Kirsty Thompson
MEng Product Design Engineering
Final Year Project, 10-Page Summary

THE GLASGOW SCHOOL OF ART
University of Glasgow

Problem & Opportunity

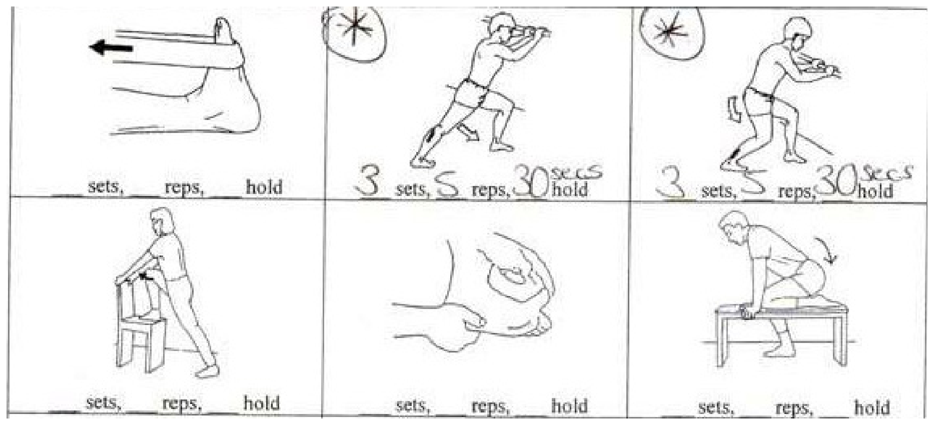
Overview

Home exercise programs (HEPs) are one of the most important aspects of physiotherapy. They are individual sets of therapeutic exercises given to patients to do at home to maintain the strength and increase therapeutic gains.

Patients initially go through their exercises with their physio / PT to ensure they have proper form and experience no pain. However, non-adherence to home exercise programs has been shown to be as high as 50-65% for general Musculoskeletal (MSK) conditions [1]. Which has been made even worse through telehealth replacing face-to-face meetings.

Patients find it hard to stay consistent with a HEP due to busy lives. They also find it difficult to know if they are doing their exercises the exact same way as they learned during their physio visit.

Written exercise programs can confuse patients even more due to basic sketches, for example the short program below.



[1] Bassett SF. The assessment of patient adherence to physiotherapy rehabilitation. NZ J Physiother, 2003, 31: 60–66
[2] Foothills Rehab (online)

Importance of Physio

- Improves muscle memory
- Significantly more successful at achieving rehab goals & experience relief from pain more quickly
- Beginning of a new active lifestyle
- Helps prevent recurrent injuries & flare ups
- Body will heal more naturally
- Body will be stressing less once the patient gains their ability to move again

Patient Engagement

Patients need to complete their HEP consistently to have an overall successful rehab experience.

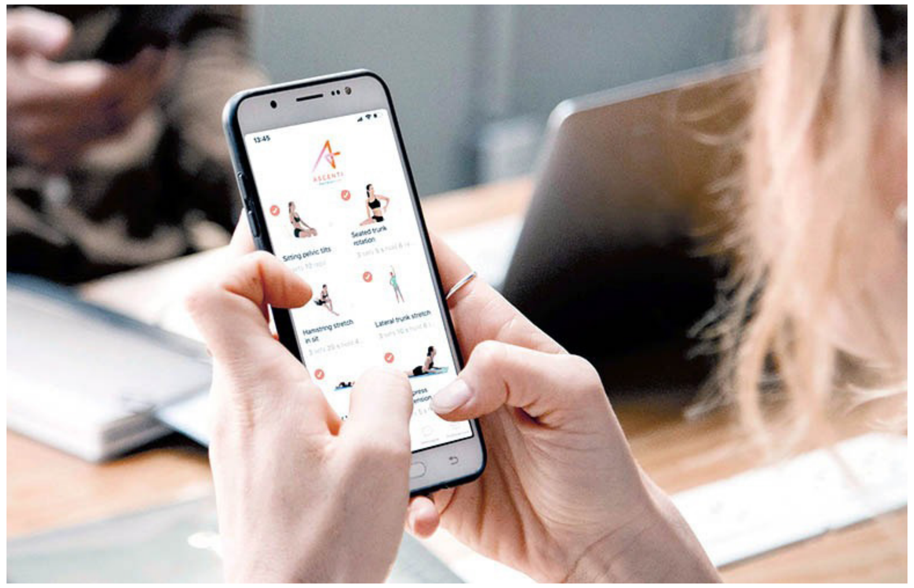
Non-adherence increases the risk of recurrent injuries or flare-ups with less positive outcomes long term and results in the physiotherapist believing that their current treatment is not effective [2].

Injuries can be made worse if exercises are performed wrongly so proper patient engagement is necessary.

Opportunity

Currently there are limited options available when it comes to supporting and encourage patients to keep up with their HEP. It's mostly down to physiotherapists themselves which is only possible to do within appointments.

More recently this has expanded into basic physio apps to provide a digital copy of exercise programs.



The Brief

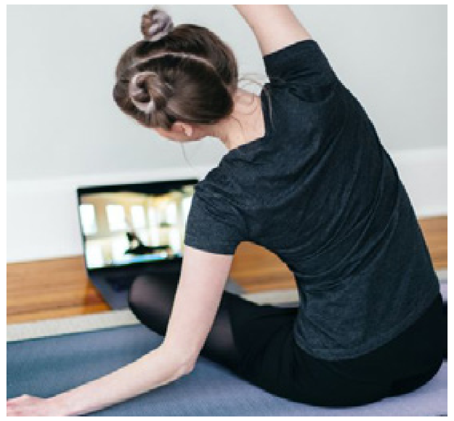
Design a solution for at home physiotherapy for those who want to oversee their own ankle injury whilst improving adherence to exercise programs.

Research

The Experts

From speaking to physiotherapists, I learnt that some people are really engaged and diligent with their exercises, while others are honest about not doing them often or at all

Lockdown also affected their practise and changed the way they will treat their patients in the future. Overall they found virtual appointments beneficial but missed assessing and treating in person.



