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Usability and feasibility testing of a smart phone app (Suhriday) for heart failure self-care remote monitoring in a resource constrained setting

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Title: Usability and feasibility testing of a smart phone app (Suhriday) for heart failure self-care remote monitoring in a resource constrained setting

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Abstract

Background/Objectives: Remote monitoring as a component of chronic heart failure management programs have demonstrated utility in terms of reducing the risk of re-hospitalization and mortality. There is a dearth of evidence on mobile health app facilitated remote monitoring in India. We conducted a pilot usability study using a customized application for heart failure patients (Suhriday) which evaluated measures of effectiveness, efficiency and satisfaction.

Methods: We used a mixed methods design. We trained 5 purposively sampled patients with chronic stable heart failure and their caregivers (n=10) (based on health literacy and gender) on self-care monitoring and app use. We assessed task completion, time required for task completion and user satisfaction. We analyzed transcripts with deductive codes. The number and types of medical alerts transmitted through the app were captured, escalated to the treating team.

Results: Critical tasks involving (a) opening the app and identifying task list, (b) blood pressure, weight, heart rate and fluid intake reporting and (c) symptom reporting were completed within 60 seconds by four patients. Mean system usability scale (SUS) score was 74.5 (SD 25.58) indicating good usability. There were 62 alerts from four patients over 30 days, with blood pressure variations (16) and fluid intake alerts (36) being most frequent. There were no re-hospitalizations during this period.

Conclusion: Overall usability and satisfaction with Suhriday were good and we were able to remotely manage patients during the COVID-19 pandemic lockdown. However, patients with limited health literacy and those professing technological challenges will require active structured telephone support.

Strengths and limitations of this study

- To the best of our knowledge, this is the first Indian study among heart failure patients to evaluate usability measures (effectiveness, efficiency and satisfaction) and to provide information about smartphone app usage patterns and preferences.
- We ensured patients/caregivers representing different levels of health literacy were included, which helped us identify a wide variety of usability problems across the socio-economic spectrum.
- This study is a stepping stone that has informed the design of a large trial with a complex intervention centered on mobile health and task sharing to improve self-care and outcomes in patients with chronic heart failure.
- Though patients/ caregivers suggested app having a chat/video call option, we were not able to include these features due to financial and time constraints.

Summary

What is already known?

- m-health based remote monitoring of chronic disease conditions is employed as standard of care in Western healthcare systems, but has yet to be systematically evaluated and incorporated in resource constrained healthcare systems in LMICs.
- Usability and feasibility assessment of mobile health applications are an important first step to assess patient acceptability, identify 'pain-points' and bottlenecks and develop decision making workflows in preparation for large trials and scaling-up interventions.

What does this paper add?

- This pilot usability/ feasibility study demonstrates that a significant proportion of chronic heart failure patients can use our app, designed to improve selfcare and remotely monitor patients, with ease and with a high degree of consistency and acceptability.
- However, caregivers also play an important role in this process and patient preferences/ health literacy levels need to be considered and active, structured telephone support delivered where needed.

Introduction:

Heart failure (HF) is a rapidly growing cardiovascular disorder which affects about 38 million individuals worldwide. The incidence of heart failure in India varies from 1.3 to 23 million [1]. **Self-care** is a naturalistic decision-making process that addresses the prevention and management of chronic illness based on the core elements of maintenance, monitoring, and management by one's own self [2]. Interventions to improve optimum self-care among heart failure patients reduced the composite risk of HF hospitalization or all-cause death by 20% [3]. **mHealth** modalities are becoming increasingly common as a way to bridge the patient-provider care gap in heart failure, and can play a role in improving self-care. Remote telemonitoring helps to collect or send data on the health and well-being of a patient to a monitoring centre to assist in diagnosis and management [4].

A systematic review and meta-analysis of the outcomes of structured telephone support (STS) or remote telemonitoring as the primary component of chronic heart failure management in

8323 patients demonstrated a 34% risk reduction in all-cause mortality with telemonitoring. Additionally, STS and telemonitoring reduced HF-related hospitalization by 23% and 21% respectively [5]. A qualitative study conducted in Canada reported that essential characteristics of any telemonitoring system that contributed to improved heart failure management included utilizing immediate self-care and clinical feedback [6].

However, there is a dearth of evidence on mobile health app facilitated remote monitoring in India. We developed a mobile based application named Suhriday ('Well Heart'). It has multiple capabilities including facilitating remote telemonitoring of heart failure patients. We intend to use it as a part of a complex intervention in a larger randomized controlled trial. We therefore conducted a pilot usability and feasibility testing of Suhriday on a small sample of heart failure patients (involving their caregivers) with the objectives of evaluating Suhriday app's usability measures (effectiveness, efficiency and satisfaction) and the ability to remotely monitor patients using Suhriday. The information from this pilot study will inform the development of a complex intervention to improve self-care in heart failure patients, of which remote monitoring is one of the components.

Methods: We conducted a usability and feasibility testing of Suhriday, using a mixed methods approach.
Setting: This study was carried out in the cardiology and internal medicine departments in both inpatient and outpatient wards of St. John's Medical College Hospital, a tertiary care, teaching charitable hospital in South India from March to July 2020.

Eligibility criteria, sampling and ethics: The participants for the study include patients with a clinical diagnosis of heart failure and at least 1 of their caregivers, who consent to use the smartphone app for 4 weeks at home. We excluded patients who in the opinion of the treating cardiologist had a survival prognosis at baseline of less than 3 months and those for whom an intervention procedure had been planned in the next one month. We conducted purposive sampling to ensure that at least one patient was female, one patient with inadequate health literacy and two patients from semi-urban or rural areas. We obtained ethics approval from the Institutional Ethics Committee of St. John's Medical College Hospital (Reference number: 124/2017). Written informed consent was obtained from all participants.

Suhriday app: The mHealth application has been developed by One Health Solutions (OHS) Pvt. Ltd., a company incorporated in Bangalore, India. This application works on both Android and iOS. It uses JavaScript, Hypertext Markup Language (HTML) and Cascading Style Sheets (CSS) and can be deployed for both desktop and mobile versions.
Functions: The application is intended for care providers (nurses and treating physicians) to remotely monitor key parameters of patients with a primary diagnosis of heart failure who are on treatment. The application will also be able to generate reminders for medication and lifestyle modification adherence, based on information entered by a healthcare provider nurse into the application at discharge. The patients or their caregivers, after self-measurement using validated instruments, will record key parameters - blood pressure, heart rate, body weight and fluid intake into the app. The app also has a validated questionnaire for symptom/sign reporting[7]. It can identify and alert the study nurse, when there are outlying values. The nurse will be able to view these alerts and escalate them so that the treating team can then take

appropriate action. This action will be in the form of nurses intimating the treating physician/cardiologist, who can then resolve the escalated issue (e.g., order a titration of doses of high ceiling diuretics). The security features of this system include encryption of data on the device, user authentication and a secure Hypertext Transfer Protocol-based data transmission system.

Study procedures and Recruitment:

Step 1: Training a study nurse – We recruited a nurse with a master's degree. She was trained for two months on heart failure by three physician investigators using lectures and bedside demonstration to recognize worsening signs and symptoms and medications for heart failure. She was educated on the importance of self-care in heart failure including monitoring, maintenance and management. Furthermore, she was empowered to train patients and caregivers on measuring blood pressure, fluid intake, to check weight, and use the Suhriday app (detailed in *Appendix 1 - Table 1*).

Step 2: Training for patients/caregivers - Patients and their caregivers were educated on salient aspects of heart failure selfcare. The study nurse demonstrated and trained the patients on measuring blood pressure and fluid intake. They were also trained to check weight and to recognize worsening signs and symptoms. Once patients and caregivers were consented and trained to use the app and perform tasks assigned which included – (a) entry of details regarding daily medications consumed, (b) recordings of heart rate, blood pressure, weight, and fluid intake, (c) reporting worsening symptoms/ signs and (d) viewing and sharing of medical records including prescriptions.

Step 3: Setting for usability testing of the patient interface - The patients/caregivers were asked to measure their blood pressure, heart rate and body weight in the presence of the nurse. Then they were instructed to open the link from the message received, to download the app and open the application. The patients or their caregivers were asked to perform the "think aloud" exercise to perform and complete the assigned tasks. (Tasks detailed in *Appendix 1 - Table 1* and Usability measures definitions detailed in *Appendix 1*)

Step 4: Usability testing of the patient interface - To assess usability, we equipped 5 patients/caregivers (n = 10) with the smartphone enabled mHealth application (Suhriday app), and followed the method as described below:

Think-aloud approach: The purpose of this approach was to capture ease of use and understanding interface issues. Patients/caregivers were instructed to "think aloud" (i.e., verbalize their thoughts) as they interact with Suhriday app (while the mobile screens were recorded through the screen recorder option in android phone, after consent). They were asked to perform particular tasks (detailed in *Appendix 1 - Table 1*) using the app. The study team observed and made notes about completeness of tasks with patients/caregivers. We measured effectiveness of task completion by noting whether patients/caregivers (i) completed tasks with ease, (ii) completed tasks with difficulty and needed intervention from the study nurse to complete the task or (iii) failed to perform task. We also measured efficiency by noting time taken to perform tasks. The data collected of users' interactions

typically included the screen recording of Suhriday app screens along with the corresponding audio recording of patient/caregiver verbalizations as they used the app [8–10].

Qualitative in-depth semi structured interviews: At the end of think-aloud approach, we interviewed the patient and caregiver as a dyad to capture the acceptability and barriers of the app and suggestions for improving its features.

Satisfaction measurement: Patient and caregiver's satisfaction was measured utilizing the System Usability Scale (SUS). Scores were calculated according to Brooke's guidelines [10].

Step 5: Feasibility study in the context of technology development is an analytical method used to determine if the components of a project can perform together in order to create a technically and operationally viable concept [11]. Patients/principal caregivers who participated in the usability testing were provided a smartphone enabled with the Suhriday app, a BP monitoring device and an LCD weighing scale. Patients and/or caregivers were asked to self-measure BP, body weight every morning for a minimum of 30 days and to report measured values using the application. In addition, they were asked to monitor and report symptoms or other signs through the app.

We provided the study nurse with a smart phone onto which the Suhriday application was installed. The study nurse monitored the patients for a minimum of 30 days and made telephone calls to address alerts received for variance in values of measurements and symptoms/signs (detailed in *Appendix 1 - Table 2*) in addition to weekly structured telephone follow-up calls. During the course of the study, the nurse maintained a paper and an electronic diary to capture type of issue (medical or app-related), details of medical issues, person the issue was escalated to, and description of resolution. All heart failure related issues were escalated to the cardiology resident and physician on call; while general medical queries were escalated to the clinical pharmacologist or to medicine.

After 1 month of continuous use of the application, we conducted semi-structured feasibility interviews with the patients or their caregivers. We used a structured feasibility interview guide for this purpose (*Appendix 1 - Feasibility interview guide*). The interviews were audio-recorded, transcribed and translated to English. Satisfaction was measured utilizing the SUS instrument.

Sample size and Analysis: It has been demonstrated that using 5 participants can detect over 80% of usability problems [12]. Therefore, we carried out the usability and feasibility testing in 5 patients. For usability analysis, we made a note in the usability assessment form of effectiveness (task completion), efficiency (time required for task completion, noted through the screen recorder and/or audio recording) and user satisfaction (SUS score). We analyzed transcripts with deductive coding for acceptability and barriers related to app use, as well as suggestions for improving app functionality [9,10,13–15]. For feasibility testing, we analyzed transcripts with deductive coding. We measured user satisfaction using the SUS instrument at the end of the study. Components of acceptability were measured using a Likert scale.

Role of public and patient involvement: While the public was not involved with the study, patients and their caregiver's feedback on the utility and ease of app usability were investigated in detail as described in the results.

Results: We conducted this study from March 2020 to July 2020 and recruited five patients.

1. Patient demographics and models of app use: Salient details are presented in table 1.

Table 1: Patient demographics, clinical features (type of heart failure – reduced [HFrEF] or preserved ejection fraction [HFpEF], New York Heart Association [NYHA] class at recruitment and etiology) and models of app use

2.1 Usability, Effectiveness: The task completion effectiveness results are presented in Figure 1. The critical tasks involving (a) opening the app and identifying task list (task 1), (b) blood pressure, weight, heart rate and fluid intake reporting (tasks 3, 4, 5, 6 respectively) and (c) symptom reporting – understanding and reporting (task 7) were done easily. Majority of the tasks (tasks 1, 3, 4, 5, 6 and 7) were completed with ease by 4 (80%) of the participants. Task 8 (viewing shared medical records) and task 9 (sharing medical records) were reported as the most difficult to complete. Among five participants, 2 (40%) and 1 (20%) completed tasks 8 and 9 respectively, both of whom had adequate health literacy.

Errors: One participant (Participant 1) had initial difficulty and made the error of swiping across instead of just a tap on task 2 (acknowledgement for medication reminder). Majority of the errors were with only one participant (Participant 4, male, inadequate health literacy), who completed task 2 with difficulty, as the drug names were not translated to Tamil (a South Indian language and his mother tongue). This participant also took 7 attempts to complete task 3 (entry of blood pressure values) which was due to the inability to locate the number mode (which he

forgot), after locating the area to enter the value. He completed task 6 (to enter fluid intake of the previous day) after 3 attempts due to difficulty in locating and placing the decimal point.

2.2 Usability, Efficiency: The task efficiency results are presented in Figure 2. For one participant, we could not record the think-aloud approach through the screen recorder as the caregiver of the patient was not comfortable with it. We could not record the time taken to complete the task through audio recording, as it was difficult to perform the tasks systematically. The study team observed and made notes on completeness of tasks with this participant. Participant 4 who made the most errors took the longest time.

2.3 Usability, Satisfaction: The average SUS score for usability of all the 5 participants was 74.5 (SD 25.58), indicating good satisfaction. Participants 1 and 2 gave a score of 92.5 and 97.5 indicating high usability, participants 3 and 5 gave 75 each indicating acceptable usability and participant 4 gave 32.5 indicating poor usability.

2.4 Qualitative interview results: We conducted interviews with all 5 participants after think-aloud approach while using Suhriday app for the first time to determine acceptability, barriers of use and suggestions for improvement (table 2).

Table 2: Acceptability and barriers of the app, suggestions for improving app features at baseline

Themes	Codes	Extracts
Acceptability of the app	**Effective, useful for monitoring**	**"**This app is ***very good*** for like my kind of HCM people, congestive heart failure people. This is ***very effective*** and what I feel is every time it will be ***like awareness*** for you people, also for us also." (Patient 1, female)
	Very easy, very useful	**"**This is there we can be with a ***regular kind of checkup*** day by day" "And this is ***very easy to use***"
	Monitor easily	"I guess this app is very useful to everyone ***easily*** we ***can monitor***" (Patient 1, female)
		"The performance of the app is ***very good*** and the reaction time most the opening of the ***app and individual components within*** that are all ***very good***" (Caregiver of Patient 3, male)
	Useful reminder for medication taking, easy to use	"I open it and I go to all of the tablets and medication, which have to be taken, which are in red. I open each one of them and I complete them and click on save and this ***hardly takes me any time***" "This was also fine the ***weight reading, fluids intake*** and all that was **fine.**" (Caregiver of Patient 2, male)

Barriers of the app	**Small font**	"Instead of entering values in mobiles just I am telling see instead of entering ***small small (font size) values***" (Caregiver of Patient 2, male)
		"This one is a bit of a problem, because for me ***to type these numbers are really small***" (Caregiver of Patient 3, male)
	Unclear images	**"**It (discharge summary image) is very **unclear**" (Patient 1, female, high health literacy)
Suggestions for improving app functionality	**Alarm feature**	"It would be nice if anything turns red that the ***phone rings or alarms*** are there." (sic) (Caregiver of Patient 3, male)
	Adjustment scale feature	"These adjustment bars they are actually of no use. Because the spacing is really small." "The ***scale (BP)*** have to be completely ***different representative***" (Caregiver of Patient 3, male)
	Help guide	"The symptoms what I noticed was, if some patients who may want to understand, what is better ……. what is much worse mean" "like on what basis do I tell much better? If there is a ***help guide*** or something like that" (Caregiver of Patient 3, male)

Remote monitoring through Suhriday app: Overall, patients were managed remotely throughout the 30-day evaluation period with no unplanned re-hospitalizations due heart failure or deaths.

Alerts, number and type: There were a total of 62 alerts (detailed in *Appendix 2 - Table 1*) from four patients and their caregivers who used the app for a minimum of 30 days (snapshots of alerts in *Appendix 2*). We received alerts related to fluid intake (58.1%), variance in diastolic blood pressure (19.4%), symptom worsening (16.1%) and variance in systolic blood pressure (0.06%). The maximum number of alerts were from patient 1 (n=44, 70.96%), followed by patient 2 (n=12, 19.35%), patient 3 (n=5, 8.06%) and patient 5 (n=1, 1.61%). Patient 4 hardly used the app, but reported issues through structured telephone support. This was monitored actively by the study nurse and there were no heart failure related escalations over a 30-day period. Overall, five issues were remotely managed in three out of five patients. Heart failure related escalations led to up-titration of loop diuretics (3 times) and general medical queries were addressed for constipation and iron deficiency anemia.

Resolution process and time (for alert led issues and other medical issues): The study nurse made telephone calls to cardiologists to resolve issues. 21 phone calls made to the cardiologists were regarding heart failure symptom/sign related alerts (5), non-heart failure related escalations/ general medical escalations (4), prescription confirmation and drug dose queries (4), blood pressure (4), OPD visit follow up queries (3) and investigation related (1). All 14 medical issues were resolved of which 8 issues were resolved within 60 minutes, 2 issues

within a day which included 1 instance of reduction in blood pressure and other instance drug anticoagulant was procured for the next day with refill in the evening, and 4 issues took more than a day which included two instances of patient's delay in visiting OPD due to personal choice, 1 instance of inability to procure drug refill on time due to lockdown during the COVID-19 pandemic, and 1 case of patient preferring to make a dietary change rather than consume a laxative syrup for constipation.

App issues at nurse interface: These were totally 29 in number. Difference in getting alerts with two different phones (8), log in issues (5), alert sync issues between two different phones (3), alert sync lag from patient to nurse (2) were the predominant issues at the nurse's interface. App issues at patient interface are summarized in *Appendix 2 - Table 2*.

3.1 Feasibility interview: We conducted interviews among three out of five participants. Findings are in table 3.

Table 3: Feasibility of the app and impact of pilot intervention

Themes	Codes	Extracts
Overall experience using app	**Good improvement, daily monitoring**	"I have ***good improvement*** ma'am with this app. What exactly it is means like from this I came to know what is my blood pressure, ***day to day routine*** thing and the heart rate also ***I maintained***." "Plus, the water intake and medicines like what time to what time like it will be mentioned in that." (Patient 1, female)
		"In this critical situation (covid situation) this is the best option". "It has become a habit, daily everyday morning we have to do all these things"
	Good experience, maintained health well, reduced hospitalization	"People are not able to come to the hospital so we can give him then through phone call or any video conference or video call something or this kind of app will be helpful in future also going forward" (Caregiver of Patient 2, male)
		"I got lot of ***good experience***" "I ***maintained myself very well***." "Usually, I ***used to get hospitalized*** a lot but ***now it has become less***." (Patient 1, female)
	Very positive, friendly to use, part of routine	"I would say the experience have been ***very positive***. What I mean by positive is the app is really ***friendly to use***." "And once you start using this, it becomes the ***part of your routine***." (Caregiver of Patient 3, male)

Interaction with study staff	**Change in treatment plan, helpful** **Gave solution** **Dedicated, committed, knowledgeable, professional and patient - friendly**	"I was not keeping well, my legs got swollen, my stomach got swollen, so I used to contact mam" "according to the doctors she ***used to tell me the prescription***" "There was ***lots of help*** sir" (Patient 1, female) "There were 3 or 4 occasions where the ***issue was to be escalated*** right" "we contacted you and you ***provided us with a solution***" (Caregiver of Patient 3, male) "***Dedicated*** to this and ***committed*** and you were ***very knowledgeable*** and you were ***highly professional*** and ***patient friendly***." "Immediate triage that is the most significant aspect of this." (Caregiver of Patient 3, male)
Impact of education on self-care	**Training on symptoms, signs of worsening led to awareness and improved self-monitoring**	"From this app I came to know that, particularly I ***used to check*** all these things (blood pressure, weight)" (Patient 1, female, high health literacy) "All the symptoms you people explained me from that I ***got lot of education***". "I have ***improved a lot*** sir, like I used to know what exactly happens if I take lot of fluids." (Patient 1, female) "It is improved. On daily basis also he is taking care of all" (Caregiver of Patient 2, male) "It had ***great value***. I will tell you why doctor." "He used to drink as much water as possible" "This ***whole weight management aspect*** we never actually took into consideration" "swelling of legs as an ***indicator to overall heart condition***" "being aware of what is the ***threshold level for BP***" (Caregiver of Patient 3, male)
Satisfaction with the team	**Suggestions and support to solve problems** **Quick resolution of problems, perfect**	"I had many times problems, I used to contact you, you will be suggesting, you will be contacting doctors, give me ***proper prescription***" "You have ***supported me a lot***." (Patient1, female) "***As soon as possible you used to contact*** me and you used to suggest me" "the ***anxiety aspect was removed***." "I think it was ***perfect***." "On a scale of ten I would give it 11" (Caregiver of Patient 3, male)
After stopping app use	**Self-maintenance**	"I'm noting down in a book and I'm WhatsApping you. ***Everyday*** I'm maintaining" "***In my one book I'm maintaining***." (Patient 1, female) "I am doing. Up to date I am doing. Till today" (Patient 2, male)

Suggestions to improve the app	**Video call option** **Chat tool within app**	"If it is a ***video call*** it will be better" (Patient1, female) "Can't your app actually have a ***chat interface*** wherein I can post?" (Caregiver of Patient 3, male)

3.2 Feasibility, SUS, overall satisfaction, acceptability: Feasibility results among the three participants showed a mean SUS score of 93.3 (SD 6.29) which represents high usability with an overall satisfaction adjective rating of 'excellent' (2 participants) and 'best imaginable' (1 participant). In the context of acceptability, all three participants felt that they were confident in using the Suhriday app and would be able to teach others to do the same to a large extent (detailed in *Appendix 1 - Figure 1*).

Discussion:

This is the first report from an Indian setting about how Indian patients with heart failure respond to a remote monitoring application, their patterns of use, 'pain-points' experienced, symptoms/ signs that resulted in escalations, and how they were resolved.

Among five participants, four performed tasks assigned through Suhriday. There were of 62 alerts, among which 10 (16%) were related to symptom worsening. Total number of calls made to cardiologists to resolve issues was 21. All medical issues were resolved. This also helped us in developing a decision-making algorithm for symptom management. Escalations led to changes in prescriptions for participants 1 and 3. During the lockdown and heavy restriction with movements during COVID-19, all patients were managed remotely through the app and by structured telephone support to manage issues. During remote monitoring for a minimum of four weeks, we did not have any unplanned hospital readmission or unplanned emergency/outpatient visit related to heart failure symptom/sign worsening.

Our usability assessment of Suhriday demonstrated satisfactory usability for remotely monitoring four of the five patients in our study. Most of the critical tasks were completed with ease. This implies that these tasks were straight forward and had few steps, were easy to navigate and remember. This has been reflected in the time taken per task. Inter quartile range for tasks 1, 2 and 3 were within one minute and for tasks 4, 5 and 6 were well within half a minute. This efficiency would imply that the app is easy to use.

Participant 4 completed majority of the critical tasks with difficulty, took the longest time, made many errors, and had poor usability in contrast to rest of the participants. This might be linked to his inadequate health literacy levels in general and educational attainment. He and his wife (caregiver) had initial apprehensions and were reluctant to use technology. Though they had smart phones, they were only accustomed to making calls. Although we trained participant 4 slowly and tried to build confidence, they could not sustain performing daily tasks (remote monitoring and feasibility section). The patient could maintain manual records for monitoring symptoms, blood pressure, heart rate and fluid intake. For these patients, structured active telephone support would be an imperative. Alternatively, patients could improvise by monitoring themselves, noting down data on a paper chart, taking photos and transmitting them through a phone in the neighborhood. This might reduce the gap of digital divide.

Participants expressed that the app was user-friendly, became part of their routine, helped maintain health and reduce hospitalization. They also expressed that training led to awareness and improved self-monitoring. Participants opined that they were satisfied with the team's turnaround time to resolve issues quickly. Having video call option and chat tool within the app were a few suggestions made towards improvement of the app.

Mobile-phone based applications for remote monitoring of health are an important step in technological interventions for facilitating healthcare in India. Especially during the COVID-19 pandemic – wherein India had one of the highest infection rates coupled with a lockdown – remote monitoring of patients has gained importance; it will gain further significance in other situations where routine health information needs to be relayed to medical personnel who may be out of reach, such as during natural disasters and in very remote locations. These interventions also help build trust towards technological interventions in healthcare, and instill routines of self-care, responsibility, and independence among patients. However, there are notes of caution that must be reflected upon before expanding interventions further (or developing new ones), despite their robust successes at the experimental level. These are not merely 'technical' issues (such as in *Appendix 2 - Table 2*) but issues around technological experience and social variables.

The user is the first citizen of a technology. Their personal technological experience is principally important, and this makes the user interface of the app paramount [16]. If designed effectively for trouble-free functioning, the actual efficacy of the app and its long-term use would improve. A well-designed app – with the interface in one's native language made available, and with a minimalist ease of operation, will convey the user's confidence to technicians and health professionals, expanding the latter's space and time to develop it further. It would be useful to borrow and adopt the user interfaces of popular apps, where the patient (or caregiver) can spend little time in learning and progress quickly toward more effective usage.

Other important concerns around healthcare-facilitating technological interventions revolve around access to, and literacy with, a digital device. Variations in gender, age, and affluence among patients and caregivers emerge critically important in technological engagement. Participant 4, for instance, who faced a multitude of issues, did so since he and his caregiver were on the negative side of the above-mentioned variations. Their technological experience is influenced by their rural background and lower economic affluence. They appear to conceptualize the phone as purely a communication device, and little else. Such cases are not exceptions, and may in fact be the norm in many non-affluent (or even affluent) communities [17], where patients and caregivers are aged or ageing, often women, and those who are digitally unfamiliar. They may end up feeling more pressured trying to negotiate the device and the app, which might add to the already existing pressures of everyday livelihood, coping with morbidities, and so on. Hence, the issue of interface arises here again, where an effective interface must not put technological stress on the already stressed caregiver and patient.

This begs the question – will a technological intervention's success hinge on digital fluency of caregivers? Will patients and their caregivers end up dependent on tech-savvy individuals

around them, therefore re-negotiating their domestic interpersonal relationships? Probably not, if (like in this study) adequate training is provided to the patient and the caregiver on using the technological intervention, and with the possibility of a back-up option such as, in our study, access to healthcare professional by regular telephone conversation through structured telephone support. All issues discussed here gain importance if technological interventions in healthcare are envisioned, developed, experimented, and diffused bearing these social variables in mind. After all, patients, caregivers, healthcare workers and other stakeholders have their own individual relationship with technology, and these relationships are pivotal in the experience of the technological interventions.

Conclusion:

This study demonstrated that while Suhriday was acceptable and easy to use among most patients, patients' health literacy and preferences need to be considered while enrolling Indian patients into m-health based intervention programs. This study is a stepping stone that has also informed the design of a large trial with a complex intervention centered on mobile health and task sharing to improve self-care and outcomes in patients with chronic heart failure.

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Data sharing:

Currently, we have not deposited the raw data in an open access repository. However, we are willing to share the raw data with all interested investigators. Interested investigators may send an email to corresponding author with the brief write up of the research question, objectives and ethics approval for the proposal.

Contributors:

BKB, DYK, ISJ, JS, DX and SK contributed to the idea and design of the study. BKB and DYK developed interview guides. KV, JS, ISJ and BKB recruited patients. BKB, DYK and ISJ followed up and escalated issues from patients/caregivers. JS, KV, DYK, BKB and SK addressed the escalated issues. BKB, PR and DYK performed the analysis. BKB drafted the manuscript, with revisions from DYK, ISJ, JS, AK, PR, SK, KV and DX.

