

JANUARY 2023

MONASH HEALTHCARE INNOVATION SUMMER SCHOLARSHIPS

Project Activus



Monash Partners
Academic Health Science Centre



**MONASH
YOUNG
MEDTECH
INNOVATORS**

Current Team: David Cheng
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Affiliations

Executive Summary

Sarcopenia and frailty are common disorders for patients with chronic kidney disease or on haemodialysis. This is because individuals undergoing haemodialysis often spend long recurring bouts of time being inactive due to the stationary nature of haemodialysis, leading to an increasingly sedentary lifestyle that contributes to sarcopenia and frailty. Exercise has been shown to be an effective treatment and preventative measure for sarcopenia and frailty, but issues arise with low patient adherence and a lack of access to quality intradialytic and interdialytic exercise programs in Australia. This project aims to identify current implementations of exercise programs around the world, problems with failed attempts, and feasibility in Australian renal units. Then, a solution is discussed to encourage long term personalised intradialytic and interdialytic exercise routines for patients undergoing haemodialysis so that and independence can be regained.

Acceptance Criteria

- 1. Be portable, easy to set up, easy to integrate, affordable, and easy to use.**
- 2. Track patient exercise progress.**
- 3. Provide evidence based adherence features.**
- 4. Offer both upper and lower limb exercises.**
- 5. Be affordable, and suitable for a clinical/home setting**

Gaps analysis

The Gold Standard:

The current gold standard for intra and inter dialytic exercise are manually monitored and often self-directed programs. Successful examples of dialysis units initiating their own exercise program such as those in Japan or in Singapore utilize commercially available exercise equipment but are paired with strict guidelines and procedures; some dialysis units may refuse treatment if patients do not do a prescribed amount of exercise. Other examples around the world rely on specialists and a dedicated team to run tailored exercise programs or rely on patients to find their own physiotherapist to aid in their exercises. All these solutions require specialists to initiate and sustain tailored programs, increasing the barrier to implementation and increasing reliance on said specialists.

Existing solution 1: One-on-one exercise programs

A one-on-one exercise program is often the type of intra/interdialytic exercise program used in Australia. They often involve a physiotherapist actively supervising and guiding a patient to perform exercises. [1] The costs of this program are generally incurred by the patient themselves, and although outcomes are generally improved, cannot be scaled to include all hemodialysis patients. [1]

Existing solution 2: Tailored integrated exercise programs

A tailored exercise program is one specifically developed for a renal unit. They often involve dedicated staff and require the entire renal unit to actively promote and encourage exercise during hemodialysis. An example includes the SitFit exercise program at the University of Virginia Renal Services, where an 'exercise leader' is required at each unit, quarterly exercise team meetings are held, and reporting procedures are established. [2] While this is a solution that works, it is a complex solution, and there are barriers in that there is a heavy reliance of manual organizational systems and expertise required to start and sustain a program. It may also be relatively expensive in that dedicated staff are required to run the program.

Existing solution 3: Pre/intra-dialysis exercise programs

Examples of relatively simple exercise programs include those in Japan and Singapore, where exercise is integral to the haemodialysis treatment provided [3]. These solutions work by actively encouraging patients to exercise either during or before haemodialysis; sometimes outright refusing treatment unless an exercise program is completed. This solution while effective, may be considered unethical and is therefore not an option in Australia.

Systems Map

PROJECT ACTIVUS SYSTEMS MAP

KEY:

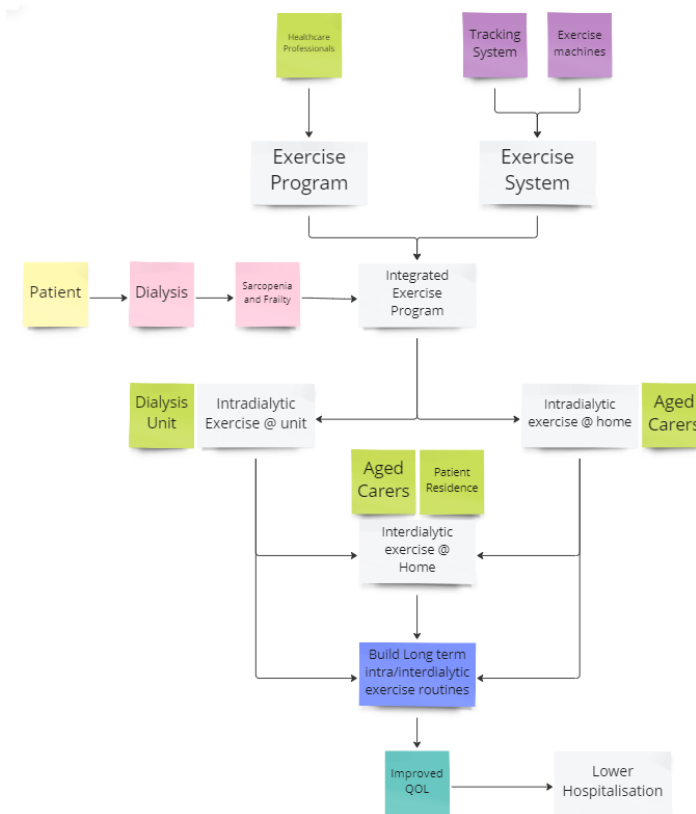
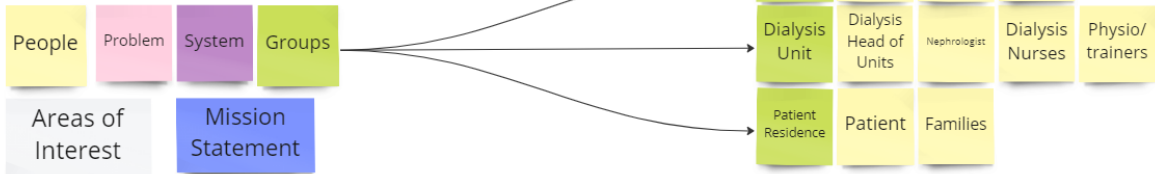


Figure 1: Systems Map

A simplified systems map of the various groups of people, individuals, and areas of interest for the project. Major areas of interest involves the creation of an integrated exercise program, whereby the exercise program and equipment are specifically tailored for a renal unit and use by healthcare professionals and patients. People represented as being yellow, systems in purple, groups in green, areas of interest in grey, and the mission statement in blue.

Link for the full systems map:

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Stakeholder Map

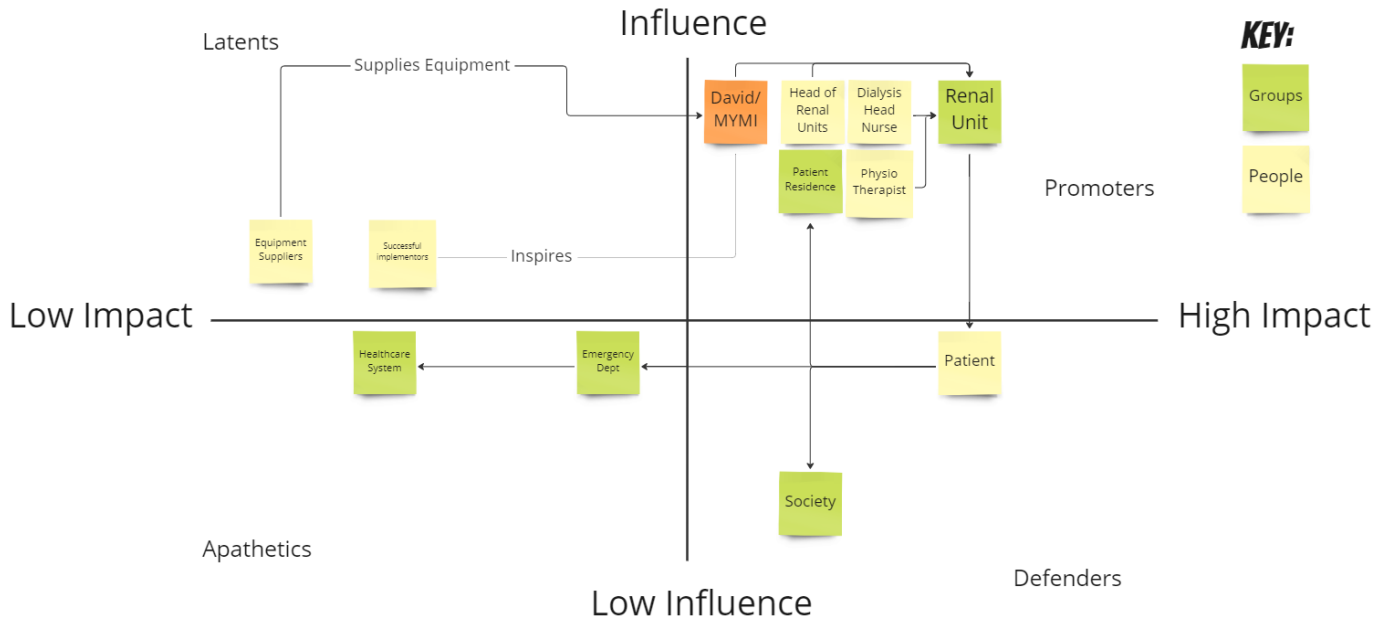


Figure 2. Stakeholder Map

Visual representation of the different stakeholders and their level of direct involvement in the project, as well as the effects the project will have on them. The level of influence each stakeholder may have on the project as well as the impact the project will have on each stakeholder is represented according to their relative location. Groups of stakeholders are represented as being green, with individual stakeholders represented as being yellow. There are 5 main groups of stakeholders, with the most influential group being the renal unit. They are the also most important group of stakeholders as the project may alter their procedures and impact their level of care.

Link for the full stakeholder map:

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Outcomes of Qualitative and Quantitative Research

Sarcopenia and frailty as diseases

Sarcopenia is broadly defined as a disability due the degradation of skeletal muscle tissue, resulting in low muscle strength and/or low physical performance [4]. Frailty is a syndrome characterized by a reduction in functional capacity, with an increased susceptibility for developing adverse outcomes upon exposure to stressors [5]. There is considerable overlap between sarcopenia and frailty in that there is a significant reduction in an individual's physical capacity, but frailty encompasses a broader functional spectrum including cognitive and social components as well.

Consequences of sarcopenia and frailty

Individuals with sarcopenia or frailty have an increased risk of falls and fractures, an impaired ability to perform activities of daily living, declined cognitive function, loss of independence, need for long term care placement, and death. Sarcopenia and frailty can also be exacerbated by acute illness or injury, and CKD patients with sarcopenia or frailty are strongly associated with all-cause mortality [6]. There is also evidence that frail kidney transplant recipients are more susceptible to early post-transplant complications than non-frail kidney transplant patients and are also more likely to develop delirium and experience early hospital readmission [6].

Pathophysiology

Low physical activity due to either a sedentary lifestyle or a disease related immobility have also been linked to sarcopenia. This is because skeletal muscle is continuously remodeled in response to workload, tension and nutrition [6]. Low physical activity, inadequate intake of energy, or limited access to healthy foods limits skeletal muscle remodeling and development. Individuals on hemodialysis are disproportionally affected as they are often required to spend long bouts of time being sedentary due to the immobile nature of haemodialysis.

Problems in solutions

It has long been known that continual exercise during and in-between haemodialysis yields clinically significant benefits for patients with regards to sarcopenia and frailty [7]. However, despite willingness among healthcare professionals for an exercise program, the difficulty in achieving long term patient adherence to these programs and a lack of time for healthcare professionals derail the beneficial effects of an exercise program. As a result, there are no major renal units in Australia that actively use exercise as an integral part of dialysis.

Solution Concept Discussion

- top 2

Smart wearable

A smart wearable device such as a smart watch is meant to track patient activity, and send this data to clinicians and/or display it to the patient themselves. This idea, while convenient and capable of tracking patient activity throughout the day, fails in providing patients guidance and support for more intense workouts. The small screen on smartwatches will be an issue for those with haemodialysis patients impaired vision, and is expected to cost a lot of money (>\$300).



Smartphone app

A smartphone app has many of the features found in the smart wearable device in that many have the capacity to track patient activity, send data to clinicians, and available for the patient to view. Additionally, they are expected to be a cheaper implementation compared to smart wearables it can be assumed that the vast majority of patients will already have a smartphone, and it's larger screen will mean patients may find it easier to read exercise information. The issue with a smartphone app as the sole component of a solution is that there is still no physical exercise solution suited for a haemodialysis unit. This means that it only really acts as a fitness tracker, meaning exercise during dialysis and the gamification components associated with it will be limited.



