A ResearchKit App to Monitor Patient Recovery

COM3610 Individual Project

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Final Report

This report is submitted in partial fulfilment of the requirement for the degree of BSc Computer Science by William Redwood

Declaration

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William Redwood

Abstract

Aortic stenosis is a condition affecting approximately 1 out of every 8 people over the age of 75, and many sufferers undergo surgery in one form or another to replace their aortic valve. However, a significant minority derive no benefit post-op.

This project showcases how smartphones may be used as medical research tools, using Apple's ResearchKit to gather quantitative and qualitative health data using 2 respected medical questionnaires. More specifically, this project utilises the KCCQ-12 and Katz Index of Independence in Activities of Daily Living questionnaires and is targeted towards patients who have undergone aortic valve replacement.
The project also creates a website to display the data collected, with tools provided to show this in tables, charts, and multiple download formats.

The iOS application has since been released on the App Store, and the website is live for researchers to use. The project is thus ready for use in a real-world research scenario in an effort to improve future patient selection and avoid futile surgery.

Acknowledgements

I am grateful to my supervisor, Dr Paul Watton, for his assistance in this project, and to Dr Maria-Cruz Villa-Uriol for her additional assistance.
I am grateful to Dr Christopher Allen of Guy's and St Thomas' NHS Foundation Trust for his guidance, support, and testing of the application and website.
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1 Introduction

1.1 Background

Aortic stenosis (AS) is the narrowing of the aortic valve, the valve allowing blood to exit the left ventricle of the heart. In the United States, it is estimated that 2.5 million people over the age of 75 suffer from AS, which is equivalent to 12.4% of that population[1]. The three main symptoms of severe AS are anginal chest pain, syncope (fainting), and dyspnea (breathlessness)[2].

The traditional method for treating this is an open heart operation and aortic valve replacement. However, many patients are elderly and considered high-risk for this operation. Transcatheter aortic valve implantation (TAVI) is a transformative technology used to treat symptomatic severe AS that was first performed on human patients in 2002[3]. TAVI has since been shown to have a much higher post-operative survival rate compared to valve replacement by open heart surgery[4].

However, it seems that a significant minority of patients derive no functional benefit from TAVI despite an optimal procedural result. In a US study involving 299 hospitals and 12182 patients, there was a mortality rate of 23.7%[5]. It is therefore necessary to improve patient selection to avoid futile, or potentially dangerous, TAVI interventions in those patients unlikely to benefit.

1.2 Project Description

This project aims to create an iOS application (hereafter, this may also be referred to as "application", "iOS app", "app") using Apple's own ResearchKit[6][7] that will collect data on patient's recovery.

The application itself will have the primary purpose of data collection only - no data analysis will be performed, nor feedback provided to patients.
The data will be gathered using a series of questions, namely the KCCQ-12 survey[1] and Katz Index of Independence in Activities of Daily Living (ADL)[2], as well as supplementary data gathered through HealthKit implementation[9].

The intention is for the patients to fill out one survey every two weeks, both before and after their operation. This data will then be provided to Guy's and St Thomas' Hospital to perform their own analysis.

The resulting data will then be viewable to researchers on a password-protected website.

[1] KCCQ-12 survey: Appendix A, article: reference: [8]
[2] Katz Index of Independence in Activities of Daily Living: Appendix B

2 Literature Survey

2.1 Aortic Stenosis Overview

Aortic stenosis (AS) is the calcification of the aortic valve opening, resulting in a narrowing of said opening (Figure 1). This restricts the blood flow from the left ventricle of the heart to the aorta, meaning the heart must pump harder, leading to heart failure as the heart muscle gets stiffer and weaker.

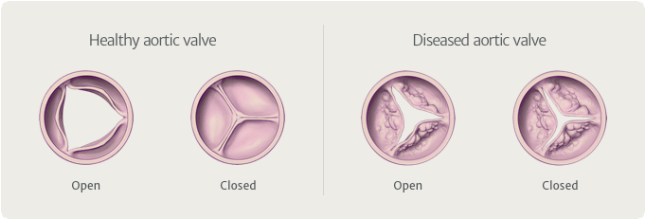


Figure 1: Comparison between healthy and diseased aortic valves[10]

Aortic stenosis has a statistically significant increase in prevalence with age. A 1993 study found that 4.8% of people aged 75-86 had at least moderate AS, with no cases of AS being found in persons aged 55-71 years[11].

Overall, women are more likely to suffer from AS, and yet have a significantly lower 5-year mortality rate when compared to men ≥65 years old (between 10-21% across the studied age bands, according to a 2017 study[12]). In a 2014 study it was found that men and women have similar rates of progression of AS, however yet again women had a 31% lower overall all-cause mortality rate. Both studies also found that female suffers of AS tended to be older on average than men with similar AS progression.

Left untreated, symptomatic severe aortic stenosis has a survival rate of just 27%, worse than many cancers, compared to 87% for those treated surgically with aortic valve replacement[13]. Elsewhere it is suggested that survival after onset of symptoms is 50% at two years and 20% at five years[14]. The average time to death for angina, syncope, and dyspnea, untreated, are 5, 3, and 2 years respectively (Figure 2).

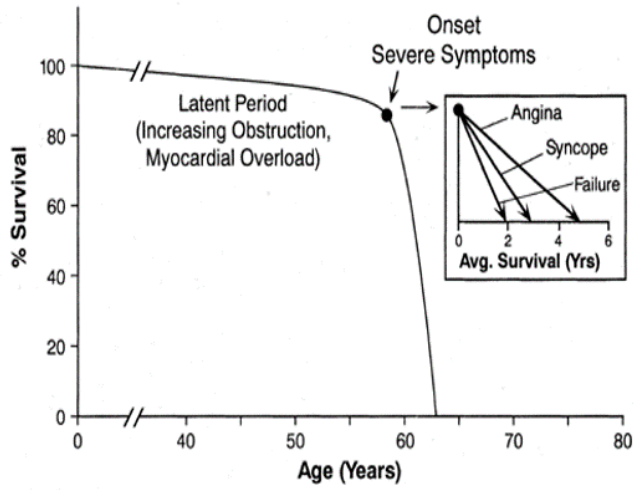


Figure 2: Valvular Aortic Stenosis in Adults (Average Course)[15]

2.2 Diagnosis of Aortic Stenosis

Aortic stenosis (AS) has three core symptoms: anginal chest pain, syncope, and dyspnea[2]. Initially, however, patients may not experience these symptoms and instead only a gradual decrease in exercise tolerance. This is especially prevalent in older patients[16].

Angina is pain or discomfort felt in the chest and caused by a number of complex mechanisms ultimately leading to reduced blood flow to the heart muscles. Syncope is "brief reversible loss of consciousness and usually occurs from interruption of cerebral blood flow"[17] and is the most serious of the three symptoms. Dyspnea "is the term generally applied to sensations experienced by individuals who complain of unpleasant or uncomfortable respiratory sensations"[18].

Other symptoms may include heart palpitations[19], and sadly some patients have sudden death as their first presenting symptom.

The diagnosis is often first made when a physician hears a heart murmur, and then most often followed up with further checks using an echocardiogram, or scans such as computed tomography (CT) or magnetic resonance imaging (MRI)[20][21][19]. It is recommended that "surgical intervention should be performed promptly once even... minor symptoms occur"[22].

2.3 TAVI Operation

A transcatheter aortic valve implantation, or TAVI for short, is a procedure first performed on human patients in 2002 by Professor Alain Cribier[3]. As of early 2018, it is estimated that over 300,000 patients have undergone TAVIs and that the global market is worth $2 billion per year[23].

Either local or general anaesthesia are used on patients undergoing TAVI operations, and there is no difference in safety between the two[24]. Access to the femoral artery is first gained with the help of fluoroscopy or ultrasound using a needle and a wire (0.035" diameter). A sheath is then inserted to keep this entryway open. This is approximately 20-30cm long and 5-6mm in diameter and reaches the descending aorta, stopping around the level of the kidneys. At the outer end there is a valve to prevent blood loss. Through this sheath a catheter and wire are inserted, with a soft, curly-tipped wire leading into the left ventricle to be used as a guide for the replacement valve. This valve, positioned on a delivery system and compressed accordingly, is then fed over this wire and positioned with the help of the fluoroscopy and some dye/contrast. Once happy with positioning, the heart is then paced rapidly to temporarily decrease cardiac output, whilst the valve is expanded using a valvuloplasty balloon. Once complete, the equipment is removed from the patient's body and the puncture in the artery is sutured. This newly placed valve acts as a replacement for the calcified natural valve.

Currently over 95% of procedures are performed under local anaesthesia with sedation and the procedure typically takes less than 1 hour. Patients are awake immediately after the procedure and usually go home within 24 to 48 hours later. The procedure is successful in over 95% of cases. Recovery is very quick, and they are able to return to full activities within a few days[25].

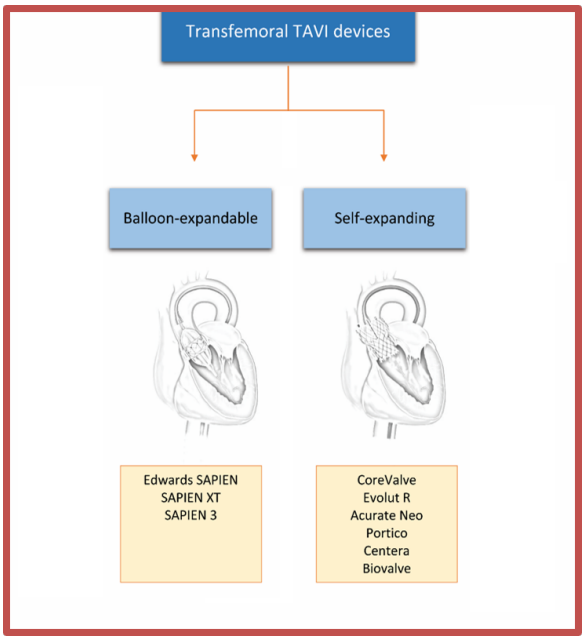
Figure 3(a) shows the clothing worn by a surgeon during the operation, with surgical gloves having been removed before the photo. Figure 3(b) shows clothing worn by me when spectating. It is required that all personnel wear lead radiation clothing over their scrubs (to protect yourself from the radiation from the fluoroscopy), hair nets, surgical masks, and either sterile shoes or shoe covers. The surgical team must also wear lead thyroid collars, gloves, and a surgical gown.

For additional safety, radiation monitoring badges are also worn both underneath and on the outside of the lead radiation clothing. The fluoroscopy machine itself also monitors the amount of radiation it emits to ensure the patient is not receiving a dangerously high dose during the operation.

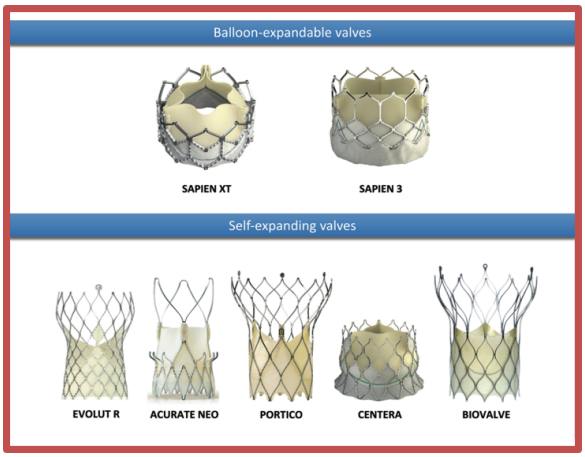
(a) Surgeon clothing

(b) Spectator clothing

Figure 3: Clothing worn by medical personnel during TAVI operations



(a) Valve deployment methods



(b) Replacement valve examples

Figure 4: Two images depicting different TAVI valves

2.4 Mobile Applications

A mobile application was chosen due to the growing impact smartphones have on our daily lives. As of June 2018 there were 3.6 billion active smartphones in use[26], and a 2017 survey showed 85% of citizens in the UK now own a smartphone, compared to just 52% in 2012[27]. More recently, and more specifically, in 2018 a survey by Deloitte found that 77% of 55-75-year-olds either own or have ready access to smartphones[28]. A mobile application will therefore likely be more appealing as well as more accessible than paper questionnaires, such as through adjustable text sizes. Data will also be collected more quickly and easily, with instant reception of survey answers, rather than needing phone calls or hospital visits to gather answers.

2.4.1 iOS and the App Store

Of the aforementioned 3.6 billion active smartphones, a September 2018 report estimates that Apple holds a share of approximately 24% worldwide[26]. In February 2018, Apple themselves announced that their active installed base of devices reached 1.3 billion, with 77.3 million iPhones being sold in the first quarter of 2018 alone[29]. iOS also has the aforementioned ResearchKit, which includes frameworks for visual consent flows, dynamic active tasks (using the inbuilt sensors, such as pedometer, touch, or accelerometer), and surveys.

Android is the biggest competitor to iOS, and overall dwarfs the worldwide market share of iOS with an estimated 75.9% of smartphones running Android[30]. However, Android is extremely fragmented, with the current version, Android 9 (Pie), being released on 6 August 2018, whilst up to that point the previous version, Android 8 (Oreo), had only been installed on 12% of Android Devices[31]. At the time of writing, the majority of Android devices are running Android Nougat, a version 2 iterations prior to the current[32]. This has the potential to cause issues with both hardware and operating system support, compared to the iOS ecosystem where, at the time of writing, 60% of all active iOS devices were running the latest version of iOS, iOS 12, and a further 29% were running the prior version, iOS 11[33].

2.4.2 Wearables and HealthKit

Apple also sell their own wearables, named Apple Watch, with the first (Series 0) being introduced in September 2014[34] and released April 2015[35]. In 2017 alone it is estimated that 18 million Apple Watches were sold worldwide, an increase of 54% from the previous year[36], and in July 2018 it was estimated that the Apple Watch market share was 34%[37]. It is likely this will further exponentially increase with recent health-related developments and additions to the Apple Watch line-up, such as the inclusion of ECG functionality in the 2018 Series 4 iteration[38], especially as a 2015 survey suggested that a majority of Apple Watch users highly value the health-related features[39].

Apple Watch has inbuilt support for heart rate monitoring, including heart rate notifications (alerting the wearer when their BPM is above or below a chosen threshold whilst they have been inactive for 10 minutes)[40]. Other data collected includes general activity data, such as active calories burned, number of minutes of exercise, and number of hours in which the user has stood and moved for at least a minute. These are collated in the aptly named Activity app[41], as well as the inbuilt Health app[42]. These are all complemented with additional data such as total walking/running distance, number of individual steps, and number of flights climbed, amongst others.

Other wearables include those offered by Fitbit[43] and Garmin[44]. A notable issue with Fitbit, however, is that they offer no official support for syncing data to iOS's Health app[45], making the data gathered by Fitbit devices more difficult for developers to access. Some third party solutions do exist[46], however these solutions are unlikely to be utilised by the majority of Fitbit users. Garmin do offer full support for Apple's Health app[47].

Even without utilising any wearables, an iPhone alone can gather health data such as number of flights climbed (using the barometer in the iPhone 6 or later), number of steps, and total distance run/walked.

Any data which is written to the Apple Health app is accessible to developers, with explicit user permission (Figure 5), through the HealthKit API[9]. This allows apps to both read and write data to a user's Health app, giving access to at least a basic activity count and potentially much more[48].

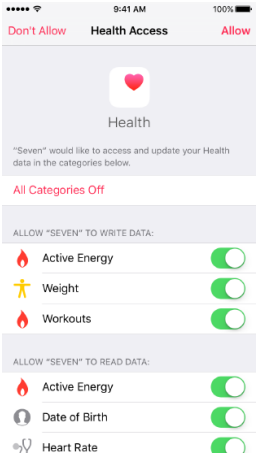


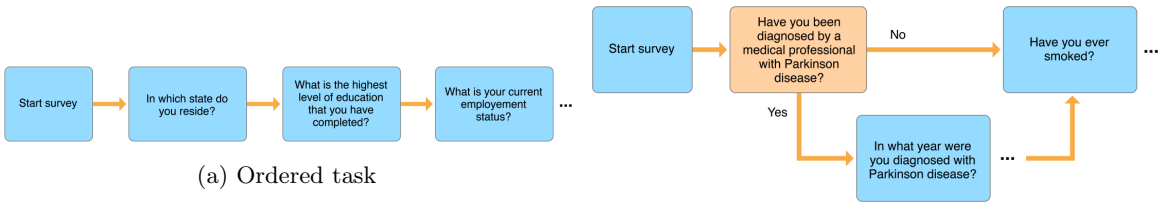
Figure 5: A screenshot showing an example HealthKit authorisation screen[48]

2.5 ResearchKit

ResearchKit is an "open source framework introduced by Apple that allows researchers and developers to create powerful apps for medical research"[7]. Announced on 9 March 2015[49], it has since been made an open source project on GitHub[50].