Figure 1: Task completion rate for usability - effectiveness

Figure 2: Box and whisker plot for usability efficiency measure, inter quartile range

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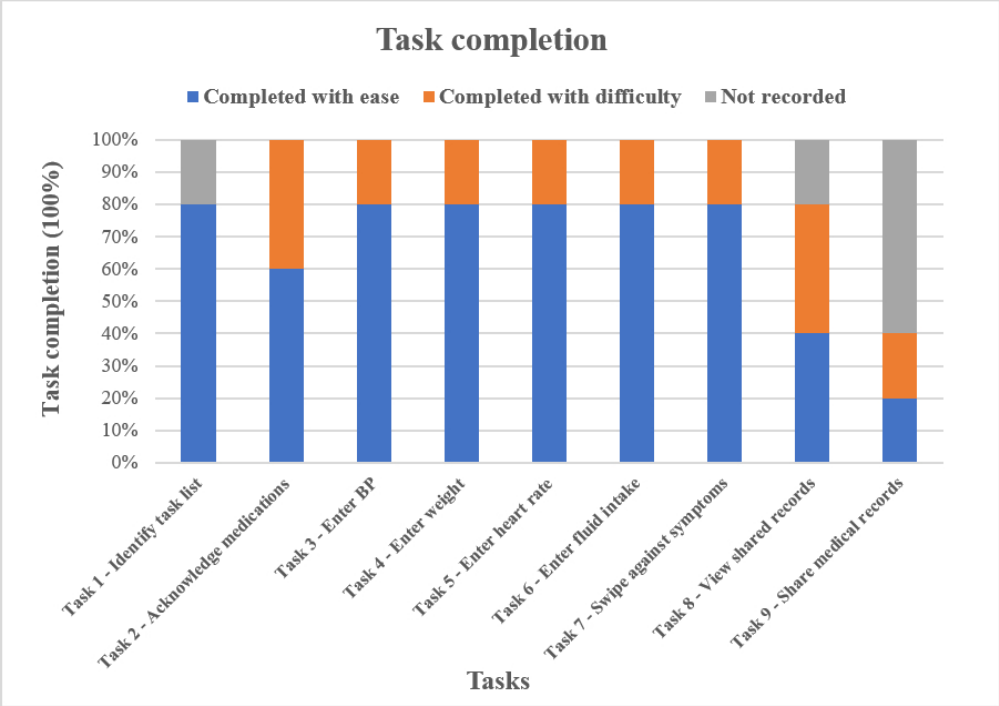

Figure 1: Task completion rate for usability - effectiveness

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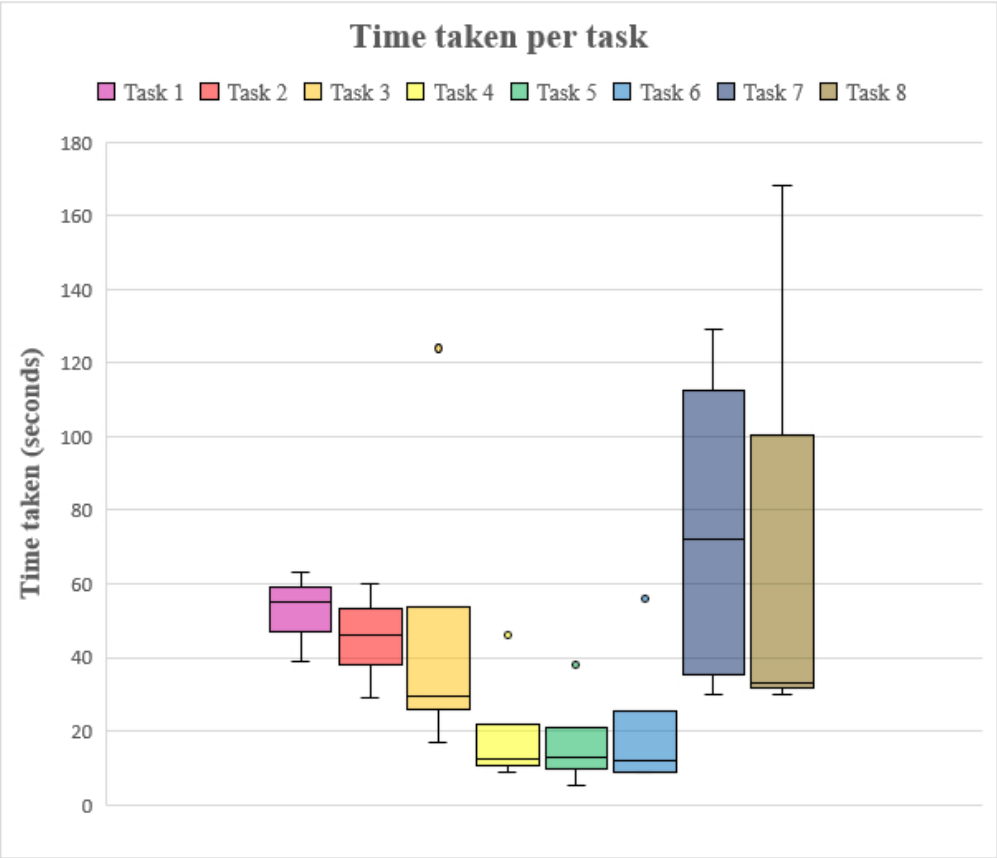

Figure 2: Box and whisker plot for usability efficiency measure, inter quartile range

160x137mm (96 x 96 DPI)

Appendix 1

1. App interface/ design/ features

The app is designed to have two interfaces.

The app **(at patient interface)** is designed for remote monitoring of heart failure patients. The app has a validated questionnaire for symptom/sign reporting, feature to enter self-measured body weight, blood pressure, heart rate and fluid intake; swiping functionality to acknowledge intake of medications and a feature to store medical records and share images of prescriptions.

The app **(at care provider interface)** is designed to capture demographic data of patients, to enter a few key investigation values and to store and share medical records such as discharge summaries, prescription re-fills or fresh prescriptions and investigation reports with the patients. The app has a feature where care providers can assign tasks to patients such as entering measured blood pressure values, heart rate, fluid intake, and body weight; medication intake notification reminders and symptoms/signs monitoring and reporting (Details in **Table 1**). The app is also designed to receive alerts when these measurements are outside the mentioned cut off ranges (Details in **Table 2**).

Table 1: List of tasks at care provider interface and patient interface

Care provider/ Nurse		Patient / Caregiver	
Task 1	Enter demographic details of patients from source documents and save	**Task 1**	Identify task list
Task 2	Capture medical records by either taking a picture/ selecting it from the phone gallery and share those with the patient (e.g.: discharge summary, recent lab investigation reports, prescriptions)	**Task 2**	Acknowledge medications taken throughout the day by tapping against each medication reminder
Task 3	Enter comorbidities (select the comorbidities/ add comorbidities if they do not appear in the existing list) and save	**Task 3**	Enter measured BP (both systolic and diastolic, correctly against each)
Task 4	Enter key investigations and save	**Task 4**	Enter measured weight
Task 5	Set medication reminders	**Task 5**	Enter measured heart rate
Task 6	Instruct patient to enter BP value and weight measured	**Task 6**	Enter fluid intake of the previous day
Task 7	Instruct patient to enter heart rate value measured	**Task 7**	Swipe against symptoms which are present
Task 8	Instruct patient to measure fluid intake of the previous day and enter the same	**Task 8**	View shared medical records
Task 9	Monitor the six symptoms and respond as Yes or No	**Task 9**	Share medical records
Task 10	Recognize alerts (heart rate, diastolic BP, systolic BP, weight, symptoms, fluid intake, medication)		

Table 2: Alerts for limits in values for measurements and symptoms/signs

Vitals to be measured	With symptoms		Without symptoms	
	Minimum	Maximum	Minimum	Maximum
Heart Rate	50	100	40	110
Blood pressure (Systolic)	90	160	80	170
Blood pressure (Diastolic)			60	100
Fluid intake	> 1 litre / day			

Alerts are also generated if the patient answers 'Yes' for any of the following questions:

1. Have you felt more short of breath since yesterday?
2. Have you noticed swelling since yesterday?
3. Have you had dizziness in the last 24 hours?
4. Did you wake up with cough along with shortness of breath last night?
5. Did you sleep on a chair propped up with a pillow last night?

If the patient responds to the question below as 'Worse' or 'Much worse'

6. Compared to yesterday are you better, same, worse or much worse?

2. Definitions/ terminologies

Background: We have created the mobile health application, named ***Suhriday*** for remotely monitoring patients with chronic heart failure. As a part of remote monitoring, we will ask patients to report worsening of symptoms or signs, blood pressure, body weight and fluid intake every day, measured at home, for duration of 4 weeks. The data will be monitored centrally by a trained nurse. Issues will be escalated by nurse to physician/cardiologist (treating team). Further actions will be documented by the nurse in a diary.

Definitions – The following definitions are in compliance with ISO 9241-11 [1,2]

1. Usability - Usability means that any part of a system must be easy to operate, learn, remember and helpful to the user and must guide the designers in the design process. "It is the extent to which a product can be used by specified users to achieve specific goals with effectiveness, efficiency and satisfaction in a specified context of use."

1.1 Usability/ Effectiveness – To what extent the user can achieve a goal with accuracy and completeness.

1.2 Usability/ Efficiency – The level of effort and resource usage which is required by the user in order to achieve a goal in relation to accuracy and completeness.

1.3 Usability/ Satisfaction (based on ease of use, ease of learning, error minimization and recall capacity) – The positive associations and absence of discontent that the user experiences during the performance.

2. Description of evaluation approaches -

2.1 Think Aloud Approach [2,3] – The think aloud approach involves the subject speaking out loud, whatever s/he sees on screen regarding the content of the application, the tasks that appear on screen, while navigating between tasks or pages, **difficulties encountered, likes/ dislikes and any other errors or difficulties encountered through to task completion**. The patient/caregiver's speech and the screen navigation will be recorded using the mobile phone's in-built recording system (has both audio recording of what participant speaks and video recording of screen).
Observer will note whether tasks are completed successfully or not (effectiveness) and the time taken to complete tasks (efficiency). The audio content will be analyzed for errors related to breaks in flow, patient preferences and dislikes and salient themes will be identified by content analysis.

2.2 System Usability Scale for assessment of subject Satisfaction -

SUS instrument – 10-item Likert scale, items have a range of 1-5. For items 1, 3, 5, 7, 9 one point subtracted from resulting score, for items 2, 4, 6, 8, 10 five points subtracted from resulting score. To get overall satisfaction value, final sum of all scores should be multiplied by 2.5. SUS scores ranging from 0-100. The following cut-offs will be used –
> 70 - acceptable/ good usability, **≥ 85 -** high level of usability or excellent score, **≤ 50 –** Poor/ unacceptable usability.

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3. Blank E, Tuikong N, Misoi L, Kamano J, Hutchinson C, Kimaiyo S, et al. Usability of implementing a tablet-based decision support and integrated record- keeping (DESIRE) tool in the nurse management of hypertension in rural Kenya. Stud Health Technol Inform. 2013;192:1002.

3. Usability and Feasibility Assessment

3.1 Usability assessment of Patient/Caregiver for Suhriday app pilot - Baseline

Pt. ID: **Age**: **Sex**: **Date: dd/mm/yyyy**

Residence: **Health literacy**:

3.1.1 Task completion

Outcome of task	Task 1	Task 2	Task 3	Task 4	Task 5	Task 6	Task 7	Task 8	Task 9
Failed to complete task									
Completed with difficulties									
Completed with ease									

3.1.2 Time taken for each task

	Task 1	Task 2	Task 3	Task 4	Task 5	Task 6	Task 7	Task 8	Task 9
Time taken (sec)									

3.1.3 Satisfaction - System Usability Scale

Please choose any one between 1 to 5, where 1 = strongly disagree; 5 = strongly agree

1. I think that I would like to use this app frequently — 1 2 3 4 5

2. I found the app unnecessarily complex — 1 2 3 4 5

3. I thought the app was easy to use — 1 2 3 4 5

4. I think that I would need the support of a technical person to be able to use this app — 1 2 3 4 5

5. I found the various functions in this app were well integrated — 1 2 3 4 5

6. I thought there was too much inconsistency in this app — 1 2 3 4 5

7. I would imagine that most people would learn to use this app very quickly — 1 2 3 4 5

8. I found the app very cumbersome to use — 1 2 3 4 5

9. I felt very confident using the app — 1 2 3 4 5

10. I needed to learn a lot of things before I could get going with this app — 1 2 3 4 5

SUS score:

Open ended questions

i. If you strongly agree that the app was complex, what was complex? Can you specify?

ii. If you strongly agree and think that you need the support of a technical person to be able to use this app, can you please specify which point you needed assistance?

iii. If you strongly agree and think there was too much inconsistency in this app, can you please specify what was inconsistent?

iv. If you strongly agree and find the app very cumbersome to use, can you specify what was cumbersome?

v. If you strongly agree and felt that you needed to learn a lot of things before you could get going with this app, can you please specify, what was that learning you needed to do?

3.2.1 Feasibility interview guide

1) You have used the Suhriday application for about two months. Could you please describe your overall experience using the application and interacting with the study team?

Probes – As they start off, the objective is to elicit their emotions and opinions about the utility of the system. We are looking for a very general response with words like 'difficult', 'cumbersome', 'thankful', 're-assuring', 'useful', 'easier contact with the system' and so on. The following probe questions to be used –

- If it was difficult or cumbersome, please tell us what difficulties?
- If it was helpful, please tell us how it was helpful? Can you remember and tell us about some situations where it helped?

2) What were the changes that happened in your everyday life with regard to caring for your own health due to the education that was given at discharge and the system that we implemented?

Probes - The patient may be asked to imagine and compare with his previous (prior to intervention) care behavior. Specific questions pertaining to symptom and sign recognition, medication taking/planning and management, lifestyle modification to be enquired for.

3) Were you satisfied with the manner in which we (our team) responded?

Probes–We're looking for issues concerning (i) mode of issue resolution (over the telephone, by SMS, etc.) (ii) time taken to resolve the problem (iii) any issues with the solutions proposed such as 'restrict fluids', 'increase the dose of x drug', etc., and (iv) trust in our team.

4) You may have now stopped using the application. Are you continuing to take care of your health in the same manner?

Probe – We need to ascertain whether they are continuing home BP, fluid and body weight monitoring; documenting it and whether they have taken any action if parameters are abnormal.

5) Do you have any suggestions to further improve the mobile application?

Probe – for responses pertaining to ***frequency of entering information***, language, font size, font type, navigation issues, and color.

6) Lastly, do your caregivers or family members have any opinion about the app and the system? Has our education brought about any changes in their lifestyle?

3.2.2 Feasibility assessment of Patient/ Caregiver for Suhriday app pilot - End of study

Satisfaction - System Usability Scale

Please choose any one between 1 to 5 where 1 = strongly disagree; 5 = strongly agree

1. I think that I would like to use this app frequently	1 2 3 4 5
2. I found the app unnecessarily complex	1 2 3 4 5
3. I thought the app was easy to use	1 2 3 4 5
4. I think that I would need the support of a technical person to be able to use this app	1 2 3 4 5
5. I found the various functions in this app were well integrated	1 2 3 4 5
6. I thought there was too much inconsistency in this app	1 2 3 4 5
7. I would imagine that most people would learn to use this app very quickly	1 2 3 4 5
8. I found the app very cumbersome to use	1 2 3 4 5
9. I felt very confident using the app	1 2 3 4 5
10. I needed to learn a lot of things before I could get going with this app	1 2 3 4 5

SUS score:

3.2.3 Acceptability questionnaire (Likert scale):

1. How confident do you feel using the mHealth application?
   a) Not at all
   b) To some extent
   c) To large extent

2. Do you prefer using mobile health application as routine care?
   a) Not at all
   b) To some extent
   c) To large extent

3. Will you be able to teach other patients/their caregivers how to use this application?
   a) Not at all
   b) To some extent
   c) To large extent

4. Would you recommend using mobile health application to patients with similar conditions?
   a) Not at all
   b) To some extent
   c) To large extent

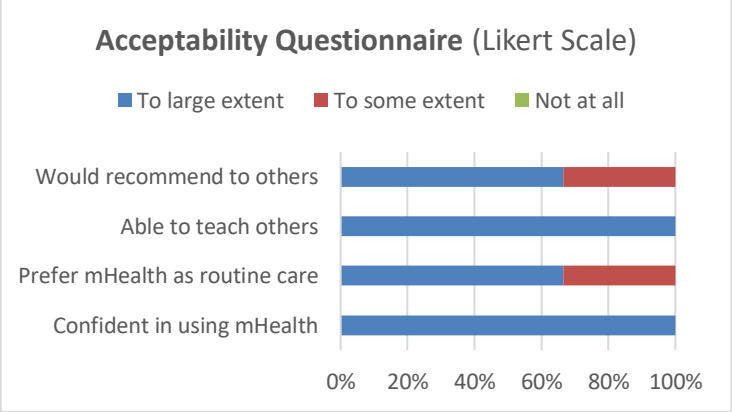


Figure 1: Summary of the results from the acceptability questionnaire

3.2.4 Overall satisfaction of App features, functionality, ease to use

Adjective rating (Circle any one of the below)

a. Worst imaginable
b. Poor
c. OK
d. Good
e. Excellent
f. Best imaginable

3.2.5 Acceptability

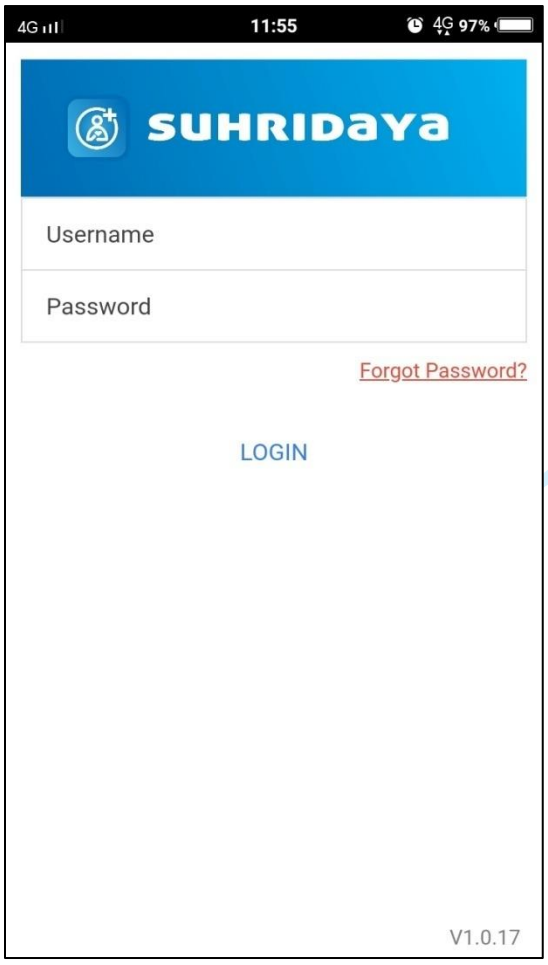
(Circle one of the below)

a. Not acceptable
b. Marginal - low
c. Marginal - high
d. Acceptable

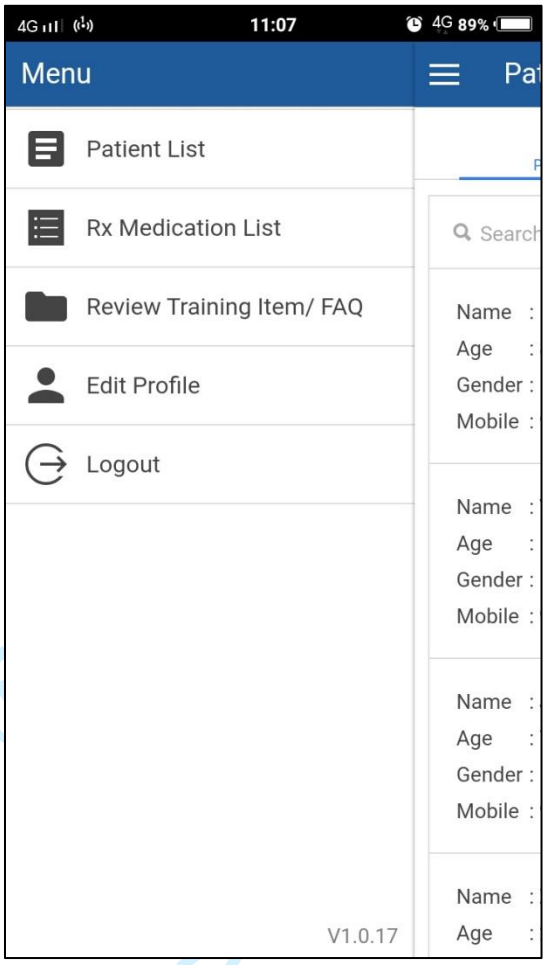
Appendix 2: App design and features

App at nurse interface:

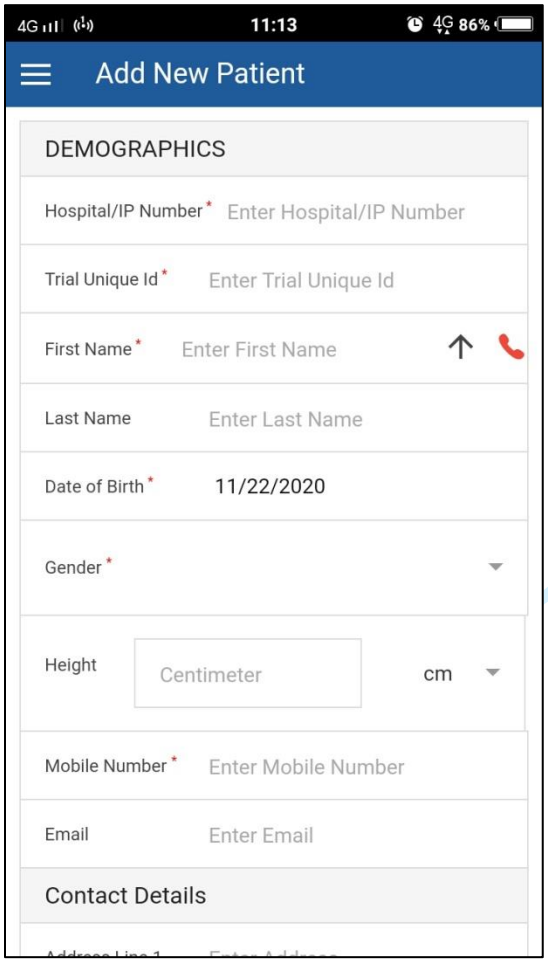
1. Log in page



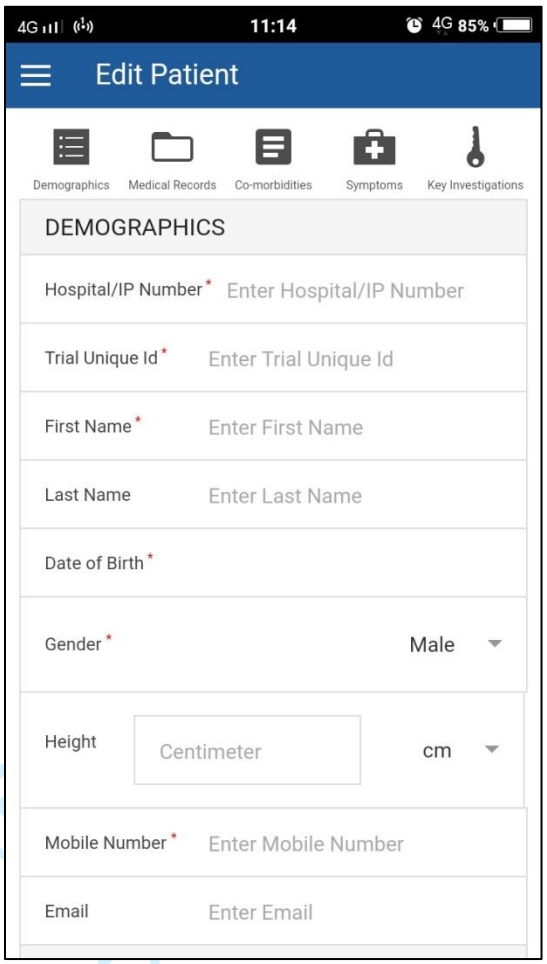
2. Menu



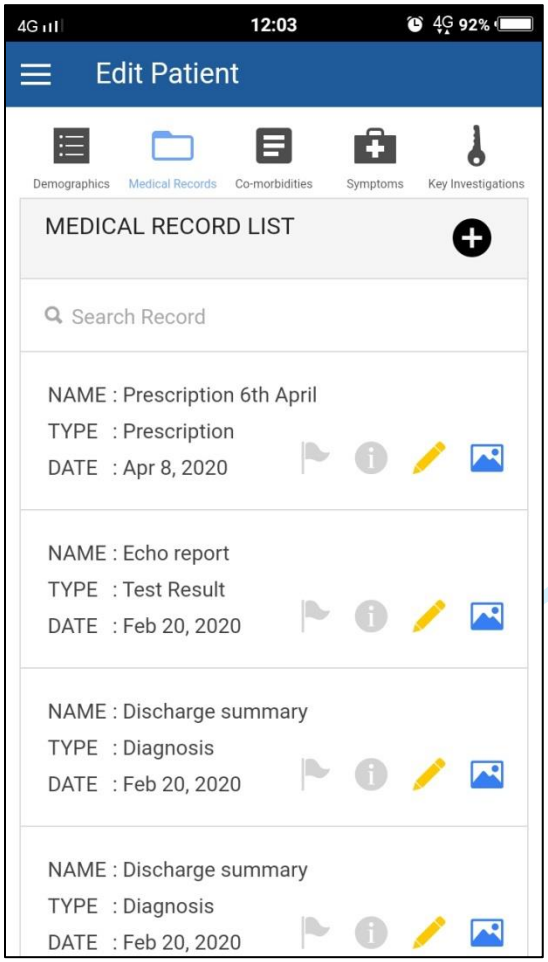
3. Add new patient



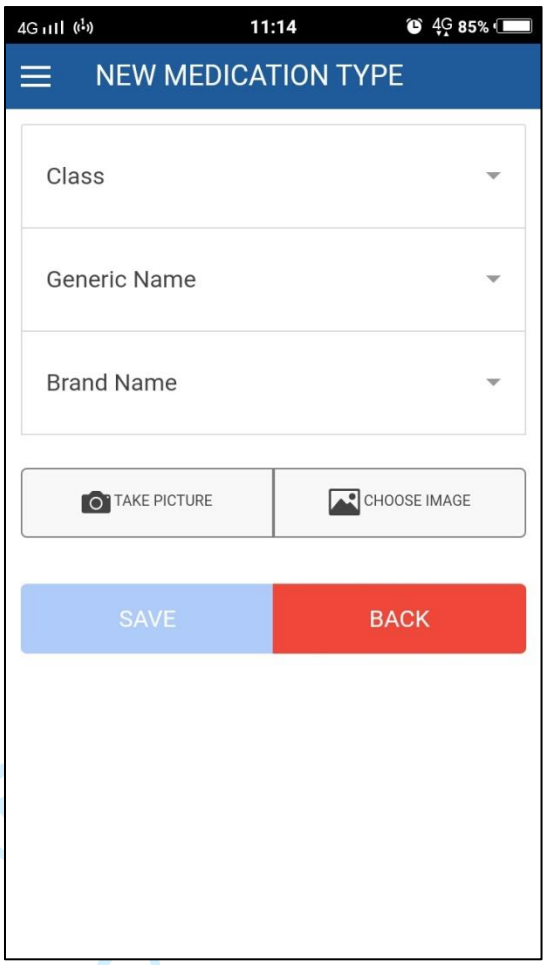
4. Patient detailed profile



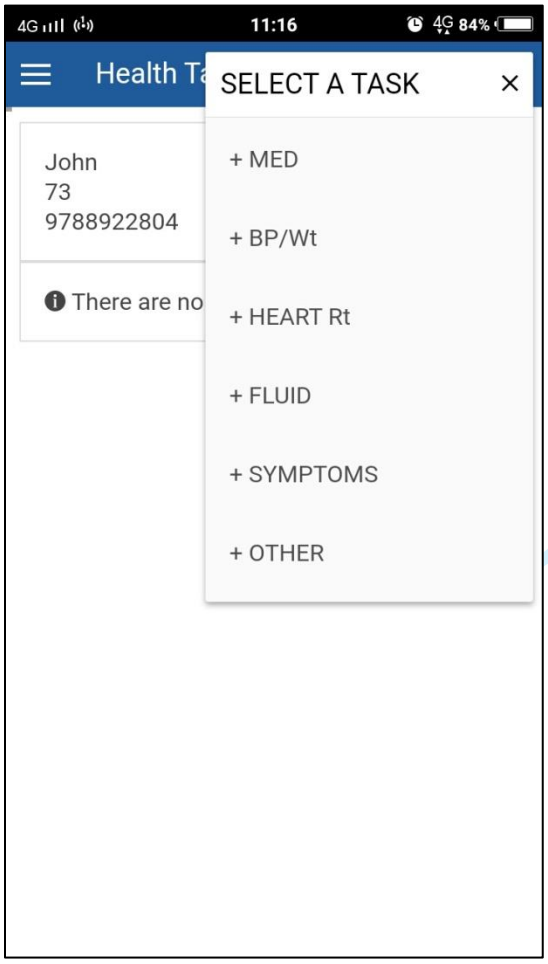
5. Patient medical records



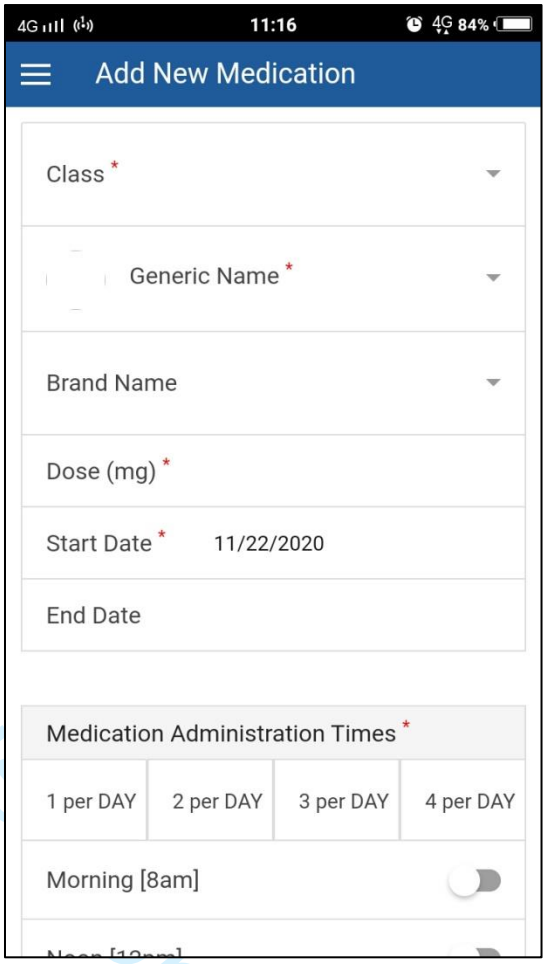
6. To create medication list



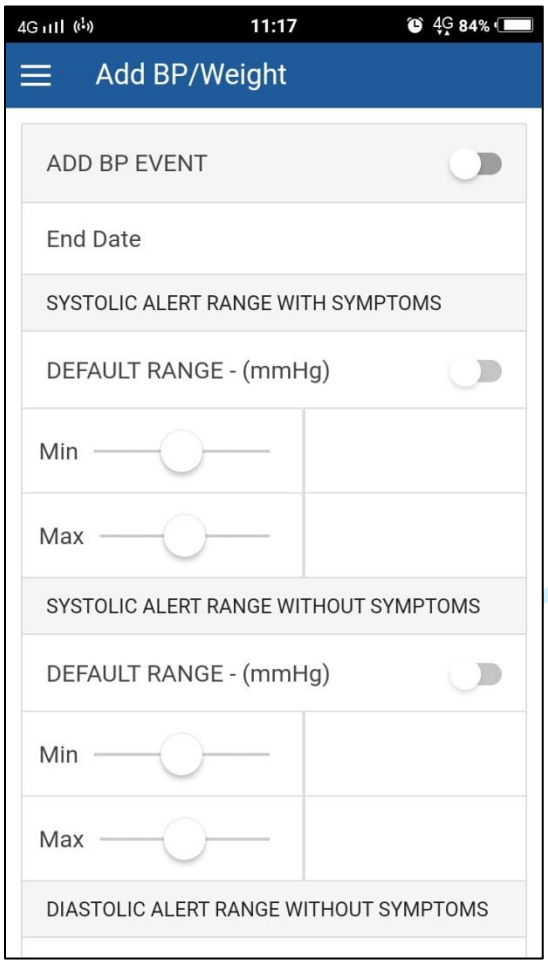
7. Assigning task



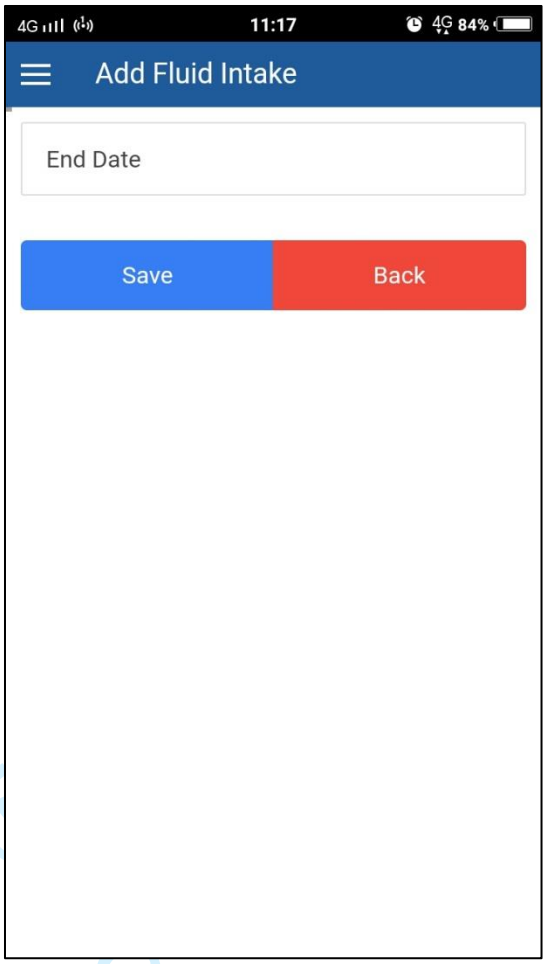
8. Assign medication reminder after filling medication details



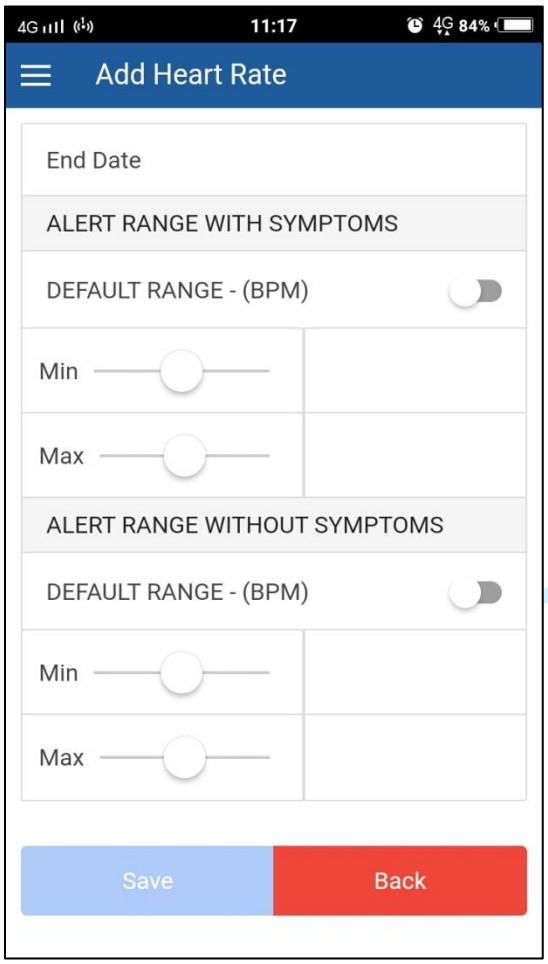
9. Assign BP/weight task



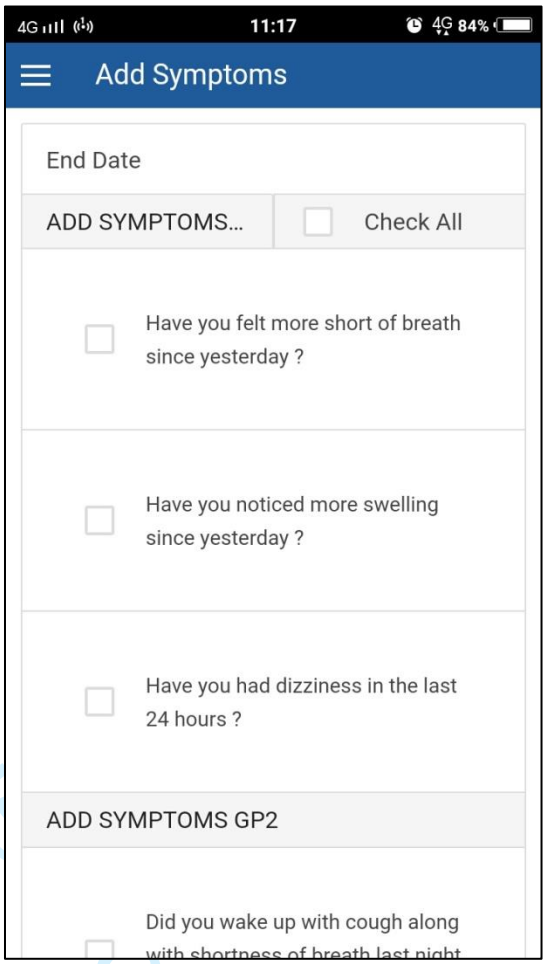
10. Assign fluid intake task



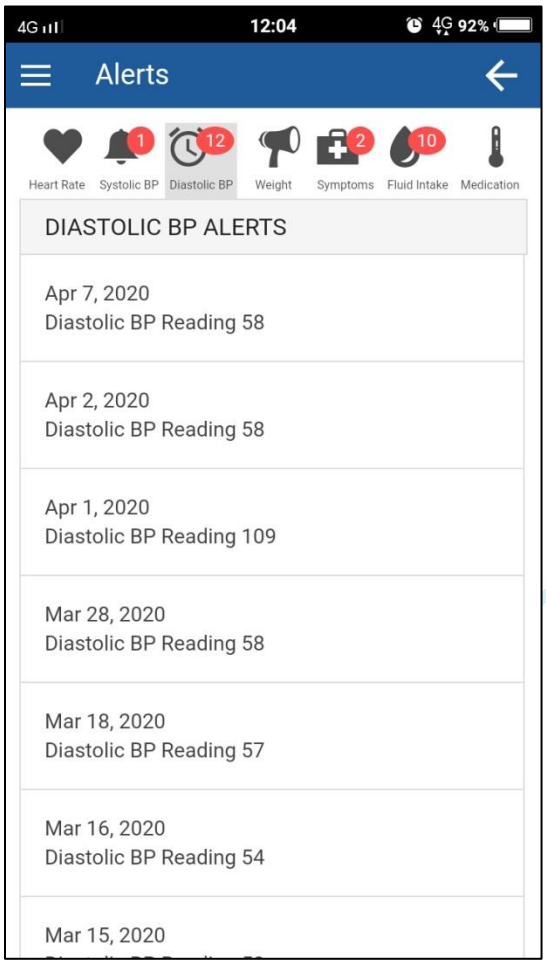
11. Assign heart rate task



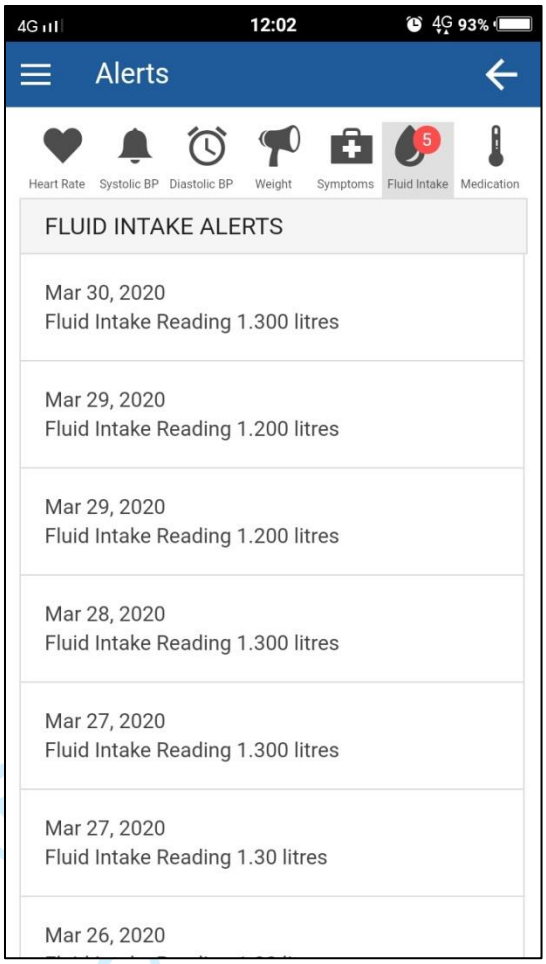
12. Assign symptom/sign monitoring task



13. Recognizing alerts, Diastolic blood pressure



14. Recognizing fluid intake alerts



15. Recognizing symptom/sign alert

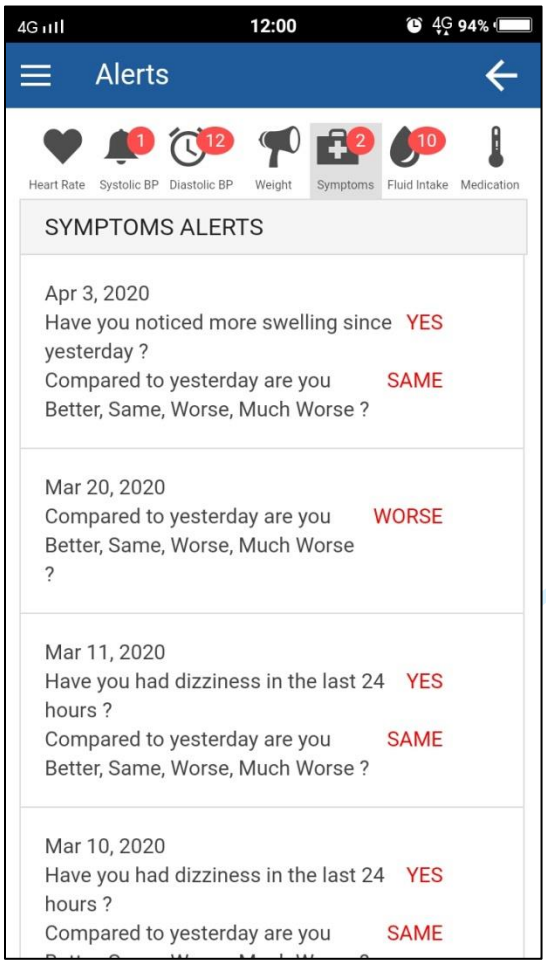
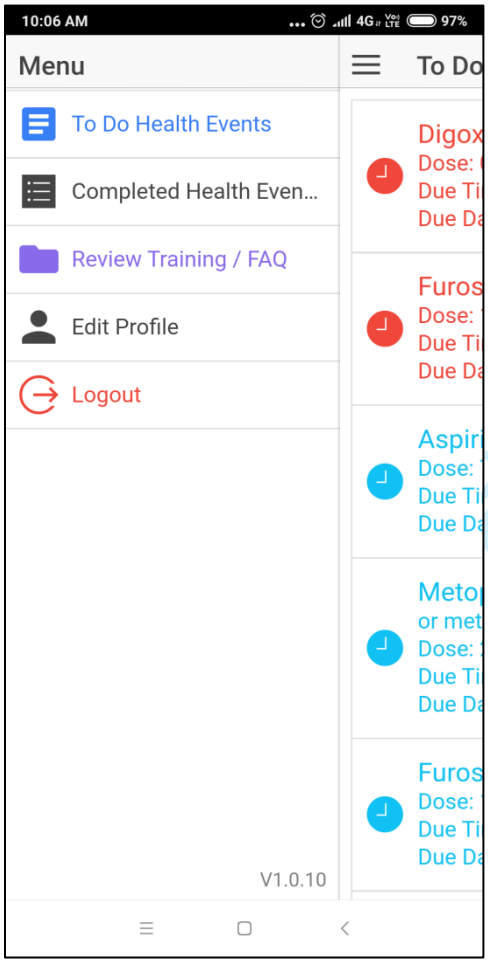


Table 1: Alerts reported by patients/ caregivers:

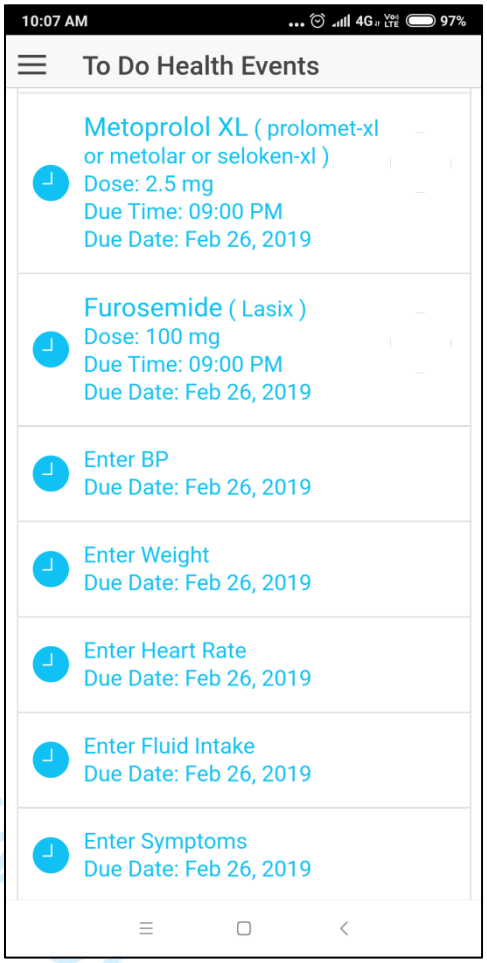
Alerts reported, N = 62	**No. of alerts** n (%)
Fluid intake	36 (58.1)
Variance in diastolic BP	12 (19.4)
Symptom worsening	10 (16.1)
Variance in systolic BP	4 (0.06)

App at patient interface:

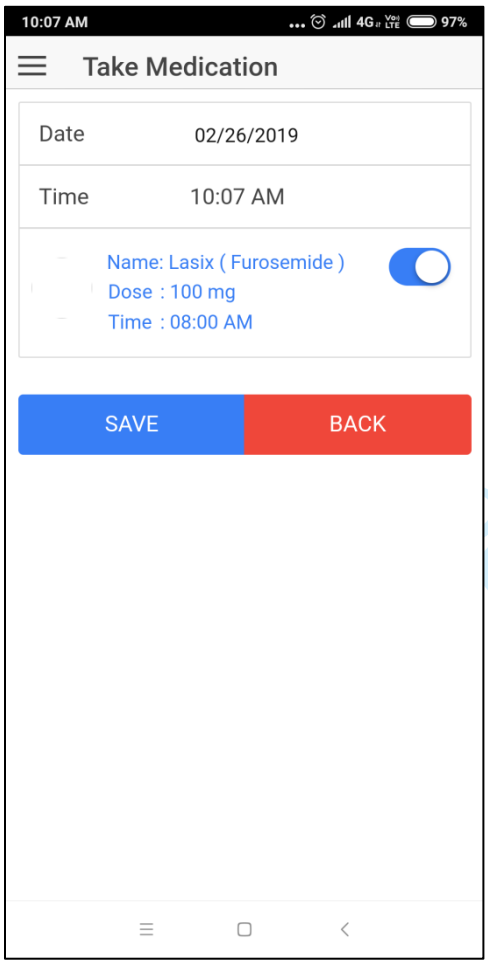
1. **Menu**



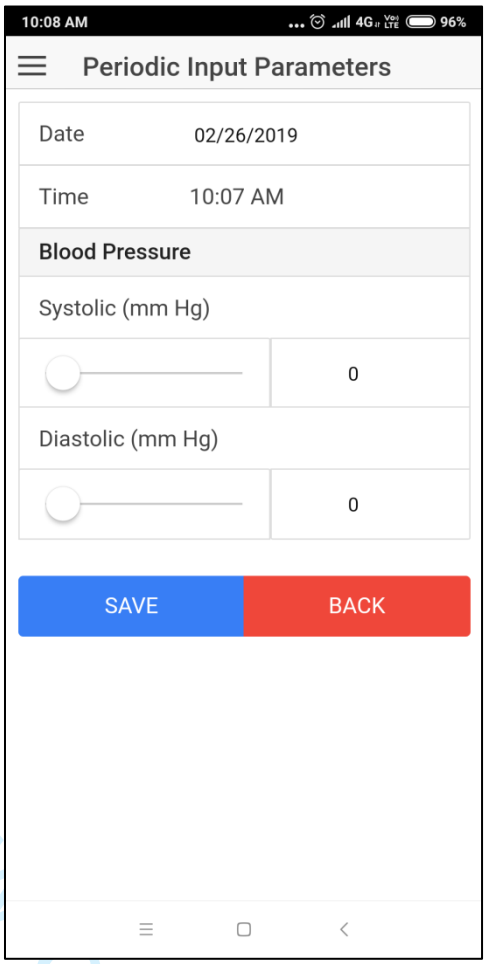
2. **To do health events**



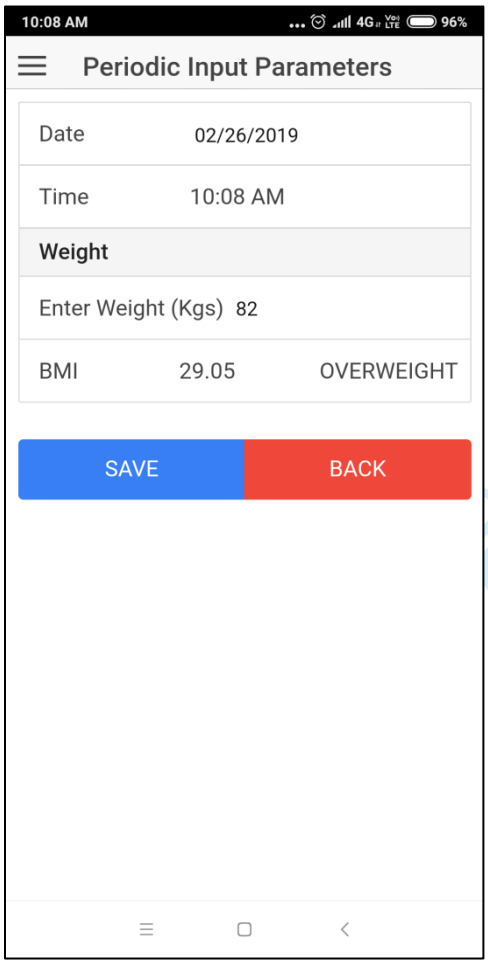
3. Medication taking & acknowledgement



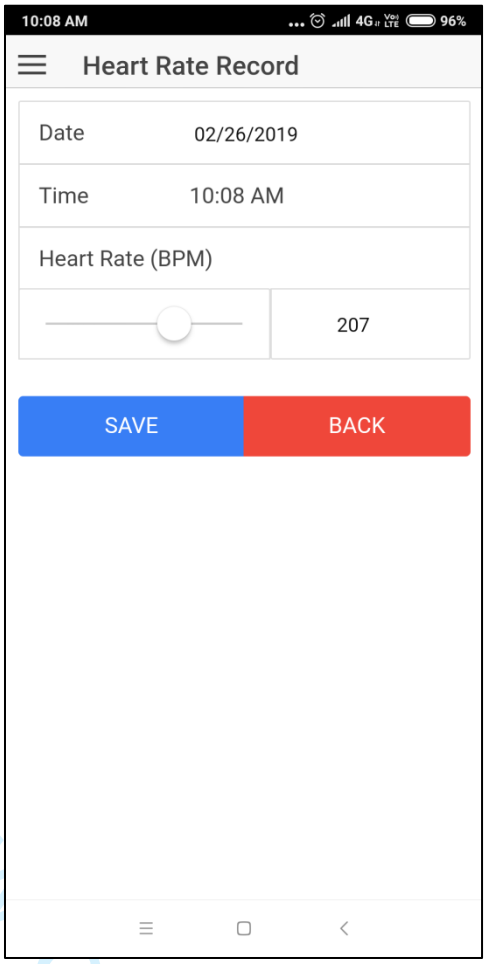
4. Completing task of entering



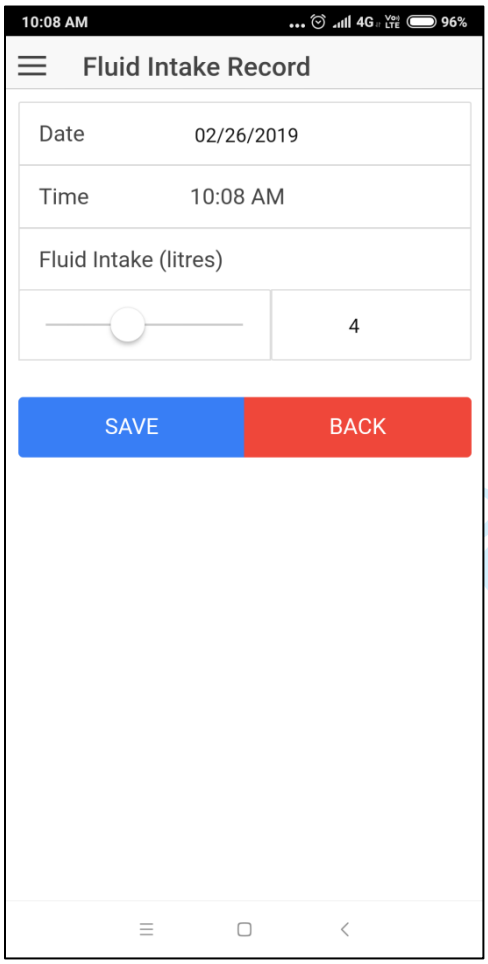
5. Completing task on entering weight



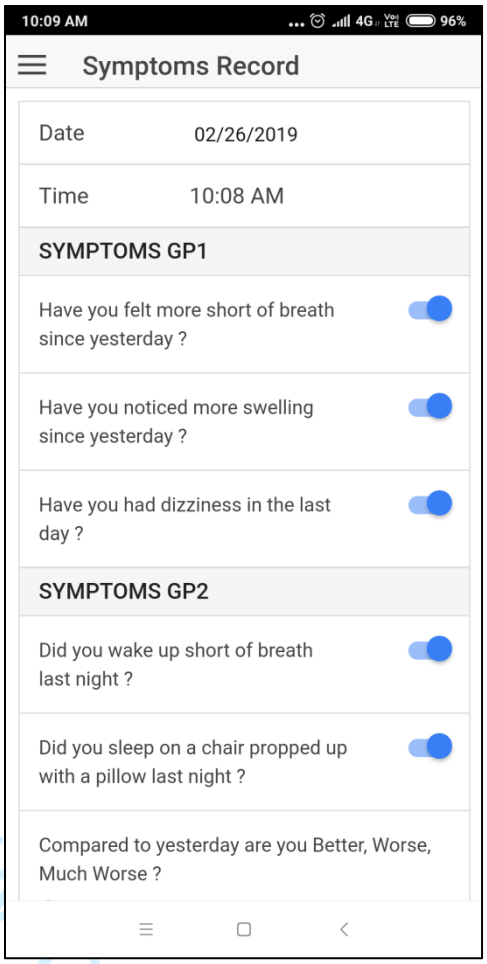
6. Completing task on heart rate



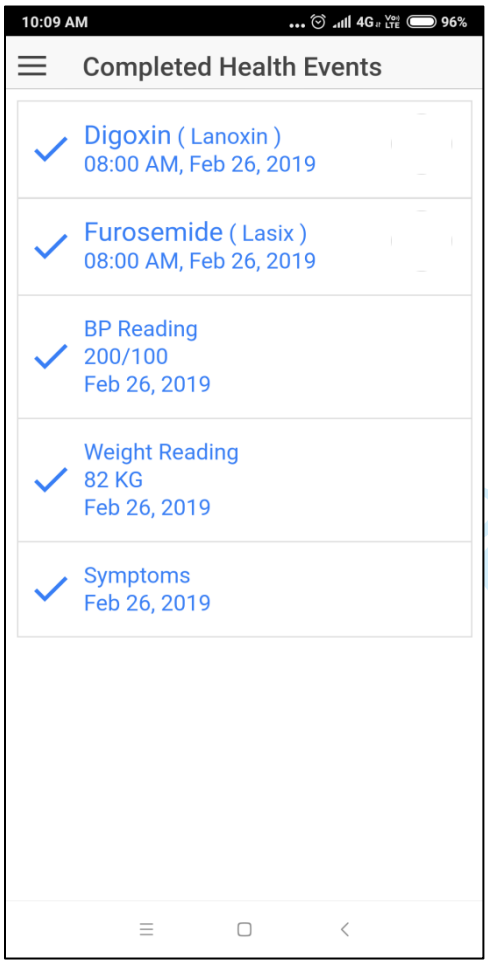
7. Completing task on entering fluid intake



8. Reporting symptoms/signs task



9. Completed health events



10. Viewing uploaded medical record

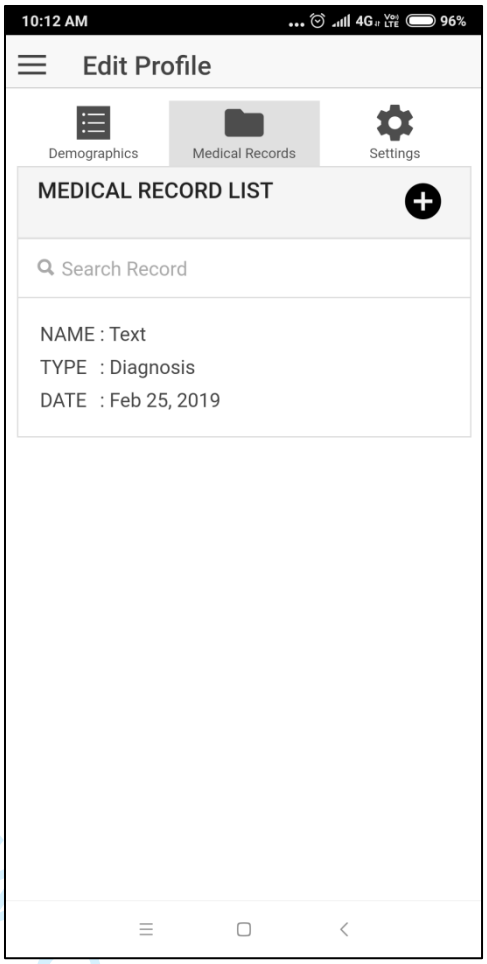


Table 2: App issues at patient/caregiver interface:

Technological issues at patient interface	No. of issues
App download issue	3
Log in issue	1
Medication swipe issue	1
Translations missing (drug names and symptom questions)	1
Non-reflection of medication/ task lists	3
Total	**9**

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Usability and Feasibility assessment of a smartphone application (Suhriday) for heart failure self-care remote monitoring in an Indian tertiary health care setting – A pilot mixed methods study

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Title: Usability and Feasibility assessment of a smartphone application (Suhriday) for heart failure self-care remote monitoring in an Indian tertiary health care setting – A pilot mixed methods study

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Abstract

Background/ Objectives: Remote monitoring as a component of chronic heart failure (CHF) management programs have demonstrated utility of reducing the risk of re-hospitalization and mortality. There is little evidence on mobile health app facilitated remote monitoring in India. We conducted a pilot usability and feasibility assessment of a smartphone-based application (Suhriday) to remotely monitor CHF patients.