The physiotherapists I have spoken to are still offering virtual appointments as it offers their patients reassurance, without having to wait months on a waiting list to see someone in person.

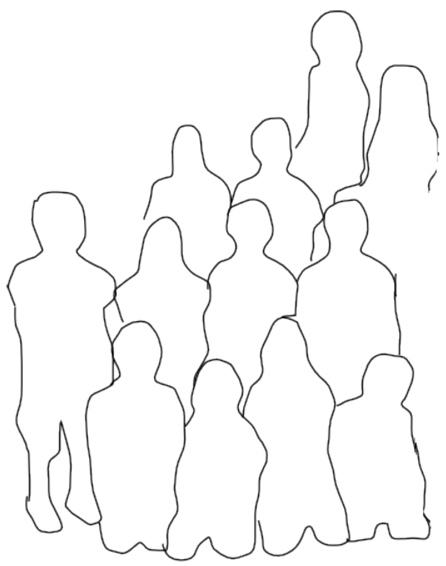
I also learnt about all the different areas of injury which are included in MSK physiotherapy. The main injuries / area of injury treated by MSK physiotherapists are lower back pain, rotator-cuff (shoulder) related pain, Achilles tendinopathy (ankle) /calf strains, neck pain and knee pain.

User Engagement

Through reaching out to family, friend and previous sports clubs which I have been a member of, I was able to connect with a number of people (n=20) who have experience with physiotherapy.

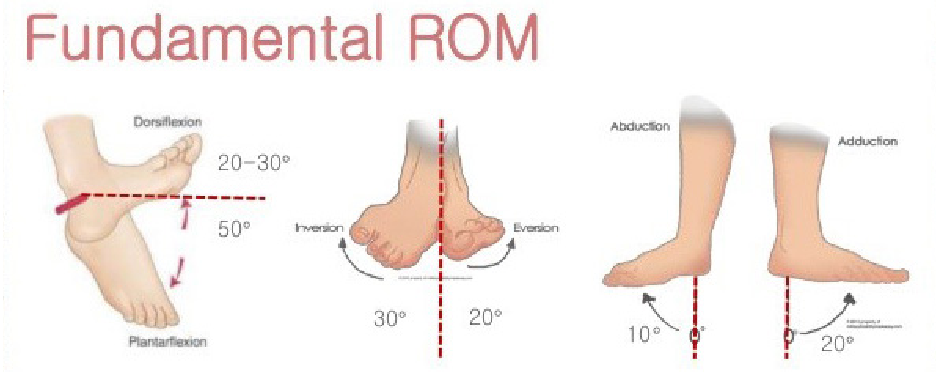
User surveys were created throughout the project to gain further insights into what the most common MSK injury are and why patients do not adhere to their exercises. As well as what would encourage them to do their exercises more often. It was even found that some people don't attend physiotherapy due to not being referred or they are too busy.

> "Some sort of gauge for obscure exercises would have been good"
>
> "Was very busy so sometimes didn't have time to do it"



A user group of 12 physically active individuals, ranging from recreational sports to competing internationally in sports such as judo & athletics, was created. They also have a range of experience with physiotherapy & sports injuries. They were contacted throughout the project, providing feedback on ideas.

Desk Work



Further desk work concluded that for this project ankle injuries would be focused on.

2/3 — Physiotherapy appointments are for Musculoskeletal (MSK) Conditions

Sprains & Strains — Are the most prevalent MSK conditions for those who are physically active

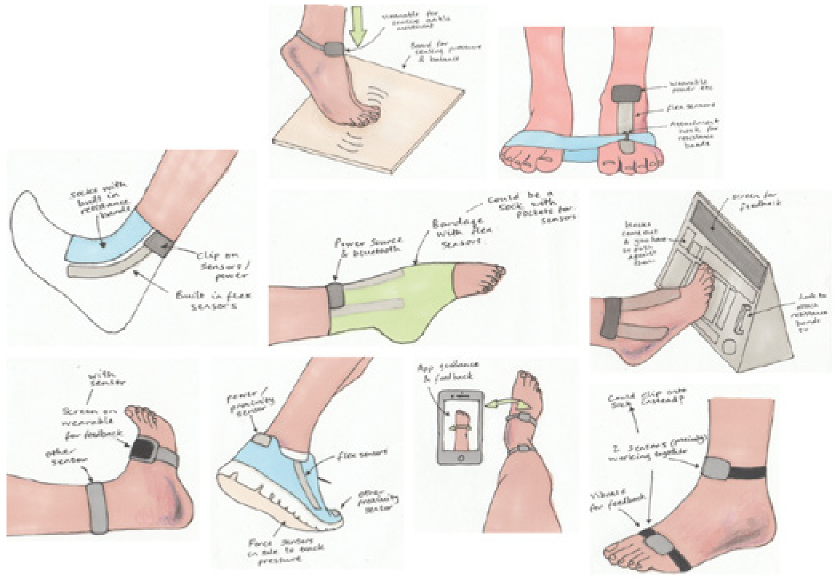
1 Million — Ankle Sprains occur each year in the UK

Key Insights

1. Service Fault
   - People are not being referred even though they should and want to be
2. Unclear Home Exercise Programs
   - Leading to them being performed wrong
3. Expensive
4. Convenience is a major factor
   - Especially for those who are always on the go
5. People don't do their exercises
6. Prehab is more important than rehab
   - To prevent the injuries from occurring