Each application developed utilising ResearchKit has available to it 3 core components: visual consent flows, surveys, and active tasks[7].

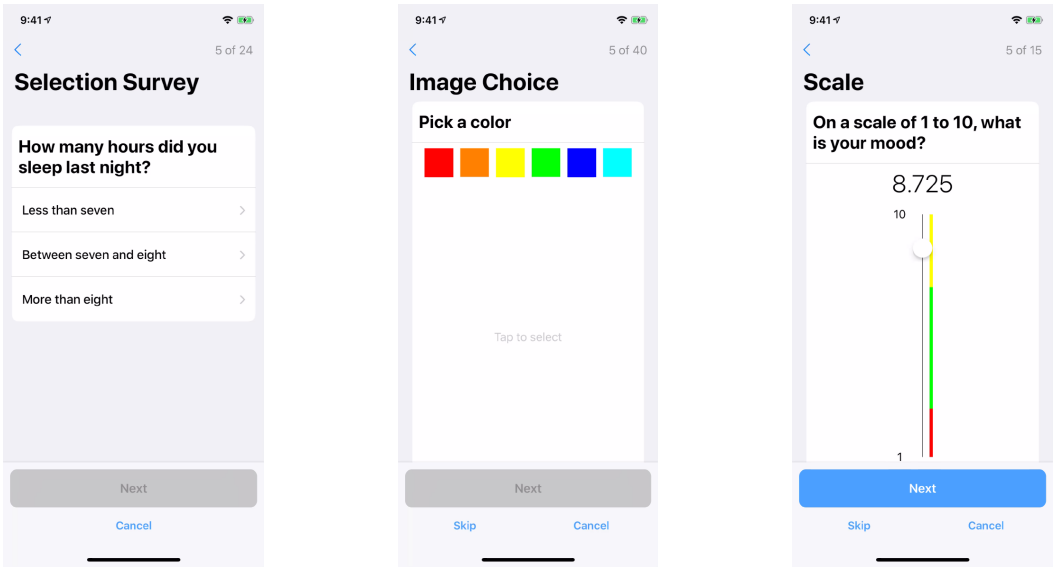
- **Informed Consent:** ResearchKit provides an easy way of creating and displaying an informed consent document, with predefined layouts for sections such as Overview, Privacy, Data Gathering, Data Use, and Withdrawal. These may also be required for the app review (in order to go live on the App Store)[51].
- **Surveys:** Surveys are a sequence of questions used to collect data and could be ordered or navigable (Figure 6). Answers may be in one of the many of the provided formats, with examples including Boolean, value picker, image choice, text choice, or numeric. For this project, all answers will be in the format of a single text choice answer, as shown in Figure 7(a)[52].



(a) Ordered task

(b) Navigable ordered task

Figure 6: Two flowcharts depicting ResearchKit survey task type examples[52]



(a) Single text choice (b) Image choice (c) Vertical scale

Figure 7: ResearchKit survey answer format examples[52]

- **Active Tasks:** Active tasks allow users to utilise the inbuilt sensors in their device to collect data. These may include using the accelerometer for a balance test, the microphone for a speech test, or the touchscreen for a tapping speed test (Figure 8)[53].

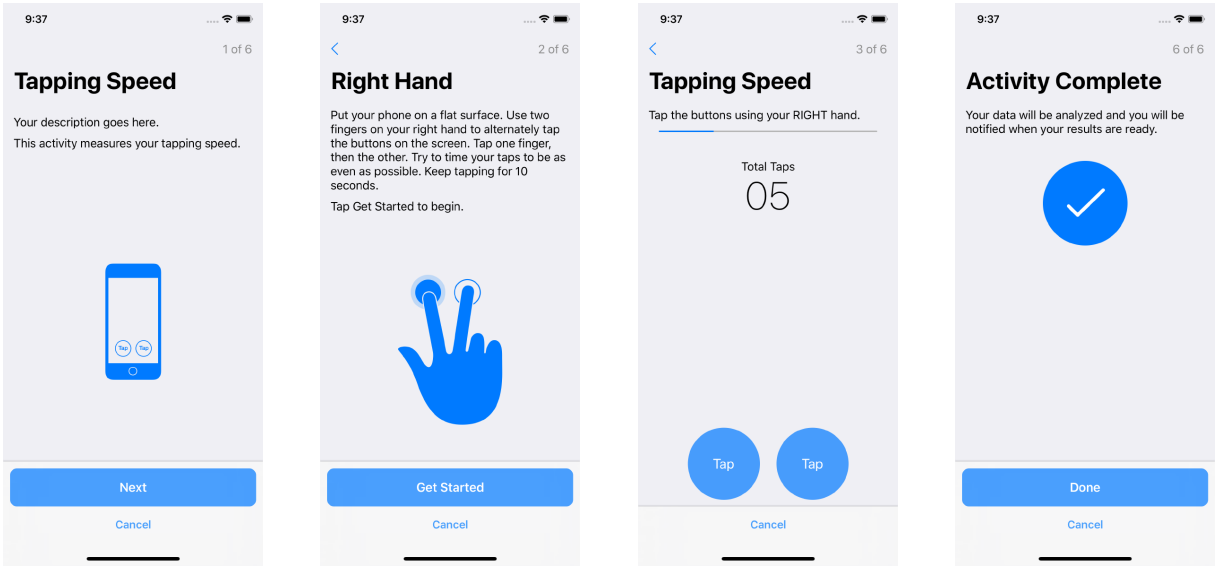
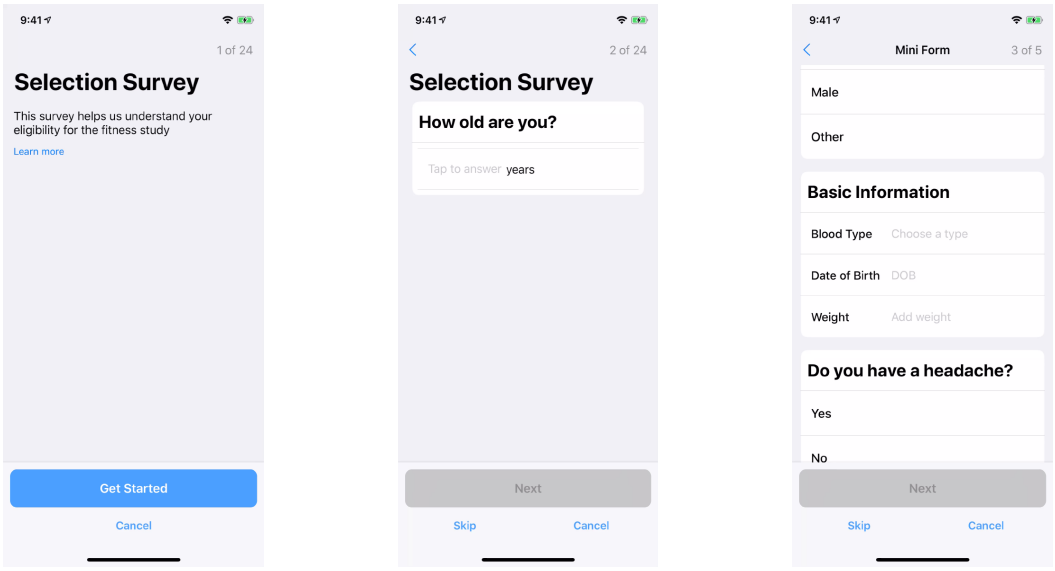


Figure 8: Abridged ResearchKit active task example[53]

These are each presented using tasks (ORKTask), which consist of steps (ORKStep). For example, surveys may consist of instruction steps, question steps, and form steps (Figure 9)[52].



(a) ORKInstructionStep example (b) ORKQuestionStep example (c) ORKFormStep example

Figure 9: ResearchKit `ORKStep` examples[52]

This is perfect for developing an application to monitor patient recovery post-op. The inbuilt support for getting consent and creating surveys means no time need be wasted on coding user-friendly methods for this from scratch.

2.5.1 Other ResearchKit Apps

Many existing ResearchKit applications are based in the US and are not available in the UK. Indeed, even on Apple's UK website the apps mentioned under "You can participate in a study. Download one of these apps today." are US-only[6]. However, there are some ResearchKit apps that are aimed at UK residents too, such as Stanford University's MyHeart Counts[54]. This application is stated to be a "personalized tool that can help you measure daily activity, fitness, and cardiovascular risk." The research behind this application purportedly aims to "help people be more informed and empowered in their health."

The application I am developing is in no way intended to compete with any other pre-existing ResearchKit apps. Rather, it will only be used by a select group of people, namely patients involved in the hospital's study and those testing the application.

2.6 Regulation of apps

In general, all iOS apps go through Apple's review process[55], and are all subject to Apple's App Review Guidelines[56]. Apple state that, on average, 50% of apps are reviewed in 24 hours, and over 90% are reviewed in 48 hours[57]. Extenuating circumstances, such as urgent bug fixes, may be requested and the review will be expedited[57].

Medical apps have additional requirements, depending on what their intended use and functionality is. The Medical Devices Directive (Directive 93/42/EEC)[58] defines medical devices as:

> any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:
>
> - diagnosis, prevention, monitoring, treatment or alleviation of disease,
> - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
> - investigation, replacement or modification of the anatomy or of a physiological process,

- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

More specifically, the Medicines & Healthcare products Regulatory Agency has published guidelines specific to medical software applications[59], which on page 12, under the heading "Non medical functions", states that:

Software is unlikely to be a device if:

- It just reproduces a paper document in digital format - it is down to the health care professional to make the decisions based on the advice displayed.

It is this statement that most accurately pertains to the application I am developing - as stated in Section 1.2, no diagnostic information will be given to patients, and the user-facing side of the application replicates the pre-existing KCCQ-12 and Katz Index of Independence in Activities of Daily Living questionnaires.

It is of note that full ethical approval has been granted by the University of Sheffield for this project (application reference number 023841).

3 Requirements and Analysis

Having discussed the reasoning behind this project, this chapter presents the requirements for this project to be deemed successful as high-level agile user stories, and discusses how survey answers will be gathered, with work-in-progress examples included. Finally, it provides further analysis and dialogue regarding both previously tackled and any foreseen problems which may arise.

3.1 Agile User Stories

User stories are informal representations of features in a software system[60]. These are formatted as such:

As a (role), I want (something) so that (benefit)[61].

In this project, the differing user roles will be defined as follows:

- Users will be the end users of the iOS app itself, namely the testing group and patients.
- Researchers will be the doctors who are part of the backing study.
- Admins will be myself and the doctors who are part of the backing study.

Table 1 shows the user stories for this project.

Story	Difficulty	Priority
1. As a User, I want to answer questions so that I can complete the survey.	8	1
2. As a User, I want to input my Patient ID so that I am identifiable to the Researchers.	8	1
3. As a User, I want to be able to consent so that I can participate in the study.	4	1
4. As a Researcher, I want to be able to view the results of the surveys so that I can analyse them.	16	1
5. As a Researcher, I want to see the results for a specific Patient ID so that I can identify them.	16	1
6. As an Admin, I want to be able to manage the data collected so that I can easily remove the data related to withdrawn Users.	8	1
7. As a User, I want to passcode protect the app so that no one may answer on my behalf.	4	2
8. As a User, I want to receive reminders so that I remember to complete the survey at the required intervals.	8	2
9. As a User, I want to be able to withdraw from the study so that I am not partaking in the study any more.	2	2
10. As a User, I want to be able to complete a survey without interruption after completing the initial consent process, so that I do not need to repeat this	1	2
11. As a Researcher, I want the application to require a login so that no unauthorised members of the public may take part.	8	2
12. As a Researcher, I want to be able to view the signed consent form for a specific Patient ID so that I may keep it for my records.	4	3

Table 1: Agile user stories

3.2 User Interface

As the core output of this project will be an end user-facing iOS app, importance is placed on the user interface and usability. As noted before, ResearchKit provides templates for surveys, and these will be utilised where appropriate.

Figure 10 shows the work-in-progress user flow design, created using FlowMapp[62]. Upon first installing and running the application, and on every launch thereafter, a check will first be run to determine whether a user-created passcode for the app exists in the device's keychain. If not, the user will be directed to the consent task, which consists of reading through and agreeing to the consent document, inputting their given Patient ID,

and then creating a passcode to protect the application. They will then be directed to the app's main page, a work-in-progress screenshot of which can be seen in Figure 11. Users may then complete a survey, which will redirect them to the main page upon completion. They may also choose to withdraw from the survey, which will give instructions to contact the researcher at the hospital (if applicable) and remove their passcode from their device's keychain.

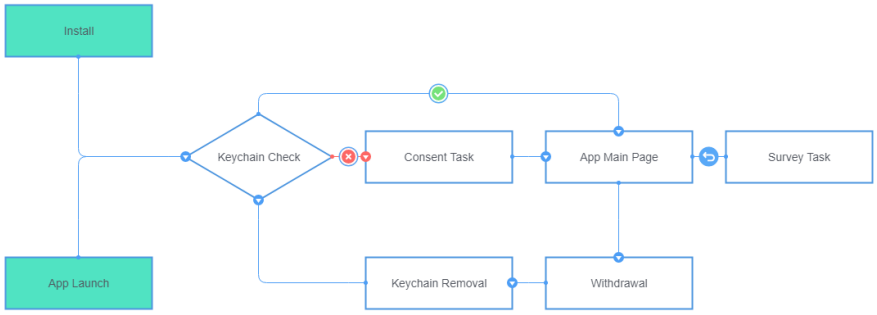


Figure 10: A user flow diagram for the iOS application

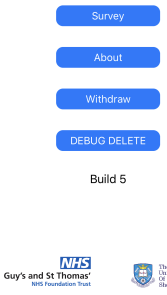
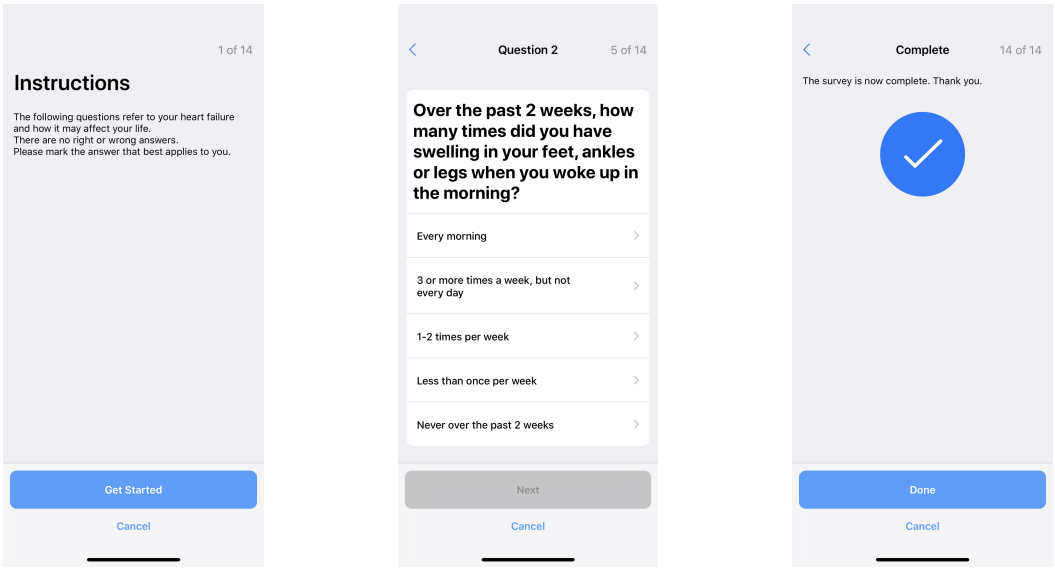


Figure 11: A screenshot of the work-in-progress main page of the application

Figure 12 shows examples of the (work-in-progress) survey process itself, with the 3 screenshots showing the instructions stage, a sample question, and the completion stage, respectively.