Methods: We used a mixed methods design. Usability testing consisted of the think-aloud approach followed by semi-structured in-depth interviews (SSIs) and a satisfaction questionnaire. Feasibility testing was done using acceptability and user satisfaction questionnaires in addition to SSIs. We trained five purposively sampled patients with CHF (based on health literacy and gender) and their caregivers (n=10) in self-care monitoring and app use. Usability was assessed using metrics such as task completion, time required for task completion and user satisfaction using Brooke's System Usability Scale (SUS). Content analysis of the transcripts with deductive coding was performed for both usability and feasibility interviews. The number and types of medical alerts transmitted through the app were captured and escalated to the treating team.

Results: Critical tasks involving (a) opening the app and identifying task list, (b) reporting blood pressure, weight, heart rate and fluid intake and (c) reporting symptoms were completed within 60 seconds by four patients. Median (IQR) SUS score was 85 (75–92.5) indicating high level of usability. There were 62 alerts from four patients over 4 weeks, with 36 (58.1%) excess fluid intake alerts and 16 (25.8%) blood pressure variations being the most frequent. One participant had challenges using the app and was monitored through active phone calls.

Conclusion: Overall usability and satisfaction with Suhriday were good and we were able to remotely manage patients. However, patients with limited health literacy and those facing technological challenges required active structured telephone support.

Strengths and limitations of this study

- To the best of our knowledge, this is the first Indian study among CHF patients to assess usability and feasibility of smart-phone based application for remote monitoring.
- The sampled participants were from diverse socio-economic backgrounds which helped us identify usability and feasibility problems.
- This study is a stepping stone that has informed the design of a large trial with a complex intervention centered on mobile health and task sharing to improve self-care and outcomes in patients with CHF. Based on the characteristics of participant 4 in the pilot study who was unable to use the app successfully, we incorporated structured telephone and WhatsApp-based support as alternate options for remote monitoring.
- Think-aloud approach was conducted for all five participants, however, semi-structured in-depth interviews for usability and feasibility were only possible in three patients out of five. A usability study of the nurse interface was not done. Ideally, this interface would also need to be evaluated to ensure that it is simple and not time-consuming. Feasibility interviews had to be conducted telephonically due to the COVID-19 pandemic.
- Although suggestions regarding the incorporation of a chat or video call option were made by a few participants, these features could not be included in the app due to financial constraints.

Summary

What does this paper add?

- This study gives us new information about how Indian patients with CHF respond to and utilize an Android-enabled remote monitoring application.
- Patients with high health literacy can be easily trained and were able to regularly use the app through the total lockdown of the first COVID-19 wave. They reported high levels of satisfaction.
- Patients with low health literacy or older patients who are technologically inexperienced and training averse, may prefer not to use the app. In such situations, younger committed family members/ caregivers who agree to monitor and input data regularly into the app may be trained. Alternatively, such patients need to be offered active structured telephone support.
- The results of this pilot study provide insights into preferences, usage patterns and the different medical problems that were detected through remote monitoring and resolved. It can help inform trials designed to improve self-care and remote monitoring in heart failure utilizing application-based mHealth technologies in the developing world.

Introduction: Heart failure (HF) is a rapidly growing cardiovascular disorder which affects about 38 million individuals worldwide[1]. The INDUS study estimated the prevalence of HF in India in 2016 as 1% of the total population; that accounts for nearly 8 to 10 million patients[2]. Self-care is essential for patients with HF and is comprised of treatment adherence in addition to health maintenance behaviors. Patients need to learn to take medications as prescribed, understand how to monitor signs and symptoms of worsening HF, as well as what to do in response to such symptoms when they occur[3]. A cluster randomized controlled trial conducted in Ethiopia concluded that self-care education significantly improved self-care adherence score among HF patients[4].

The 2022 ACC/AHA/HFSA guidelines for the management of HF documented the role of interventions that aim to improve self-care knowledge and skill, and those that focus on enhancing medication adherence or reinforcing self-care with structured telephone support as being effective in patients with HF. In addition to improving HF self-care significantly, such strategies also reduce the risk of HF-related hospitalization, all-cause hospitalization and all-cause mortality. There is some uncertainty regarding improvement of self-care in patients with HF through educational interventions delivered through mobile health applications[3]. A systematic review and meta-analysis of the outcomes of structured telephone support (STS) or remote telemonitoring as the primary component of CHF management in 8,323 patients demonstrated a 34% risk reduction in all-cause mortality with telemonitoring. Additionally, STS and telemonitoring reduced HF-related hospitalization by 23% and 21% respectively[5].

There is a dearth of evidence on mobile health app facilitated remote monitoring in India. Hence, we developed a mobile-based application named Suhriday ('Well Heart') which has multiple capabilities including facilitating remote monitoring of HF patients (details described below under the app section *Functions*). We intend to use it as a part of a complex intervention in a larger randomized controlled trial. Hence, we conducted a study to assess the usability and feasibility of smartphone-based application (Suhriday) in remotely monitoring patients with heart failure involving caregivers. The information from this pilot study will inform the mHealth component of a complex intervention to improve self-care in HF patients.

Methods: We conducted a usability and feasibility testing of Suhriday, using a mixed methods study. The mixed methods approach which includes qualitative and quantitative methods provides a detailed understanding of user view of the app with regards to immediate engagement as well as attitude and perceptions with the continued use of the app[6].

Setting: This study was carried out in the Cardiology and Internal Medicine departments in both inpatient and outpatient wards of St. John's Medical College Hospital, a tertiary care teaching hospital in South India from March to July 2020.

Eligibility criteria, Sampling and Ethics: The participants for the study include patients with a clinical diagnosis of HF and at least 1 of their caregivers, who consent to use the smartphone app for four weeks at home. We excluded patients who in the opinion of the treating cardiologist had a survival prognosis at baseline of less than three months and those for whom an intervention procedure had been planned in the next one month. We conducted purposive sampling to ensure that at least one patient was female, one had inadequate health literacy, and two were from semi-urban or rural areas. The health literacy scale has three validated questions

related to ability to read and understand medical records[7]. Based on the score obtained, health literacy can be classified as low, marginal or adequate.

We obtained ethical approval from the Institutional Ethics Committee of St. John's Medical College Hospital (Reference number: 124/2017) and written informed consent from all participants. During the consenting process, among other elements, we emphasized data confidentiality, especially of the qualitative data. Participants were also assured that they would receive standard care from their treating cardiologist and physician apart from the study interventions. Further, they could make visits to the out-patient department for physician specified follow-ups and to the emergency department in case there were medical emergencies.

Suhriday app: The mHealth application has been developed by One Health Solutions (OHS) Pvt. Ltd., a software company based in Bangalore, India. This application works on both Android and iOS. It uses JavaScript, Hypertext Markup Language (HTML) and Cascading Style Sheets (CSS), and can be deployed for both desktop and mobile versions.

Functions: The application is intended for care providers (nurses and treating physicians) to remotely monitor key parameters of patients with a primary diagnosis of HF who are on treatment. The application will also be able to generate reminders for medication adherence based on information entered by a healthcare provider nurse into the application at discharge. The patients or their caregivers, after measurement of key parameters (blood pressure, heart rate, body weight and fluid intake) using validated instruments, will enter the same data into the app. The app also has a validated questionnaire for symptom/sign reporting[8]. It can identify and alert the study nurse when there are outlying values. The nurse will be able to view these alerts and escalate them so that the treating team can then take appropriate action (e.g., order a titration of doses of high ceiling diuretics). The security features of this system include encryption of data on the device, user authentication and a secure Hypertext Transfer Protocol-based data transmission system. We used the Apache CouchDB database on a secure web server and the backend data were stored securely in the Cloud.

Study Procedures:

Step 1: Training a study nurse – We recruited a nurse with a master's degree. She was trained for two months on heart failure by three physician investigators using lectures and bedside demonstration to recognize worsening signs and symptoms as well as medications for HF. She was educated on the importance of self-care in HF including monitoring, maintenance and management. Furthermore, she was empowered to train patients and caregivers to measure blood pressure, fluid intake, check weight and use the Suhriday app (detailed in *Appendix 1 - Table 1*).

Step 2: Training for patients/caregivers – Patients and their caregivers were educated on salient aspects of HF self-care. Participants received training in measuring blood pressure, fluid intake and weight from the study nurse. They were also trained to recognize worsening signs and symptoms of HF. Following this, detailed app training to perform the tasks assigned was provided to the participants (Tasks detailed in *Appendix 1 - Table 1*).

Step 3: Setting for usability testing at the patient interface – The patients/ caregivers were asked to measure their blood pressure, heart rate and body weight in the presence of the nurse.

Then they were instructed to open the link from the message received, to download the app and open the application. The patients or their caregivers were asked to perform the think-aloud exercise while performing and completing the in-app tasks. (Usability measures definitions detailed in *Appendix 1*)

Step 4: Usability testing at the patient interface – To assess usability, we equipped five patients or their caregivers with the smartphone-enabled mHealth application, Suhriday, and used the following methods:

Think-aloud approach: The purpose of this approach was to capture ease of use and an understanding of potential interface issues. Patients/ caregivers were instructed to "think aloud" (i.e., verbalize their thoughts) as they interact with the Suhriday app while the mobile screens were recorded through the screen recorder option of Android phones. The study team observed and made notes about completeness of tasks with patients/ caregivers. We measured effectiveness of task completion by noting whether tasks were (i) completed with ease, (ii) completed with difficulty requiring intervention from the study nurse or (iii) not completed. We also measured efficiency by noting time taken to perform tasks using the mobile screen and/ or audio recordings[9-11].

Qualitative semi-structured in-depth interviews: At the end of think-aloud approach, we interviewed the patient and caregiver as a dyad to capture the acceptability and barriers of the app and suggestions for improving its features. Details about qualitative data collection have been described below.

Satisfaction measurement: Patient and caregiver's satisfaction was measured utilizing Brooke's System Usability Scale (SUS). The SUS has been evaluated for validity, reliability, and sensitivity[12-16]. Scores were calculated according to Brooke's guidelines[12] and is detailed in *Appendix 1*.

Step 5: Feasibility study in the context of technology development is an analytical method used to determine if different components of a project can perform together in order to create a technically and operationally viable concept[17]. The guidance from the Medical Research Council (MRC), UK on the development and evaluation of complex interventions recommends an early phase of assessing feasibility prior to a full evaluation. Patients and their principal caregivers who participated in the usability testing were provided a smartphone enabled with the Suhriday app, a BP monitoring device and an LCD weighing scale. They were asked to measure BP and body weight every morning for a minimum of 4 weeks and to report measured values using the application. In addition, they were asked to monitor and report symptoms or other signs through the app.

We provided the study nurse with a smartphone onto which the Suhriday application was installed. The study nurse monitored the patients for a minimum of 4 weeks and made telephone calls to address alerts received for variance in values of measurements and symptoms/signs (detailed in *Appendix 1 - Table 2*) in addition to weekly structured telephone follow-up calls. During the course of the study, the nurse maintained a paper dairy and an electronic diary (MS Excel Issue Tracker) to capture type of issue (medical or app-related), details of medical issues, person the issue was escalated to, and description of resolution.

Alerts and resolution process: The study nurse was the primary recipient of the alerts through the Nurse interface of the Suhriday app. She would call patients and ask them additional questions related to their symptoms from a pre-prepared list by the investigators. Salient data retrieved including present complaints, past history, key investigation parameters and the current list of prescribed medications would then be informed to the study physicians. General medical escalations were attended by the Internist or the Clinical Pharmacologist (medically qualified in India), while HF symptom-related queries were escalated to the on-call Cardiology resident. If more information was required, the nurse would be asked to make an additional call to gather the same. Based on the physicians' assessment, the escalation would either be (i) resolved over the phone, (ii) advised an out-patient visit for follow-up, (iii) advised an emergency room visit, or (iv) advised hospitalization following an emergency room or out-patient visit**.**

A feasibility study conducted with qualitative research methods can help identify fundamental problems with the intervention workflow process or trial conduct[18]. Hence, after 4 weeks of continuous use of the application, we conducted semi-structured feasibility interviews with the patients or their caregivers. We used a feasibility interview guide for this purpose (*Appendix 1 - Feasibility interview guide*). The interviews were audio-recorded, transcribed and translated to English. Satisfaction was measured utilizing the SUS instrument.

Sample size, Data collection and Analysis: We carried out the usability and feasibility testing in five participants as it has been demonstrated that this can detect over 80% of usability problems[10]. For usability analysis, we noted effectiveness (task completion), efficiency (time required for task completion, noted through the screen recorder and/or audio recording) and user satisfaction (SUS score)[9-12,19]. Interviews were conducted (for usability – in the Cardiology Research Office, for feasibility – telephonic) by KD and BB with the help of JI, and recorded using an audio recorder. The interviews were transcribed verbatim and then translated into English by a research assistant. This was verified for content accuracy by either KD or BB. Transcripts were manually analysed using content analysis approach and deductive coding for acceptability and barriers related to app use, as well as suggestions for improving app functionality. For feasibility testing, while we intended to interview all five participants, we were only able to interview three due to the COVID-19 disruptions. Content analysis codes from these interviews were categorized as those indicating the overall experience, interaction with study staff, impact of training on HF self-monitoring, satisfaction with the team and suggestions to improve the app. We measured user satisfaction using the SUS instrument at the end of the study. Components of acceptability (not validated) were measured using a Likert scale.

Role of public and patient involvement: While the public was not involved in the study, patients and their caregiver's feedback on the utility and ease of app usability were investigated in detail as described in the results.

Results: We conducted this study from March 2020 to July 2020 and recruited five patients.

1. Patient demographics and Models of app use: Of the five patients, three were from urban areas, one from semi-urban and one from rural India. Clinical features such as type of HF –

reduced [HFrEF] or preserved ejection fraction [HFpEF], New York Heart Association [NYHA] class at recruitment and etiology were captured (Table 1).

2.1 Usability, Task completion: The task completion results are presented in Figure 1. The critical tasks involving (a) opening the app and identifying task list (task 1), (b) blood pressure, weight, heart rate and fluid intake reporting (tasks 3, 4, 5, 6 respectively) and (c) symptom reporting – understanding and reporting (task 7) were done easily. Majority of the tasks (tasks 1, 3, 4, 5, 6 and 7) were completed with ease by four (80%) of the participants. Task 8 (viewing shared medical records) and task 9 (sharing medical records) were reported as the most difficult to complete. Among five participants, two (40%) and one (20%) completed tasks 8 and 9 respectively, both of whom had adequate health literacy.

Errors: One participant made the error of swiping across instead of tapping on task 2 (acknowledgement for medication reminder). Majority of the errors were faced with a single participant (Participant 4, male, rural, inadequate health literacy), who completed task 2 with difficulty, as the drug names were not translated to his native language, Tamil. This participant also took 7 attempts to complete task 3 (entry of blood pressure values) due to the inability to locate the number mode after locating the area to enter the value as he forgot the instruction. He completed task 6 (entry of fluid intake the previous day) after three attempts due to difficulty in locating and placing the decimal point.

2.2 Usability, Time taken per task: The time taken per task results are presented in Figure 2. For one participant (Participant 3), we did not record the think-aloud approach through the screen recorder as the caregiver of the patient was not comfortable with it. We were not able to record the time taken to complete tasks through the audio recording, as the tasks were not performed systematically. The study team observed and made notes on completeness of tasks for this participant. Participant 4 who made the most errors took the longest time.

2.3 Usability, Satisfaction: The median (IQR) SUS score for usability of all the five participants was 85 (75–92.5), indicating high level of usability. Participant 4 however had a score of 32.5 indicating poor usability.

2.4 Qualitative Interview: Among five participants who completed think aloud process with the app, interviews were conducted with three participants (reasons explained in *Discussion*) to determine acceptability, barriers of use and suggestions for improvement (Table 2).

Table 2: Acceptability and barriers of the app, suggestions for improving app features at baseline

Themes	Codes	Extracts

Acceptability of the app	**Effective, useful for monitoring**	**"**This app is ***very good*** for like my kind of HCM people, congestive heart failure people. This is ***very effective*** and what I feel is every time it will be ***like awareness*** for you people, also for us also." (Patient 1, female)
	Very easy, very useful **Monitor easily**	**"**This is there we can be with a ***regular kind of checkup*** day by day" "And this is ***very easy to use***" "I guess this app is very useful to everyone ***easily*** we ***can monitor***" (Patient 1, female)
		"The performance of the app is ***very good*** and the reaction time most the opening of the ***app and individual components within*** that are all ***very good***" (Caregiver of Patient 3, male)
	Useful reminder for medication taking, easy to use	"I open it and I go to all of the tablets and medication, which have to be taken, which are in red. I open each one of them and I complete them and click on save and this ***hardly takes me any time***" "This was also fine the ***weight reading, fluids intake*** and all that was **fine.**" (Caregiver of Patient 2, male)
Barriers of the app	**Small font**	"Instead of entering values in mobiles just I am telling see instead of entering ***small small (font size) values***" (Caregiver of Patient 2, male)
		"This one is a bit of a problem, because for me ***to type these numbers are really small***" (Caregiver of Patient 3, male)
	Unclear images	**"**It (discharge summary image) is very **unclear**" (Patient 1, female, high health literacy)
Suggestions for improving app functionality	**Alarm feature**	"It would be nice if anything turns red that the ***phone rings or alarms*** are there." (sic) (Caregiver of Patient 3, male)
	Adjustment scale feature	"These adjustment bars they are actually of no use. Because the spacing is really small." "The ***scale (BP)*** have (sic) to be completely ***different representative***" (Caregiver of Patient 3, male)
	Help guide	"The symptoms what I noticed was, if some patients who may want to understand, what is better, what is much worse mean" "like on what basis do I tell much better? If there is a ***help guide*** or something like that" (Caregiver of Patient 3, male)

Remote monitoring through Suhriday app: Overall, patients were managed remotely throughout the 4-week evaluation period with no unplanned re-hospitalizations due HF or deaths.

Alerts, number and type: There were a total of 62 alerts (detailed in *Appendix 2 - Table 1*) from four participants (snapshots of alerts in *Appendix 2*). Alerts related to fluid intake (58.1%), variance in diastolic blood pressure (19.4%), HF symptom worsening (16.1%) and variance in systolic blood pressure (6.5%) were received at nurse interface. Patients were counselled over the phone for fluid intake alerts. For alerts related to BP, the nurse ascertained whether patients were measuring it correctly. If the value was deemed accurate and uncontrolled, it was escalated to the study investigators. Patient 4 hardly used the app, but reported issues through structured telephone support. This was monitored actively by the study nurse and there were no HF related escalations over a 4-week period. Overall, five issues were remotely managed for three out of five patients. HF related escalations led to up-titration of loop diuretics three times, and general medical queries were addressed for constipation and iron deficiency anemia.

Resolution process and time (for alert-led issues and other medical issues): The study nurse made 21 telephone calls to Cardiologists and Internists/ Clinical Pharmacologist to resolve issues regarding HF symptom/sign related alerts, general medical queries, prescription confirmation and drug dose queries, as well as blood pressure variations. Majority of the medical issues were resolved within 60 minutes.

App issues at Nurse interface: These were totally 29 in number. Difference in getting alerts with two different phones (8), log in issues (5), alert sync issues between two different phones (3), alert sync lag from patient to nurse (2) were the predominant issues at the nurse's interface. App issues at patient interface are summarized in *Appendix 2 - Table 2*.

3.1 Feasibility Interview: We conducted telephonic interviews with three out of five participants (reasons explained in *Discussion*). Findings are in Table 3.

Table 3: Feasibility of the app and impact of pilot intervention

Themes	Codes	Extracts

Overall experience using app	**Good improvement, daily monitoring**	"I have ***good improvement*** ma'am with this app. What exactly it is means (sic) like from this I came to know what is my blood pressure, ***day to day routine*** thing and the heart rate also ***I maintained***." "Plus, the water intake and medicines like what time to what time like it will be mentioned in that." (Patient 1, female)
	Good experience, maintained health well, reduced hospitalization	"In this critical situation (COVID-19 situation) this is the best option". "It has become a habit, daily everyday morning we have to do all these things" "People are not able to come to the hospital so we can give him then through phone call or any video conference or video call something or this kind of app will be helpful in future also going forward" (Caregiver of Patient 2, male) "I got lot of ***good experience***" "I ***maintained myself very well***." "Usually, I ***used to get hospitalized*** a lot but ***now it has become less***." (Patient 1, female)
	Very positive, friendly to use, part of routine	"I would say the experience have been ***very positive***. What I mean by positive is the app is really ***friendly to use***." "And once you start using this, it becomes the ***part of your routine***." (Caregiver of Patient 3, male)
Interaction with study staff	**Change in treatment plan, helpful**	"I was not keeping well, my legs got swollen, my stomach got swollen, so I used to contact mam" "according to the doctors she ***used to tell me the prescription***" "There was ***lots of help*** sir" (Patient 1, female)
	Provided solutions	"There were 3 or 4 occasions where the ***issue was to be escalated*** right" "we contacted you and you ***provided us with a solution***" (Caregiver of Patient 3, male)
	Dedicated, committed, knowledgeable, professional and patient -friendly	"***Dedicated*** to this and ***committed*** and you were ***very knowledgeable*** and you were ***highly professional*** and ***patient friendly***." "Immediate triage that is the most significant aspect of this." (Caregiver of Patient 3, male)

Impact of training on HF self-monitoring	**Training on symptoms, signs of worsening led to awareness and improved self-monitoring**	"From this app I came to know that, particularly I ***used to check*** all these things (blood pressure, weight)" (Patient 1, female, high health literacy) "All the symptoms you people explained me from that I ***got lot of education***". "I have ***improved a lot*** sir, like I used to know what exactly happens if I take lot of fluids." (Patient 1, female) "It is improved. On daily basis also he is taking care of all" (Caregiver of Patient 2, male) "It had ***great value***. I will tell you why doctor." "He used to drink as much water as possible" "This ***whole weight management aspect*** we never actually took into consideration" "swelling of legs as an ***indicator to overall heart condition***" "being aware of what is the ***threshold level for BP***" (Caregiver of Patient 3, male)
Satisfaction with the team	**Suggestions and support to solve problems** **Quick resolution of problems, perfect**	"I had many times problems, I used to contact you, you will be suggesting, you will be contacting doctors, give me ***proper prescription***" "You have ***supported me a lot***." (Patient1, female) "***As soon as possible you used to contact*** me and you used to suggest me" "the ***anxiety aspect was removed***." "I think it was ***perfect***." "On a scale of ten I would give it 11" (Caregiver of Patient 3, male)
After stopping app use	**Self-maintenance**	"I'm noting down in a book and I'm WhatsApping (sic) you. ***Everyday*** I'm maintaining" "***In my one book I'm maintaining***." (Patient 1, female) "I am doing. Up to date I am doing. Till today" (Patient 2, male)
Suggestions to improve the app	**Video call option** **Chat tool within app**	"If it is a ***video call*** it will be better" (Patient1, female) "Can't your app actually have a ***chat interface*** wherein I can post?" (Caregiver of Patient 3, male)

3.2 Feasibility, SUS, overall satisfaction, acceptability: Feasibility results among the three participants showed a median (minimum, maximum) SUS score of 92.5 (87.5, 100) which represents high usability with an overall satisfaction adjective rating of 'excellent' (2 participants) and 'best imaginable' (1 participant). In the context of acceptability, all three participants felt that they were confident in using the Suhriday app and would be able to teach others to do the same to a large extent (detailed in *Appendix 1 - Figure 1*).

Discussion: This is the first report from an Indian setting on how patients with HF respond to a remote monitoring application, pain points experienced, symptoms/ signs that resulted in escalations, and how they were resolved.

The usability assessment (think-aloud approach, in-depth interviews and SUS) of Suhriday demonstrated satisfactory usability for remotely monitoring among four of the five participants in our study. Most of the critical tasks were completed with ease (Figure 1) which was comparable to the usability assessment of the HeartMapp study[20]. IQR for tasks 1, 2 and 3 were within one minute and for tasks 4, 5 and 6 were well within half a minute. Our findings from Table 2, Figure 1 and 2 reflects that the app is easy to use.

However, participant 4 completed majority of the critical tasks with difficulty, took the longest time, made many errors, and had poor usability in contrast to rest of the participants. This may be due to inadequate health literacy levels and educational attainment. Both patient and caregiver had initial apprehensions and were reluctant to use technology. Though they had smartphones, they were only accustomed to making calls. Although we trained them patiently and tried to build confidence, they could not sustain performing daily tasks and instead maintained manual records. Active structured telephone support was imperative in this case. The insights gained helped us plan contingencies for the randomized controlled trial, where we planned to incorporate active structured telephonic and WhatsApp-based support among patients who preferred not to use the app.

A decision-making algorithm for symptom management was developed based on the queries and alerts received. Escalations led to changes in prescriptions for participants 1 and 3. During the COVID-19 pandemic lockdown and heavy restriction imposed on movements, all patients were managed remotely through the app and by structured telephone support to manage issues. During remote monitoring, we did not have any unplanned hospital readmission or unplanned emergency/outpatient visit related to HF symptom/sign worsening when compared to a study by Heiney et al having one hospital admission and an emergency OPD visit during a 6-week study[21].

During the feasibility assessment, interviewed participants expressed that the app was user-friendly, became part of their routine, helped maintain health and reduce hospitalization. They also expressed that training led to awareness and improved self-monitoring. Participants opined that they were satisfied with the team's turnaround time to resolve issues quickly. Having video call option and chat tool within the app were a few suggestions made towards improving the app (findings from Table 3).

The limitation of the study was that in-depth interviews for usability and feasibility were conducted in only three out of five participants. The usability interview for Participant 4 could not be conducted initially due to in-hospital time constraints, and later due to COVID-related disruptions. On the other hand, the feasibility interview was not conducted as he had not used the app.