Concept Development

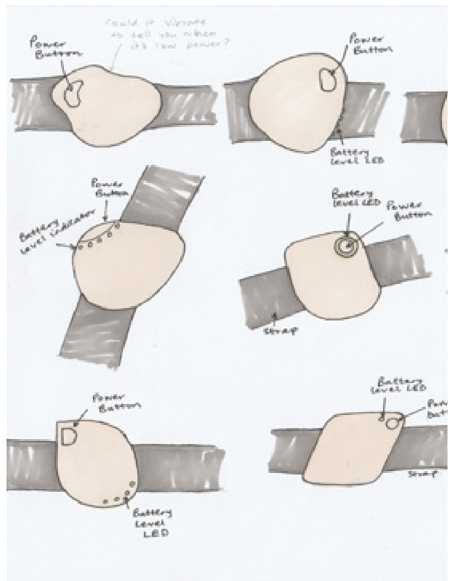
2D Exploration



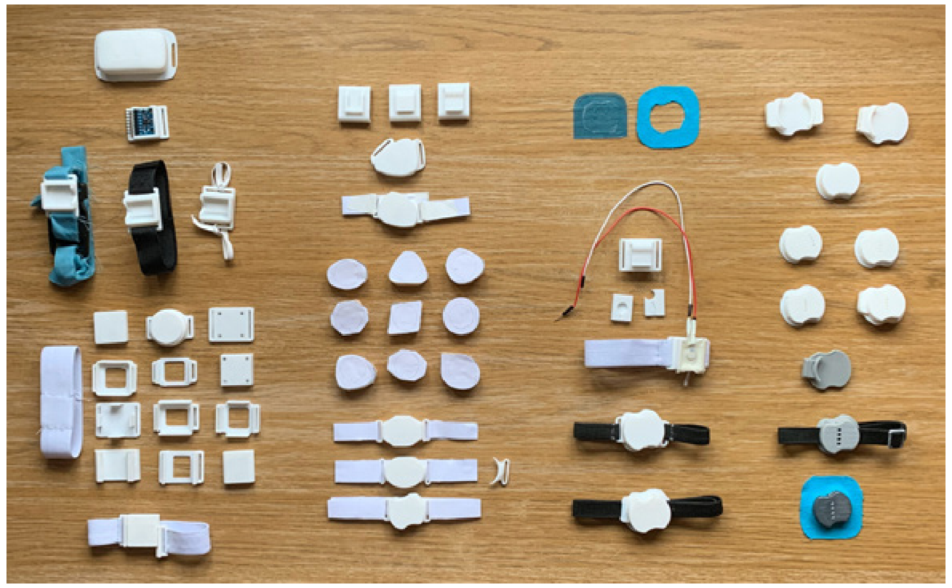
2D exploration allowed me to quickly evaluate concepts and easily share them with my user group. Although some initial concepts included the use of specialised shoes, socks, bandages and equipment, I decided to move away from this as it would restrict the user to only do their exercises when they had access them. Instead, a small wearable device was created to provide the freedom of doing exercises anywhere.

2D exploration was also useful whilst developing attachment methods, the physical form of the device and the placement of physical features such as buttons and LEDS.

It was also used for clearly communicating the user journey of the product in its early stages.



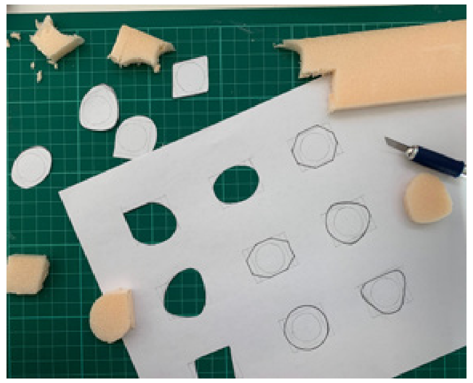
3D Exploration



A sensor module was created and a range of mechanisms were tested to find the easiest method of connecting the module to 3 attachment methods; strap, clip and adhesive. A range of snap fits, sliding and magnets were all tested.

Again, after testing with my user group, a sliding mechanism was chosen.

Due to a product dealing with injuries, the method of attaching a wearable to the skin was very important. The device needed to be comfortable when worn and not interfere with sensitive areas. While working with my user group it was found that everyone had their own preference of how it could be attached to the skin. Therefore it was decided that the device should allow the patient the freedom to chose the device it attached.



Lastly the form of the device was explored. Firstly using foam and then developed to include the chosen sliding mechanism. The form and sliding mechanisms were both developed further.

Stakeholder Engagement

I spoke to a number of current and past physiotherapy patients to gain more insights into what they need from a physiotherapy device.

I engaged further with a few of the physiotherapists who I had previous spoke throughout the project. They provided valuable insights into rehab and prehab and if concepts would be beneficial.

Catriona Dourish, LMTherapies

Andrew Pattie, NHS Physio

Adelle Smener PT, DPT, CSCS The Prehab Guys

Product Overview

Flexio is a wearable physiotherapy device with a partner app to show patients how to perform their exercises and ensure the correct the form is adopted. It also allows them to view their progress for further encouragement.

It is aimed at physically active people in the age range of 18 - 35 and is used for both rehab (recovering from an injury) and prehab (preventing injuries from occurring in the first place).

Flexio provides the flexibility of being able to be guided through exercises from anywhere, e.g. at home, work or outside. As well as 3 attachment methods for the patient to chose from.

1 Flexio Kit = 1 sensor module, 1 strap attachment, 1 clip attachment and 20 adhesive attachments.

Flexio could save the NHS £148.80 per patient by reducing the number of appointments required from 6 to 3 buy buying each patient a £49.20 Flexio Kit.