(a) The initial survey instructions (b) Survey question example (c) Survey completion page

Figure 12: Screenshots of the work-in-progress survey task

3.3 Problems

Numerous problems may occur during development of this application and the accompanying backend service, with some having already been overcome.

For example, when undergoing the consent step in ResearchKit, one is provided with the options to "Agree", "Disagree", or "Cancel". If a user selected "Disagree", the remainder of the consent step (including signature gathering and Patient ID input) would be skipped, and the user would be taken to the application's main page. To prevent this, I modified the ResearchKit code downloaded from GitHub and imported into my project and removed this option entirely. Users are now given the option to either Agree or Cancel, the latter of which returns them to the "Join Study" page.

I have decided to use Realm[63] as a data storage option, rather than Apple's solution, Core Data. I have previously used Core Data in other applications, such as the upcoming TAVI Heart Team App[64], but found that Realm is much easier to learn how to use, as well as coding read/write functions. I also found it easier to view stored Realm data. Core Data uses an SQLite database whereas Realm uses a proprietary format but has a free Mac App Store application that associates with the database's .realm file type for easy opening.

It was also necessary to add an extra step to the consent task to allow Patient ID input, which then needed to be extracted and saved to a newly created results file, where the future survey answers would be saved. This extraction code is shown in Appendix C. The code is fairly self-explanatory: a list of all of the results from the task is created, and then from this list the result(s) from the patientIDstep is attained as an array. The first, and hopefully only, item in this array is then stored as a String named patientID. This is then saved to a file with the Realm Object definition "SurveyResults" (Appendix D).

In order to export the survey answers, I perceive it will be easiest to save these firstly as CSV files. I believed that Realm had support for this with their Realm Cocoa Converter[65] (RCC), however it soon transpired that this was for the macOS version of Realm only, not for iOS applications. Nevertheless, I was able to modify the provided code and get this working with iOS. I took the CSVDataExporter.swift and DataExporter.swift files from the RCC GitHub repository[66], as this was the only functionality from RCC I needed. The code used to export the survey answers is shown in Appendix F. Effectively I save the survey results to the aforementioned Realm file as usual, wait 3 seconds, and then export the saved Realm data as a CSV file. The example output is shown in Appendix G (random data was used).

Other minor issues discovered so far included the default ability to skip survey questions, which was an easy code fix.

3.4 Progress, Conclusions, and Project Plan

To date **(December 2018)**, I have created a working front-end of the iOS application itself. The UI is not final, and the current main page may be seen in Figure 11. There is partial backend working, including saving survey results to the device and tying these to a given Patient ID. Signed PDF versions of the consent document are also generated and saved on the device, and I intend to either automatically send these to a server, or give users the option to share it themselves. An example PDF is included as Appendix H, however the consent document in the app has not yet been populated and thus placeholders are shown here under the headings.

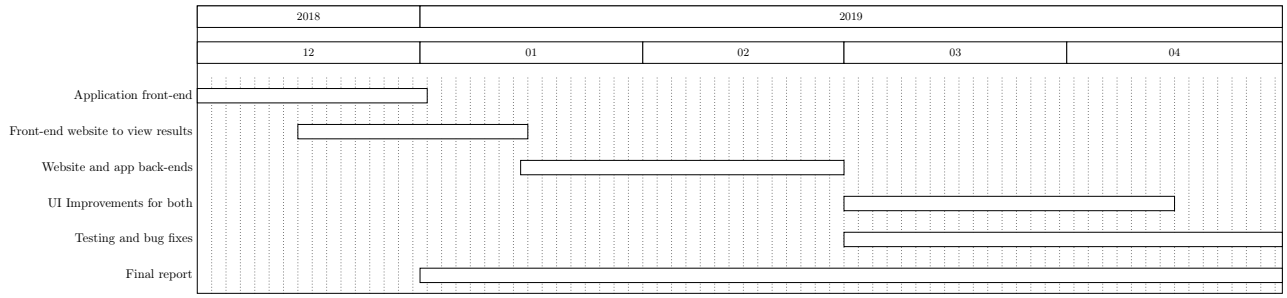


Figure 13: Gantt Chart showing work plan

4 Subsequent Progress

Having lightly discussed progress as of December 2018, this section discusses the ensuing development. A greater emphasis is placed on the technical detail behind the progress made, with comprehensive discussion on the technologies used. Finally, the testing process is reviewed and justified.

4.1 iOS App

Some progress had been made by December 2018, as discussed in Section 3. However, at this stage I had only implemented a placeholder UI and survey task, with no results being saved, or indeed any backend functionality whatsoever.

4.1.1 Development Environment

Coding was done exclusively using Xcode[67], Apple's own IDE. A screenshot of this may be seen in Figure 14, utilising macOS Mojave's Dark Mode[68]. The Standard editor is displayed, with the file "InitialVC.swift" being shown. Other options for editors here include the Assistant editor and the Version editor, represented by the two interlinked circles and the two arrows near the top right, respectively.
The left-hand side shows the Navigator, where one can load the different available navigators using the Navigator selector located near the top. These include the Project navigator, as shown in Figure 14, the Source Control navigator (e.g. for Git), and the Issue navigator, amongst others. The Debug area is displayed at the bottom, which remains empty until the app is built and run. Finally, the Inspectors are displayed on the right-hand side. These provide details and settings for the selected file. All 3 of these areas may be toggled in the top right.

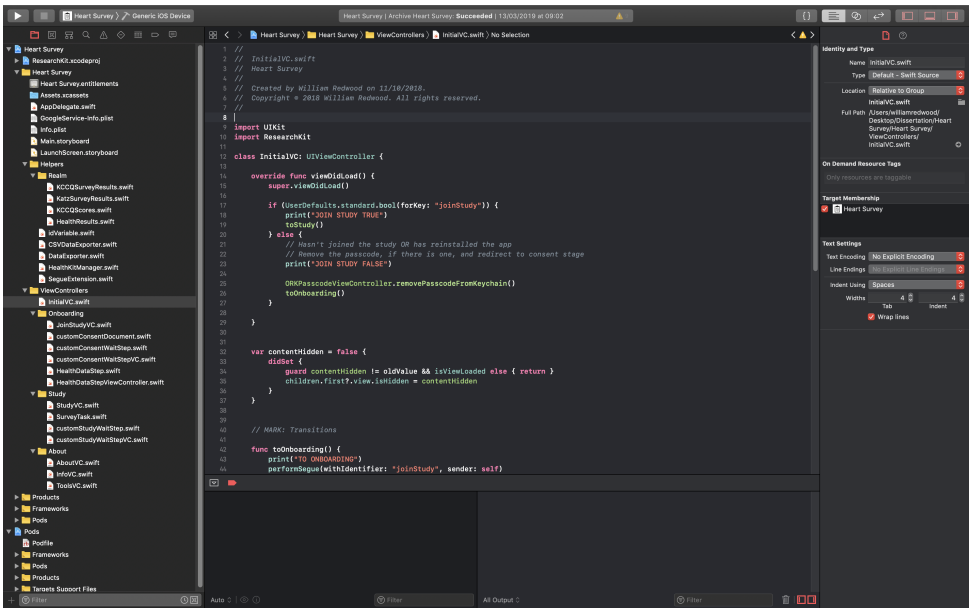


Figure 14: A screenshot showing the Xcode IDE

4.1.2 Swift

For this project, I coded entirely in Swift[69]. Swift is a programming language developed by Apple, released with Xcode 6 in 2014, but having begun development in 2010[70].
Swift has similar functionality to Objective-C but is arguably easier to understand due to its higher-level nature. Comparisons may be seen in Figure 15 and Figure 16.

Figure 15: A screenshot showing a comparison between Objective-C and Swift[71]

```
1  NSString*str =@"HelloWorld";
2
3  NSLog(@"%@", str)
```

```
1  let str ="HelloWorld"
2
3  println("\(str)")
```

Figure 16: A screenshot showing a Hello World program on Objective-C and Swift[72]

ResearchKit, however, is coded entirely in Objective-C. I did touch on Objective-C a little in order to modify the ResearchKit controllers to suit my needs, such as removing the "Disagree" button mentioned in Section 3.3. My rough notes of modifications made may be seen in Appendix I, such as lines 9-13 showing the "Disagree" button removal mentioned in Section 3.3. These small modifications will be discussed further later on.

4.1.3 Major Changes

Surveys
The initial plan for the application was for patients to fill out one KCCQ-12 survey every two weeks, and for their health data to be automatically sent along with the survey answers. To increase the functionality of the application, and subsequent research potential, another survey was added: the Katz Index of Independence in Activities of Daily Living (ADL)[73]. This survey can be seen in Appendix B. This survey is presented as soon as the KCCQ-12 survey is complete - both are included in the same survey task.
Automatic KCCQ-12 score calculation was also added. As can be seen in Appendix A, a number is assigned to each answer. To calculate the overall score, the calculations are broken down: the physical limitation score involves questions 1a-c, the symptom frequency score involves questions 2-5, the quality of life score involves question 6-7, and the social limitation score involves questions 8a-c. Each are calculated separately, and differently, and the overall score is the mean of these 4 scores.

UserDefaults
The first major change from the progress made as of December 2018 is in the user flow design (previous in Figure 10), with the new user flow design shown in Figure 17. The main change here is the use of a UserDefaults check, rather than the keychain check previously specified. During development, I found that should a user sign up and set a passcode (and thus have said passcode added to their device's keychain), deleting the application after this would not remove the reference in their device's keychain. Thus, if they were to then reinstall the application, they would be immediately redirected to the application's main page, without first going through the consent process. This caused issues as it is during this consent process that the set Patient ID is stored on the device, and this is removed when the user uninstalls the application.

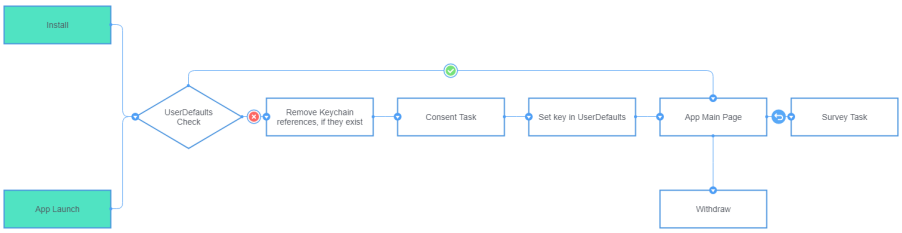


Figure 17: An updated user flow diagram for the iOS application

A new key set in UserDefaults, which is a database wherein an application may store key-value pairs persistently[74], gets removed when the application is uninstalled, and thus the initial check using this works as expected. Should there be no key found, any keychain reference that exists is removed and the user is directed to the consent stage. At the end of the consent stage the appropriate key is set in UserDefaults. The code used for this check may be seen in Appendix J.

Results Handling

In Section 3.3, I discussed exporting survey answers and associated patient data (e.g. health data) in CSV format using a slightly modified Realm Cocoa Converter[75]. At the time, I believed that exporting the data as CSV files and then handling said files with an appropriate backend would be the best approach. I have since decided to use Firebase, which will be discussed in more detail in Section 4.1.4.

CSV files are still exported (and saved on the patient's device), and this is now done automatically at the end of each survey, and includes 4 separate CSV files:

`patientID-KCCQSurveyResults.csv`, `patientID-KatzSurveyResults.csv`, `patientID-KCCQScoresResults.csv`, and `patientID-HealthResults.csv`, where "`patientID`" is replaced by the respective patient's Patient ID. These are automatically uploaded to Firebase's Cloud Storage for access on the backend website, however a user may also choose to manually send the CSV directly from their device by going to "About" on the UITabBarController at the bottom of the app, and then "Admin Tools" and "Export Data", as shown in Figure 18. Figure 18(d) shows the UIAlertController shown if a patient has not yet completed a survey (and thus no CSV files have been saved for exporting).

Saving the CSV files to the patient's device at the end of each survey has the additional benefit of mitigating the risk of data loss. For example, if the results failed to upload to Firebase automatically, such as due to a loss of internet connection, they would still be saved to the device and recoverable.

(a) About Tab (b) Admin Tools (c) Activity View Controller (d) Example Error

Figure 18: Screenshots showing the steps required to manually export a user's data

4.1.4 iOS Backend

For the backend functionality, I decided to use Firebase[76]. At the time of writing, Firebase has 18 products[77], ranging from analytic tools[78] to web hosting services[79].

I chose to use Firebase as it contains nearly everything necessary to create the application's backend functionality in one modular package. I used CocoaPods[80] for dependency management. "CocoaPods is a dependency manager for Swift and Objective-C Cocoa projects. It has over 58 thousand libraries and is used in over 3 million apps."[80]. The Podfile may be seen in Appendix K, showing the use of the core Firebase module as well as Cloud Storage for Firebase[81], Firebase Realtime Database[82], Firebase Cloud Messaging[83], and Firebase Crashlytics[84].

Firebase Crashlytics is used for realtime crash reports, and although not used very heavily during the development phase, it has the potential to be useful when released to the patients. Ideally, however, there will be no crashes of course, and thus Crashlytics will remain inapplicable.

Cloud Storage for Firebase is used by the application to upload and store the patient's signed consent form, as well as the .csv versions of their data.

Firebase Realtime Database handles the patients' survey results, KCCQ-12 scores, and health data, as well as the list of Patient IDs. A screenshot of this is shown in Appendix L, with sample data from myself. Each time a patient goes through the onboarding process their Patient ID is added to `patientIDs`. Each of the other properties are added to each time a patient completes a survey.

4.2 Website

Development of the website began by creating a basic site using Bootstrap[85] and hosted using Firebase Hosting[79]. Firebase Hosting uses Node.js, which is "an asynchronous event driven JavaScript runtime, [and] is designed to build scalable network applications"[86].

Firebase Authentication[87] was also utilised for the website. When accessing the site, users are required to either sign in or sign up, and this protects the patient data stored. The only issue I had with this is how Firebase does not allow disabling sign-up without disabling sign-in for all users[88]. This means that should someone access the website, they will be able to sign up and thus view the site itself, and there is no way of disabling this. To combat this, the data stored (through Firebase Realtime Database and Cloud Storage for Firebase) is protected by read/write rules. The write rules for both require the user to be signed in, with no limitations on who the user actually is (`".write": "auth != null"` for the database). However, the website is not affected by these rules as it is for viewing/downloading data only - this only affects the iOS application. The rules were added to avoid potential interference from malicious parties.
The rules for reading data require a user to be signed in and on a list of approved users. For the database, this is `".read": "auth.uid == 'USER UID' || auth.uid == 'USER UID 2'"`, where UID is the user's unique identifier. Although this approach requires manual approval of newly signed up users (by adding their UID to the rules), it is acceptable for this project as there are only 2 researchers who needed to be authorised, which has already been done.

4.2.1 Results

Firebase allows the database to be accessed as a .json using a direct link, with the url in the following format: `'https://heart-survey.firebaseio.com/kccqTableResponses/' + selectedID + '.json?auth=' + idToken;`, where `selectedID` is the selected Patient ID from a dropdown, and `idToken` is the website user's UID, retrieved using `firebase.auth().currentUser.getIdToken(true).then(function(idToken)`.

`kccqTableResponses` changes depending on the data retrieved, and how it would be displayed. For example, to show KCCQ-12 responses in a chart this would be `kccqChartResponses`.

Charts
To display the charts for health, survey answers, and KCCQ-12 scores, ChartJS is used. ChartJS is described as a "simple yet flexible JavaScript charting for designers & developers"[89][90].