Final Concept

The final concept is called “Retro-FIT”, a service where existing commercial exercise machines are retrofitted with modern electronics to efficiently interconnect exercise data from patients to clinicians, promote adherence through gamification, and follow personalised exercise routines. These smart exercise machines, through a smartphone app or a standalone fitness tracker, will send relevant data to clinicians where they will be able to monitor progress or identify problem areas.

This solution involves off the shelf exercise machines such as a pedalling machine and cadence sensors, meaning there is a zero hardware manufacturing capacity required. Specific exercise machines and trackers can be recommended to renal units to work well with a custom smartphone app or fitness tracker, which will then send data to a specialised fitness tracking software for clinicians to use.

Regulatory considerations and strategy

There are no patentable features expected in this solution, as all components are devices or combinations of devices that are already found on the market. Code in a smartphone app and the group fitness tracking software used will be automatically covered by copyright. This solution is also not expected to be considered a medical device, as it is intended to only be used as a fitness tracker – all medical diagnoses will be solely made by healthcare professionals, and will only monitor fitness in patients. The decision to keep the solution a fitness tracker means less regulations, and the ability to rapidly prototype and implement changes.

Clinical considerations

A great deal of thought was devoted to ensuring that the solution did not interfere with the processes already at renal units. The recommended fitness devices will be portable, easy to set up, and easy to use: ensuring healthcare professionals do not spend an extended amount of time managing the exercise machines. Additionally, the software solutions such as the group management software and smartphone app will use human centred and intuitive design features to ensure smooth operation. Pilot studies and small scale trials will be used to validate and refine the solution, aiming to provide renal units evidence of efficacy and encourage the adoption of small scale implementations before larger ones are made.

Technical considerations

The largest technical risk revolves around the stability and development of the smartphone app. Used not only to send information back to a central location for monitoring but as a gamification platform, means complex app development. De-risking strategies include compartmentalising app components to enable parallel development, and expertise can be found to develop specific areas of the app. Technical milestones will involve the seamless connection of patient exercise information to a smartphone app and a central unit, the development of a gamification system, the development of an exercise programmer, and the ability for the solution to interconnect with other dialysis unit infrastructure.

Business Model

Reimbursement strategy

The renal unit will be responsible for funding the shared exercise equipment and associated software to manage and monitor the exercise of patients. Alternatively, patients can be charged on a subscription model, with the money going back into paying back for the exercise equipment. This means that the renal units will earn their money back, essentially meaning they will obtain the exercise equipment for free. Alternatively, raising funds through hospital or medical center grants, patient memorial funds, patient donations, and community events to pay for exercise equipment.

Revenue generation strategy

The program will sustain itself through 3 different streams of revenue:

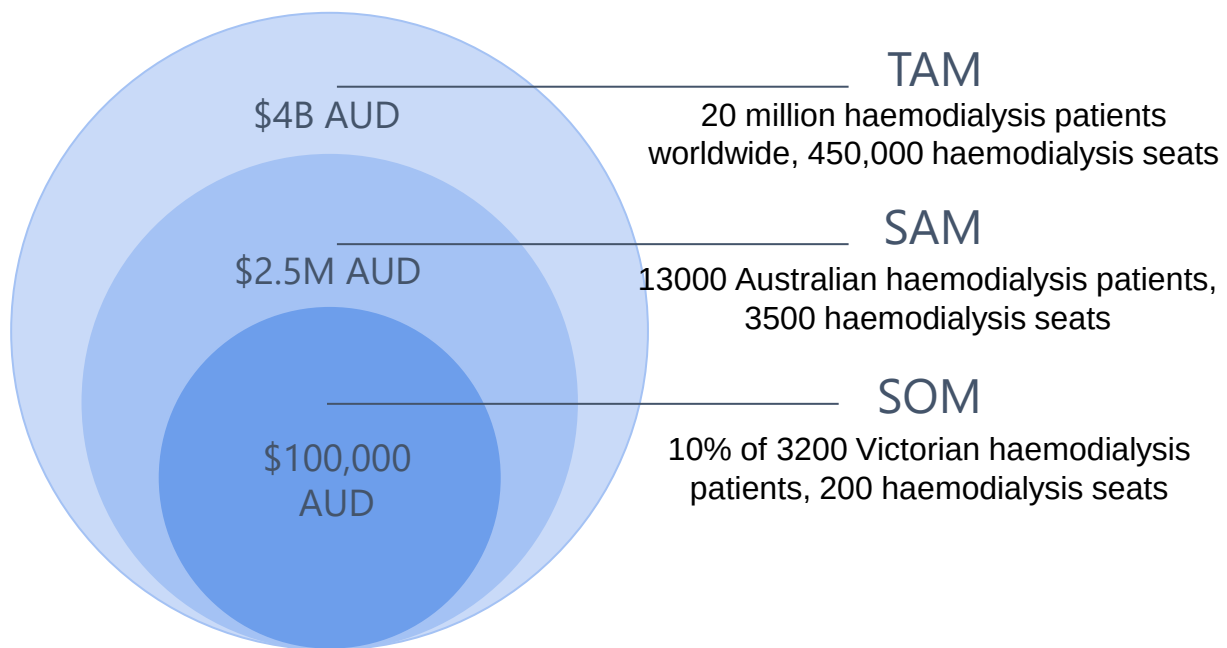
1. Consulting and installation services: Expertise can be provided in terms of selecting the correct commercial products to purchase and the special installation of these products to suit the requirements of the exercise program. A guidebook can also be sold if a renal unit chooses to pursue an exercise program on their own.
2. The app may involve some form of payment for access. This includes a onetime payment for each user, or a subscription model for using the app. The subscription costs may be used for any maintenance costs that are incurred - both for the exercise machines and associated software.
3. A standalone tracking device can be made and sold to renal units or patients that do not wish to use the smartphone app. It is not expected that this will be a popular option due to the ease of use of a smartphone app; but is an option for outlier cases and/or special cases where a smartphone app cannot be used. This includes patients that may not be able to or comfortable enough to use a smartphone app.

Market penetration strategy?

The market penetration strategy is to first get a pilot study to evaluate and improve our product. This is because once a pilot study is conducted, theories can be validated before further development of the smartphone app, dashboard monitoring system, etc are conducted. Additionally, a pilot study may provide exposure once published about the various systems used, and further drive interest and sales.

Funding has been listed as one of the biggest hurdles facing the implementation of exercise programs. Therefore, one market penetration strategy is for MYMI to fund the procurement of the exercise machines and all other associated capital expenditures. Patients will then be given a 6-month free trial to use the machines and services available - after the fact will be charged monthly as an opt in option. Alternatively, encouraging results may convince renal units themselves to cover the cost of equipment and/or the subscription costs of the smartphone app. The feasibility of this strategy is detailed in the next few sections, but from the perspective of a renal unit, they will obtain smart exercise machines without any costs. In the market penetration phase, the installation of these machines can be carried out by volunteer efforts of the team.

Market Analysis



Above: Diagram of Total addressable market (TAM), Serviceable addressable market (SAM), Serviceable obtainable market (SOM).

Market Competitors

Competitors would be existing smart exercising manufacturers and app makers. They have the potential to create a really streamlined albeit more expensive option. They shouldn't be too much of a threat though because an exercise program is just as important as the machines, of which they may find it harder to enter.

Market Expansion

Haemodialysis patients aren't the only group of individuals that need exercise. Particularly elderly individuals in general who may spend a considerable amount of time being seated may benefit from this device. Additionally, other rehabilitation applications may be an area where this solution can expand into.

What are the major market forces?

Funding to get the solution off the ground will be crucial to the start of the program. From there, trial success will determine how well the solution performs for a wider range of dialysis patients.

Proposed KPIs

Economic profile

The current standard operating procedure of a renal unit does not involve an exercise program. Therefore, any implementation of an exercise program with the associated equipment will mean the renal unit will be losing money with the solution. However, on a wider scale where the entire healthcare system is considered, the potential benefits of the exercise program in reducing falls and conditions associated with a sedentary lifestyle may outweigh the procurement and maintenance costs of the solution. It is estimated that in the year 2000, 1.5% or 17.5B USD of total healthcare expenditure in the United States was attributed to sarcopenia. [8] Frailty was also independently associated with increased direct costs, indirect costs, and total costs associated with clinical admissions, with frail patients often incurring 50% higher costs compared to non-frail patients [8]. Frailty may also complicate kidney transplants or other invasive procedures, as frailty increases recovery times and risk of mortality.