Button indicates orientation

Additional app feature: Video record exercise

Charge wirelessly after 3 hours of use

Feedback from Physiotherapists:

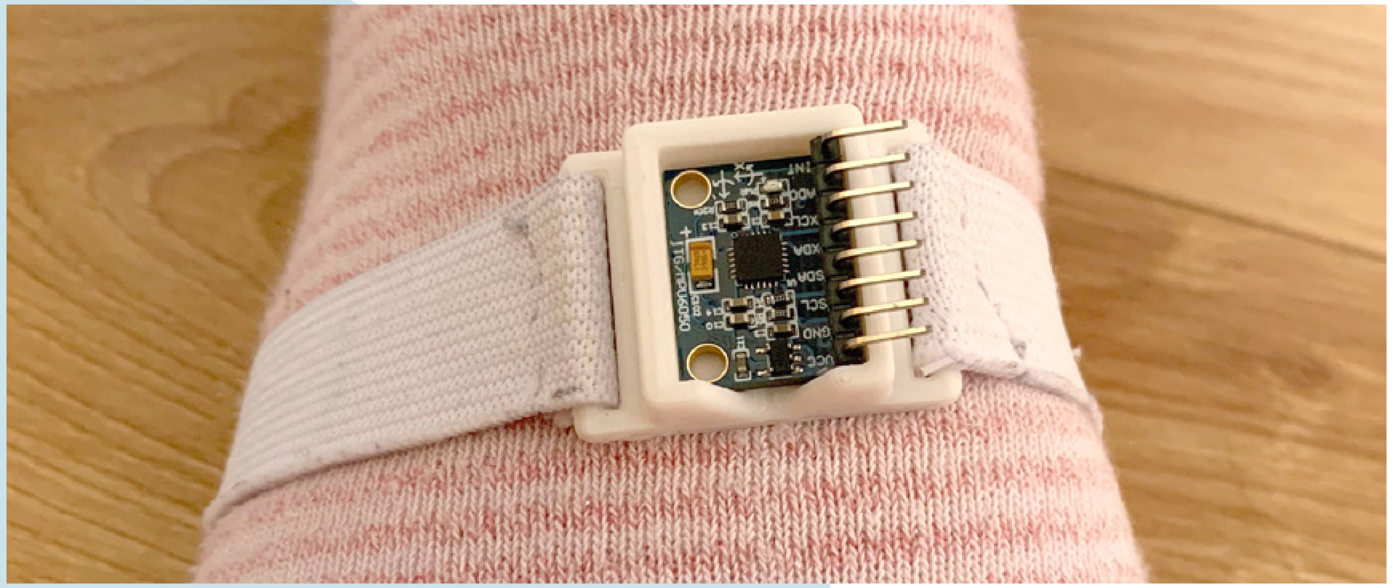
"Great adjunct to physiotherapy"
- Catriona Dourish, LMTherapies

"Catches patients who aren't cooperating, love the feedback feature"
- Andrew Pattie, NHS Physiotherapist

"A perfect compliment to foot/ankle prehab programs if someone does not want or "need" traditional PT"
- Adelle Smener, The Prehab Guys

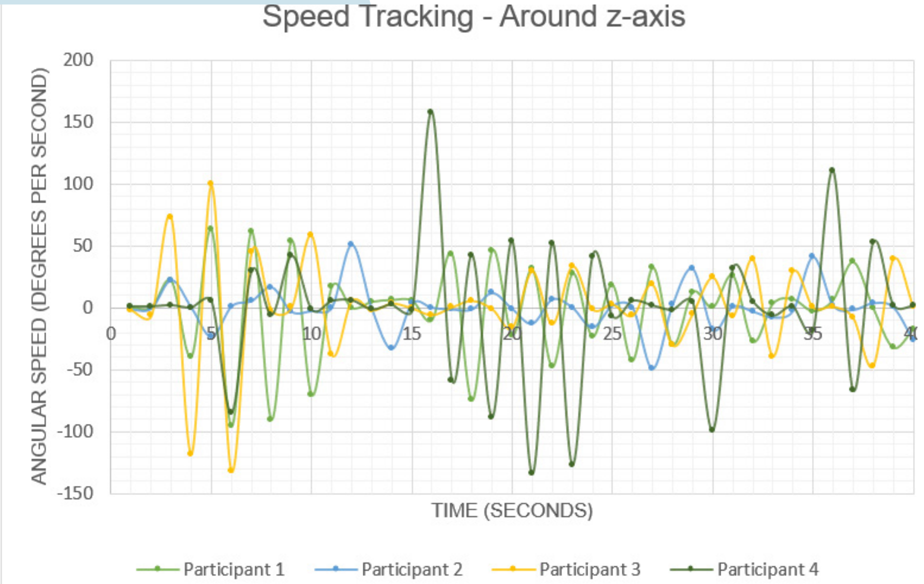
Ankle Motion Tracking

Experiments



To prevent the need for the user to place the wearable precisely on a certain area of their foot each time they use the device, and to accommodate for the differences in every user's foot, calibration is required to set a reference point for taking angles from.

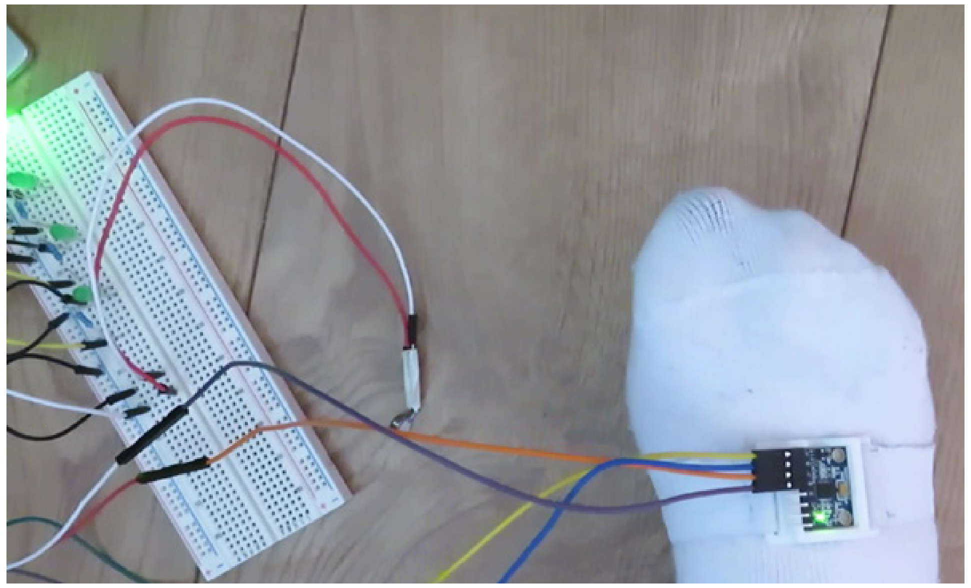
An experiment was carried out to work out for how long the user should be required to stand still, for an accurate reference point to be taken, using an MPU-6050 IMU.