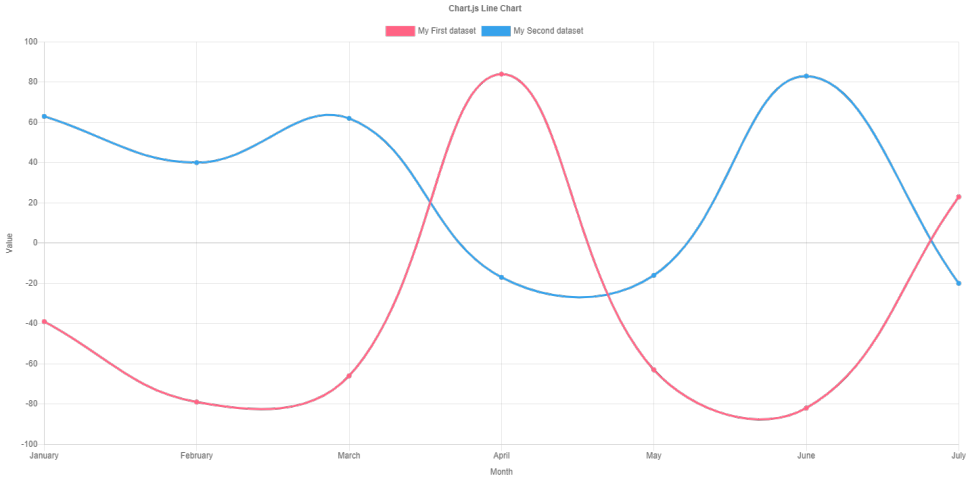


Figure 19: An example ChartJS line chart[91]

Tables

To display this same data in a table, Tabulator is used. Tabulator is described as the "easy to use, fully featured, interactive table JavaScript library"[92][93] and also has built in functionality to download the data it displays in numerous formats: .csv, .xlsx, .json, and .pdf. Tabulator has a Bootstrap 4-compatible theme[94] which was used to help keep the look of the website consistent.

Name	Task Progress	Activity	Gender	Rating	Favourite ...	Date Of Birth	Driv...
Oli Bob			male		red	19/02/1984	✓
Mary May			female		blue	14/05/1982	✓
Christine Lobowski			female		green	22/05/1982	✓
Brendon Philips			male		orange	01/08/1980	✗
Margret Marmajuke			female		yellow	31/01/1999	✗
Frank Harbours			male		red	12/05/1966	✓
Jamie Newhart			male		green	14/05/1985	✓

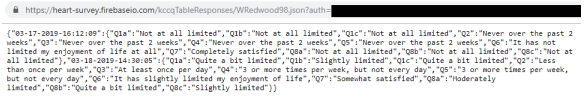
First Prev 1 2 3 Next Last

Figure 20: An example Tabulator table[93]

Examples

Figure 21(a) shows the .json retrieved for patient data set to be displayed in a table, and Figure 21(b) shows said data displayed.

Figure 22(a) shows a .json for the same results, however for this the results are in integer format depending on the answer chosen by the patient. For example, the answer for Question 1a is given as "5", as "Not at all limited" is answer option 5 (starting at 0 for the first option available). The number format used allows data to be more easily displayed on a chart, as shown in Figure 22(b).

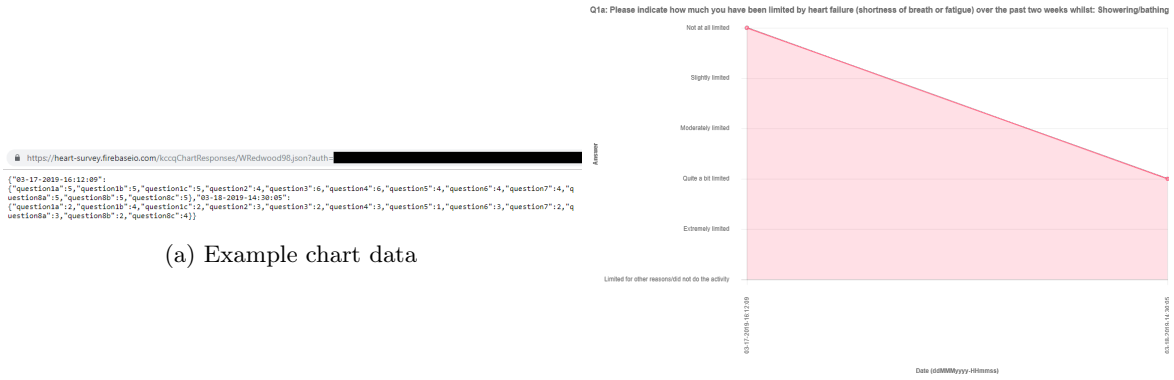


(a) Example table data

Question	03-17-2019-16:12:09	03-18-2019-14:30:05
Q1a	Not at all limited	Quite a bit limited
Q1b	Not at all limited	Slightly limited
Q1c	Not at all limited	Quite a bit limited
Q2	Never over the past 2 weeks	Less than once per week
Q3	Never over the past 2 weeks	At least once per day
Q4	Never over the past 2 weeks	3 or more times per week, but not every day
Q5	Never over the past 2 weeks	3 or more times per week, but not every day
Q6	It has not limited my enjoyment of life at all	It has slightly limited my enjoyment of life
Q7	Completely satisfied	Somewhat satisfied
Q8a	Not at all limited	Moderately limited
Q8b	Not at all limited	Quite a bit limited
Q8c	Not at all limited	Slightly limited

(b) Example table

Figure 21: An example table on the website, with its associated data



(a) Example chart data

(b) Example chart

Figure 22: An example chart on the website, with its associated data

4.3 Testing

4.3.1 iOS App

Preliminary testing was performed using Xcode and its associated debugging tools, as well as with the iOS Simulator[95]. I was able to personally test using an iPhone X and an iPad Air 2, and used the Simulator application to see how the app would look on the smallest screen my app would support (iPhone 5S).
External testing involved recruiting volunteer testers, with the aim of having a participant pool with a wide demographic range. Testers were given the form shown in Appendix M to fill in once they had installed the app, signed up, and completed at least one survey.

Testers could install the application using TestFlight, Apple's own beta testing solution[96]. TestFlight allows up to 10,000 testers at any time, and I was able to recruit testers by sharing a public link with them.
Overall, I recruited 14 external testers. Testers were all sent a link to install the application through TestFlight at the same time and were asked to complete the tasks assigned within 48 hours, at which point I would check the feedback form and delete any associated data from Firebase. The utilisation of a public link for TestFlight and the feedback form used allowed anonymity when providing feedback, however some testers chose to follow up with me further (of their own accord).

Out of the 14 testers, 10 were between 18-24 years' old, 2 were between 40-60 years' old, and 2 were between 25-39 years' old. Unfortunately, I was unable to recruit anyone over the age of 60 for testing. All testers used an iPhone for testing, and no major issues were encountered, with all numerical feedback questions scoring either 4 or 5 out of 5.

More detailed feedback was provided in the answer to the question "What would you change about this app to make it more user-friendly, if anything?".
One tester said the following:

> "If participant is required to repeatedly take the survey, it may be useful to have a reminder/link to calendar, to remind the patient when to next take the survey. I don't (knowingly) use the iPhone Health App, I use the Fitbit App instead- so may be more useful/more accurate information about heart rate/fitness/steps etc. to sync data with that app (or other similar)"

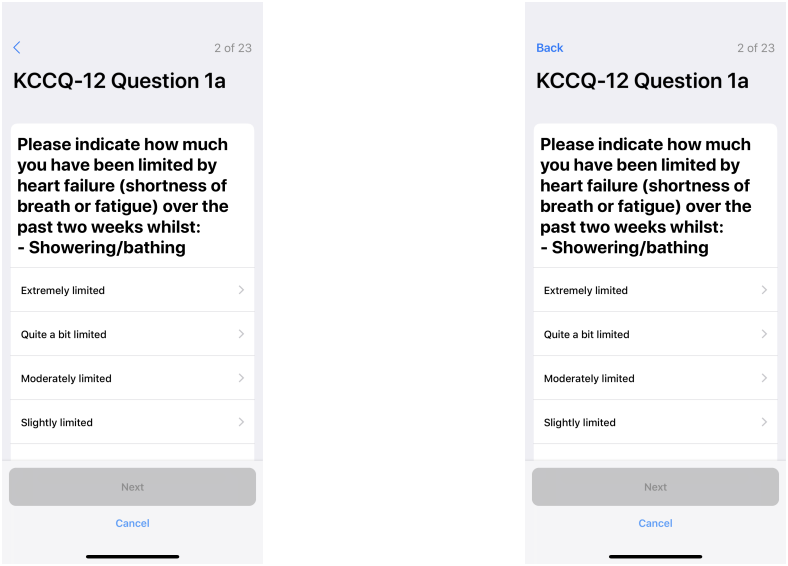
A push notification reminder system had actually been implemented in the build this user tested, however acting upon this feedback I added a notice at the end of each survey that a reminder would be given to complete a survey every 14 days: " You will be automatically reminded to complete another survey in 14 days' time. ".
In response to the remainder of this feedback, the user is referring to the automatic health data retrieval from HealthKit[9]. The patients in this study will be wearing Garmin-branded fitness trackers, which do fully integrate with HealthKit, as noted in Section 2.4.2.

Another tester added the following:

> "It could be missed that you have to scroll to get all the answers. There also wasn't a back button should you click the wrong answer. Especially as it autosubmits when an answer is selected rather

than requiring you to press next"

The scrolling issue is especially prevalent on smaller devices. In the instructions displayed at the beginning of each survey it states: " PLEASE NOTE: You may need to scroll to see all available answer options. ". The ideal solution here would be to reduce the text size of the question titles and answers, however it was decided not to do this in effort to avoid the text potentially becoming too small for end users to read, especially as the target audience may have worsened eyesight.
The back button issue was duly noted and acted upon - there was actually already a back button, but it appeared as a small arrow in the top left. This was instead replaced with bold text stating "Back", as shown in Figure 23.



(a) Before (b) After

Figure 23: Screenshots showing the changes made to the survey's back button following testing feedback

One tester also found that survey answers and other data would not be sent to Firebase should they close the app as soon as they had finished the survey (even after pressing "Done" on the completion screen). This was due to the associated data extraction functions, such as the .csv saving, taking a few seconds to run, and then a few more seconds to upload to Firebase. This was solved by adding in an `ORKWaitStep` [97] which would automatically progress to the completion screen once said functions had completed running.

4.3.2 Website

Testing the backing website gave access to sensitive user data, and thus was limited to myself and the researchers. Testing this was fairly straightforward - it was often clear to see if each page was working as expected or not.

Although the site is designed to be used on a desktop or laptop browser, mainly due to the presentation issues of both the charts and tables on smaller screens, I still tested this using my phone. One issue encountered was downloading files. For example, the site has the ability to download patient consent forms in .pdf format, but on iOS this would fail due to the error " `The operation couldn't be completed. (WebKitBlobResource error 1.)` ". I solved this by adding in a check to see if the device was running iOS, as seen in Appendix N.

4.3.3 Remaining Issues

I would also have liked to have been able to change the font size and weight of some text in question titles. Unfortunately, this is not yet possible, but I have received a response from an Apple employee assuring me that they will look into adding it[98].

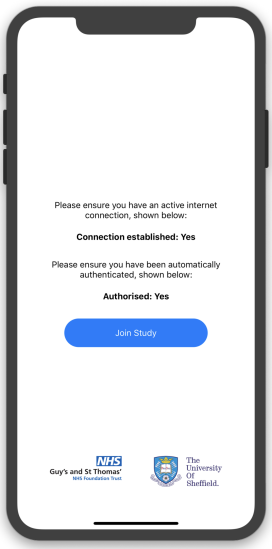
5 Final Implementation

Development is now complete, and the application has been released on the App Store. It is intended for there to be up to 40 patients participating in this study, beginning April-May 2019.
This section showcases the final implementation of the end user-facing iOS application, and the backend website which will be accessed by researchers. The process of having the application released on the App Store is also discussed, as well as the issues faced with Apple's approval process.

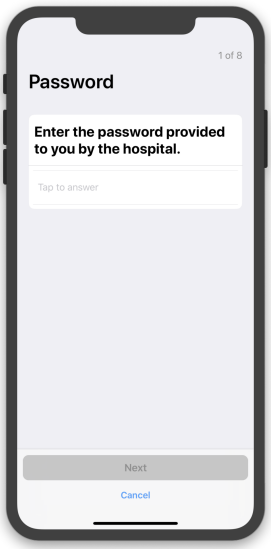
5.1 iOS App

5.1.1 Onboarding

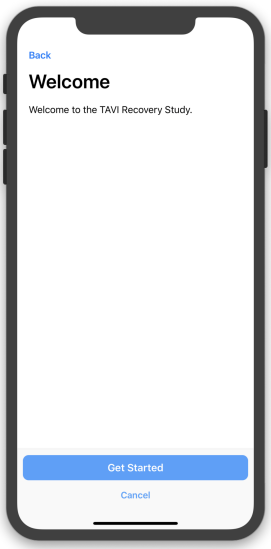
Before using the app each patient must go through the onboarding process. This consists of an eligibility check (in the form of a password, which ensures they are a patient at the hospital and not a member of the public), informed consent, and health data permission[99]. A slightly abridged version of this is shown in Figure 24. In the released version, there are more consent information steps: Data Gathering, Privacy, Data Use, Time Commitment, Study Survey, Study Tasks, and Withdrawing.
Each patient must simply tap through each step, with the option to read more about each section of the consent document. They must then enter the Patient ID provided to them by the hospital, fill out their name and signature, and then set a passcode for the app. Once complete, the signed consent PDF is automatically uploaded to Firebase, and available to download from the website. A fully-populated signed PDF may be seen in Appendix O.