Users are the first citizens of a technology; hence their personal technological experiences are principally important[22]. Variations in age, gender, affluence and profession among patients and caregivers emerge as critically important factors in technological experience and engagement[23,24]. The issues that participant 4 faced, for instance, might be attributed to his social variables. Such cases are more likely to be encountered in communities where patients and caregivers are aged or ageing, and consequently digitally unfamiliar. It is well-evidenced in literature that ageing affects familiarity and fluency with digital devices[25], and the digital divide hinders the elderly from using technology to enhance their quality of life[26,27]. Other

studies [28-30] have shown evidence that factors such as self-efficacy, cognitive decline, declining motor skills and disorientation with hypertext structure heavily influence Information and Communication Technologies (ICTs) among the aged.

This pilot study helped inform a randomized controlled trial designed to improve self-care and remote monitoring in HF patients utilizing a smartphone application in a lower middle-income country setting.

Conclusion: This study demonstrated that Suhriday was acceptable and easy to use among most patients. Health literacy and preferences need to be considered while enrolling Indian patients into mHealth based intervention programs. This study has informed the design of an ongoing multicentre trial with a complex intervention centered on mobile health and task sharing to improve self-care and outcomes in patients with chronic heart failure.

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Data sharing: Data are available upon reasonable request. Currently, we have not deposited the raw data in an open access repository. However, we are willing to share the raw data with all interested investigators. Interested investigators may send an e-mail to corresponding author with the brief write-up of the research question, objectives and ethics approval for the proposal.

Contributors: BB, KD, JI, SJ, XD and KS contributed to the conception and design of the study. VK, SJ, JI and BB were involved in acquisition of data from recruited participants. BB, RP and KD performed the analysis. BB, KD, JI, SJ, KS and VK were involved in interpretation. BB drafted the manuscript, with revisions from KD, JI, SJ, KA, RP, KS, VK and XD. All authors declare no conflicts of interest.

Ethical approval statement: We obtained ethical approval from the Institutional Ethics Committee of St. John's Medical College Hospital (Reference number: 124/2017) and written informed consent from all participants.

Figure 1: Task completion rate for usability – effectiveness

Figure 2: Box and whisker plot for usability efficiency measure, inter quartile range

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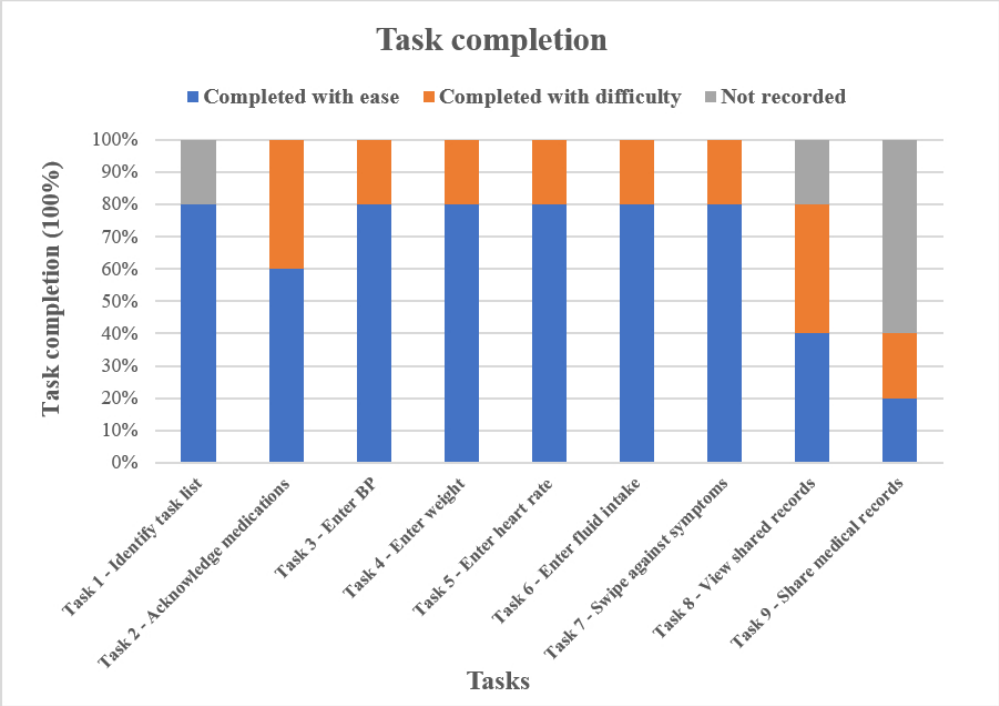

Figure 1: Task completion rate for usability - effectiveness

238x169mm (96 x 96 DPI)

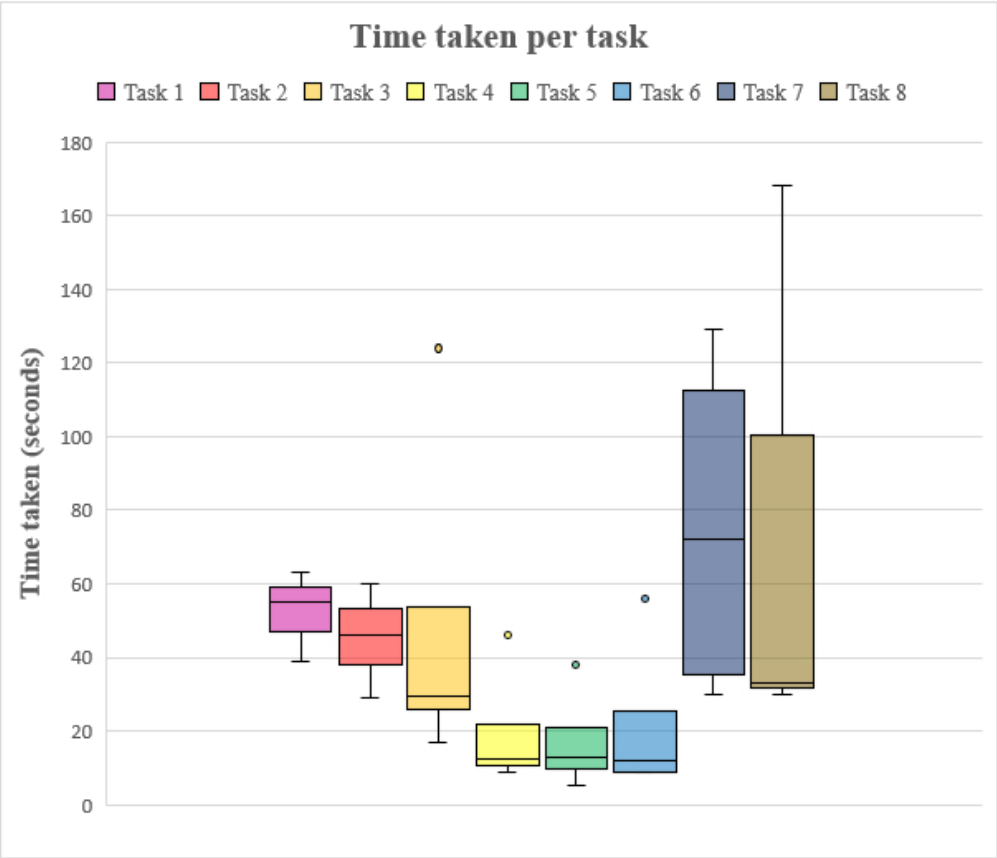

Figure 2: Box and whisker plot for usability efficiency measure, inter quartile range

160x137mm (96 x 96 DPI)

Appendix 1

1. App interface/ design/ features

The app is designed to have two interfaces.

The app **(at patient interface)** is designed for remote monitoring of heart failure patients. The app has a validated questionnaire for symptom/sign reporting, feature to enter self-measured body weight, blood pressure, heart rate and fluid intake; swiping functionality to acknowledge intake of medications and a feature to store medical records and share images of prescriptions.

The app **(at care provider interface)** is designed to capture demographic data of patients, to enter a few key investigation values and to store and share medical records such as discharge summaries, prescription re-fills or fresh prescriptions and investigation reports with the patients. The app has a feature where care providers can assign tasks to patients such as entering measured blood pressure values, heart rate, fluid intake, and body weight; medication intake notification reminders and symptoms/signs monitoring and reporting (Details in **Table 1**). The app is also designed to receive alerts when these measurements are outside the mentioned cut off ranges (Details in **Table 2**).

Table 1: List of tasks at care provider interface and patient interface

Care provider/ Nurse		Patient / Caregiver	
Task 1	Enter demographic details of patients from source documents and save	**Task 1**	Identify task list
Task 2	Capture medical records by either taking a picture/ selecting it from the phone gallery and share those with the patient (e.g.: discharge summary, recent lab investigation reports, prescriptions)	**Task 2**	Acknowledge medications taken throughout the day by tapping against each medication reminder
Task 3	Enter comorbidities (select the comorbidities/ add comorbidities if they do not appear in the existing list) and save	**Task 3**	Enter measured BP (both systolic and diastolic, correctly against each)
Task 4	Enter key investigations and save	**Task 4**	Enter measured weight
Task 5	Set medication reminders	**Task 5**	Enter measured heart rate
Task 6	Instruct patient to enter BP value and weight measured	**Task 6**	Enter fluid intake of the previous day
Task 7	Instruct patient to enter heart rate value measured	**Task 7**	Swipe against symptoms which are present
Task 8	Instruct patient to measure fluid intake of the previous day and enter the same	**Task 8**	View shared medical records
Task 9	Monitor the six symptoms and respond as Yes or No	**Task 9**	Share medical records
Task 10	Recognize alerts (heart rate, diastolic BP, systolic BP, weight, symptoms, fluid intake, medication)		

Table 2: Alerts for limits in values for measurements and symptoms/signs

Vitals to be measured	With symptoms		Without symptoms	
	Minimum	Maximum	Minimum	Maximum
Heart Rate	50	100	40	110
Blood pressure (Systolic)	90	160	80	170
Blood pressure (Diastolic)			60	100
Fluid intake	> 1 litre / day			

Alerts are also generated if the patient answers 'Yes' for any of the following questions:

1. Have you felt more short of breath since yesterday?
2. Have you noticed swelling since yesterday?
3. Have you had dizziness in the last 24 hours?
4. Did you wake up with cough along with shortness of breath last night?
5. Did you sleep on a chair propped up with a pillow last night?

If the patient responds to the question below as 'Worse' or 'Much worse'

6. Compared to yesterday are you better, same, worse or much worse?

2. Definitions/ terminologies

Background: We have created the mobile health application, named ***Suhriday*** for remotely monitoring patients with chronic heart failure. As a part of remote monitoring, we will ask patients to report worsening of symptoms or signs, blood pressure, body weight and fluid intake every day, measured at home, for duration of 4 weeks. The data will be monitored centrally by a trained nurse. Issues will be escalated by nurse to physician/cardiologist (treating team). Further actions will be documented by the nurse in a diary.

Definitions – The following definitions are in compliance with ISO 9241-11 [1,2]

1. Usability - Usability means that any part of a system must be easy to operate, learn, remember and helpful to the user and must guide the designers in the design process. "It is the extent to which a product can be used by specified users to achieve specific goals with effectiveness, efficiency and satisfaction in a specified context of use."

1.1 Usability/ Effectiveness – To what extent the user can achieve a goal with accuracy and completeness.

1.2 Usability/ Efficiency – The level of effort and resource usage which is required by the user in order to achieve a goal in relation to accuracy and completeness.

1.3 Usability/ Satisfaction (based on ease of use, ease of learning, error minimization and recall capacity) – The positive associations and absence of discontent that the user experiences during the performance.

2. Description of evaluation approaches -

2.1 Think Aloud Approach [2,3] – The think aloud approach involves the subject speaking out loud, whatever s/he sees on screen regarding the content of the application, the tasks that appear on screen, while navigating between tasks or pages, **difficulties encountered, likes/ dislikes and any other errors or difficulties encountered through to task completion**. The patient/caregiver's speech and the screen navigation will be recorded using the mobile phone's in-built recording system (has both audio recording of what participant speaks and video recording of screen).
Observer will note whether tasks are completed successfully or not (effectiveness) and the time taken to complete tasks (efficiency). The audio content will be analyzed for errors related to breaks in flow, patient preferences and dislikes and salient themes will be identified by content analysis.

2.2 System Usability Scale for assessment of subject Satisfaction -

SUS instrument – 10-item Likert scale, items have a range of 1-5. For items 1, 3, 5, 7, 9 one point subtracted from resulting score, for items 2, 4, 6, 8, 10 five points subtracted from resulting score. To get overall satisfaction value, final sum of all scores should be multiplied by 2.5. SUS scores ranging from 0-100. The following cut-offs will be used –
> 70 - acceptable/ good usability, **≥ 85 -** high level of usability or excellent score, **≤ 50 –** Poor/ unacceptable usability.

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3. Usability and Feasibility Assessment

3.1 Usability assessment of Patient/Caregiver for Suhriday app pilot - Baseline

Pt. ID: **Age**: **Sex**: **Date: dd/mm/yyyy**

Residence: **Health literacy**:

3.1.1 Task completion

Outcome of task	Task 1	Task 2	Task 3	Task 4	Task 5	Task 6	Task 7	Task 8	Task 9
Failed to complete task									
Completed with difficulties									
Completed with ease									

3.1.2 Time taken for each task

	Task 1	Task 2	Task 3	Task 4	Task 5	Task 6	Task 7	Task 8	Task 9
Time taken (sec)									

3.1.3 Satisfaction - System Usability Scale

Please choose any one between 1 to 5, where 1 = strongly disagree; 5 = strongly agree

1. I think that I would like to use this app frequently — 1 2 3 4 5

2. I found the app unnecessarily complex — 1 2 3 4 5

3. I thought the app was easy to use — 1 2 3 4 5

4. I think that I would need the support of a technical person to be able to use this app — 1 2 3 4 5

5. I found the various functions in this app were well integrated — 1 2 3 4 5

6. I thought there was too much inconsistency in this app — 1 2 3 4 5

7. I would imagine that most people would learn to use this app very quickly — 1 2 3 4 5

8. I found the app very cumbersome to use — 1 2 3 4 5

9. I felt very confident using the app — 1 2 3 4 5

10. I needed to learn a lot of things before I could get going with this app — 1 2 3 4 5

SUS score:

Open ended questions

i. If you strongly agree that the app was complex, what was complex? Can you specify?

ii. If you strongly agree and think that you need the support of a technical person to be able to use this app, can you please specify which point you needed assistance?

iii. If you strongly agree and think there was too much inconsistency in this app, can you please specify what was inconsistent?

iv. If you strongly agree and find the app very cumbersome to use, can you specify what was cumbersome?

v. If you strongly agree and felt that you needed to learn a lot of things before you could get going with this app, can you please specify, what was that learning you needed to do?

3.2.1 Feasibility interview guide

1) You have used the Suhriday application for about two months. Could you please describe your overall experience using the application and interacting with the study team?

Probes – As they start off, the objective is to elicit their emotions and opinions about the utility of the system. We are looking for a very general response with words like 'difficult', 'cumbersome', 'thankful', 're-assuring', 'useful', 'easier contact with the system' and so on. The following probe questions to be used –

- If it was difficult or cumbersome, please tell us what difficulties?
- If it was helpful, please tell us how it was helpful? Can you remember and tell us about some situations where it helped?

2) What were the changes that happened in your everyday life with regard to caring for your own health due to the education that was given at discharge and the system that we implemented?

Probes - The patient may be asked to imagine and compare with his previous (prior to intervention) care behavior. Specific questions pertaining to symptom and sign recognition, medication taking/planning and management, lifestyle modification to be enquired for.

3) Were you satisfied with the manner in which we (our team) responded?

Probes–We're looking for issues concerning (i) mode of issue resolution (over the telephone, by SMS, etc.) (ii) time taken to resolve the problem (iii) any issues with the solutions proposed such as 'restrict fluids', 'increase the dose of x drug', etc., and (iv) trust in our team.

4) You may have now stopped using the application. Are you continuing to take care of your health in the same manner?

Probe – We need to ascertain whether they are continuing home BP, fluid and body weight monitoring; documenting it and whether they have taken any action if parameters are abnormal.

5) Do you have any suggestions to further improve the mobile application?

Probe – for responses pertaining to ***frequency of entering information***, language, font size, font type, navigation issues, and color.

6) Lastly, do your caregivers or family members have any opinion about the app and the system? Has our education brought about any changes in their lifestyle?

3.2.2 Feasibility assessment of Patient/ Caregiver for Suhriday app pilot - End of study

Satisfaction - System Usability Scale

Please choose any one between 1 to 5 where 1 = strongly disagree; 5 = strongly agree

1. I think that I would like to use this app frequently	1 2 3 4 5
2. I found the app unnecessarily complex	1 2 3 4 5
3. I thought the app was easy to use	1 2 3 4 5
4. I think that I would need the support of a technical person to be able to use this app	1 2 3 4 5
5. I found the various functions in this app were well integrated	1 2 3 4 5
6. I thought there was too much inconsistency in this app	1 2 3 4 5
7. I would imagine that most people would learn to use this app very quickly	1 2 3 4 5
8. I found the app very cumbersome to use	1 2 3 4 5
9. I felt very confident using the app	1 2 3 4 5
10. I needed to learn a lot of things before I could get going with this app	1 2 3 4 5

SUS score:

3.2.3 Acceptability questionnaire (Likert scale):

1. How confident do you feel using the mHealth application?
    a) Not at all
    b) To some extent
    c) To large extent

2. Do you prefer using mobile health application as routine care?
    a) Not at all
    b) To some extent
    c) To large extent

3. Will you be able to teach other patients/their caregivers how to use this application?
    a) Not at all
    b) To some extent
    c) To large extent

4. Would you recommend using mobile health application to patients with similar conditions?
    a) Not at all
    b) To some extent
    c) To large extent

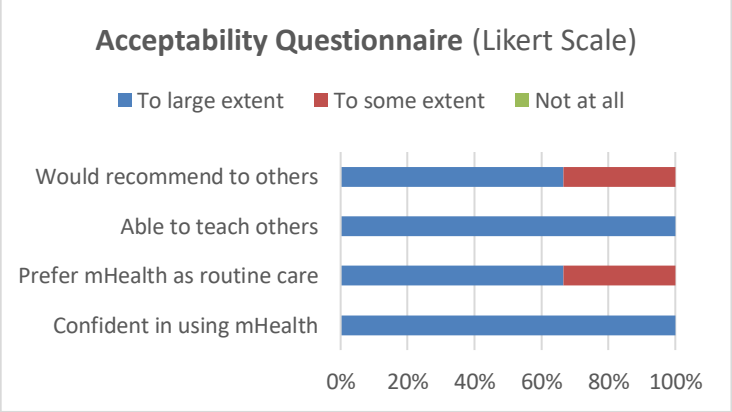


Figure 1: Summary of the results from the acceptability questionnaire

3.2.4 Overall satisfaction of App features, functionality, ease to use

Adjective rating (Circle any one of the below)

a. Worst imaginable
b. Poor
c. OK
d. Good
e. Excellent
f. Best imaginable

3.2.5 Acceptability

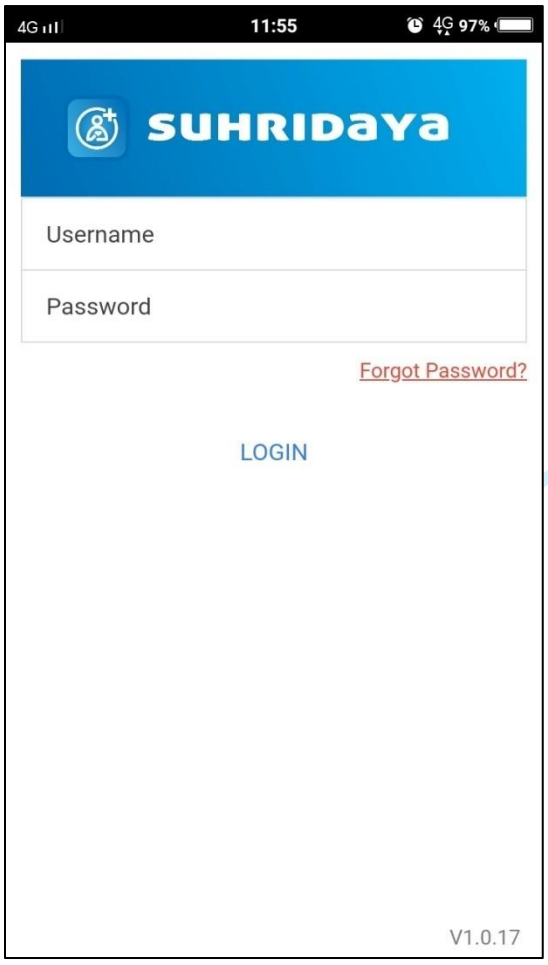
(Circle one of the below)

a. Not acceptable
b. Marginal - low
c. Marginal - high
d. Acceptable

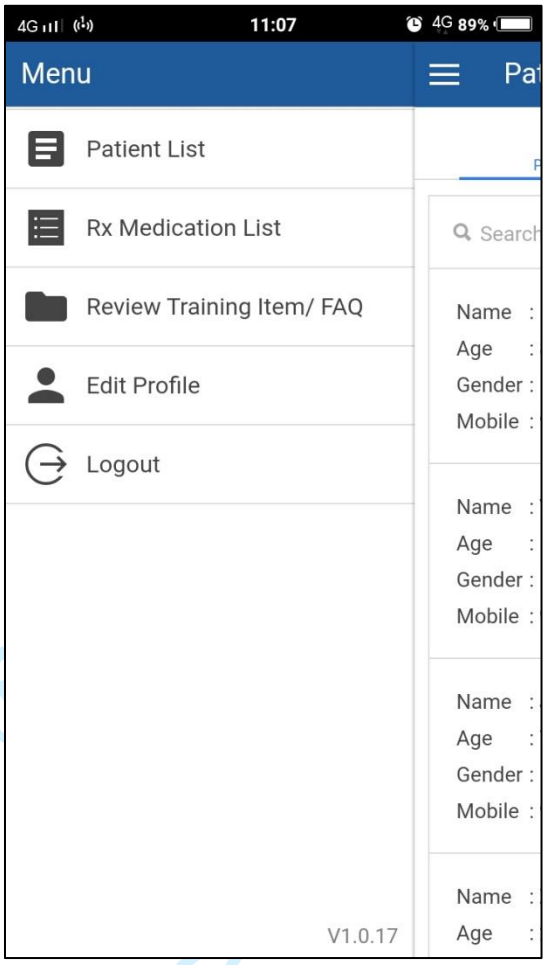
Appendix 2: App design and features

App at nurse interface:

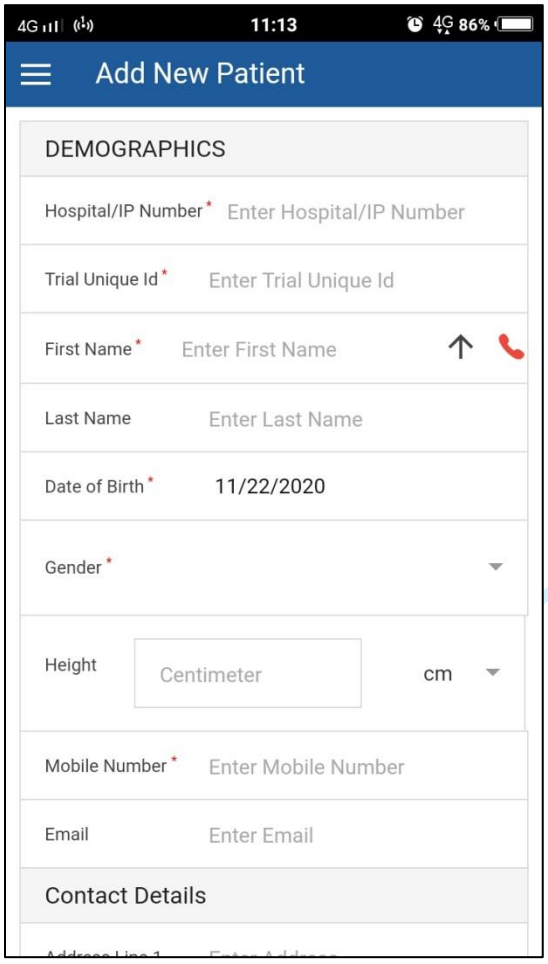
1. Log in page



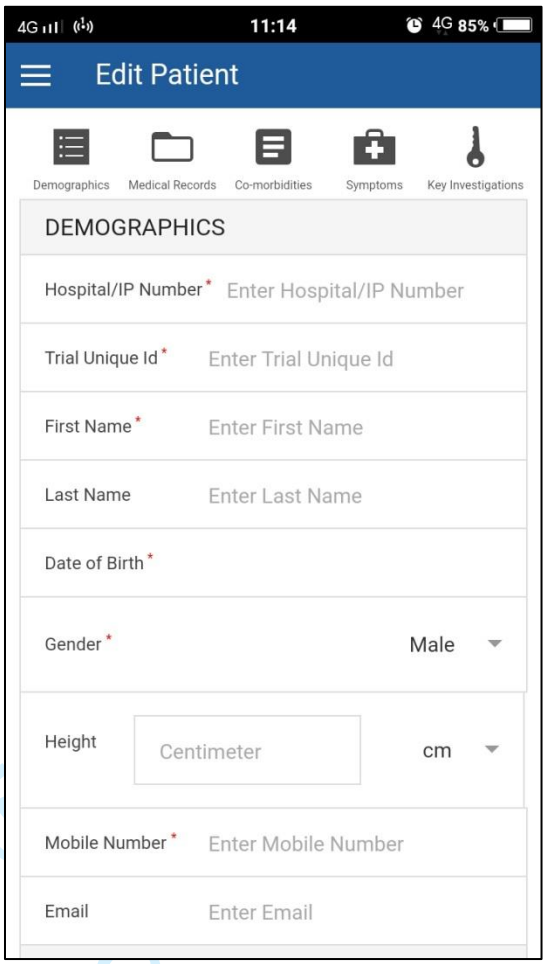
2. Menu



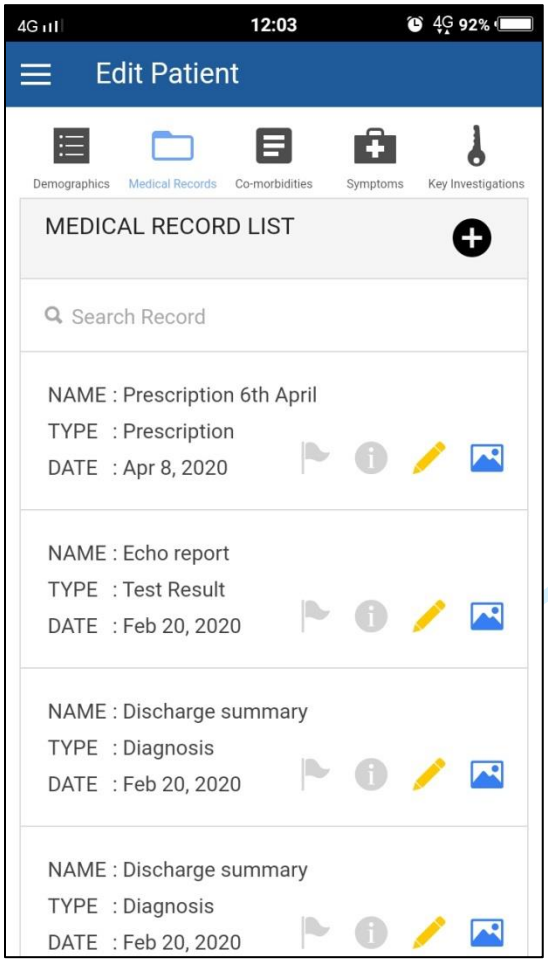
3. Add new patient



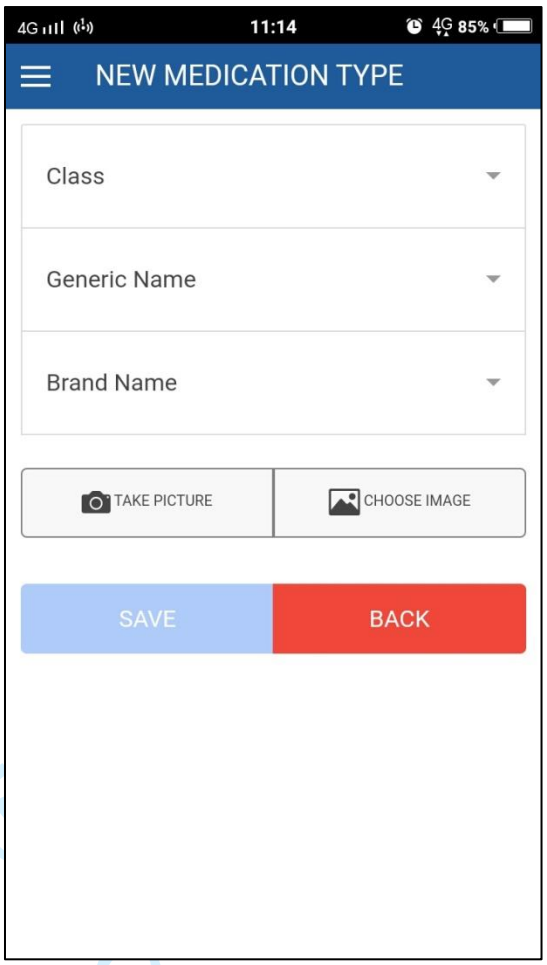
4. Patient detailed profile



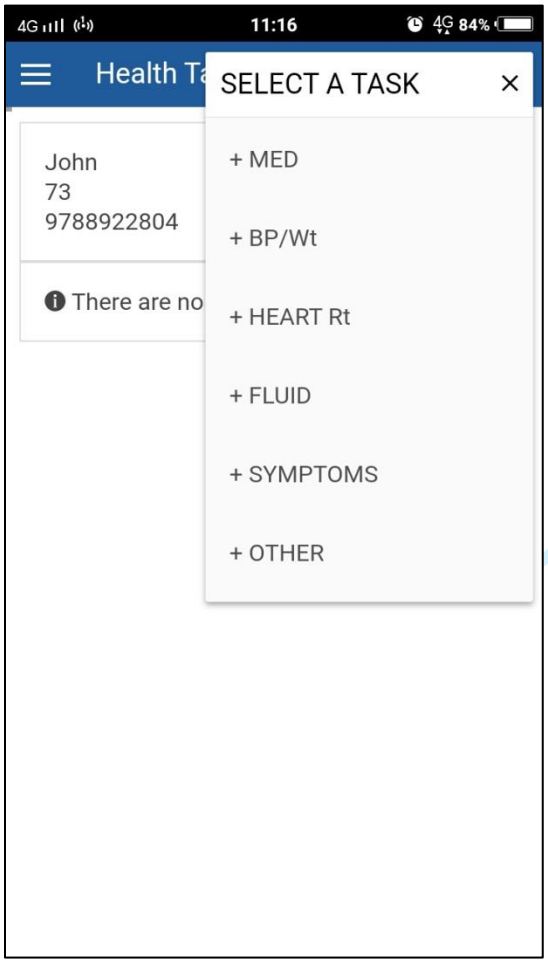
5. Patient medical records



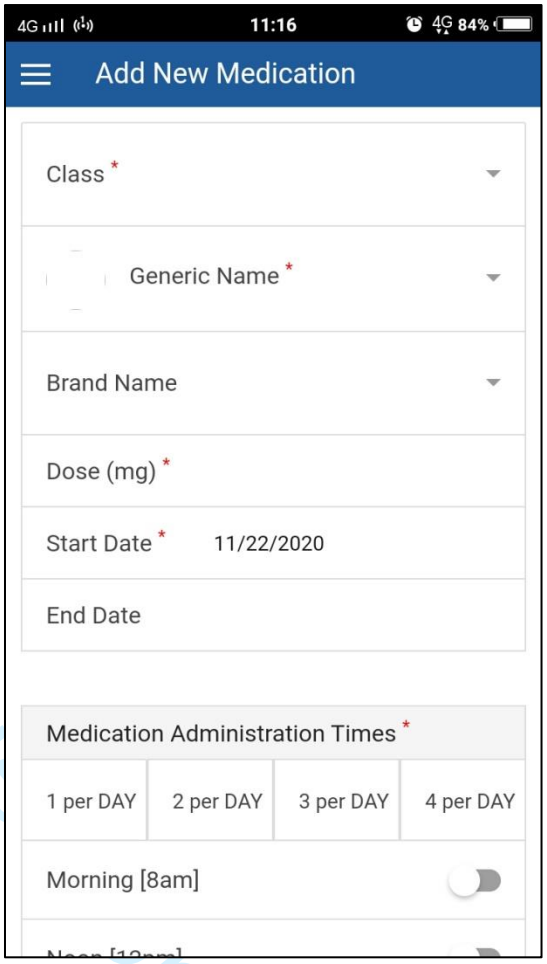
6. To create medication list



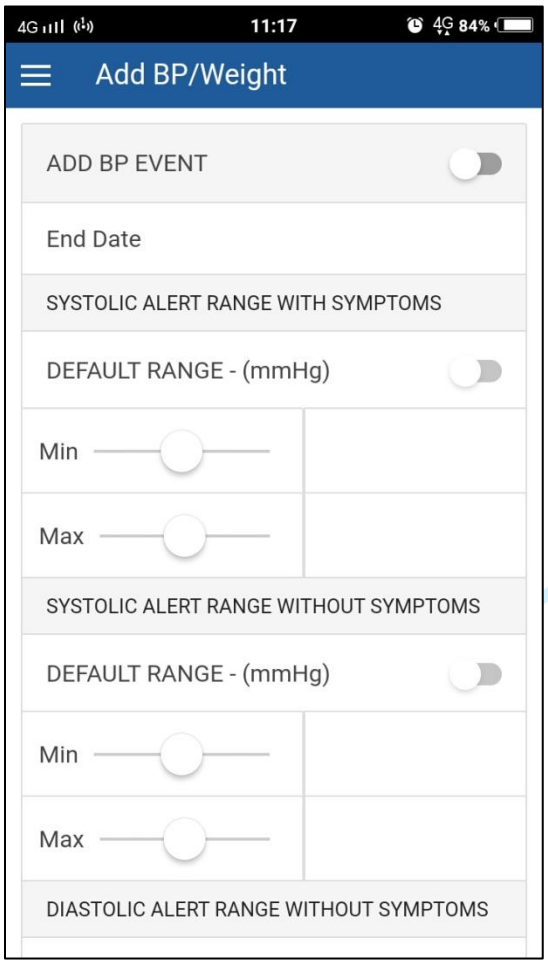
7. Assigning task



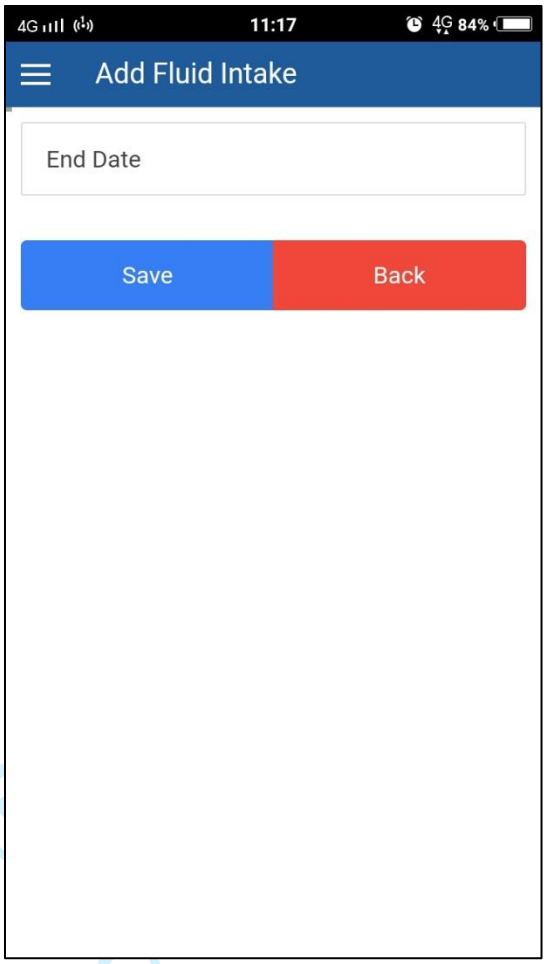
8. Assign medication reminder after filling medication details



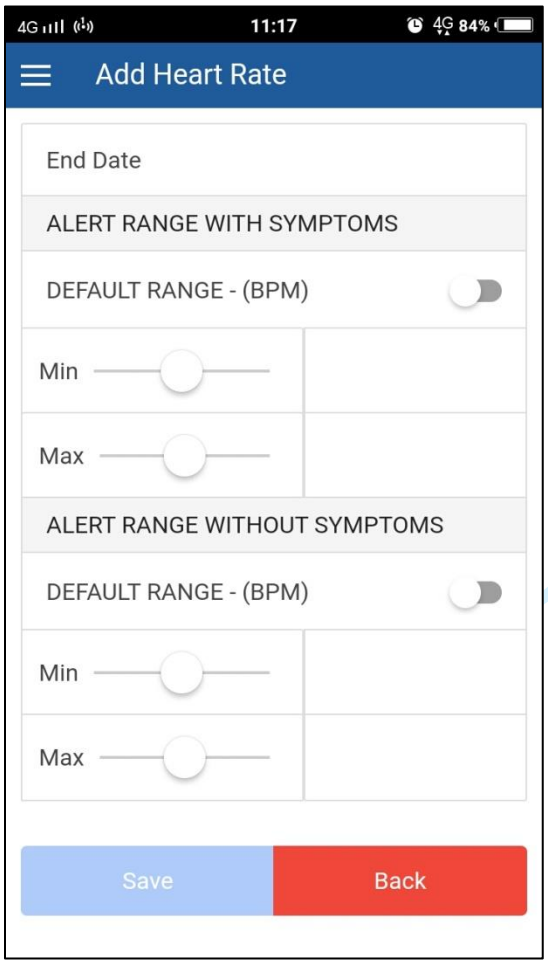
9. Assign BP/weight task



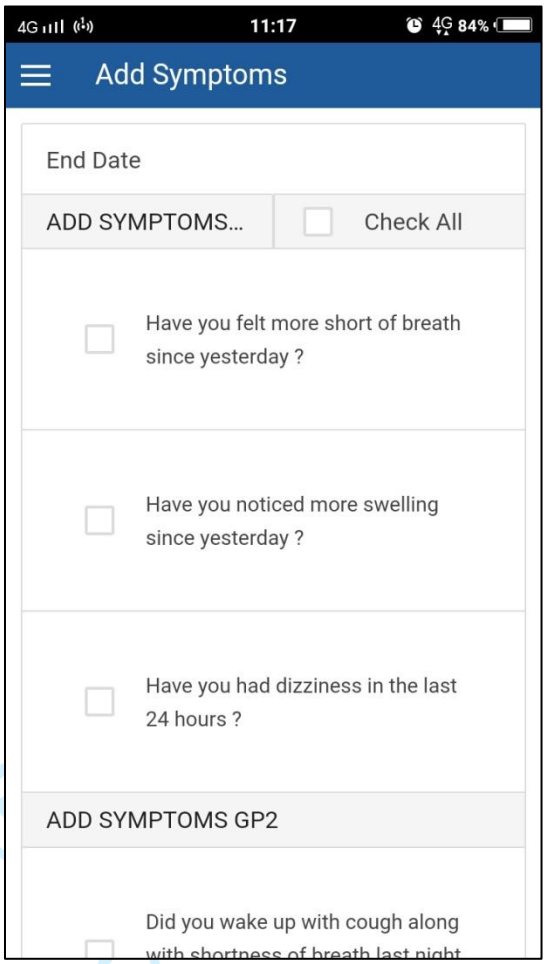
10. Assign fluid intake task



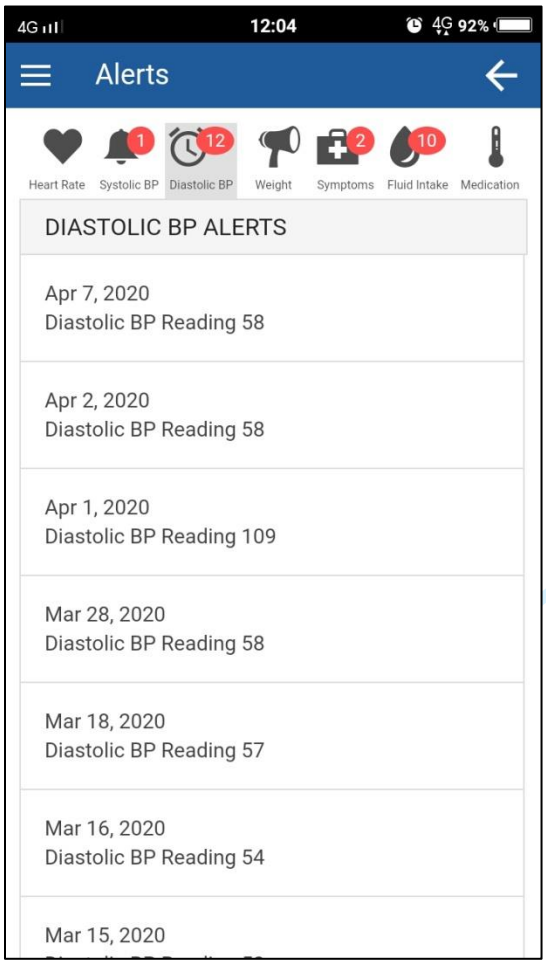
11. Assign heart rate task



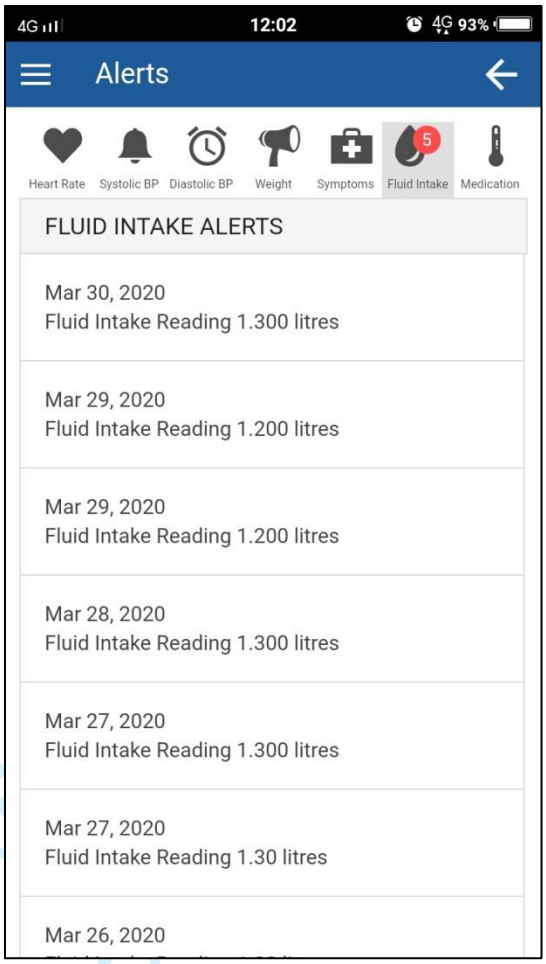
12. Assign symptom/sign monitoring task



13. Recognizing alerts, Diastolic blood pressure



14. Recognizing fluid intake alerts



15. Recognizing symptom/sign alert

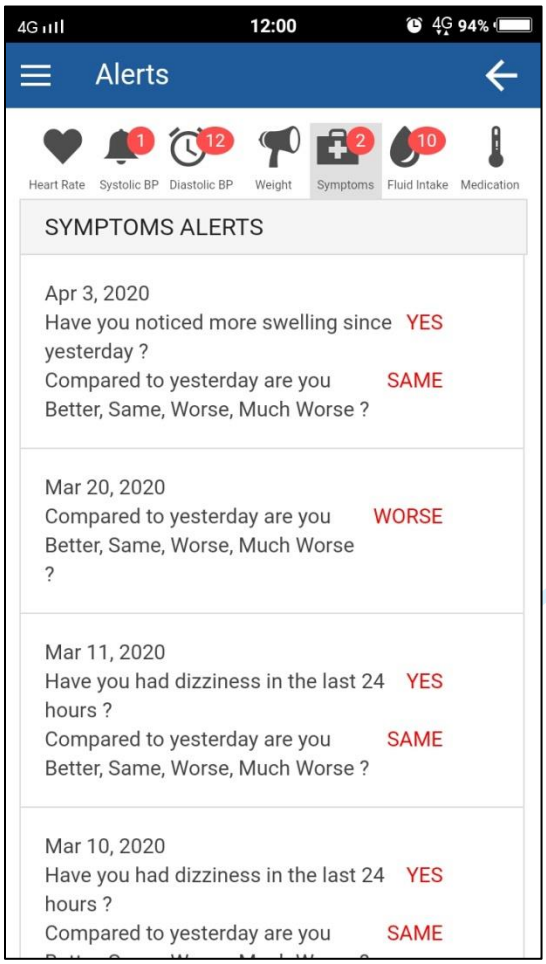
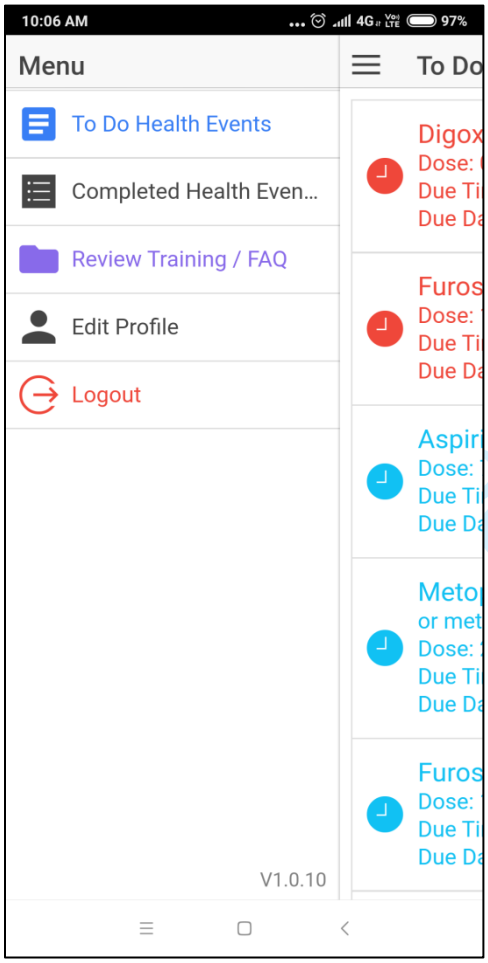


Table 1: Alerts reported by patients/ caregivers:

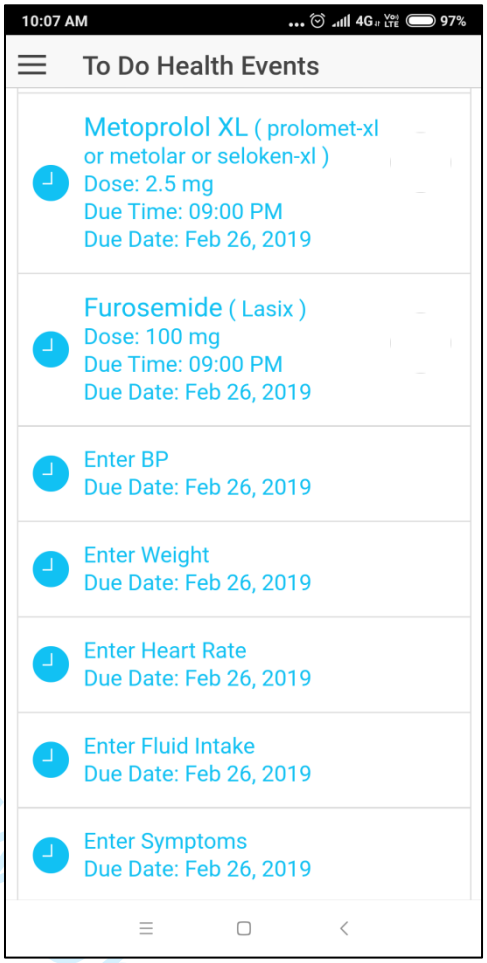
Alerts reported, N = 62	**No. of alerts** n (%)
Fluid intake	36 (58.1)
Variance in diastolic BP	12 (19.4)
Symptom worsening	10 (16.1)
Variance in systolic BP	4 (6.5)

App at patient interface:

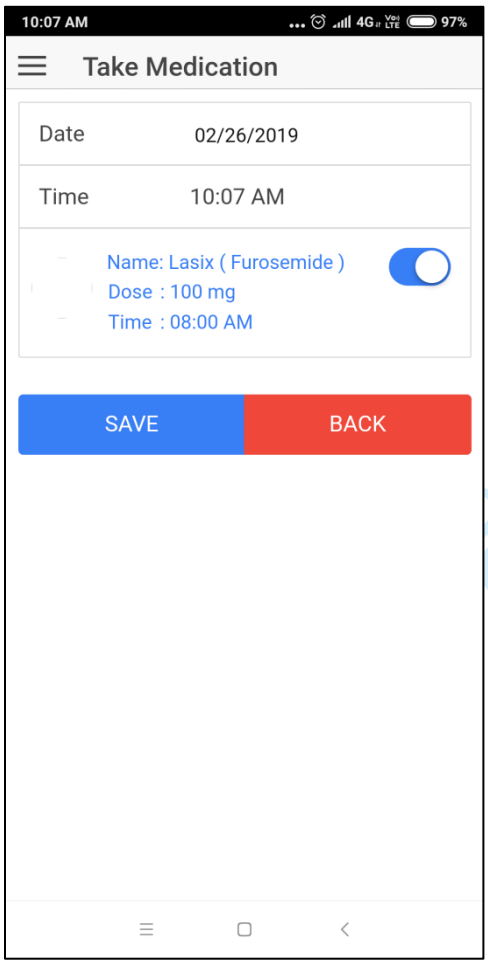
1. **Menu**



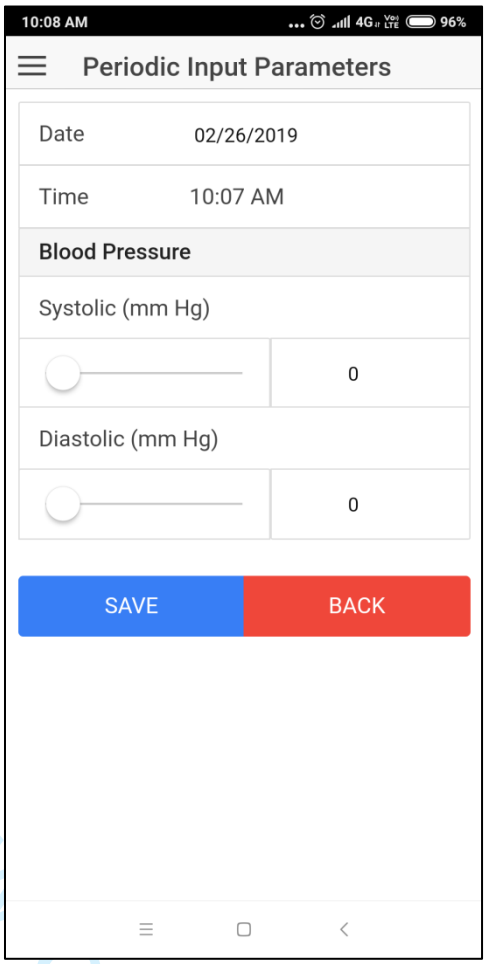
2. **To do health events**



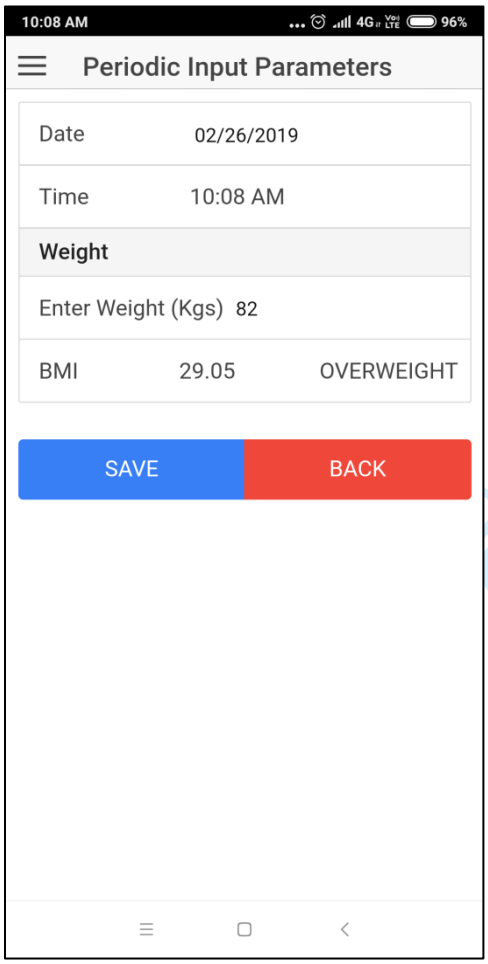
3. Medication taking & acknowledgement



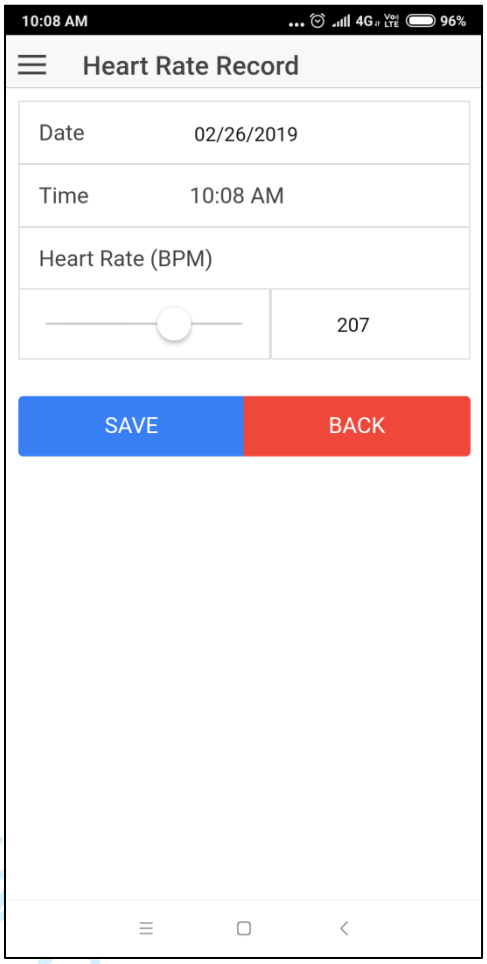
4. Completing task of entering



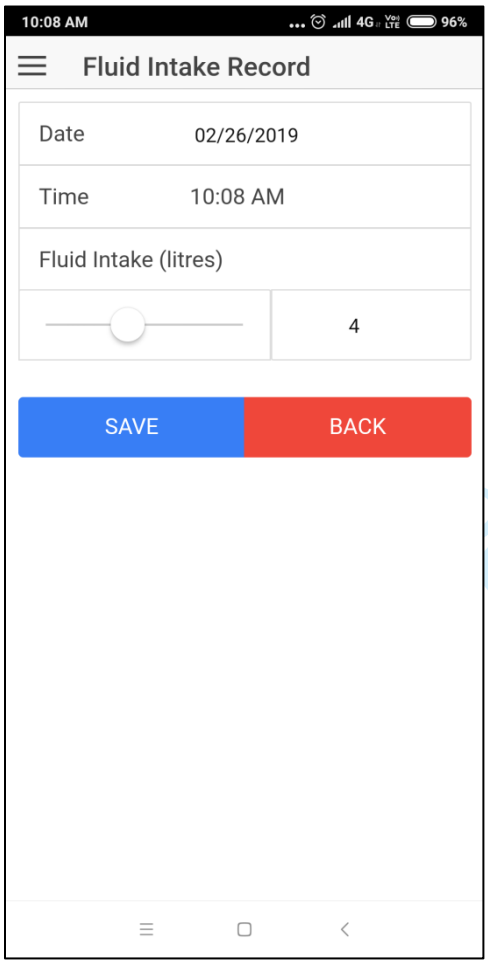
5. Completing task on entering weight



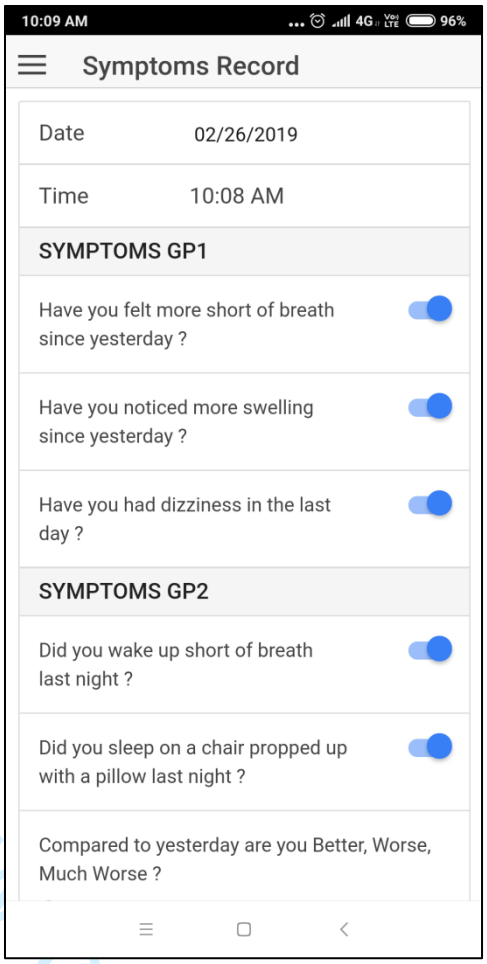
6. Completing task on heart rate



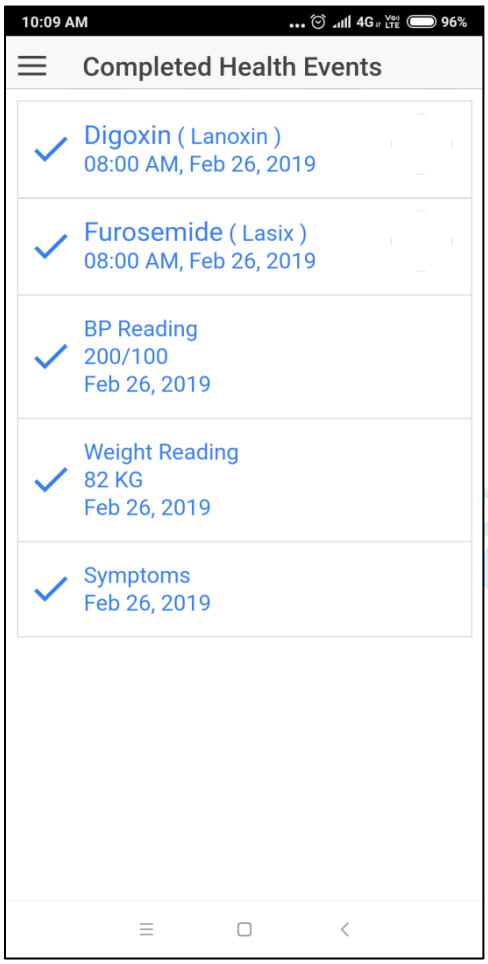
7. Completing task on entering fluid intake