Speed tracking was among some of the other experiments investigated throughout this project to ensure the chosen IMU would be able to capture enough data to facilitate tracking the speed of movement during exercise.
Overall the experiment showed that the chosen IMU was more than capable of this.

Working Prototype

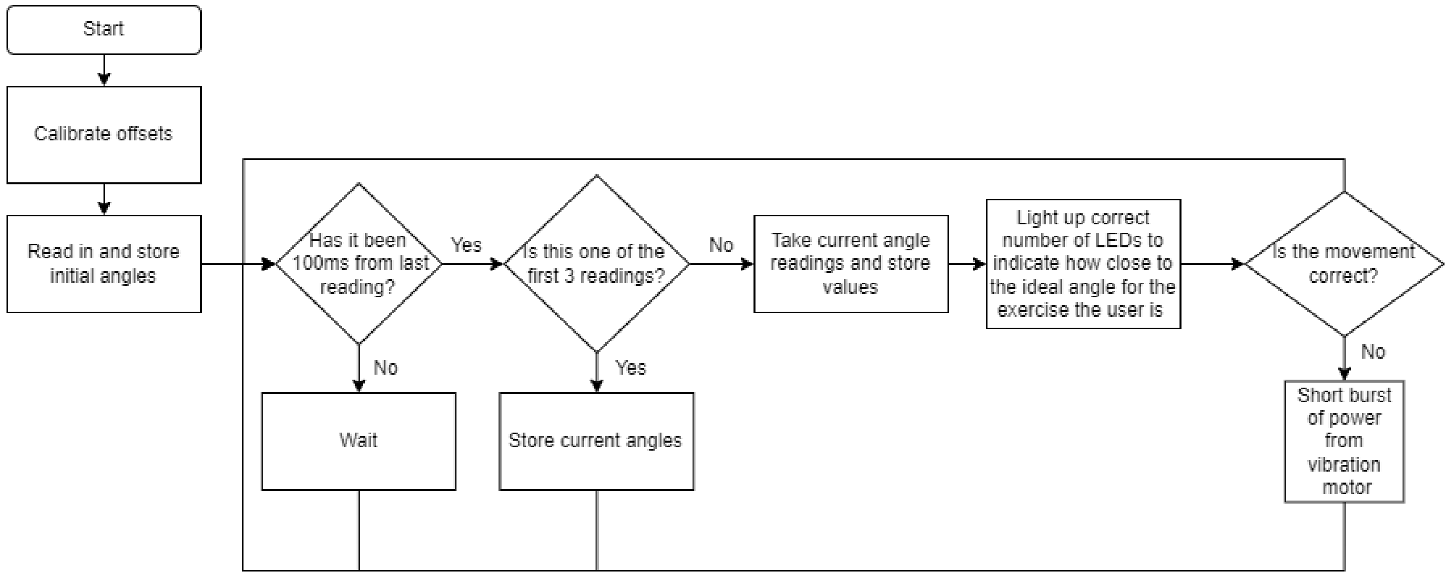
For proof of concept, a working prototype was built using an arduino, MPU-6050 IMU, 4 LEDs and a pancake vibration motor. 3 basic movements of the foot were then tested. This allowed me to physically show how the device would work and gain more feedback from users.



Only certain movements are allowed e.g, a dorsiflexion /plantarflexion exercise should only see an increase and decrease of the pitch angle, no rotation in the x or z axes.

Every 100ms the angles from the IMU will be read in,

The angles are compared with the ideal angles of the exercise and LEDs are lit up in relation to how close the current angle is to these values. The current angles are also compared to the allowable movements for the exercise, as previously explained, if the current angles are not allowed, the device will vibrate.

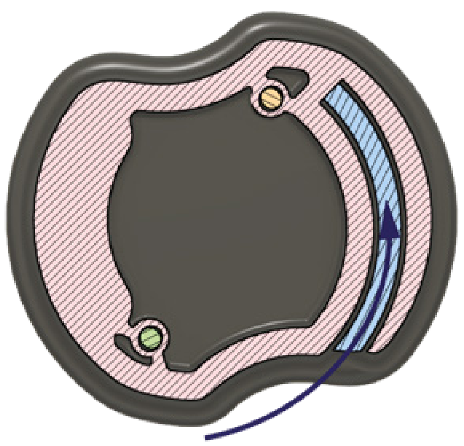


How to Attach

Attachment Methods

Strap

To attach the strap, one side is slid into the sensor module as seen below. The other side of the strap is fed into the opposite side of the sensor module and tightened.

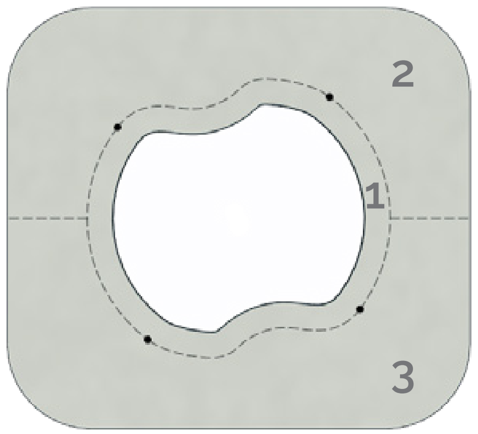


Clip

The clip also uses the sliding mechanism to attach to the sensor module. It is then clipped onto shoelaces.

Adhesive

The adhesive has a 3-step process to take backing off adhesive and to adhere to the foot as shown below.

