2	2	2	Use stronger glue for connectors. Redesign: Change ways of connections. e.g: Use screws or solder pipes instead.
boards fall off	exposed wires	2	3	3	Fix the board (but might not be that flexible to adjust)
Occurrence: 1 frequent					
Severity: 1 negligible					

***Appendix C**: Final Budget & Parts Listing*

Table 3: Budget Breakdown for Prototype

Item	Price	Quantity	Full Price
45° pipe fittings	$ 0.39	16	$ 6.24
3-way pipe fittings	$ 1.98	8	$ 15.84
PVC glue and primer	$ 11.48	1	$ 11.48
Plywood (4 x 10 " board)	$ 13.98	1	$ 13.98
LED buttons (package of 5)	$ 12.99	2	$ 25.98
wire (1 spool-100 ft)	$ 4.50	1	$ 4.50
pcb board	$ 21.00	1	$ 21.00
wire box	$ 4.05	1	$ 4.05
pipe straps	$ 0.20	12	$ 2.40
electrical tape	$ 1.99	1	$ 1.99
PVC (3/4 in dia x 10 ft)	$ 2.54	2	$ 5.08
Total Price			**$ 112.54**

***Appendix D**: Electronic attachments (Editable Files Upload to Group Folder on Sakai)*

CAD/Eagle Files

Code Listings

UDS Instruments

Class Presentations

Video of Device

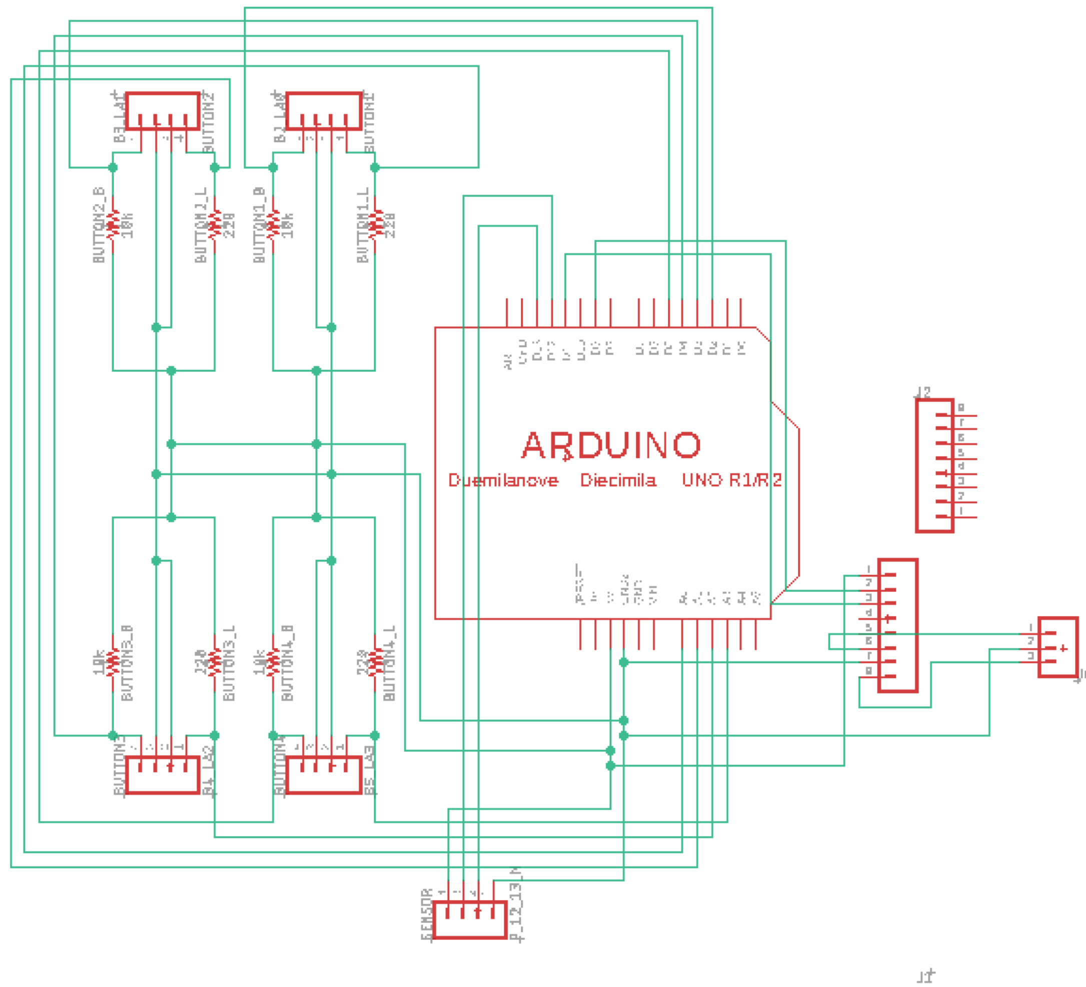

Figure 6: Circuit of the device

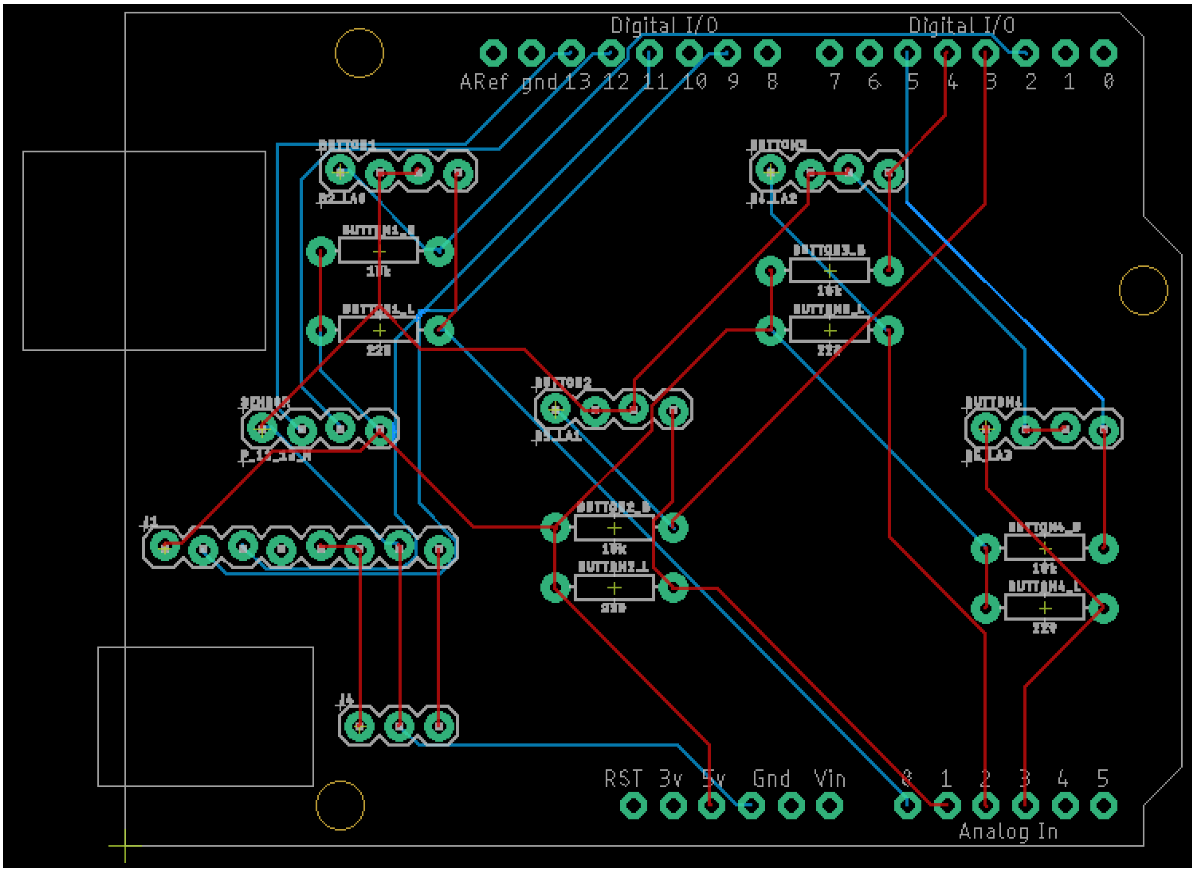

Figure 7: PCB design

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[1] Kavarna, D. (2019, May 31). Posture Disorders in Children and Causes. Retrieved from https://www.digime3d.com/en/posture-disorders-in-children-and-causes/

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Barbara Tapper

Morgan Timberlake

Dr. Kevin Caves

First Author Contact Information:

Adrianna Battle

anb72@duke.edu

703-439-7937