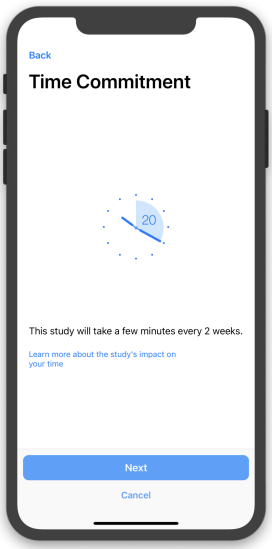
(a) First screen



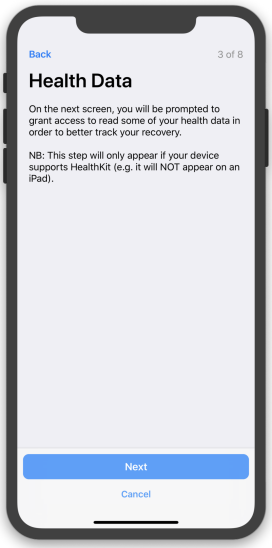
(b) Password step



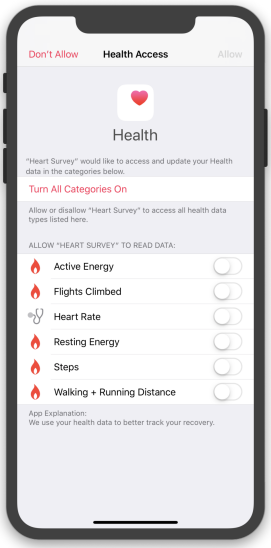
(c) Welcome page



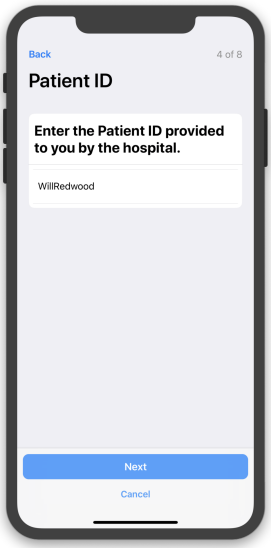
(d) Consent info



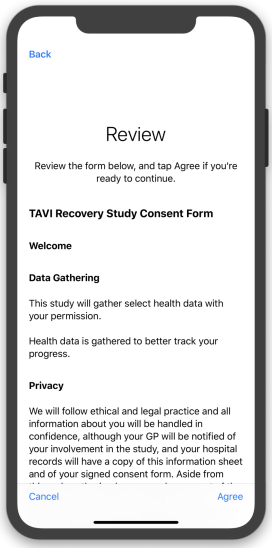
(e) Health data info



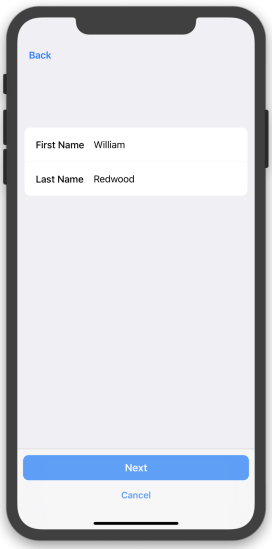
(f) HealthKit auth



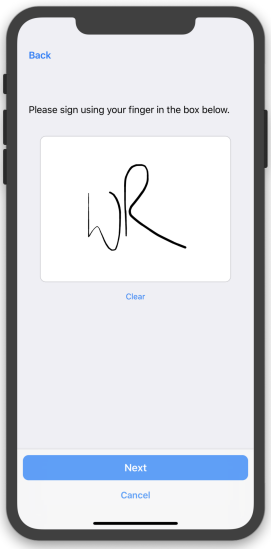
(g) Patient ID input



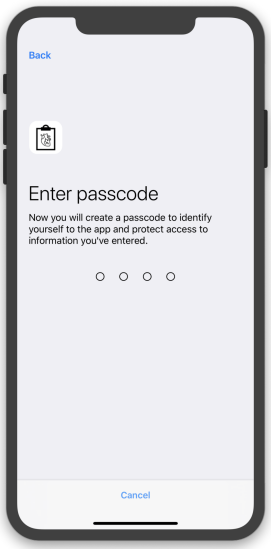
(h) Consent review



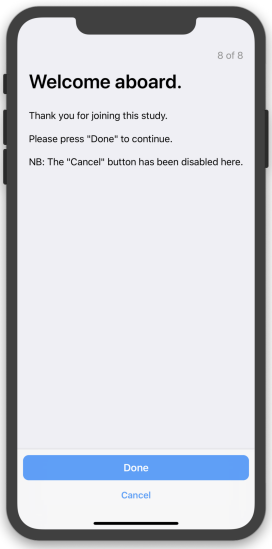
(i) Patient name



(j) Patient signature



(k) Passcode creation

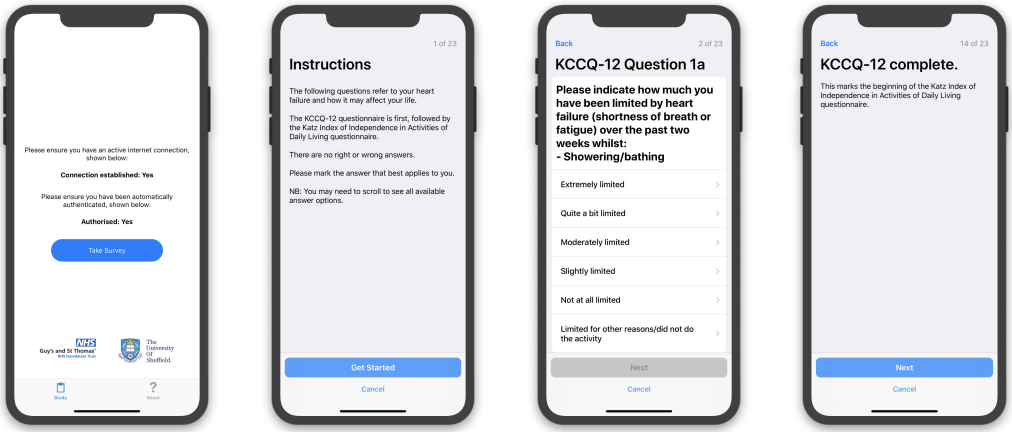


(l) Completion step

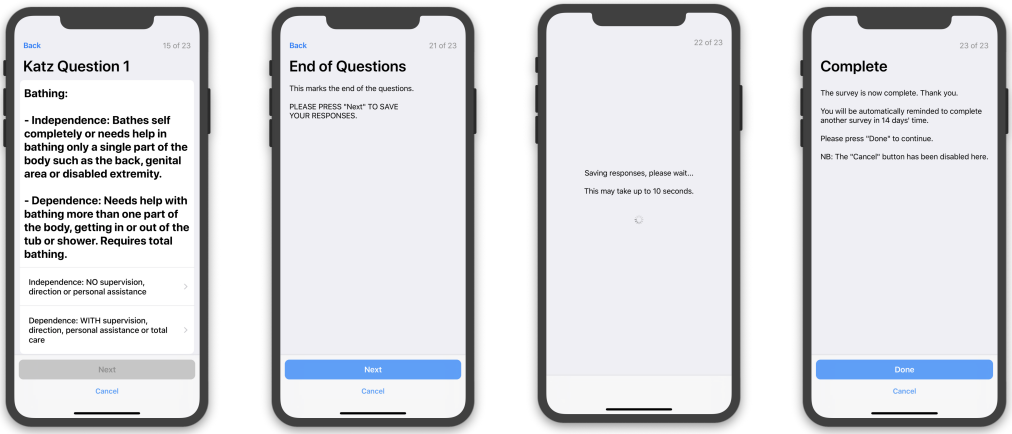
Figure 24: Screenshots demonstrating the onboarding process

5.1.2 Survey

Once onboarding is complete, each time the patient opens the app they will be presented with the main page. Figure 25 shows the survey process, with Figure 25(a) showing the main page. At the end of each survey, all queued push notifications will be removed and a new push notification scheduled for exactly 14 days' time.



(a) Main page (b) Instructions (c) KCCQ-12 question (d) Interim step



(e) Katz question (f) End of survey (g) ORKWaitStep (h) Completion step

Figure 25: Screenshots demonstrating the survey task

Notifications
User Story 8 (Table 1) discusses sending patients reminders to complete surveys. To achieve this I created a function which, when run, first removes any scheduled notifications, and then schedules a new one for exactly 14 days from when the function is run. An example notification is shown in Figure 26.

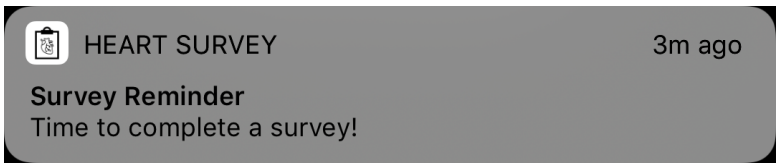


Figure 26: An example survey reminder notification

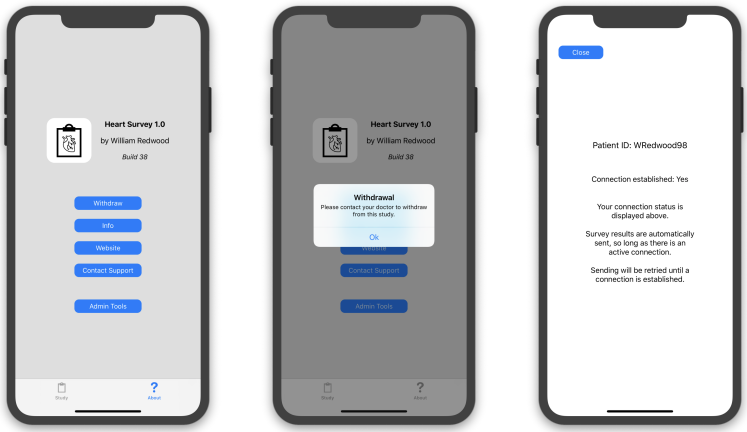
5.1.3 About Screen

The about tab is shown in Figure 27(a).

Withdrawal
Withdrawal from the study is handled by the hospital, and thus for the app a simple alert is shown if a patient taps "Withdraw", as shown in Figure 27(b).

Info
Tapping "Info" presents the screen shown in Figure 27(c). This displays the patient's Patient ID, as well as their connection status and some more information on how results are sent.

Website
The website button merely directs users to my personal website.



(a) About page (b) Withdrawal alert (c) Info screen

Figure 27: Screenshots showing the app's About tab

Contact Support
Tapping "Contact Support" should bring up a `MFMailComposeViewController` [100] with some pre-filled information, as shown in Figure 28(a). This includes my support email address, the name, version, and build of the app in question in the subject, and a line of text in the body of the email. Some devices may not be capable of using the default mail app[100] (such as if it has been uninstalled). If this is the case, an alert is shown, as seen in Figure 28(b).

(a) Email template (b) Mail services error

Figure 28: Screenshots demonstrating the contact support process

Admin Tools
The admin tools screen was briefly shown in Figure 18, showcasing the ability to manually export data, and is shown again in Figure 29.

When tapping on "Admin Tools" from the About tab, a warning is first presented (Figure 29(a)). Should the patient tap "Yes", they will be directed to the main Admin Tools page (Figure 29(b)).

Tapping "HealthKit Auth" would bring up the HealthKit authorisation screen, if permissions had not already been set in the onboarding process. If they had, an alert would be shown (Figure 29(c)) to instruct the user on how to update the permissions.
The "Export Data" functionality has already been discussed in Section 4.1.3, subsection Results Handling.
Finally, "Delete Keychain" was included purely for debugging purposes; used for testing keychain persistence, as touched upon in Section 4.1.3, subsection UserDefaults.

(a) Admin Tools warning (b) Admin Tools page (c) HealthKit Notice

Figure 29: Screenshots showing the app's Admin Tools page

5.1.4 App Store - General

As mentioned in Section 2.6, all apps are subject to Apple's App Store Review Guidelines[56]. Sections **5.1.2 "Data Use and Sharing"** and **5.1.3 "Health and Health Research"** are the most important for this project, and I shall discuss the key points now.

5.1.2(i) states:

> "Unless otherwise permitted by law, you may not use, transmit, or share someone's personal data without first obtaining their permission."

Permission is granted during the onboarding process.

5.1.2(vi) states:

> "Data gathered from the HomeKit API, HealthKit, Consumer Health Records API, MovementDisorder APIs, ClassKit or from depth and/or facial mapping tools (e.g. ARKit, Camera APIs, or Photo APIs) may not be used for marketing, advertising or use-based data mining, including by third parties. Learn more about best practices for implementing CallKit, HealthKit, ClassKit, and ARKit."

None of the data gathered is used for these purposes, and there are no advertisements in the app.

5.1.3(i) states:

> "Apps may not use or disclose to third parties data gathered in the health, fitness, and medical research context—including from the Clinical Health Records API, HealthKit API, Motion and Fitness, MovementDisorderAPIs, or health-related human subject research—for advertising, marketing, or other use-based data mining purposes other than improving health management, or for the purpose of health research, and then only with permission."

No data is disclosed to third parties.

5.1.3(ii) states:

> "Apps must not write false or inaccurate data into HealthKit or any other medical research or health management apps, and may not store personal health information in iCloud."

No data is written to HealthKit, only read, as can be seen when granting access in Figure 24(f). No data is stored in iCloud whatsoever.

5.1.3(iii) states:

> "Apps conducting health-related human subject research must obtain consent from participants or, in the case of minors, their parent or guardian. Such consent must include the (a) nature, purpose, and duration of the research; (b) procedures, risks, and benefits to the participant; (c) information about confidentiality and handling of data (including any sharing with third parties); (d) a point of contact for participant questions; and (e) the withdrawal process."

All of these are included either in the app's consent form, the physical patient consent form provided by the hospital, or both.

And finally, **5.1.3(iv)** states:

> "Apps conducting health-related human subject research must secure approval from an independent ethics review board. Proof of such approval must be provided upon request."

Full ethical approval has been granted by the University of Sheffield for this project (application reference number 023841). Ethical approval was also granted by the NHS, with NHS Research Ethics Committee Reference 18/NW/0028.

5.1.5 App Store - Submission & Release

I submitted the application to the App Store on 18 March 2019 at 22:10. On 19 March at 18:14 the status changed to "In Review", and at 19:23 on the same day the app was rejected.

The message I received from Apple regarding the rejection was as follows:

> "**Guideline 5.2.1 - Legal - Intellectual Property**
>
> The seller and company names associated with your app do not reflect the institution name in the app or its metadata, as required by Guideline 5.2.1 of the App Store Review Guidelines.
>
> **Next Steps**
>
> Your app must be published under a seller name and company name that reflects the institution name. If you have developed this app on behalf of a client, please advise your client to add you to the development team of their Apple Developer account. If your client does not yet have an Apple Developer account, they can enroll in the Apple Developer Program through the Apple Developer website.
>
> To request an update to the company name or entity type associated with this Apple Developer Program account, the Team Agent will need to edit the account information. On the Apple Developer website, go to Account, then select Membership. On the Membership page, click "Need to edit this information?" to submit your requested changes.
>
> Note that submitting documentation showing permission to publish this app on behalf of the content owner or institution will not resolve this issue. This app must be submitted under the content owner's own Apple Developer account.
>
> To request a fee waiver for nonprofit organizations, accredited educational institutions, or U.S.-based government entities, follow the steps outlined on the
> Apple Developer Program Membership Fee Waivers page."

After discussions with the App Store Review team, I discovered that the application was rejected as they believed, due to the inclusion of the University of Sheffield logo and the Guy's and St Thomas' NHS Foundation Trust logo, that I was developing the application on behalf of one of these institutions. After clarifying that the application was developed as part of my dissertation project, and merely additive to the research at Guy's and St Thomas' NHS Foundation Trust, I resubmitted the application for review.
At 01:59 on 22 March, the status of the app once again changed to "In Review" and I received the following message:

"Hello,

Thank you for providing this information.

We will continue the review, and we will notify you if there are any further issues.

Best regards,

App Store Review"

At 15:20 on 24 March 2019 the application was approved for release.

The app may be seen on the App Store at the link below, however please note that, as previously noted, it is password protected to avoid use by third parties:

http://itunes.apple.com/gb/app/id1439809838

5.2 Website

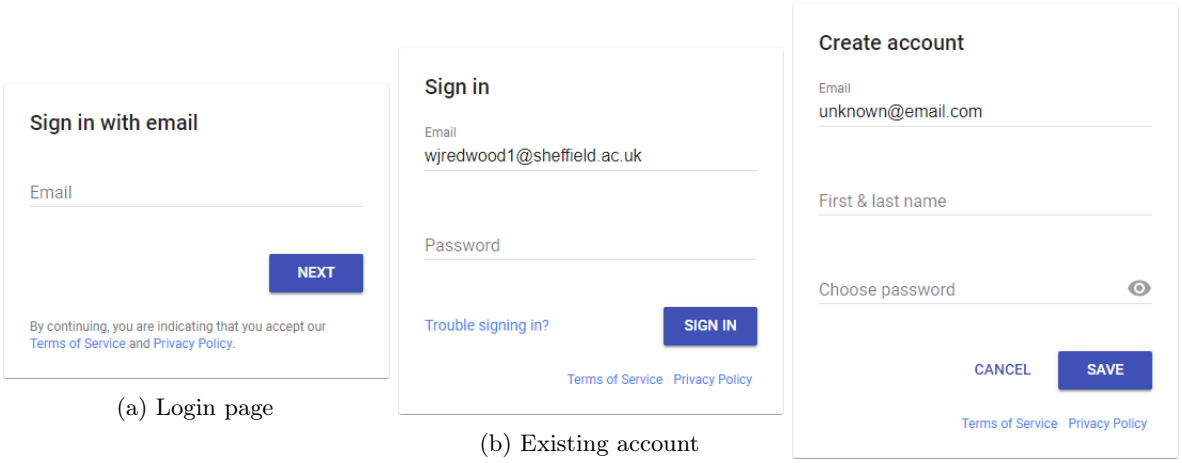
Main website: https://heart-survey.firebaseapp.com/.

As the main site handles real patient data, it would not be prudent to allow public access. Instead, I have made a demo site with no login required: http://wredwood.com/HSdemo/home.

5.2.1 Login

Figure 30 shows the login process for the website. Users are first asked to input an email and, if they already hold an account, they are then asked to input their password(Figure 30(b)). If they do not already have an account, they will be prompted to make one (Figure 30(c)).