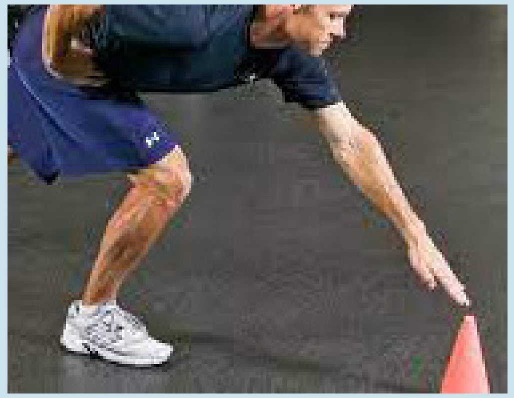


Wearable Placement

Experiments were carried out to find the best placement of the device through comparing angles recorded for 3 different placements over 6 different ankle movements. The recorded angles were analysed in relation to the ideal range of motion for each movement.

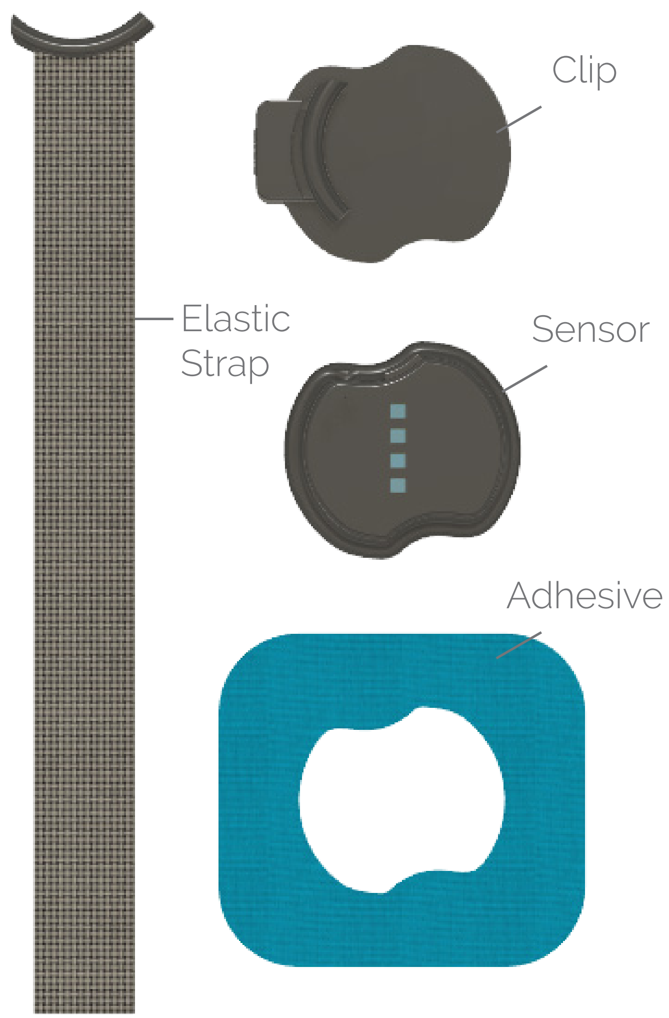
Overall, these experiments showed that the position of the wearable physiotherapy device is predominantly on top of the foot but requires to be changed to around the ankle for exercises where the foot stays in one position while the leg changes angle.

Top of the foot



Around ankle

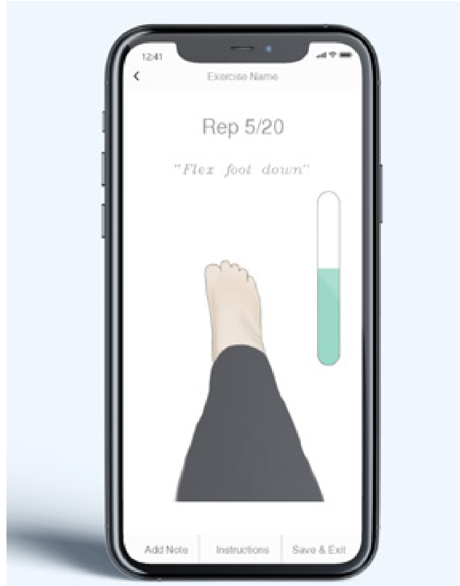
Device Set Up



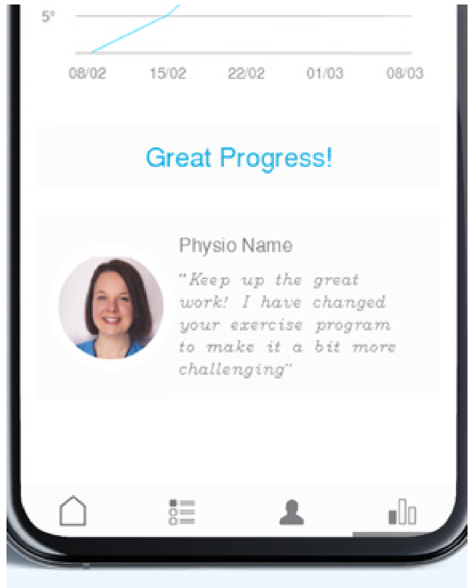
Receive the kit
(Buy online or borrow from Physiotherapist)

Once returned to a Physiotherapist, the strap attachment can be replaced and the rest of the parts should be sanitised

REHAB



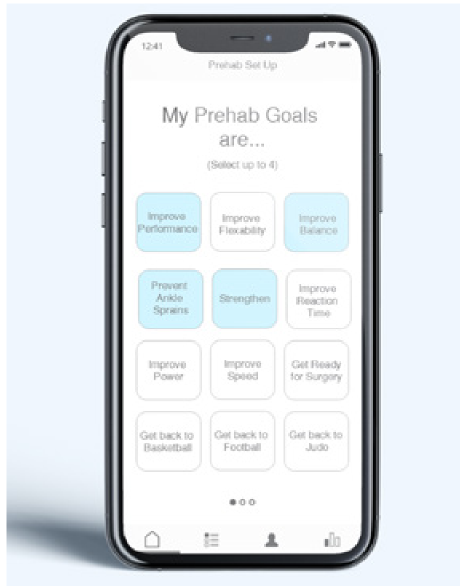
Physiotherapist provides exercise program through Telehealth or in person appointments