8. Reporting symptoms/signs task



9. Completed health events



10. Viewing uploaded medical record

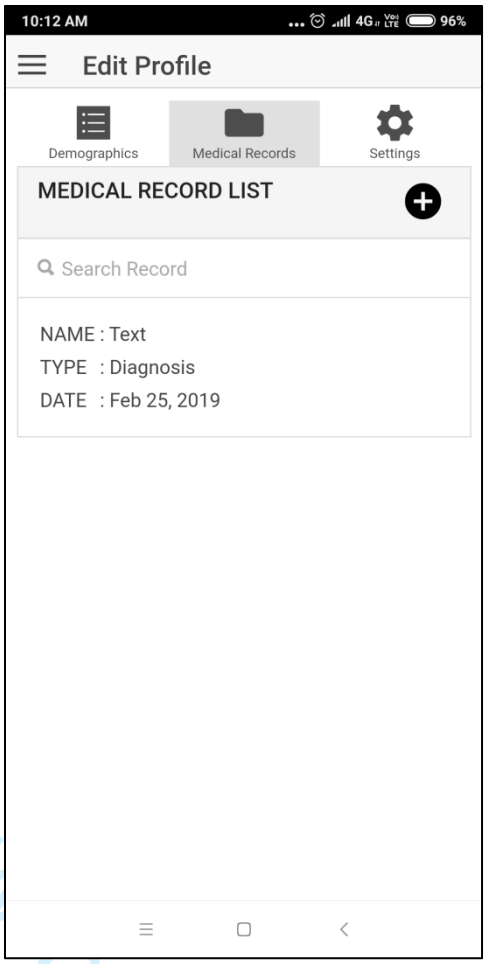


Table 2: App issues at patient/caregiver interface:

Technological issues at patient interface	No. of issues
App download issue	3
Log in issue	1
Medication swipe issue	1
Translations missing (drug names and symptom questions)	1
Non-reflection of medication/ task lists	3
Total	**9**

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Usability and Feasibility assessment of a smartphone application (Suhriday) for heart failure self-care remote monitoring in an Indian tertiary health care setting – A pilot mixed methods study

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Title: Usability and Feasibility assessment of a smartphone application (Suhriday) for heart failure self-care remote monitoring in an Indian tertiary health care setting – A pilot mixed methods study

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Keywords: Heart failure, Information technology, Cardiology

Word count: 3901

Abstract

Background/ Objectives: Remote monitoring as a component of chronic heart failure (CHF) management programs have demonstrated utility of reducing the risk of re-hospitalization and mortality. There is little evidence on mobile health app facilitated remote monitoring in India. We conducted a pilot usability and feasibility assessment of a smartphone-based application (Suhriday) to remotely monitor CHF patients.

Methods: We used a mixed methods design. Usability testing consisted of the think-aloud approach followed by semi-structured in-depth interviews (SSIs) and a satisfaction questionnaire. Feasibility testing was done using acceptability and user satisfaction questionnaires in addition to SSIs. We trained five purposively sampled patients with CHF (based on health literacy and gender) and their caregivers (n=10) in self-care monitoring and app use. Usability was assessed using metrics such as task completion, time required for task completion and user satisfaction using Brooke's System Usability Scale (SUS). Content analysis of the transcripts with deductive coding was performed for both usability and feasibility interviews. The number and types of medical alerts transmitted through the app were captured and escalated to the treating team.

Results: Critical tasks involving (a) opening the app and identifying task list, (b) reporting blood pressure, weight, heart rate and fluid intake and (c) reporting symptoms were completed within 60 seconds by four patients. Median (IQR) SUS score was 85 (75–92.5) indicating high level of usability. There were 62 alerts from four patients over 4 weeks, with 36 (58.1%) excess fluid intake alerts and 16 (25.8%) blood pressure variations being the most frequent. One participant had challenges using the app and was monitored through active phone calls.

Conclusion: Overall usability and satisfaction with Suhriday were good and we were able to remotely manage patients. However, patients with limited health literacy and those facing technological challenges required active structured telephone support.

Strengths and limitations of this study

- To the best of our knowledge, this is the first Indian study among CHF patients to assess usability and feasibility of smart-phone based application for remote monitoring.
- The sampled participants were from diverse socio-economic backgrounds which helped us identify usability and feasibility problems.
- This study is a stepping stone that has informed the design of a large trial with a complex intervention centered on mobile health and task sharing to improve self-care and outcomes in patients with CHF. Based on the characteristics of participant 4 in the pilot study who was unable to use the app successfully, we incorporated structured telephone and WhatsApp-based support as alternate options for remote monitoring.
- Think-aloud approach was conducted for all five participants, however, semi-structured in-depth interviews for usability and feasibility were only possible in three patients out of five. A usability study of the nurse interface was not done. Ideally, this interface would also need to be evaluated to ensure that it is simple and not time-consuming. Feasibility interviews had to be conducted telephonically due to the COVID-19 pandemic.
- Although suggestions regarding the incorporation of a chat or video call option were made by a few participants, these features could not be included in the app due to financial constraints.

Introduction: Heart failure (HF) is a rapidly growing cardiovascular disorder which affects about 38 million individuals worldwide[1]. The INDUS study estimated the prevalence of HF in India in 2016 as 1% of the total population; that accounts for nearly 8 to 10 million patients[2]. Self-care is essential for patients with HF and is comprised of treatment adherence in addition to health maintenance behaviors. Patients need to learn to take medications as prescribed, understand how to monitor signs and symptoms of worsening HF, as well as what to do in response to such symptoms when they occur[3]. A cluster randomized controlled trial conducted in Ethiopia concluded that self-care education significantly improved self-care adherence score among HF patients[4].

The 2022 ACC/AHA/HFSA guidelines for the management of HF documented the role of interventions that aim to improve self-care knowledge and skill, and those that focus on enhancing medication adherence or reinforcing self-care with structured telephone support as being effective in patients with HF. In addition to improving HF self-care significantly, such strategies also reduce the risk of HF-related hospitalization, all-cause hospitalization and all-cause mortality. There is some uncertainty regarding improvement of self-care in patients with HF through educational interventions delivered through mobile health applications[3]. A systematic review and meta-analysis of the outcomes of structured telephone support (STS) or remote telemonitoring as the primary component of CHF management in 8,323 patients demonstrated a 34% risk reduction in all-cause mortality with telemonitoring. Additionally, STS and telemonitoring reduced HF-related hospitalization by 23% and 21% respectively[5].

There is a dearth of evidence on mobile health app facilitated remote monitoring in India. Hence, we developed a mobile-based application named Suhriday ('Well Heart') which has multiple capabilities including facilitating remote monitoring of HF patients (details described below under the app section *Functions*). We intend to use it as a part of a complex intervention in a larger randomized controlled trial. Hence, we conducted a study to assess the usability and feasibility of smartphone-based application (Suhriday) in remotely monitoring patients with heart failure involving caregivers. The information from this pilot study will inform the mHealth component of a complex intervention to improve self-care in HF patients.

Methods: We conducted a usability and feasibility testing of Suhriday, using a mixed methods study. The mixed methods approach which includes qualitative and quantitative methods provides a detailed understanding of user view of the app with regards to immediate engagement as well as attitude and perceptions with the continued use of the app[6].

Setting: This study was carried out in the Cardiology and Internal Medicine departments in both inpatient and outpatient wards of St. John's Medical College Hospital, a tertiary care teaching hospital in South India from March to July 2020.

Eligibility criteria, Sampling and Ethics: The participants for the study include patients with a clinical diagnosis of HF and at least 1 of their caregivers, who consent to use the smartphone app for four weeks at home. We excluded patients who in the opinion of the treating cardiologist had a survival prognosis at baseline of less than three months and those for whom an intervention procedure had been planned in the next one month. We conducted purposive sampling to ensure that at least one patient was female, one had inadequate health literacy, and two were from semi-urban or rural areas. The health literacy scale has three validated questions related to ability to read and understand medical records[7]. Based on the score obtained, health literacy can be classified as low, marginal or adequate.

We obtained ethical approval from the Institutional Ethics Committee of St. John's Medical College Hospital (Reference number: 124/2017) and written informed consent from all participants. During the consenting process, among other elements, we emphasized data confidentiality, especially of the qualitative data. Participants were also assured that they would receive standard care from their treating cardiologist and physician apart from the study interventions. Further, they could make visits to the out-patient department for physician specified follow-ups and to the emergency department in case there were medical emergencies.

Suhriday app: The mHealth application has been developed by One Health Solutions (OHS) Pvt. Ltd., a software company based in Bangalore, India. This application works on both Android and iOS. It uses JavaScript, Hypertext Markup Language (HTML) and Cascading Style Sheets (CSS), and can be deployed for both desktop and mobile versions.

Functions: The application is intended for care providers (nurses and treating physicians) to remotely monitor key parameters of patients with a primary diagnosis of HF who are on treatment. The application will also be able to generate reminders for medication adherence based on information entered by a healthcare provider nurse into the application at discharge. The patients or their caregivers, after measurement of key parameters (blood pressure, heart rate, body weight and fluid intake) using validated instruments, will enter the same data into

the app. The app also has a validated questionnaire for symptom/sign reporting[8]. It can identify and alert the study nurse when there are outlying values. The nurse will be able to view these alerts and escalate them so that the treating team can then take appropriate action (e.g., order a titration of doses of high ceiling diuretics). The security features of this system include encryption of data on the device, user authentication and a secure Hypertext Transfer Protocol-based data transmission system. We used the Apache CouchDB database on a secure web server and the backend data were stored securely in the Cloud.

Study Procedures:

Step 1: Training a study nurse – We recruited a nurse with a master's degree. She was trained for two months on heart failure by three physician investigators using lectures and bedside demonstration to recognize worsening signs and symptoms as well as medications for HF. She was educated on the importance of self-care in HF including monitoring, maintenance and management. Furthermore, she was empowered to train patients and caregivers to measure blood pressure, fluid intake, check weight and use the Suhriday app (detailed in *Appendix 1 - Table 1*).

Step 2: Training for patients/caregivers – Patients and their caregivers were educated on salient aspects of HF self-care. Participants received training in measuring blood pressure, fluid intake and weight from the study nurse. They were also trained to recognize worsening signs and symptoms of HF. Following this, detailed app training to perform the tasks assigned was provided to the participants (Tasks detailed in *Appendix 1 - Table 1*).

Step 3: Setting for usability testing at the patient interface – The patients/ caregivers were asked to measure their blood pressure, heart rate and body weight in the presence of the nurse. Then they were instructed to open the link from the message received, to download the app and open the application. The patients or their caregivers were asked to perform the think-aloud exercise while performing and completing the in-app tasks. (Usability measures definitions detailed in *Appendix 1*)

Step 4: Usability testing at the patient interface – To assess usability, we equipped five patients or their caregivers with the smartphone-enabled mHealth application, Suhriday, and used the following methods:

Think-aloud approach: The purpose of this approach was to capture ease of use and an understanding of potential interface issues. Patients/ caregivers were instructed to "think aloud" (i.e., verbalize their thoughts) as they interact with the Suhriday app while the mobile screens were recorded through the screen recorder option of Android phones. The study team observed and made notes about completeness of tasks with patients/ caregivers. We measured effectiveness of task completion by noting whether tasks were (i) completed with ease, (ii) completed with difficulty requiring intervention from the study nurse or (iii) not completed. We also measured efficiency by noting time taken to perform tasks using the mobile screen and/ or audio recordings[9-11].

Qualitative semi-structured in-depth interviews: At the end of think-aloud approach, we interviewed the patient and caregiver as a dyad to capture the acceptability and barriers of the app and suggestions for improving its features. Details about qualitative data collection have been described below.

Satisfaction measurement: Patient and caregiver's satisfaction was measured utilizing Brooke's System Usability Scale (SUS). The SUS has been evaluated for validity, reliability, and sensitivity[12-16]. Scores were calculated according to Brooke's guidelines[12] and is detailed in *Appendix 1*.

Step 5: Feasibility study in the context of technology development is an analytical method used to determine if different components of a project can perform together in order to create a technically and operationally viable concept[17]. The guidance from the Medical Research Council (MRC), UK on the development and evaluation of complex interventions recommends an early phase of assessing feasibility prior to a full evaluation. Patients and their principal caregivers who participated in the usability testing were provided a smartphone enabled with the Suhriday app, a BP monitoring device and an LCD weighing scale. They were asked to measure BP and body weight every morning for a minimum of 4 weeks and to report measured values using the application. In addition, they were asked to monitor and report symptoms or other signs through the app.

We provided the study nurse with a smartphone onto which the Suhriday application was installed. The study nurse monitored the patients for a minimum of 4 weeks and made telephone calls to address alerts received for variance in values of measurements and symptoms/signs (detailed in *Appendix 1 - Table 2*) in addition to weekly structured telephone follow-up calls. During the course of the study, the nurse maintained a paper dairy and an electronic diary (MS Excel Issue Tracker) to capture type of issue (medical or app-related), details of medical issues, person the issue was escalated to, and description of resolution.

Alerts and resolution process: The study nurse was the primary recipient of the alerts through the Nurse interface of the Suhriday app. She would call patients and ask them additional questions related to their symptoms from a pre-prepared list by the investigators. Salient data retrieved including present complaints, past history, key investigation parameters and the current list of prescribed medications would then be informed to the study physicians. General medical escalations were attended by the Internist or the Clinical Pharmacologist (medically qualified in India), while HF symptom-related queries were escalated to the on-call Cardiology resident. If more information was required, the nurse would be asked to make an additional call to gather the same. Based on the physicians' assessment, the escalation would either be (i) resolved over the phone, (ii) advised an out-patient visit for follow-up, (iii) advised an emergency room visit, or (iv) advised hospitalization following an emergency room or out-patient visit**.**

A feasibility study conducted with qualitative research methods can help identify fundamental problems with the intervention workflow process or trial conduct[18]. Hence, after 4 weeks of continuous use of the application, we conducted semi-structured feasibility interviews with the patients or their caregivers. We used a feasibility interview guide for this purpose (*Appendix 1 - Feasibility interview guide*). The interviews were audio-recorded, transcribed and translated to English. Satisfaction was measured utilizing the SUS instrument.

Sample size, Data collection and Analysis: We carried out the usability and feasibility testing in five participants as it has been demonstrated that this can detect over 80% of usability problems[10]. For usability analysis, we noted effectiveness (task completion), efficiency (time

required for task completion, noted through the screen recorder and/or audio recording) and user satisfaction (SUS score)[9-12,19]. Interviews were conducted (for usability – in the Cardiology Research Office, for feasibility – telephonic) by KD and BB with the help of JI, and recorded using an audio recorder. The interviews were transcribed verbatim and then translated into English by a research assistant. This was verified for content accuracy by either KD or BB. Transcripts were manually analysed using content analysis approach and deductive coding for acceptability and barriers related to app use, as well as suggestions for improving app functionality. For feasibility testing, while we intended to interview all five participants, we were only able to interview three due to the COVID-19 disruptions. Content analysis codes from these interviews were categorized as those indicating the overall experience, interaction with study staff, impact of training on HF self-monitoring, satisfaction with the team and suggestions to improve the app. We measured user satisfaction using the SUS instrument at the end of the study. Components of acceptability (not validated) were measured using a Likert scale.

Role of public and patient involvement: While the public was not involved in the study, patients and their caregiver's feedback on the utility and ease of app usability were investigated in detail as described in the results.

Results: We conducted this study from March 2020 to July 2020 and recruited five patients.

1. Patient demographics and Models of app use: Of the five patients, three were from urban areas, one from semi-urban and one from rural India. Clinical features such as type of HF – reduced [HFrEF] or preserved ejection fraction [HFpEF], New York Heart Association [NYHA] class at recruitment and etiology were captured (Table 1).

Table 1: Patient demographics clinical features and models of app use

Patient demographics	Clinical features	Models of app use
Patient 1, 20-29 years, female	HFpEF, NYHA II, Hypertrophic obstructive cardiomyopathy	Patient directly trained and uses the app herself
Patient 2, 70-79 years, male	HFpEF, NYHA II, coronary artery disease, hypertension, type II diabetes mellitus	Patient maintains paper diary, sends photos of monitoring data through WhatsApp® to caregiver, who reports it on app
Patient 3, 70-79 years, male	HFrEF, NYHA II coronary artery disease, hypertension, type II diabetes mellitus	Caregiver was trained initially; caregiver trained patient over 10 days, who later uses it himself
Patient 4, 50-59 years, male	HFrEF, NYHA II coronary artery disease, hypertension, type II diabetes mellitus, stroke	Initial apprehension and reluctance to use technology; Study nurse trained slowly, later was confident to use

Patient demographics	Clinical features	Models of app use
Patient 5, 50-59 years, female	HFpEF, NYHA II hypertension, type II diabetes	Patient directly trained and uses the app herself

2.1 Usability, Task completion: The task completion results are presented in Figure 1. The critical tasks involving (a) opening the app and identifying task list (task 1), (b) blood pressure, weight, heart rate and fluid intake reporting (tasks 3, 4, 5, 6 respectively) and (c) symptom reporting – understanding and reporting (task 7) were done easily. Majority of the tasks (tasks 1, 3, 4, 5, 6 and 7) were completed with ease by four (80%) of the participants. Task 8 (viewing shared medical records) and task 9 (sharing medical records) were reported as the most difficult to complete. Among five participants, two (40%) and one (20%) completed tasks 8 and 9 respectively, both of whom had adequate health literacy.

Errors: One participant made the error of swiping across instead of tapping on task 2 (acknowledgement for medication reminder). Majority of the errors were faced with a single participant (Participant 4, male, rural, inadequate health literacy), who completed task 2 with difficulty, as the drug names were not translated to his native language, Tamil. This participant also took 7 attempts to complete task 3 (entry of blood pressure values) due to the inability to locate the number mode after locating the area to enter the value as he forgot the instruction. He completed task 6 (entry of fluid intake the previous day) after three attempts due to difficulty in locating and placing the decimal point.

2.2 Usability, Time taken per task: The time taken per task results are presented in Figure 2. For one participant (Participant 3), we did not record the think-aloud approach through the screen recorder as the caregiver of the patient was not comfortable with it. We were not able to record the time taken to complete tasks through the audio recording, as the tasks were not performed systematically. The study team observed and made notes on completeness of tasks for this participant. Participant 4 who made the most errors took the longest time.

2.3 Usability, Satisfaction: The median (IQR) SUS score for usability of all the five participants was 85 (75–92.5), indicating high level of usability. Participant 4 however had a score of 32.5 indicating poor usability.

2.4 Qualitative Interview: Among five participants who completed think aloud process with the app, interviews were conducted with three participants (reasons explained in *Discussion*) to determine acceptability, barriers of use and suggestions for improvement (Table 2).

Table 2: Acceptability and barriers of the app, suggestions for improving app features at baseline

Themes	Codes	Extracts

Acceptability of the app	**Effective, useful for monitoring**	**"**This app is ***very good*** for like my kind of HCM people, congestive heart failure people. This is ***very effective*** and what I feel is every time it will be ***like awareness*** for you people, also for us also." (Patient 1, female)
	Very easy, very useful **Monitor easily**	**"**This is there we can be with a ***regular kind of checkup*** day by day" "And this is ***very easy to use***" "I guess this app is very useful to everyone ***easily*** we ***can monitor***" (Patient 1, female)
		"The performance of the app is ***very good*** and the reaction time most the opening of the ***app and individual components within*** that are all ***very good***" (Caregiver of Patient 3, male)
	Useful reminder for medication taking, easy to use	"I open it and I go to all of the tablets and medication, which have to be taken, which are in red. I open each one of them and I complete them and click on save and this ***hardly takes me any time***" "This was also fine the ***weight reading, fluids intake*** and all that was **fine.**" (Caregiver of Patient 2, male)
Barriers of the app	**Small font**	"Instead of entering values in mobiles just I am telling see instead of entering ***small small (font size) values***" (Caregiver of Patient 2, male)
		"This one is a bit of a problem, because for me ***to type these numbers are really small***" (Caregiver of Patient 3, male)
	Unclear images	**"**It (discharge summary image) is very **unclear**" (Patient 1, female, high health literacy)
Suggestions for improving app functionality	**Alarm feature**	"It would be nice if anything turns red that the ***phone rings or alarms*** are there." (sic) (Caregiver of Patient 3, male)
	Adjustment scale feature	"These adjustment bars they are actually of no use. Because the spacing is really small." "The ***scale (BP)*** have (sic) to be completely ***different representative***" (Caregiver of Patient 3, male)
	Help guide	"The symptoms what I noticed was, if some patients who may want to understand, what is better, what is much worse mean" "like on what basis do I tell much better? If there is a ***help guide*** or something like that" (Caregiver of Patient 3, male)

Remote monitoring through Suhriday app: Overall, patients were managed remotely throughout the 4-week evaluation period with no unplanned re-hospitalizations due HF or deaths.

Alerts, number and type: There were a total of 62 alerts (detailed in *Appendix 2 - Table 1*) from four participants (snapshots of alerts in *Appendix 2*). Alerts related to fluid intake (58.1%), variance in diastolic blood pressure (19.4%), HF symptom worsening (16.1%) and variance in systolic blood pressure (6.5%) were received at nurse interface. Patients were counselled over the phone for fluid intake alerts. For alerts related to BP, the nurse ascertained whether patients were measuring it correctly. If the value was deemed accurate and uncontrolled, it was escalated to the study investigators. Patient 4 hardly used the app, but reported issues through structured telephone support. This was monitored actively by the study nurse and there were no HF related escalations over a 4-week period. Overall, five issues were remotely managed for three out of five patients. HF related escalations led to up-titration of loop diuretics three times, and general medical queries were addressed for constipation and iron deficiency anemia.

Resolution process and time (for alert-led issues and other medical issues): The study nurse made 21 telephone calls to Cardiologists and Internists/ Clinical Pharmacologist to resolve issues regarding HF symptom/sign related alerts, general medical queries, prescription confirmation and drug dose queries, as well as blood pressure variations. Majority of the medical issues were resolved within 60 minutes.

App issues at Nurse interface: These were totally 29 in number. Difference in getting alerts with two different phones (8), log in issues (5), alert sync issues between two different phones (3), alert sync lag from patient to nurse (2) were the predominant issues at the nurse's interface. App issues at patient interface are summarized in *Appendix 2 - Table 2*.

3.1 Feasibility Interview: We conducted telephonic interviews with three out of five participants (reasons explained in *Discussion*). Findings are in Table 3.

Table 3: Feasibility of the app and impact of pilot intervention

Themes	Codes	Extracts

Overall experience using app	**Good improvement, daily monitoring**	"I have ***good improvement*** ma'am with this app. What exactly it is means (sic) like from this I came to know what is my blood pressure, ***day to day routine*** thing and the heart rate also ***I maintained***." "Plus, the water intake and medicines like what time to what time like it will be mentioned in that." (Patient 1, female)
	Good experience, maintained health well, reduced hospitalization	"In this critical situation (COVID-19 situation) this is the best option". "It has become a habit, daily everyday morning we have to do all these things" "People are not able to come to the hospital so we can give him then through phone call or any video conference or video call something or this kind of app will be helpful in future also going forward" (Caregiver of Patient 2, male) "I got lot of ***good experience***" "I ***maintained myself very well***." "Usually, I ***used to get hospitalized*** a lot but ***now it has become less***." (Patient 1, female)
	Very positive, friendly to use, part of routine	"I would say the experience have been ***very positive***. What I mean by positive is the app is really ***friendly to use***." "And once you start using this, it becomes the ***part of your routine***." (Caregiver of Patient 3, male)
Interaction with study staff	**Change in treatment plan, helpful**	"I was not keeping well, my legs got swollen, my stomach got swollen, so I used to contact mam" "according to the doctors she ***used to tell me the prescription***" "There was ***lots of help*** sir" (Patient 1, female)
	Provided solutions	"There were 3 or 4 occasions where the ***issue was to be escalated*** right" "we contacted you and you ***provided us with a solution***" (Caregiver of Patient 3, male)
	Dedicated, committed, knowledgeable, professional and patient -friendly	"***Dedicated*** to this and ***committed*** and you were ***very knowledgeable*** and you were ***highly professional*** and ***patient friendly***." "Immediate triage that is the most significant aspect of this." (Caregiver of Patient 3, male)

Impact of training on HF self-monitoring	**Training on symptoms, signs of worsening led to awareness and improved self-monitoring**	"From this app I came to know that, particularly I ***used to check*** all these things (blood pressure, weight)" (Patient 1, female, high health literacy) "All the symptoms you people explained me from that I ***got lot of education***". "I have ***improved a lot*** sir, like I used to know what exactly happens if I take lot of fluids." (Patient 1, female) "It is improved. On daily basis also he is taking care of all" (Caregiver of Patient 2, male) "It had ***great value***. I will tell you why doctor." "He used to drink as much water as possible" "This ***whole weight management aspect*** we never actually took into consideration" "swelling of legs as an ***indicator to overall heart condition***" "being aware of what is the ***threshold level for BP***" (Caregiver of Patient 3, male)
Satisfaction with the team	**Suggestions and support to solve problems** **Quick resolution of problems, perfect**	"I had many times problems, I used to contact you, you will be suggesting, you will be contacting doctors, give me ***proper prescription***" "You have ***supported me a lot***." (Patient1, female) "***As soon as possible you used to contact*** me and you used to suggest me" "the ***anxiety aspect was removed***." "I think it was ***perfect***." "On a scale of ten I would give it 11" (Caregiver of Patient 3, male)
After stopping app use	**Self-maintenance**	"I'm noting down in a book and I'm WhatsApping (sic) you. ***Everyday*** I'm maintaining" "***In my one book I'm maintaining***." (Patient 1, female) "I am doing. Up to date I am doing. Till today" (Patient 2, male)
Suggestions to improve the app	**Video call option** **Chat tool within app**	"If it is a ***video call*** it will be better" (Patient1, female) "Can't your app actually have a ***chat interface*** wherein I can post?" (Caregiver of Patient 3, male)

3.2 Feasibility, SUS, overall satisfaction, acceptability: Feasibility results among the three participants showed a median (minimum, maximum) SUS score of 92.5 (87.5, 100) which represents high usability with an overall satisfaction adjective rating of 'excellent' (2 participants) and 'best imaginable' (1 participant). In the context of acceptability, all three participants felt that they were confident in using the Suhriday app and would be able to teach others to do the same to a large extent (detailed in *Appendix 1 - Figure 1*).