As discussed in Section 4.2, Firebase Authentication allows any user to sign up and thus access the website. Anyone may access the main site at the URL above and sign up to view the site, however no data will be accessible as they must be manually granted access.



(a) Login page

(b) Existing account

(c) New account

Figure 30: The website's login process

5.2.2 Home

Once a user has successfully signed in, they will be presented with the home page (Figure 31). This is a simple landing page, with navigation to the data and downloads in the navbar.

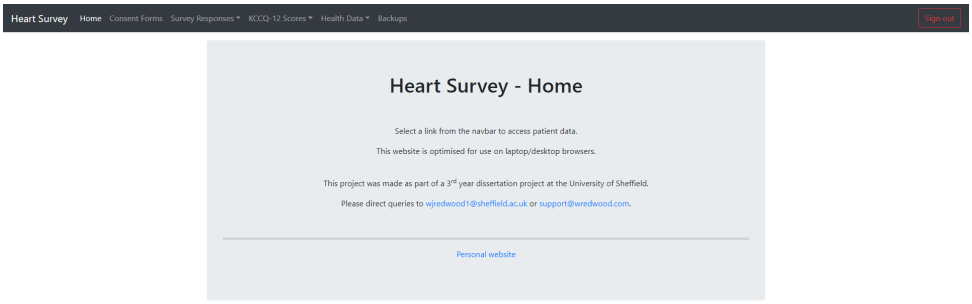


Figure 31: The website's home page

5.2.3 Consent Forms

The page for downloading signed consent forms is shown in Figure 32. The dropdown is populated with a list of Patient IDs, read from the database's `patientIDs` list (described in Section 4.1.4). An example consent form may be seen in Appendix O.

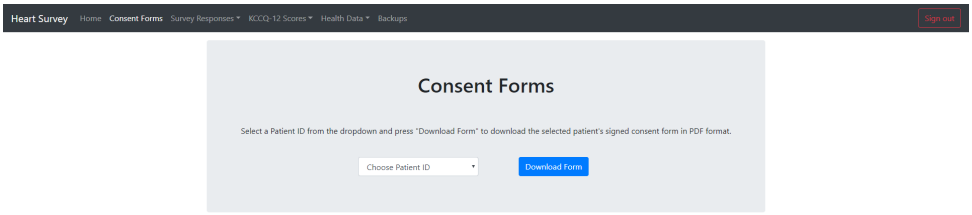


Figure 32: The website's consent forms download page

5.2.4 Results

Figure 33 shows KCCQ-12 results displayed in a table (the page for Katz results is identical). A question key is also provided, as listing the full question titles caused truncation. Below this, researchers are given the option to download the table data in a variety of formats.

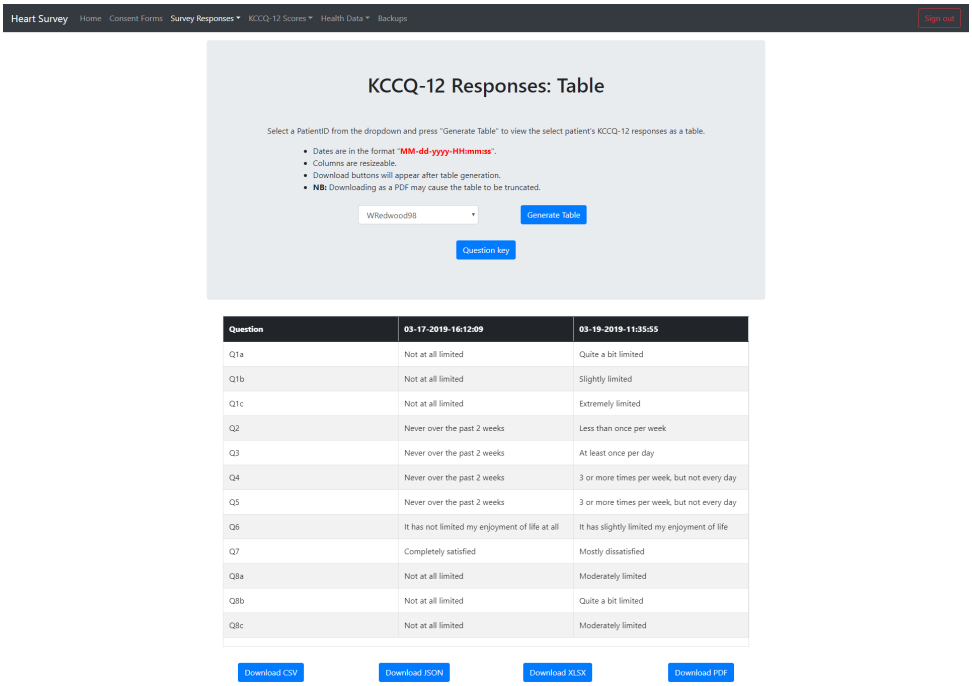


Figure 33: An example survey results table

The survey charts page is shown in Figure 34, with an example chart shown in Appendix P.

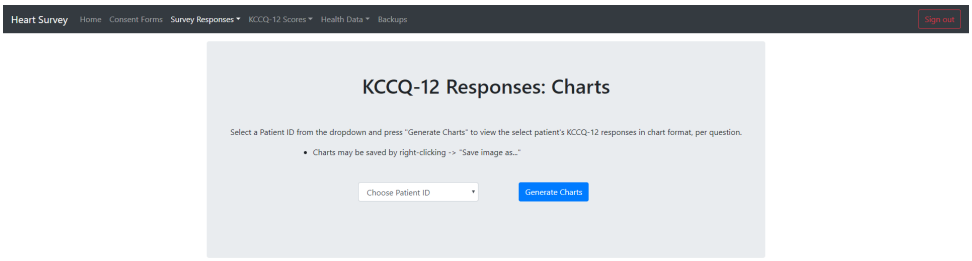


Figure 34: The website's survey charts page

KCCQ-12 scores and health data are displayed similarly through tables and charts. Example KCCQ-12 score charts may be seen in Appendix Q, and example health data charts in Appendix R.
Health data may also be viewed in a table format, however this truncates immediately due to the minimum 14 columns of data at any time. The tabulator table was still included here as it allows easy download of the data in different formats.

5.2.5 Backups

The backups page, shown in Figure 35, allows researchers to download the CSV files automatically uploaded to Firebase after each survey, as previously discussed in Section 4.1.3, subsection Results Handling. The 4 CSV files (`patientID-KCCQSurveyResults.csv` , `patientID-KatzSurveyResults.csv` , `patientID-KCCQScoresResults.csv` , and `patientID-HealthResults.csv`) relating to the chosen Patient ID are all downloaded at once. Appendices 4 to 7 show example CSV files.

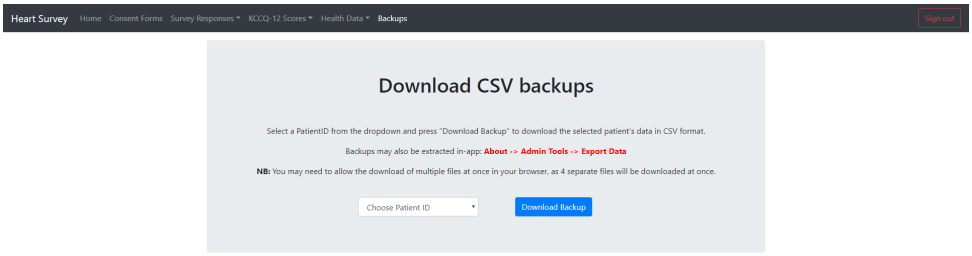


Figure 35: The website's CSV download page

5.3 Analysis Provided

No analysis was performed by myself, or any tools I developed, aside from basic presentation techniques (such as displaying the data on charts). Due to medical regulations[59], which were first discussed in Section 2.6, it was outside the scope of this project to go any further.

6 Evaluation and Conclusion

Having discussed the final implementation, testing, and release procedure, this section reviews the extent to which the original requirements were met. It also discusses how the resulting products could be developed further, including the benefits of this.

6.1 User Stories

User stories were first defined in Table 1. Table 2 reproduces these user stories with an additional column denoting the implementation of the user story, with discussion to follow.

Story	Difficulty	Priority	Status
1. As a User, I want to answer questions so that I can complete the survey.	8	1	Complete
2. As a User, I want to input my Patient ID so that I am identifiable to the Researchers.	8	1	Complete
3. As a User, I want to be able to consent so that I can partake in the study.	4	1	Complete
4. As a Researcher, I want to be able to view the results of the surveys so that I can analyse them.	16	1	Complete
5. As a Researcher, I want to see the results for a specific Patient ID so that I can identify them.	16	1	Complete
6. As an Admin, I want to be able to manage the data collected so that I can easily remove the data related to withdrawn Users.	8	1	Partial
7. As a User, I want to passcode protect the app so that no one may answer on my behalf.	4	2	Complete
8. As a User, I want to receive reminders so that I remember to complete the survey at the required intervals.	8	2	Complete
9. As a User, I want to be able to withdraw from the study so that I am not participating in the study any more.	2	2	Partial
10. As a User, I want to be able to complete a survey without interruption after completing the initial consent process, so that I do not need to repeat this	1	2	Complete
11. As a Researcher, I want the application to require a login so that no unauthorised members of the public may take part.	8	2	Complete
12. As a Researcher, I want to be able to view the signed consent form for a specific Patient ID so that I may keep it for my records.	4	3	Complete

Table 2: The updated agile user stories

1. This is the core functionality of the app itself and was one of the first user stories to be completed. There are 18 questions in total (12 from the KCCQ-12 survey, and 6 from the Katz Index of Independence in Activities of Daily Living).
2. As part of the onboarding process, the User is asked to input the Patient ID assigned to them by the hospital. The Researchers ensure that each Patient ID provided to Users is unique, with no uniqueness checks performed to allow Users to install the application on multiple devices. This is then stored on-device through Realm, and attached to any survey results and health data that is submitted through Firebase (which are also stored on-device).
3. A consent document was generated with input from the Researchers, and included during the onboarding process, which Users must agree to in order to use the app. An example consent document may be viewed in Appendix O. The consent form is then uploaded to Firebase.
4. Upon completion of a survey, both the survey results and any health data are automatically uploaded to Firebase. These are then available to view on the developed website, which only Researchers may access as it requires a login. This is important in order to avoid the disclosure of confidential patient information to members of the public.

5. All results on the website are filtered by Patient ID. There is no option to view all data at once as this was specifically vetoed by the Researchers I was in contact with - it would be purposeless for their research. The research is intended to try and discern which factors influence the success of an operation, and they require the data on a case-by-case basis to investigate this.
6. There is the option to delete a withdrawn User's data from the Firebase console, which Admins may access. However, there is currently no way to delete the data from the website itself, hence this user story was only partially completed.
7. During the onboarding process the User must create a 4-digit passcode to secure the app, which helps negate the risk of unauthorised access (for example, children using a shared device). Users also have the option to use Touch ID or Face ID (if their device supports it, and if they should wish to do so), which some Users may find more convenient.
8. Each time a User completes a survey a local notification is scheduled for 14 days' time, as the survey is intended to be completed every 2 weeks. See Figure 26 for an example.
9. The User may withdraw by contacting their assigned doctor (Researcher) at the hospital. This user story was marked as partially completed as there is no way to withdraw from the study through the app itself - the User is instead advised to contact their doctor (see Section 6.2.1).
10. As discussed in Section 4.1.3, subsection UserDefaults, the app will direct users to the main page on each launch, once they have completed the onboarding process.
11. During the onboarding process, before viewing the consent document and associated information, each user is required to input a predetermined password to gain access to the study. This was done to avoid unauthorised members of the public signing up and contaminating the data.
12. Consent forms are downloadable from the website, as discussed in Section 5.2.3, and more specifically in Figure 32.

6.2 Conclusion

In conclusion:

- I have developed an iOS application using ResearchKit, enabling the collection of qualitative and quantitative patient recovery data.
- The app was tested with multiple external testers using TestFlight, and I acted upon the feedback received from testers.
- I have successfully released said app on the App Store, meaning it met Apple's App Store Review Guidelines.
- I have developed a website to view the data collected in different formats.
- The product of this project is now ready for use in a real-world study at St Thomas' Hospital.

6.2.1 Further Work

This project has therefore achieved its core aims. Given more time, a useful addition would be the ability to withdraw a patient from the website itself, automatically deleting any data tied to their Patient ID (namely their consent form, survey results, and health data). This would negate the need for Researchers to have to log in to the Firebase console for the sole reason of removing any associated data.
This could be further developed into allowing users easier control over this through the app, making it easier for patients who may not be able to reach their doctor in person. The "Withdraw" button in-app could instead generate an email with a template request to withdraw that can be sent to the doctor/researcher assigned to them (along the lines of that shown in Figure 28(a)). The doctor could then follow up with the patient to confirm the withdrawal from the study.
It would likely not be suitable to have fully automated withdrawal in-app in case a user withdraws accidentally - even with a confirmation screen beforehand, the likely demographic is relatively old and may still accidentally confirm withdrawal. Allowing this could potentially invalidate studies as inaccurate conclusions may be drawn from incomplete data. Firebase does have a database backup feature[101], but this does not fully neutralise the risk.

6.2.2 Expansion

The application could be adapted for use in many other research areas, particularly those which heavily utilise surveys (such as mental health, more specifically the associated mood assessments). The code for the survey questions uses ResearchKit's `ORKQuestionStep`, and thus can be easily changed to have different titles and answer options. Additional questions, along with different answer formats (Figure 7), may also be easily added as part of the survey task. The backend would require potentially minor changes to accommodate these, principally database schema changes.

Using Apple's HealthKit, it would also be straightforward to add the collection of further health data, such as respiratory rate, blood glucose levels, or basal bodily temperature, among many others.

Furthermore, the application was developed with primarily function over form - the user interface was purposely left to be simplistic, whilst remaining intuitive, as the expected end-user demographic will be elderly persons. For future adaptation this could be overhauled to look more modern and attractive, catering to a different target demographic. The UI itself is complete, and using Xcodes included tools it would be straightforward to add depth - for example, a simple `CAGradientLayer` would replace the currently white background with colours of the developers choosing, with depth added through the use of gradients rather than a single solid colour.

One could also potentially make this cross-platform. The backend, Firebase, is compatible with Android too, however ResearchKit is not. There are attempts to create a similar SDK to ResearchKit for Android, such as ResearchStack[102]. However, at the time of writing, the GitHub repository for this has not been updated since January 2017.
This would have potential disadvantages relating to compatibility, however, most likely due to the fragmented nature of OS version usage, as discussed in Section 2.4.1.

6.2.3 Digital Technologies in Healthcare

The decision to use this project in a real-world study at a top London hospital showcases the growing presence, and indeed importance, of digital healthcare solutions.
The project has demonstrated how it is possible to easily collect both qualitative data in the form of survey results from patients, as well as quantitative health measurements, using mobile applications.

Digital health in general brings with it many other advantages, and in this case demonstrates access advantages. Without this particular project, the study would still have gone ahead. However, patients would have been required to visit the hospital every 2 weeks to answer the same survey questions in-person, or potentially less often. Likewise, the researchers would be manually collating any health data from the patient's smartwatches at each visit.
The project has therefore removed the necessity for patients to travel to London fortnightly, which may have caused issues for some of the elderly demographic, in addition to saving time for the doctors involved. As mentioned, it may have instead been decided to reduce the frequency of surveys, which would in turn reducing the data gathered, and thus quality of the research - but this was avoided as a result of the use of digital means.

This application therefore has huge potential across many diverse disciplines within healthcare with the aforementioned minor adaptations. A few examples include:

- Within cardiology, the application has the potential to help compare different techniques for surgical aortic valve replacement. The traditional approach is a full sternotomy - splitting the entire breastbone to gain access to the heart. In patients deemed not suitable for a TAVI operation, a more recent development is through a much smaller incision where only the top half of the sternum is divided. Although it has not yet undergone full comparison, the smaller incision is predicted to allow more rapid recovery as the lower half of the sternum remains intact, thus potentially allowing more faster mobilisation and shortened discomfort when breathing. These techniques have thus far not been as widely adopted as they are more technically challenging, and require more specific training. Having reliable data to demonstrate the more rapid recovery of function and quality of life would thus be invaluable in rolling this out as the default for those unsuitable for TAVI.
  I am currently working alongside the doctors at St Thomas' Hospital to develop a randomised trial investigating this, using the application from this dissertation as a tool to track recovery.
  This is just one example of many where less invasive techniques are being developed, but have not yet

been tested head-to-head with more traditional approaches, in which this application, or similar, has great potential.