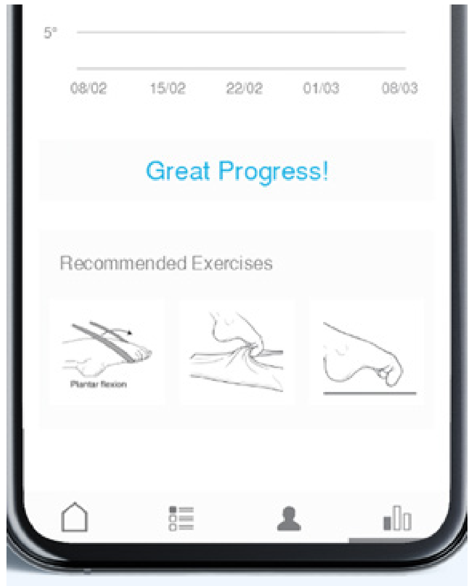
Physiotherapist can change / alter exercise programs depending on progress made

After Rehab:
A Prehab program should be set up on the app followed

PREHAB



Enter prehab goals into the partner app for an exercise program

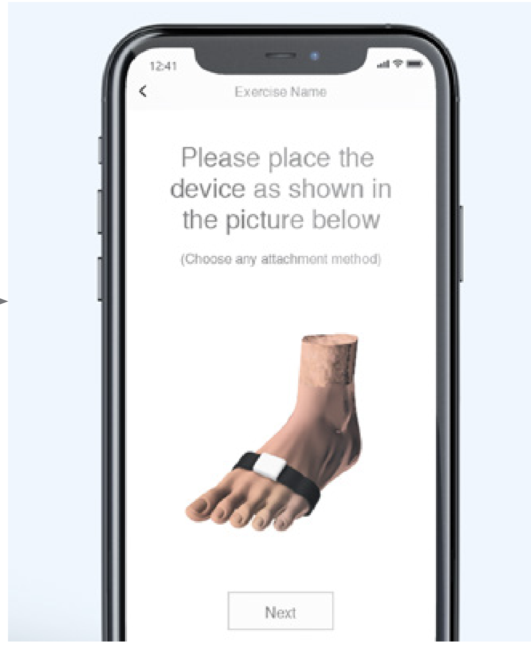


Exercises can be changed / added (from recommended exercises)

Prehab should be performed every day to reduce the chances of injury due to poor form

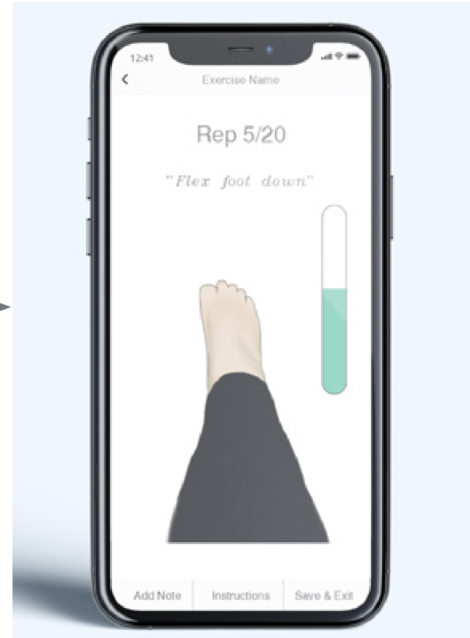
User Journey

Press on button to connect to phone

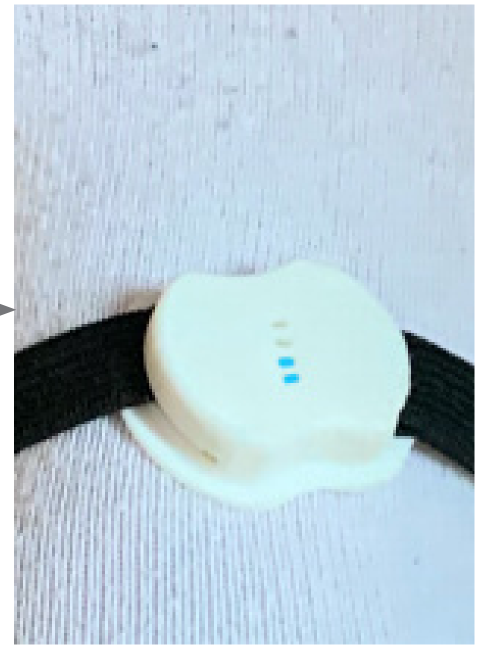


Device placement & exercise instructions

A short vibration from the device indicates the start of the exercise



Angle/Speed bar shown at the side



LEDs light up to indicate angle / speed

WRONG MOVEMENT

Device vibrates until the correct movement is adopted

/ All LED lights turn red /

Exercise instructions reappear over the animation

Advice on how to fix movement via the app

Technical Development

Battery Capacity

Component	Time of Operation (hours)	Current Draw (mA)
IMU	0.75	0.55
Bluetooth	0.75	8.7
LED 1	0.75	2
LED 2	0.67	2
LED 3	0.63	2
LED 4	0.5	2
Vibration Motor	0.1125	42

$Q = It$

Where Q = Charge (Ah), I = current (mA) and t = time (hours).