Key Performance Indicators

This solution will not currently fit within a traditional renal unit's KPIs. This is due to the non-existent nature of an exercise program to improve outcomes of patients. A broad key performance indicator could be reduced hospitalizations in general; the reduction of sarcopenia and frailty will decrease hospital admissions and reduce hospital costs.

Another key performance indicator includes the proportion of dialysis patients that have been assessed for transplant and accepted. This is due to the fitness requirements for an organ transplant, of which an exercise program may be able to help.

Ask and Next Steps

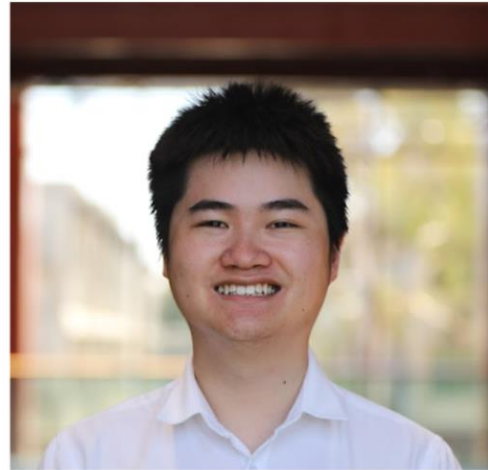


Clinical Champion

Dr Limy Wong

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Monash University (Australia).
Department of Renal Medicine

Nephrology Fellow at Eastern Health, Melbourne. Graduated First Class Honours Medicine from Royal College of Surgeons. Completed Nephrology specialist training in Ireland/UK, gained Specialty Certificate in Nephrology from Royal College of Physicians. Completed Fellowship in Transplant Nephrology at Beaumont Hospital, Ireland. Completed Wellcome Trust Clinical PhD Fellowship at University of Cambridge, studying genetics of ANCA-associated vasculitis.



Project Lead

David Cheng

Student
5th Year Biomedical Science
and Mechanical Engineering
(Honours)

Monash Young MedTech Innovators HeartHack team (Head of Impeller Engineering & Head of Computational Modelling), Precious Plastics Monash (Technical Research & Development engineer) and Monash Human Power (project lead & aerodynamicist). He has experience in rapid prototyping physical & software products & uses industry standard analysis methods to evaluate & optimize designs.

Needs for the solution

Technical needs: In order for this project to continue, software expertise is required to develop the software components of the solution. Particularly, expertise in database generations and software management systems are required. Additionally, expertise in game development will be essential for an engaging gamification experience.

Other project Needs: A pilot study is required for the verification and development of the solution. Therefore, individuals with a experience in running a pilot study or navigating the processes in a clinical setting would be highly desired.

Timeline

Feb 2023

Initial idea and planning: Come up the key features and functionalities of the app. Includes determining the resources and budget needed to develop the app. Includes work to start on generating exercise routines.

Apr 2023

Integration with smart fitness machine: the team will connect the smartphone app with the fitness machine, ensuring that any required hardware modifications are identified.

Oct 2023

Testing and QA: the team will informally test the app internally, ensuring that bugs are identified, and that all systems are ready to work in a clinical setting

Mar 2023

Design and wireframe: Create wireframes and mock-ups to visualise the layout and user flow of the app. This is to ensure that the app is user friendly and intuitive to use.

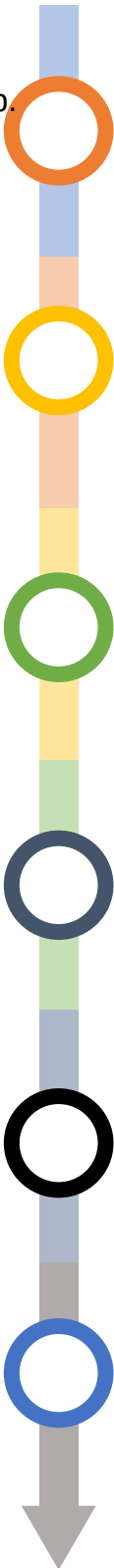
Funding application: For the pilot study.

Apr 2023

Development: the team will start the coding and building process of the app, including frontend and backend systems.

Dec 2023

Pilot study: the team will conduct a pilot study with real patients, identifying problem areas, efficiency, adherence rate, and other key performance indicators



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