- Considering the mental health example, one could include a questionnaire similar to the NHS' mood self-assessment quiz[103]. Adapting the application for this purpose would be straightfoward - it would mostly be a case of simply changing the text of the questions and answers shown. The backend (both Firebase and the Website) would also require adaptation, but again primarily simple text changes.
  If anything, one would likely want to remove certain measurements from those which are collected (such as heart rate), as these are not as applicable here. Other readily-collected measurements, such as walking distance, would remain useful due to the links between mood and exercise (as it is known that exercise helps increase serotonin[104]).

In other scenarios, digital technology may be used to connect patients in remote and rural communities, or those with lessened mobility, to medical staff through video calls and other communication methods (such as an in-app chat system). If given regulatory approval, these applications may also allow patients themselves to play a bigger part in their own recovery. Patients would be able to track their recovery on a day-to-day basis, and potentially receive tailored and up-to-date advice.
This may be combined with a digital record, such as Apple's Medical ID which helps "first responders access [a patient's] critical medical information from the Lock screen, without needing [the patient's] passcode"[105]. For example, this may contain crucial information about allergies, medications, and existing conditions. Allowing the aforementioned scenarios' example applications to access this Medical ID potentially enables better accuracy when it comes to diagnosis and treatment of new issues, giving medical staff access to a full medical history in a much easier manner.

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A KCCQ-12 Survey

Kansas City Cardiomyopathy Questionnaire (KCCQ-12)

The following questions refer to your **heart failure** and how it may affect your life. Please read and complete the following questions. There are no right or wrong answers. Please mark the answer that best applies to you.

1. **Heart failure** affects different people in different ways. Some feel shortness of breath while others feel fatigue. Please indicate how much you are limited by **heart failure** (shortness of breath or fatigue) in your ability to do the following activities over the past 2 weeks.

Activity	**Extremely** Limited	**Quite a bit** Limited	**Moderately** Limited	**Slightly** Limited	**Not at all** Limited	Limited for other reasons or did not do the activity
a. Showering/bathing	O	O	O	O	O	O
b. Walking 1 block on level ground	O	O	O	O	O	O
c. Hurrying or jogging (as if to catch a bus)	O	O	O	O	O	O
	1	2	3	4	5	6

2. Over the past 2 weeks, how many times did you have **swelling** in your feet, ankles or legs when you woke up in the morning?

Every morning	3 or more times per week but not every day	1-2 times per week	Less than once a week	Never over the past 2 weeks
O	O	O	O	O
1	2	3	4	5

3. Over the past 2 weeks, on average, how many times has **fatigue** limited your ability to do what you wanted?

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1-2 times per week	Less than once a week	Never over the past 2 weeks
O	O	O	O	O	O	O
1	2	3	4	5	6	7

4. Over the past 2 weeks, on average, how many times has **shortness of breath** limited your ability to do what you wanted?

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1-2 times per week	Less than once a week	Never over the past 2 weeks
O	O	O	O	O	O	O
1	2	3	4	5	6	7

5. Over the past 2 weeks, on average, how many times have you been forced to sleep sitting up in a chair or with at least 3 pillows to prop you up because of **shortness of breath**?

Every night	3 or more times per week but not every day	1-2 times per week	Less than once a week	Never over the past 2 weeks
O	O	O	O	O
1	2	3	4	5

Rev. 2012-04-11

6. Over the past 2 weeks, how much has your **heart failure** limited your enjoyment of life?

It has **extremely** limited my enjoyment of life	It has limited my enjoyment of life **quite a bit**	It has **moderately** limited my enjoyment of life	It has **slightly** limited my enjoyment of life	It has **not limited** my enjoyment of life at all
O	O	O	O	O
1	2	3	4	5

7. If you had to spend the rest of your life with your **heart failure** the way it is right now, how would you feel about this?

Not at all satisfied	Mostly dissatisfied	Somewhat satisfied	Mostly satisfied	Completely satisfied
O	O	O	O	O
1	2	3	4	5

8. How much does your **heart failure** affect your lifestyle? Please indicate how your **heart failure** may have limited your participation in the following activities over the past 2 weeks.

Activity	**Severely** Limited	Limited **quite a bit**	**Moderately** limited	**Slightly** limited	**Did not** limit at all	Does not apply or did not do for other reasons
a. Hobbies, recreational activities	O	O	O	O	O	O
b. Working or doing household chores	O	O	O	O	O	O
c. Visiting family or friends out of your home	O	O	O	O	O	O
	1	2	3	4	5	6

B Katz Index of Independence in Activities of Daily Living

Katz Index of Independence in Activities of Daily Living

ACTIVITIES POINTS (1 OR 0)	**INDEPENDENCE:** (1 POINT) **NO** supervision, direction or personal assistance	**DEPENDENCE:** (0 POINTS) **WITH** supervision, direction, personal assistance or total care
BATHING POINTS:_____	(1 POINT) Bathes self completely or needs help in bathing only a single part of the body such as the back, genital area or disabled extremity.	(0 POINTS) Needs help with bathing more than one part of the body, getting in or out of the tub or shower. Requires total bathing.
DRESSING POINTS:_____	(1 POINT) Gets clothes from closets and drawers and puts on clothes and outer garments complete with fasteners. May have help tying shoes.	(0 POINTS) Needs help with dressing self or needs to be completely dressed.
TOILETING POINTS:_____	(1 POINT) Goes to toilet, gets on and off, arranges clothes, cleans genital area without help.	(0 POINTS) Needs help transferring to the toilet, cleaning self or uses bedpan or commode.
TRANSFERRING POINTS:_____	(1 POINT) Moves in and out of bed or chair unassisted. Mechanical transferring aides are acceptable.	(0 POINTS) Needs help in moving from bed to chair or requires a complete transfer.
CONTINENCE POINTS:_____	(1 POINT) Exercises complete self control over urination and defecation.	(0 POINTS) Is partially or totally incontinent of bowel or bladder.
FEEDING POINTS:_____	(1 POINT) Gets food from plate into mouth without help. Preparation of food may be done by another person.	(0 POINTS) Needs partial or total help with feeding or requires parenteral feeding.

TOTAL POINTS = _____ *6 = High (patient independent) 0 = Low (patient very dependent)*

Slightly adapted from Katz, S., Down, T.D., Cash, H.R., & Grotz, R.C. (1970) Progress in the development of the index of ADL. *The Gerontologist,* 10(1), 20-30.

The Hartford Institute for Geriatric Nursing recognizes Mary Shelkey, PhD, ARNP and Meredith Wallace Kazer, PhD, APRN, A/GNP-BC as the original authors of this issue.

try this: general assessment series
Best Practices in Nursing Care to Older Adults
A series provided by The Hartford Institute for Geriatric Nursing, NYU Rory Meyers College of Nursing
EMAIL: nursing.hign@nyu.edu HARTFORD INSTITUTE WEBSITE: www.hign.org
CLINICAL NURSING WEBSITE: www.ConsultGeri.org

C Patient ID extraction code

```
let taskResult = taskViewController.result
let idStepResult = taskResult.stepResult(forStepIdentifier: "patientIDstep")
let patientID = idStepResult?.firstResult?.value(forKey: "answer") as! String
print("Patient ID: \(patientID)")

let resultsData = SurveyResults()
resultsData.patientID = patientID
do {
    try Realm().write {
        try Realm().add(resultsData)
    }
    dismiss(animated: true, completion: nil)
} catch let error as NSError {
    print("Could not save new record. \(error), \(error.userInfo)")

    let alert = UIAlertController(title: "Error",
                                  message: "Could not save patient. Please report this to the
    developer.",
                                  preferredStyle: .alert)
    let okAction = UIAlertAction(title: "Ok",
                                 style: .default)

    alert.addAction(okAction)

    present(alert, animated: true)
}

idVariable.setUserPatientID(newID: patientID)
```

D SurveyResults.swift

```
1  import Foundation
2  import RealmSwift
3
4  class SurveyResults: Object {
5
6      @objc dynamic var patientID = ""
7
8      @objc dynamic var question1a = 0
9      @objc dynamic var question1b = 0
10     @objc dynamic var question1c = 0
11     @objc dynamic var question2 = 0
12     @objc dynamic var question3 = 0
13     @objc dynamic var question4 = 0
14     @objc dynamic var question5 = 0
15     @objc dynamic var question6 = 0
16     @objc dynamic var question7 = 0
17     @objc dynamic var question8a = 0
18     @objc dynamic var question8b = 0
19     @objc dynamic var question8c = 0
20
21     @objc dynamic var surveyDate = Date()
22
23 }
```

E PDF Creation Code

```
if let stepResult = taskResult.stepResult(forStepIdentifier: "ConsentReviewStep"),
    let signatureResult = stepResult.results?.first as? ORKConsentSignatureResult {
    signatureResult.apply(to: consentDocument)

    consentDocument.makePDF { (data, error) -> Void in
        let documentsDirectoryPathString =
    NSSearchPathForDirectoriesInDomains(.documentDirectory, .userDomainMask, true).first!
        let documentsDirectoryPath = NSURL(string: documentsDirectoryPathString)!

        let pdfFilePath = documentsDirectoryPath.appendingPathComponent("signature.pdf")

        let fileManager = FileManager.default
        var isDirectory: ObjCBool = false

        if !fileManager.fileExists(atPath: (pdfFilePath?.absoluteString)!, isDirectory:
    &isDirectory) {
            let created = fileManager.createFile(atPath: (pdfFilePath?.absoluteString)!,
    contents: nil, attributes: nil)
            if created {
                print("File created ")
            } else {
                print("Couldn't create file for some reason")
            }
        } else {
            print("File already exists")
        }

        do {
            let file = try FileHandle(forWritingTo: pdfFilePath!)
            file.write(data!)
            print("PDF data was written to the file successfully!")
        } catch let error as NSError {
            print("Couldn't write to file: \(error.localizedDescription)")
        }
    }
}
```

F Survey Answer Saving

```
DispatchQueue.main.asyncAfter(deadline: .now() + .seconds(3)) {
    // EXPORT DATA TO CSV
    let path = NSSearchPathForDirectoriesInDomains(.documentDirectory, .userDomainMask,
    true).first!
    let pathString = path + "/default.realm"

    print("PATH: \(pathString)")

    let csvDataExporter = try! CSVDataExporter(realmFilePath: pathString)
    try! csvDataExporter.export(toFolderAtPath: path)
}
```

G SurveyResults.csv

patientID	question1a	question1b	question1c	question2	question3	question4	question5	question6	question7	question8a	question8b	question8c	surveyDate
wjredwood1	4	2	3	4	5	4	4	3	3	1	3	4	"2018-12-02 14:54:12 +0000"

Table 3: SurveyResults.csv

H Template Consent Document PDF

TAVI Recovery Study Consent Form

Welcome

Overview Content...

Data Gathering

Data Gathering Content...

Privacy

Privacy Content...

Data Use

Data Use Content...

Time Commitment

Time Commitment Content...

Study Tasks

Study Tasks Content...

Withdrawing

Withdrawal Content...

William Redwood		12/2/18
Participant's Name (printed)	Participant's Signature	Date

I Modification Notes

```
1  // Remove the cancel button from ORKWaitStep
2  ResearchKit -> Common -> Step -> Wait Step -> ORKWaitStepViewController.m
3
4  REMOVE:
5  _navigationFooterView.cancelButtonItem = self.cancelButtonItem;
6
7
8
9  // Remove the disagree button from ORKConsentReviewStep
10 ResearchKit -> Consent -> Review -> Document Review -> ORKConsentReviewController.m
11
12 REMOVE:
13 [[UIBarButtonItem alloc] initWithTitle:ORKLocalizedString(@"BUTTON_DISAGREE", nil)
       style:UIBarButtonItemStylePlain target:self action:@selector(cancel)]
14
15
16
17 // Replace standard back button (arrow) with localised Back text
18 ResearchKit -> Common -> UIKitCategories -> UIBarButtonItem+OrkBarButtonItem.m
19
20 REMOVE:
21 NSString *regularImageName = @"arrowLeft";
22     NSString *landscapeImageName = @"arrowLeftLandscape";
23
24 if ([UIApplication sharedApplication].userInterfaceLayoutDirection ==
       UIUserInterfaceLayoutDirectionRightToLeft ) {
25         regularImageName = @"arrowRight";
26         landscapeImageName = @"arrowRightLandscape";
27     }
28
29 UIImage *image = [UIImage imageNamed:regularImageName inBundle:ORKBundle()
       compatibleWithTraitCollection:nil];
30     UIImage *landscapeImage = [UIImage imageNamed:landscapeImageName
       inBundle:ORKBundle() compatibleWithTraitCollection:nil];
31     UIBarButtonItem *item = [[UIBarButtonItem alloc] initWithImage:image
32                                                landscapeImagePhone:landscapeImage
33
       style:UIBarButtonItemStyleDone
34                                                              target:target
35                                                              action:selector];
36
37
38 REPLACE WITH:
39 UIBarButtonItem *item = [[UIBarButtonItem alloc]
       initWithTitle:ORKLocalizedString(@"AX_BUTTON_BACK", nil)
40
       style:UIBarButtonItemStyleDone
41                                                              target:target
42                                                              action:selector];
```

J InitialVC.swift

```
import UIKit
import ResearchKit

class InitialVC: UIViewController {

    override func viewDidLoad() {
        super.viewDidLoad()

        if (UserDefaults.standard.bool(forKey: "joinStudy")) {
            print("JOIN STUDY TRUE")
            toStudy()
        } else {
            // Hasn't joined the study OR has reinstalled the app
            // Remove the passcode, if there is one, and redirect to consent stage
            print("JOIN STUDY FALSE")

            ORKPasscodeViewController.removePasscodeFromKeychain()
            toOnboarding()
        }
    }


    var contentHidden = false {
        didSet {
            guard contentHidden != oldValue && isViewLoaded else { return }
            children.first?.view.isHidden = contentHidden
        }
    }


    // MARK: Transitions

    func toOnboarding() {
        print("TO ONBOARDING")
        performSegue(withIdentifier: "joinStudy", sender: self)
    }

    func toStudy() {
        print("TO STUDY")
        performSegue(withIdentifier: "toStudy", sender: self)
    }


    // Used in JoinStudyVC
    @IBAction func unwindToStudy(segue:UIStoryboardSegue) {
        toStudy()
    }

}
```