$$Q_{IMU\_Blue} = (0.55 * 0.75) + (8.7 * 0.75) = 6.938\ mAh$$

$$Q_{LEDs} = 2 * (0.75 + 0.67 + 0.63 + 0.5) = 5.1\ mAh$$

$$Q_{vibration} = 42 * 0.1125 = 4.725\ mAh$$

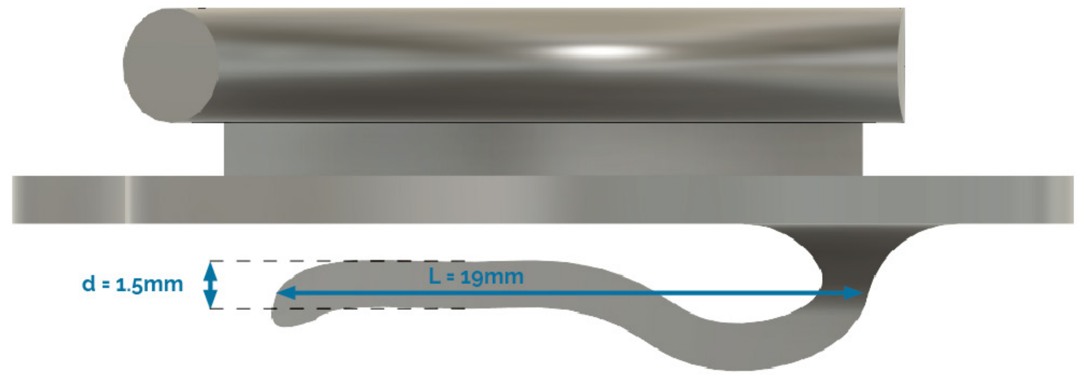
Capacity for 1 x 45minute operation:

$$Q_{Total} = Q_{IMU\_Blue} + Q_{LEDs} + Q_{vibration}$$

$$Q_{Total} = 16.763\ mAh$$

For 4 uses of the device, the required battery capacity is approximately 67mAh. Therefore, a CR1620, with a capacity of 70mAh and dimensions of 16mm diameter x 2mm thickness, was chosen for this product

Clip Stress



Where:
Delta = Deflection of beam = 1.7mm
F = Force Applied (N)
L = Length of beam = 19mm
c = d/2 = 0.75mm
I = Moment of Inertia (mm^4)
E = Young's Modulus of ABS = 2020MPa
$Sigma_{max}$ = Maximum Stress (MPa)

Research showed that shoelace thickness ranges from 2mm to 6mm and are manufacture by braiding therefore, hollow inside and can be compressed to at least half of its thickness.

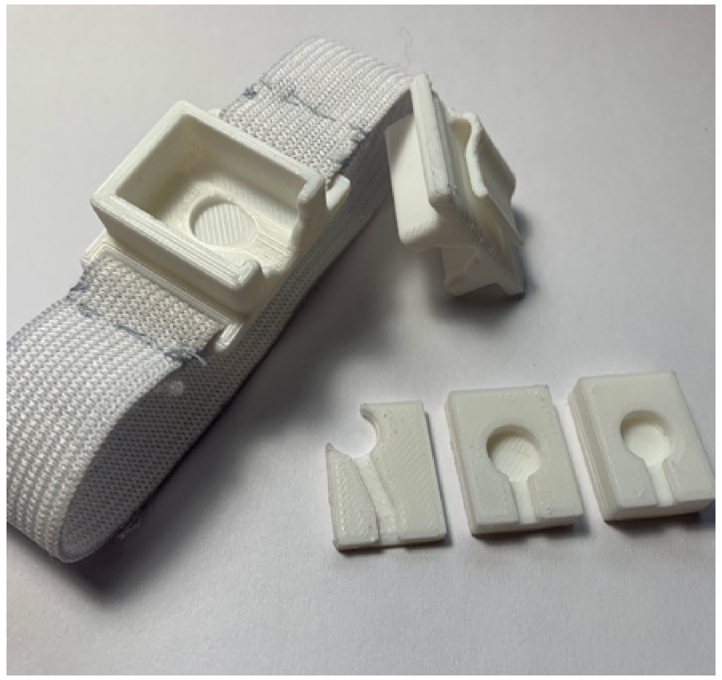
To achieve the ideal deflection of 1.7mm, a force of 8.88N is required. This deflection is the maximum required by a 6mm thick shoelace. It would see a maximum stress of 21.41MPa which ideal as it is not enough to snap the clip.

$$I = \frac{bd^3}{12} = \frac{21 * 1.5^3}{12} = 5.91mm^4$$

$$F = \frac{3\delta EI}{L^3} = \frac{3 * 1.7 * 2020 * 5.91}{19^3} = 8.88N$$

$$\sigma_{max} = \frac{FLc}{I} = \frac{8.88 * 19 * 0.75}{5.91} = 21.41MPa$$

Placement of Vibration Motor



Attachment Type	Average Vibration Power Rating at			
	1mm	3mm	5mm	7mm
Strap	●●●●	●●●	●●●●	●●●
Adhesive	●●●●	●●●●	●●●●	●●●
Clip	●●●	●●●●	●●●	●●

The table above shows the results from the vibration motor placement testing. The strap and adhesive attachments performed very similarly. The clip attachment, however, was less intense but users stated that they could feel vibrations through the whole foot with this attachment as the vibrations travelled throughout the shoe.
Therefore, there is no real difference in placing the vibration motor at the bottom of the sensor module compared to at the top.

Design For Manufacture

Component	Part Description	Material & Manufacturing	Quantity
Main Body of Casing	Holds and protects all of the electronic components	Injection Moulded from ABS	1
Threaded Inserts	Set inside the main body of the casing during injection moulding to allow use of screws	Standard Part	2
Base of Casing	Holds the electronics & facilitates the use of attachments	Injection Moulded from ABS	1
Light Pipe Mouldings	Protects the LEDs	Standard Part	4
Outer Button	Protects the button	Injection Moulded from ABS	1
Button	To turn the product on and off	Standard Part	1
Vibration Motor	To provide haptic feedback	Standard Part	1
IMU	To detect the angles and angular speed of the foot	Standard Part	1
Bluetooth Module	To connect to the phone	Standard Part	1
MCU	To ...	Standard Part	1
RGB LED	To provide feedback to the user	Standard Part	4
CR1620 Battery	70mAh Battery	Standard Part	1
Wireless Receiver Coil	To facilitate wireless charging	Standard Part	1
M2 x 4mm Screws	To secure the 2 parts of the casing together	Standard Part	2
Strap	To wrap around foot/ankle	Nylon Elastic Webbing over moulded with ABS	1
Clip	To attach to shoelaces	Injection Moulded from ABS	1
Kinesiology Tape	To attach to the sensor module and to the foot	Die Cut (including perforation)	20

Manufacturing Cost per Kit = £16.40 based on producing 100k units