K Podfile

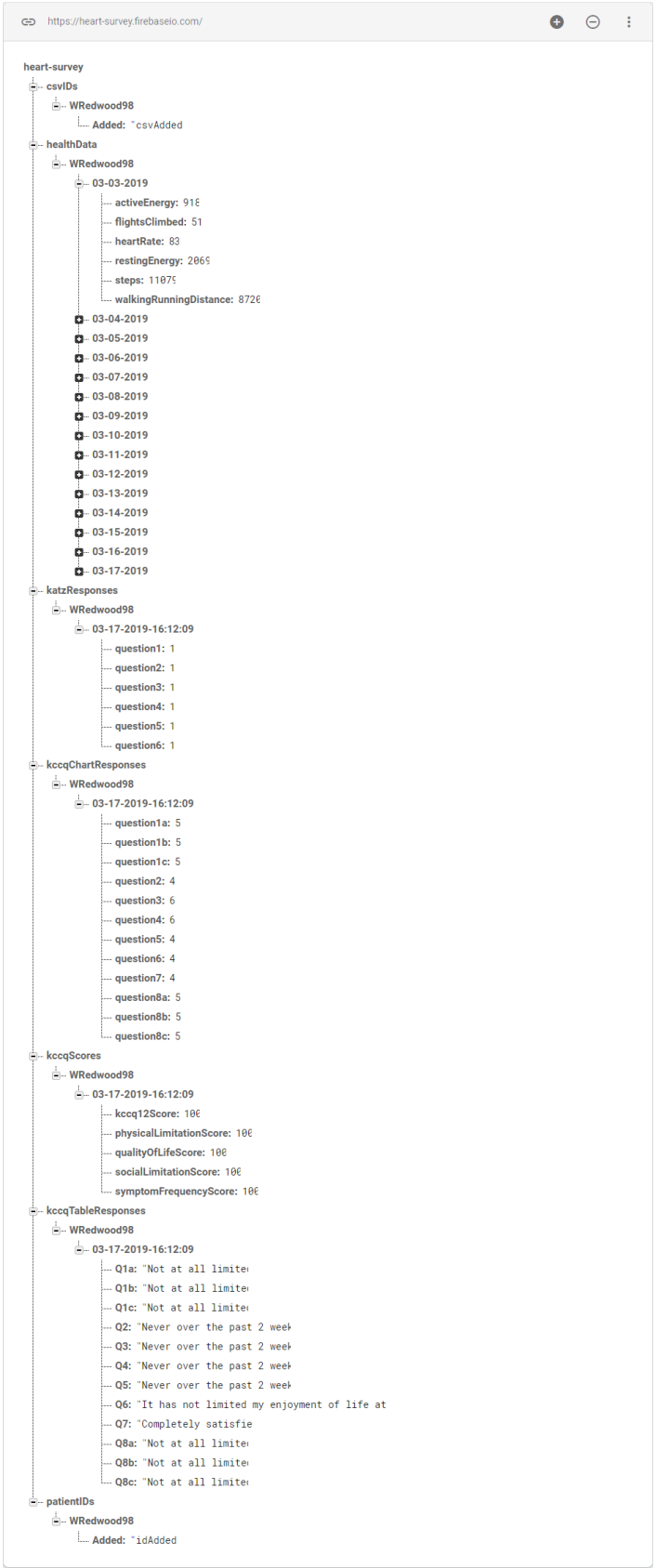
```
# Uncomment the next line to define a global platform for your project
platform :ios, '11.0'

target 'Heart Survey' do
  # Comment the next line if you're not using Swift and don't want to use dynamic
    frameworks
  use_frameworks!

  # Pods for Heart Survey
  pod 'RealmSwift'
  pod 'PathKit'
  pod 'Firebase/Core'
  pod 'Firebase/Database'
  pod 'Firebase/Messaging'
  pod 'Firebase/Storage'
  # Crashlytics
  pod 'Fabric'
  pod 'Crashlytics'

end
```

L Database Schema



M Feedback Form

Heart Survey App Feedback

This form should only take a few minutes to complete.

Before continuing, please ensure you have downloaded and trialled the Heart Survey app for iOS.
If not, please contact William Redwood: wjredwood1@sheffield.ac.uk.

*Required

Demographic Information

How old are you? *

- ◯ <18
- ◯ 18-24
- ◯ 25-39
- ◯ 40-60
- ◯ Over 60

How computer literate would you say you are? *

	1	2	3	4	5	
Not at all	◯	◯	◯	◯	◯	Very

What device did you use for testing? *

- ◯ iPhone 5/5S/SE
- ◯ iPhone 6/6S/7/8
- ◯ iPhone 6 Plus/6S Plus/7 Plus/8 Plus
- ◯ iPhone X/XS/XR
- ◯ iPhone XS Max
- ◯ iPad Pro 3rd Gen (Latest, Face ID enabled)
- ◯ Other iPad

NEXT Page 1 of 2

Never submit passwords through Google Forms.

Heart Survey App Feedback

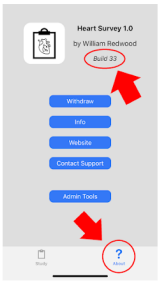
*Required

Application Feedback

Please enter the build number of the application you are testing: *

This can be found by opening the app and tapping "About" at the bottom - see example below.

Your answer



Please rate your experience while navigating through this app. *

	1	2	3	4	5	
Confusing	○	○	○	○	○	Very Clear

Please rate the overall look and feel of the app. *

	1	2	3	4	5	
Not Pleasing	○	○	○	○	○	Pleasing

The app is well-suited for first-time visitors. *

	1	2	3	4	5	
Disagree	○	○	○	○	○	Agree

The app is well-suited for returning visitors. *

	1	2	3	4	5	
Disagree	○	○	○	○	○	Agree

Anyone would be able to use this app. *

	1	2	3	4	5	
Disagree	○	○	○	○	○	Agree

What do you like about this app?

- [ ] Speed
- [ ] Stability
- [ ] Look and feel
- [ ] Functionality
- [ ] Navigation
- [ ] Other:

What do you *not* like about this app, if anything?

- [ ] Speed
- [ ] Stability
- [ ] Look and feel
- [ ] Functionality
- [ ] Navigation
- [ ] Other:

What would you change about this app to make it more user-friendly, if anything?

Your answer

Please list any bug/glitches, spelling/formatting errors, or parts of this app that were inaccessible, if you encountered any.

Your answer

Any other comments?

Your answer

BACK SUBMIT Page 2 of 2

Never submit passwords through Google Forms.

N consentDownload.js

```
$(document).ready(function() {
  $('#downloadButton').click(function() {

    // Get the selected Patient ID
    let selectedID = $('#consentForms-dropdown').val();

    // Null if default dropdown value used
    if (selectedID !== null) {
      var storage = firebase.storage();
      var pathReference = storage.ref('consent/' + selectedID + '.pdf');

      // For iOS
      var windowReference = window.open();

      pathReference.getDownloadURL().then(function(url) {
        // 'url' is the download URL for 'consent/' + selectedID + '.pdf'

        if (iOS()) {
          console.log("iOS DEVICE")
          windowReference.location = url;
        } else {
          $.ajax({
            url: url,
            method: 'GET',
            xhrFields: {
              responseType: 'blob'
            },
            success: function(data) {
              var a = document.createElement('a');
              var url = window.URL.createObjectURL(data);
              a.href = url;
              a.download = selectedID + '.pdf';
              a.click();
              window.URL.revokeObjectURL(url);
            }
          });
          console.log("NOT iOS DEVICE")
        }
      }).catch(function(error) {
        // Handle any errors
        console.log(error);
      });

    } else {
      console.log("NULL ID");
    }

  });
});

function iOS() {
  var iDevices = [
    'iPad Simulator',
    'iPhone Simulator',
    'iPod Simulator',
    'iPad',
    'iPhone',
    'iPod'
  ];

  if (!!navigator.platform) {
```

```
62      while (iDevices.length) {
63        if (navigator.platform === iDevices.pop()) {
64          return true;
65        }
66      }
67    }
68    return false;
69  }
```

O Consent PDF

TAVI Recovery Study Consent Form

Welcome

Data Gathering

This study will gather select health data with your permission.

Health data is gathered to better track your progress.

Privacy

We will follow ethical and legal practice and all information about you will be handled in confidence, although your GP will be notified of your involvement in the study, and your hospital records will have a copy of this information sheet and of your signed consent form. Aside from this, only authorised persons who are part of the research team will have access to your information. We will keep the data collected in anonymised form on our password encrypted computers for up to five years after the study has finished.

Data Use

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital will have any identifying details, such as your name and address, removed so that you cannot be recognised from it. The information that we analyse for the results will also be anonymous. Any information which contains your personal details will be in hard copy form only (not on computers) and will be kept in a locked cabinet accessible only by the researchers. This information will be kept for up to twelve months after the study has been completed, before being destroyed.

Time Commitment

This study will take a few minutes every 2 weeks.

Study Survey

Questionnaires are an important part of this research study. We will ask you to complete fortnightly questionnaires about your health.

Study Tasks

To track your progress, we will ask you to complete 2 simple questionnaires (in one sitting) every 2 weeks.

Withdrawing

You can choose to withdraw from the study at any point, without providing a reason if you do not wish to. If you choose to withdraw from the study, we will destroy all your identifiable information, but we will use the data collected up to the time of your withdrawal.

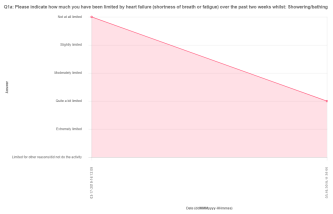
To withdraw, please contact your doctor.

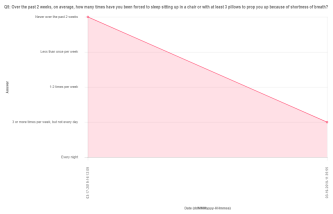
Patient Signature

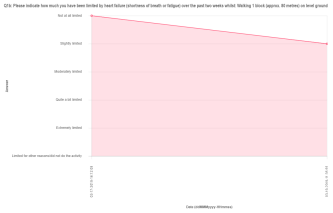
I agree to participate in this study.

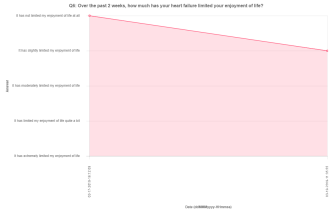
William Redwood		18-Mar-2019-22:08:01
Patient's Name (printed)	Patient's Signature	Date

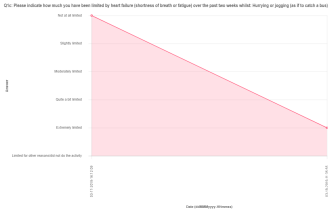
P Survey Charts

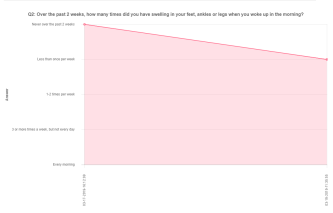


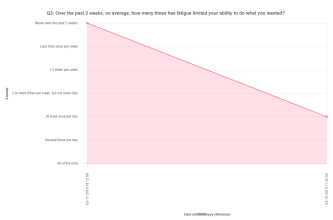


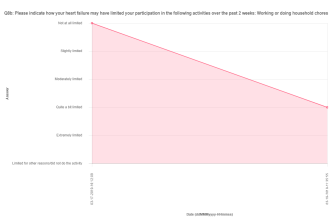


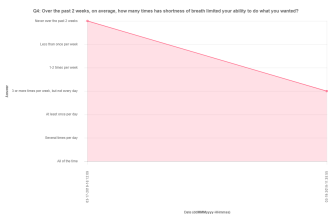


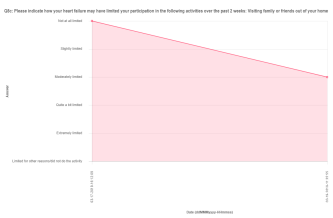




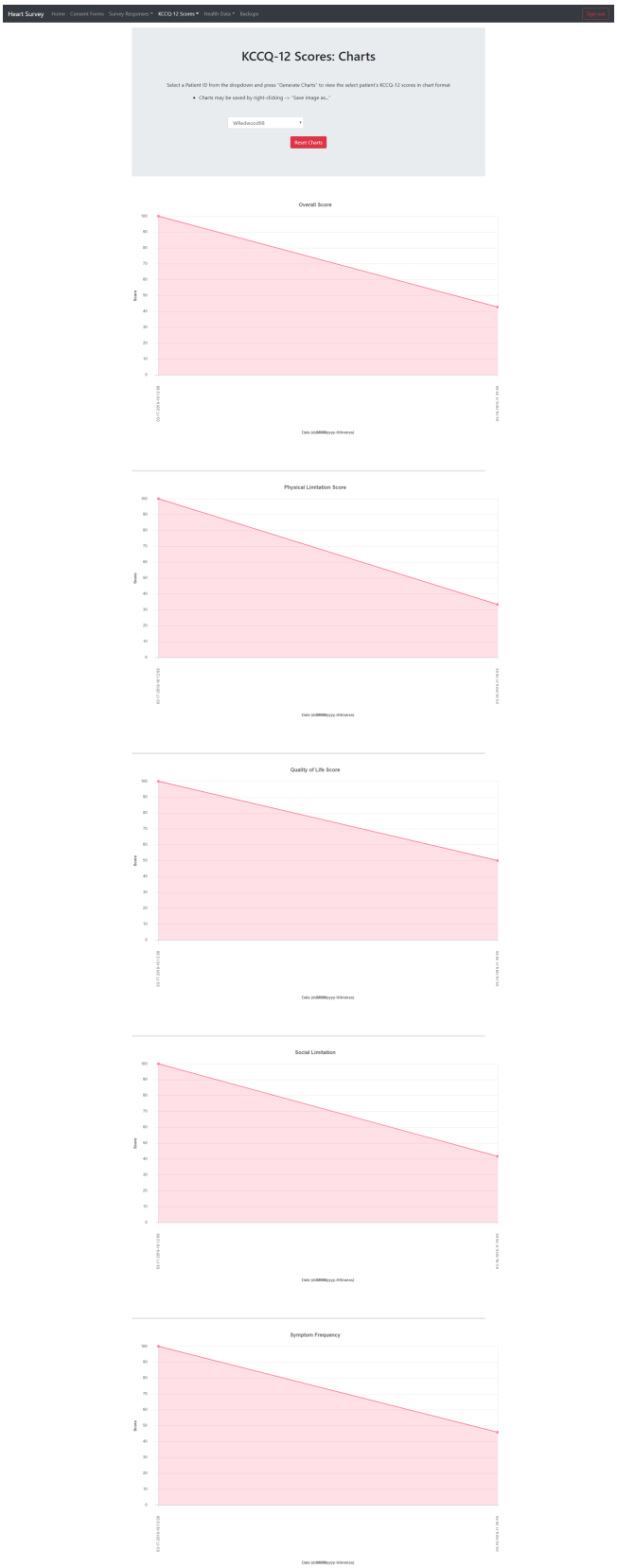








Q KCCQ-12 Scores Charts



R Health Data Charts

S WRedwood98-KCCQSurveyResults.csv

surveyDate	patientID	question1a	question1b	question1c	question2	question3	question4	question5	question6	question7	question8a	question8b	question8c
2019-03-18 22:08:08 +0000	WRedwood98												
2019-03-19 11:35:55 +0000	WRedwood98	Quite a bit limited	Slightly limited	Extremely limited	Less than once per week	At least once per day	3 or more times per week, but not every day	3 or more times per week, but not every day	It has slightly limited my enjoyment of life	Mostly dissatisfied	Moderately limited	Quite a bit limited	Moderately limited

Table 4: WRedwood98-KCCQSurveyResults.csv

T WRedwood98-KatzSurveyResults.csv

surveyDate	patientID	question1	question2	question3	question4	question5	question6
2019-03-19 11:35:55 +0000	WRedwood98	1	1	0	1	0	1

Table 5: WRedwood98-KatzSurveyResults.csv

U WRedwood98-KCCQScoresResults.csv

surveyDate	patientID	physicalLimitationScore	symptomFrequencyScore	qualityOfLifeScore	socialLimitationScore	kccq12score
2019-03-19 11:35:55 +0000	WRedwood98	33.33333333333334	45.83333333333334	50	41.66666666666666	42.71

Table 6: WRedwood98-KCCQScoresResults.csv

V WRedwood98-HealthResults.csv

healthDate	patientID	activeEnergy	flightsClimbed	heartRate	restingEnergy	steps	walkingRunningDistance
03-05-2019	WRedwood98	49	1	61	697	176	119
03-06-2019	WRedwood98	0	0	0	0	0	0
03-07-2019	WRedwood98	0	0	0	0	0	0
03-08-2019	WRedwood98	0	0	0	0	0	0
03-09-2019	WRedwood98	0	0	0	0	0	0
03-10-2019	WRedwood98	0	0	0	0	0	0
03-11-2019	WRedwood98	0	0	0	0	0	0
03-12-2019	WRedwood98	0	0	0	0	0	0
03-13-2019	WRedwood98	432	16	92	1001	6580	5014
03-14-2019	WRedwood98	474	21	82	2071	3967	3126
03-15-2019	WRedwood98	606	41	73	2050	6358	4871
03-16-2019	WRedwood98	644	24	77	2104	5902	4762
03-17-2019	WRedwood98	698	15	110	2028	4665	3920
03-18-2019	WRedwood98	386	5	73	2050	2610	2177

Table 7: WRedwood98-HealthResults.csv