Discussion: This is the first report from an Indian setting on how patients with HF respond to a remote monitoring application, pain points experienced, symptoms/ signs that resulted in escalations, and how they were resolved.

The usability assessment (think-aloud approach, in-depth interviews and SUS) of Suhriday demonstrated satisfactory usability for remotely monitoring among four of the five participants in our study. Most of the critical tasks were completed with ease (Figure 1) which was comparable to the usability assessment of the HeartMapp study[20]. IQR for tasks 1, 2 and 3 were within one minute and for tasks 4, 5 and 6 were well within half a minute. Our findings from Table 2, Figure 1 and 2 reflects that the app is easy to use.

However, participant 4 completed majority of the critical tasks with difficulty, took the longest time, made many errors, and had poor usability in contrast to rest of the participants. This may be due to inadequate health literacy levels and educational attainment. Both patient and caregiver had initial apprehensions and were reluctant to use technology. Though they had smartphones, they were only accustomed to making calls. Although we trained them patiently and tried to build confidence, they could not sustain performing daily tasks and instead maintained manual records. Active structured telephone support was imperative in this case. The insights gained helped us plan contingencies for the randomized controlled trial, where we planned to incorporate active structured telephonic and WhatsApp-based support among patients who preferred not to use the app.

A decision-making algorithm for symptom management was developed based on the queries and alerts received. Escalations led to changes in prescriptions for participants 1 and 3. During the COVID-19 pandemic lockdown and heavy restriction imposed on movements, all patients were managed remotely through the app and by structured telephone support to manage issues. During remote monitoring, we did not have any unplanned hospital readmission or unplanned emergency/outpatient visit related to HF symptom/sign worsening when compared to a study by Heiney et al having one hospital admission and an emergency OPD visit during a 6-week study[21].

During the feasibility assessment, interviewed participants expressed that the app was user-friendly, became part of their routine, helped maintain health and reduce hospitalization. They also expressed that training led to awareness and improved self-monitoring. Participants opined that they were satisfied with the team's turnaround time to resolve issues quickly. Having video call option and chat tool within the app were a few suggestions made towards improving the app (findings from Table 3).

The limitation of the study was that in-depth interviews for usability and feasibility were conducted in only three out of five participants. The usability interview for Participant 4 could not be conducted initially due to in-hospital constraints, and later due to COVID-related disruptions. On the other hand, the feasibility interview was not conducted as he had not used the app. Another limitation was that no caregiver details were collected.

Users are the first citizens of a technology; hence their personal technological experiences are principally important[22]. Variations in age, gender, affluence and profession among patients and caregivers emerge as critically important factors in technological experience and engagement[23,24]. The issues that participant 4 faced, for instance, might be attributed to his social variables. Such cases are more likely to be encountered in communities where patients and caregivers are aged or ageing, and consequently digitally unfamiliar. It is well-evidenced in literature that ageing affects familiarity and fluency with digital devices[25], and the digital divide hinders the elderly from using technology to enhance their quality of life[26,27]. Other

studies [28-30] have shown evidence that factors such as self-efficacy, cognitive decline, declining motor skills and disorientation with hypertext structure heavily influence Information and Communication Technologies (ICTs) among the aged.

This pilot study helped inform a randomized controlled trial designed to improve self-care and remote monitoring in HF patients utilizing a smartphone application in a lower middle-income country setting.

Conclusion: This study demonstrated that Suhriday was acceptable and easy to use among most patients. Health literacy and preferences need to be considered while enrolling Indian patients into mHealth based intervention programs. This study has informed the design of an ongoing multicentre trial with a complex intervention centered on mobile health and task sharing to improve self-care and outcomes in patients with chronic heart failure.

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Data sharing: Data are available upon reasonable request. Currently, we have not deposited the raw data in an open access repository. However, we are willing to share the raw data with all interested investigators. Interested investigators may send an e-mail to corresponding author with the brief write-up of the research question, objectives and ethics approval for the proposal.

Contributors: BB, KD, JI, SJ, XD and KS contributed to the conception and design of the study. VK, SJ, JI and BB were involved in acquisition of data from recruited participants. BB, RP and KD performed the analysis. BB, KD, JI, SJ, KA, KS and VK were involved in interpretation. BB drafted the manuscript, with revisions from KD, JI, SJ, KA, RP, KS, VK and XD. All authors declare no conflicts of interest.

Ethical approval statement: We obtained ethical approval from the Institutional Ethics Committee of St. John's Medical College Hospital (Reference number: 124/2017) and written informed consent from all participants.

Figure 1: Task completion rate for usability – effectiveness

Figure 2: Box and whisker plot for usability efficiency measure, inter quartile range

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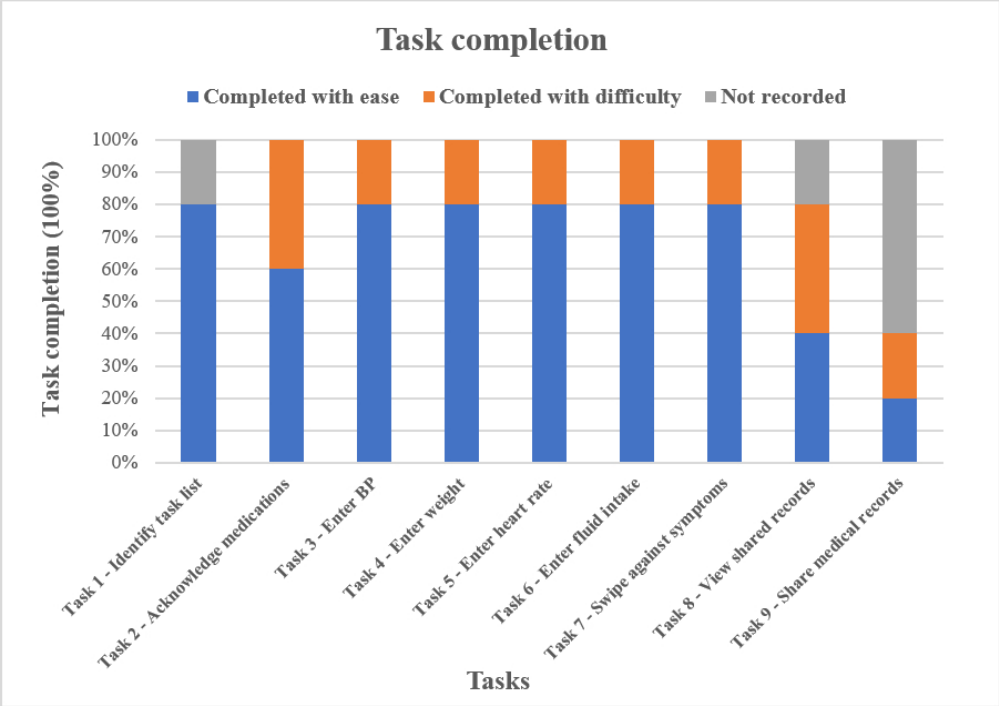

Figure 1: Task completion rate for usability - effectiveness

238x169mm (96 x 96 DPI)

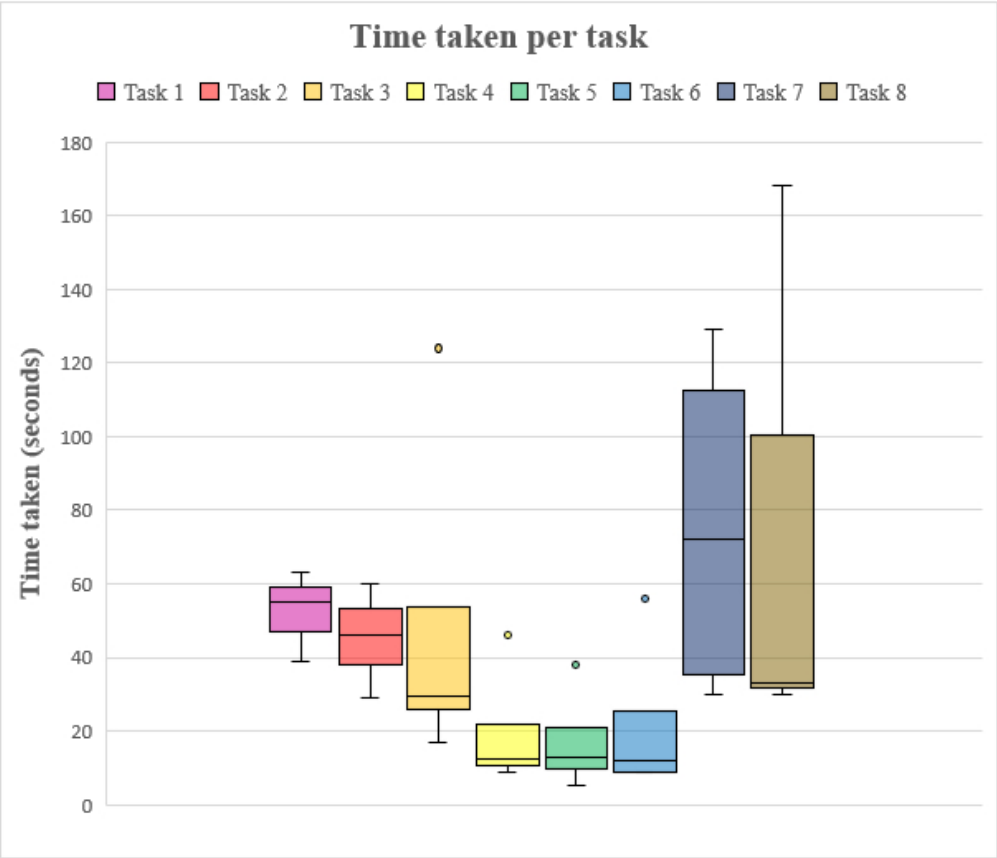

Figure 2: Box and whisker plot for usability efficiency measure, inter quartile range

160x137mm (96 x 96 DPI)

Appendix 1

1. App interface/ design/ features

The app is designed to have two interfaces.

The app **(at patient interface)** is designed for remote monitoring of heart failure patients. The app has a validated questionnaire for symptom/sign reporting, feature to enter self-measured body weight, blood pressure, heart rate and fluid intake; swiping functionality to acknowledge intake of medications and a feature to store medical records and share images of prescriptions.

The app **(at care provider interface)** is designed to capture demographic data of patients, to enter a few key investigation values and to store and share medical records such as discharge summaries, prescription re-fills or fresh prescriptions and investigation reports with the patients. The app has a feature where care providers can assign tasks to patients such as entering measured blood pressure values, heart rate, fluid intake, and body weight; medication intake notification reminders and symptoms/signs monitoring and reporting (Details in **Table 1**). The app is also designed to receive alerts when these measurements are outside the mentioned cut off ranges (Details in **Table 2**).

Table 1: List of tasks at care provider interface and patient interface

Care provider/ Nurse		Patient / Caregiver	
Task 1	Enter demographic details of patients from source documents and save	**Task 1**	Identify task list
Task 2	Capture medical records by either taking a picture/ selecting it from the phone gallery and share those with the patient (e.g.: discharge summary, recent lab investigation reports, prescriptions)	**Task 2**	Acknowledge medications taken throughout the day by tapping against each medication reminder
Task 3	Enter comorbidities (select the comorbidities/ add comorbidities if they do not appear in the existing list) and save	**Task 3**	Enter measured BP (both systolic and diastolic, correctly against each)
Task 4	Enter key investigations and save	**Task 4**	Enter measured weight
Task 5	Set medication reminders	**Task 5**	Enter measured heart rate
Task 6	Instruct patient to enter BP value and weight measured	**Task 6**	Enter fluid intake of the previous day
Task 7	Instruct patient to enter heart rate value measured	**Task 7**	Swipe against symptoms which are present
Task 8	Instruct patient to measure fluid intake of the previous day and enter the same	**Task 8**	View shared medical records
Task 9	Monitor the six symptoms and respond as Yes or No	**Task 9**	Share medical records
Task 10	Recognize alerts (heart rate, diastolic BP, systolic BP, weight, symptoms, fluid intake, medication)		

Table 2: Alerts for limits in values for measurements and symptoms/signs

Vitals to be measured	With symptoms		Without symptoms	
	Minimum	Maximum	Minimum	Maximum
Heart Rate	50	100	40	110
Blood pressure (Systolic)	90	160	80	170
Blood pressure (Diastolic)			60	100
Fluid intake	> 1 litre / day			

Alerts are also generated if the patient answers 'Yes' for any of the following questions:

1. Have you felt more short of breath since yesterday?
2. Have you noticed swelling since yesterday?
3. Have you had dizziness in the last 24 hours?
4. Did you wake up with cough along with shortness of breath last night?
5. Did you sleep on a chair propped up with a pillow last night?

If the patient responds to the question below as 'Worse' or 'Much worse'

6. Compared to yesterday are you better, same, worse or much worse?

2. Definitions/ terminologies

Background: We have created the mobile health application, named ***Suhriday*** for remotely monitoring patients with chronic heart failure. As a part of remote monitoring, we will ask patients to report worsening of symptoms or signs, blood pressure, body weight and fluid intake every day, measured at home, for duration of 4 weeks. The data will be monitored centrally by a trained nurse. Issues will be escalated by nurse to physician/cardiologist (treating team). Further actions will be documented by the nurse in a diary.

Definitions – The following definitions are in compliance with ISO 9241-11 [1,2]

1. Usability - Usability means that any part of a system must be easy to operate, learn, remember and helpful to the user and must guide the designers in the design process. "It is the extent to which a product can be used by specified users to achieve specific goals with effectiveness, efficiency and satisfaction in a specified context of use."

1.1 Usability/ Effectiveness – To what extent the user can achieve a goal with accuracy and completeness.

1.2 Usability/ Efficiency – The level of effort and resource usage which is required by the user in order to achieve a goal in relation to accuracy and completeness.

1.3 Usability/ Satisfaction (based on ease of use, ease of learning, error minimization and recall capacity) – The positive associations and absence of discontent that the user experiences during the performance.

2. Description of evaluation approaches -

2.1 Think Aloud Approach [2,3] – The think aloud approach involves the subject speaking out loud, whatever s/he sees on screen regarding the content of the application, the tasks that appear on screen, while navigating between tasks or pages, **difficulties encountered, likes/ dislikes and any other errors or difficulties encountered through to task completion**. The patient/caregiver's speech and the screen navigation will be recorded using the mobile phone's in-built recording system (has both audio recording of what participant speaks and video recording of screen).
Observer will note whether tasks are completed successfully or not (effectiveness) and the time taken to complete tasks (efficiency). The audio content will be analyzed for errors related to breaks in flow, patient preferences and dislikes and salient themes will be identified by content analysis.

2.2 System Usability Scale for assessment of subject Satisfaction -

SUS instrument – 10-item Likert scale, items have a range of 1-5. For items 1, 3, 5, 7, 9 one point subtracted from resulting score, for items 2, 4, 6, 8, 10 five points subtracted from resulting score. To get overall satisfaction value, final sum of all scores should be multiplied by 2.5. SUS scores ranging from 0-100. The following cut-offs will be used –
> 70 - acceptable/ good usability, **≥ 85 -** high level of usability or excellent score, **≤ 50 –** Poor/ unacceptable usability.

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3. Usability and Feasibility Assessment

3.1 Usability assessment of Patient/Caregiver for Suhriday app pilot - Baseline

Pt. ID: **Age**: **Sex**: **Date: dd/mm/yyyy**

Residence: **Health literacy**:

3.1.1 Task completion

Outcome of task	Task 1	Task 2	Task 3	Task 4	Task 5	Task 6	Task 7	Task 8	Task 9
Failed to complete task									
Completed with difficulties									
Completed with ease									

3.1.2 Time taken for each task

	Task 1	Task 2	Task 3	Task 4	Task 5	Task 6	Task 7	Task 8	Task 9
Time taken (sec)									

3.1.3 Satisfaction - System Usability Scale

Please choose any one between 1 to 5, where 1 = strongly disagree; 5 = strongly agree

1. I think that I would like to use this app frequently — 1 2 3 4 5

2. I found the app unnecessarily complex — 1 2 3 4 5

3. I thought the app was easy to use — 1 2 3 4 5

4. I think that I would need the support of a technical person to be able to use this app — 1 2 3 4 5

5. I found the various functions in this app were well integrated — 1 2 3 4 5

6. I thought there was too much inconsistency in this app — 1 2 3 4 5

7. I would imagine that most people would learn to use this app very quickly — 1 2 3 4 5

8. I found the app very cumbersome to use — 1 2 3 4 5

9. I felt very confident using the app — 1 2 3 4 5

10. I needed to learn a lot of things before I could get going with this app — 1 2 3 4 5

SUS score:

Open ended questions

i. If you strongly agree that the app was complex, what was complex? Can you specify?

ii. If you strongly agree and think that you need the support of a technical person to be able to use this app, can you please specify which point you needed assistance?

iii. If you strongly agree and think there was too much inconsistency in this app, can you please specify what was inconsistent?

iv. If you strongly agree and find the app very cumbersome to use, can you specify what was cumbersome?

v. If you strongly agree and felt that you needed to learn a lot of things before you could get going with this app, can you please specify, what was that learning you needed to do?

3.2.1 Feasibility interview guide

1) You have used the Suhriday application for about two months. Could you please describe your overall experience using the application and interacting with the study team?

Probes – As they start off, the objective is to elicit their emotions and opinions about the utility of the system. We are looking for a very general response with words like 'difficult', 'cumbersome', 'thankful', 're-assuring', 'useful', 'easier contact with the system' and so on. The following probe questions to be used –

- If it was difficult or cumbersome, please tell us what difficulties?
- If it was helpful, please tell us how it was helpful? Can you remember and tell us about some situations where it helped?

2) What were the changes that happened in your everyday life with regard to caring for your own health due to the education that was given at discharge and the system that we implemented?

Probes - The patient may be asked to imagine and compare with his previous (prior to intervention) care behavior. Specific questions pertaining to symptom and sign recognition, medication taking/planning and management, lifestyle modification to be enquired for.

3) Were you satisfied with the manner in which we (our team) responded?

Probes–We're looking for issues concerning (i) mode of issue resolution (over the telephone, by SMS, etc.) (ii) time taken to resolve the problem (iii) any issues with the solutions proposed such as 'restrict fluids', 'increase the dose of x drug', etc., and (iv) trust in our team.

4) You may have now stopped using the application. Are you continuing to take care of your health in the same manner?

Probe – We need to ascertain whether they are continuing home BP, fluid and body weight monitoring; documenting it and whether they have taken any action if parameters are abnormal.

5) Do you have any suggestions to further improve the mobile application?

Probe – for responses pertaining to ***frequency of entering information***, language, font size, font type, navigation issues, and color.

6) Lastly, do your caregivers or family members have any opinion about the app and the system? Has our education brought about any changes in their lifestyle?

3.2.2 Feasibility assessment of Patient/ Caregiver for Suhriday app pilot - End of study

Satisfaction - System Usability Scale

Please choose any one between 1 to 5 where 1 = strongly disagree; 5 = strongly agree

1. I think that I would like to use this app frequently	1 2 3 4 5
2. I found the app unnecessarily complex	1 2 3 4 5
3. I thought the app was easy to use	1 2 3 4 5
4. I think that I would need the support of a technical person to be able to use this app	1 2 3 4 5
5. I found the various functions in this app were well integrated	1 2 3 4 5
6. I thought there was too much inconsistency in this app	1 2 3 4 5
7. I would imagine that most people would learn to use this app very quickly	1 2 3 4 5
8. I found the app very cumbersome to use	1 2 3 4 5
9. I felt very confident using the app	1 2 3 4 5
10. I needed to learn a lot of things before I could get going with this app	1 2 3 4 5

SUS score:

3.2.3 Acceptability questionnaire (Likert scale):

1. How confident do you feel using the mHealth application?
    a) Not at all
    b) To some extent
    c) To large extent

2. Do you prefer using mobile health application as routine care?
    a) Not at all
    b) To some extent
    c) To large extent

3. Will you be able to teach other patients/their caregivers how to use this application?
    a) Not at all
    b) To some extent
    c) To large extent

4. Would you recommend using mobile health application to patients with similar conditions?
    a) Not at all
    b) To some extent
    c) To large extent

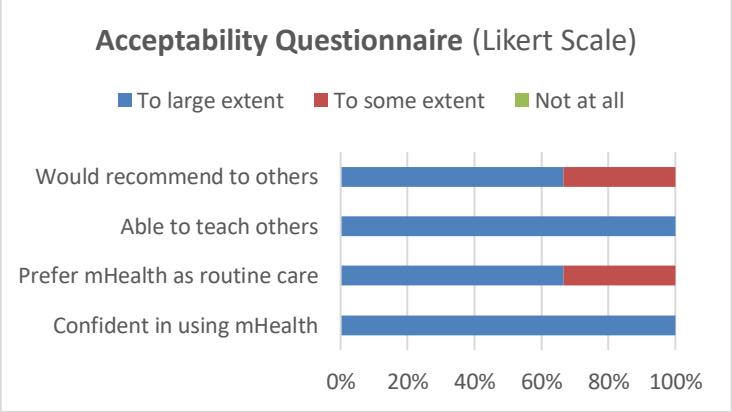


Figure 1: Summary of the results from the acceptability questionnaire

3.2.4 Overall satisfaction of App features, functionality, ease to use

Adjective rating (Circle any one of the below)

a. Worst imaginable
b. Poor
c. OK
d. Good
e. Excellent
f. Best imaginable

3.2.5 Acceptability

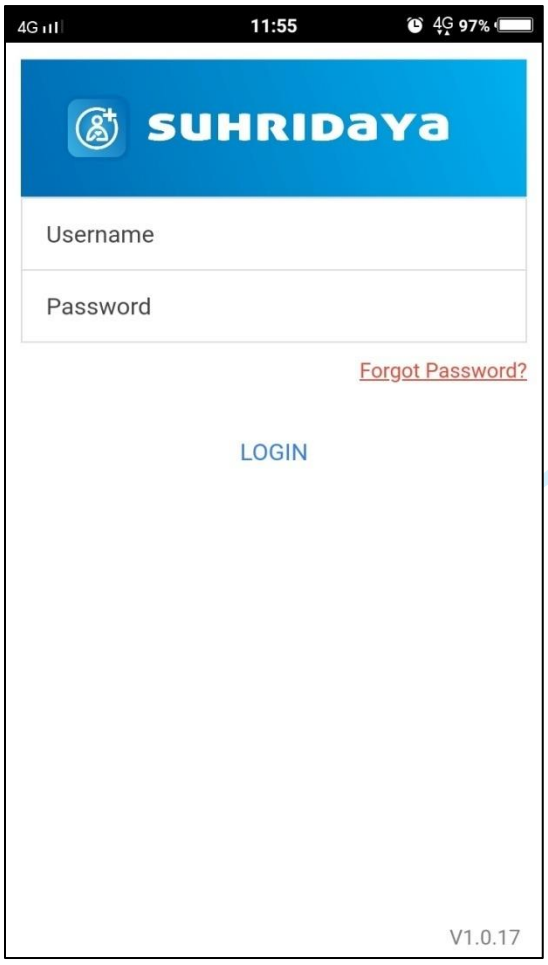
(Circle one of the below)

a. Not acceptable
b. Marginal - low
c. Marginal - high
d. Acceptable

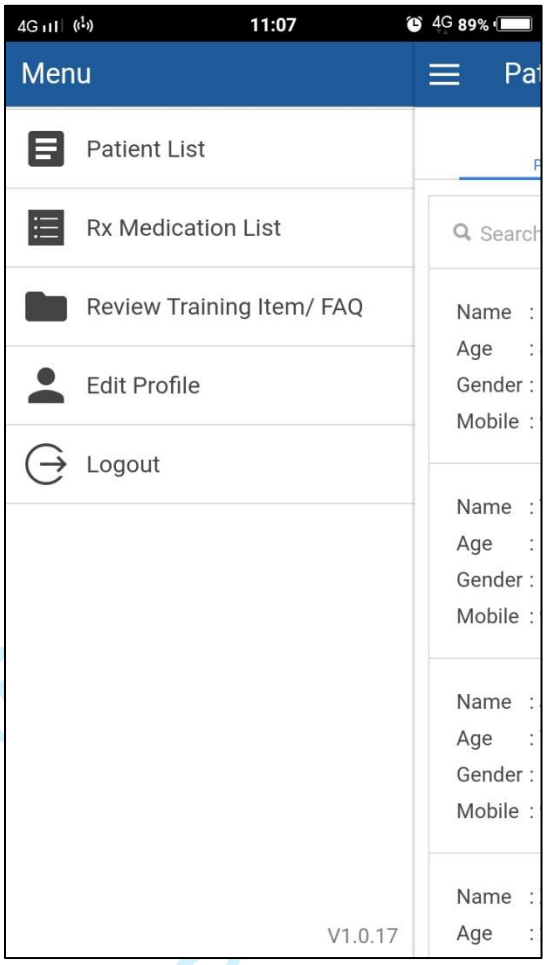
Appendix 2: App design and features

App at nurse interface:

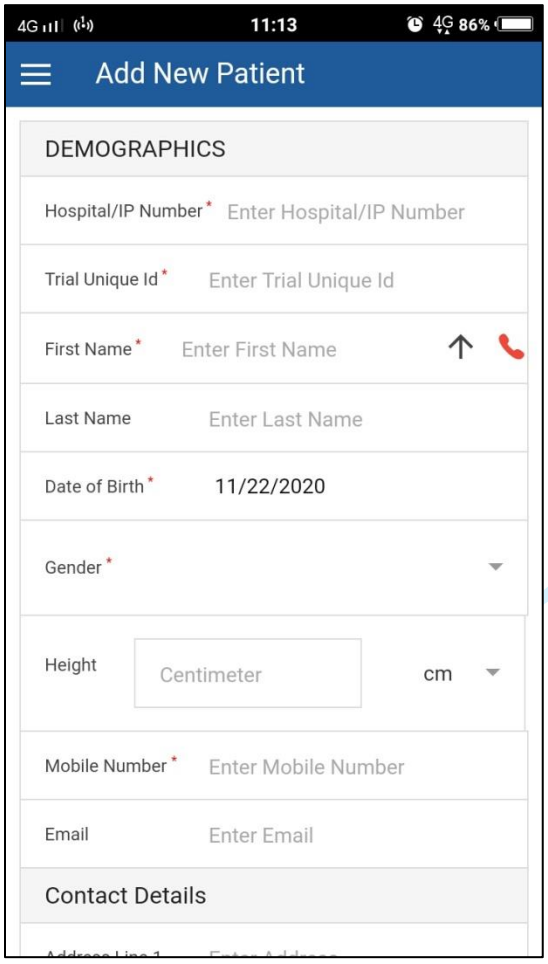
1. Log in page



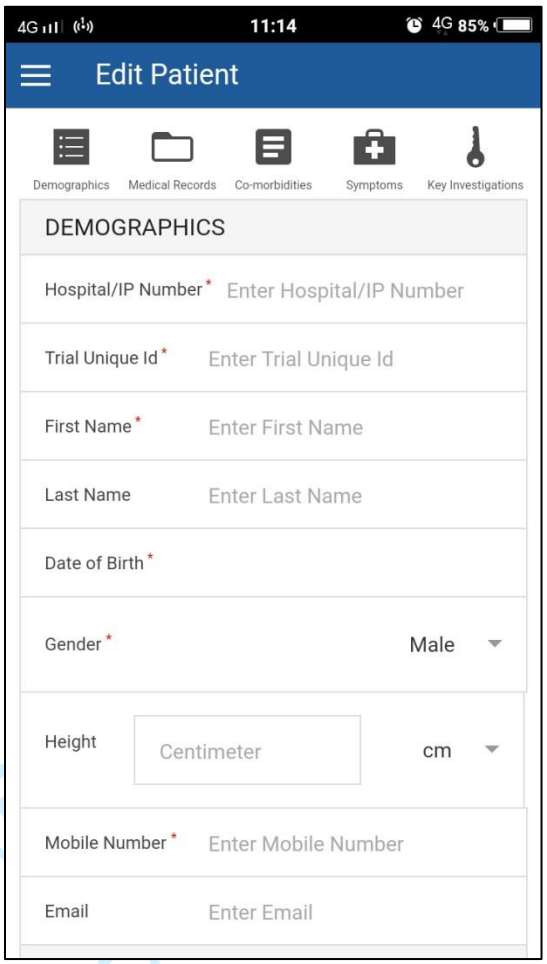
2. Menu



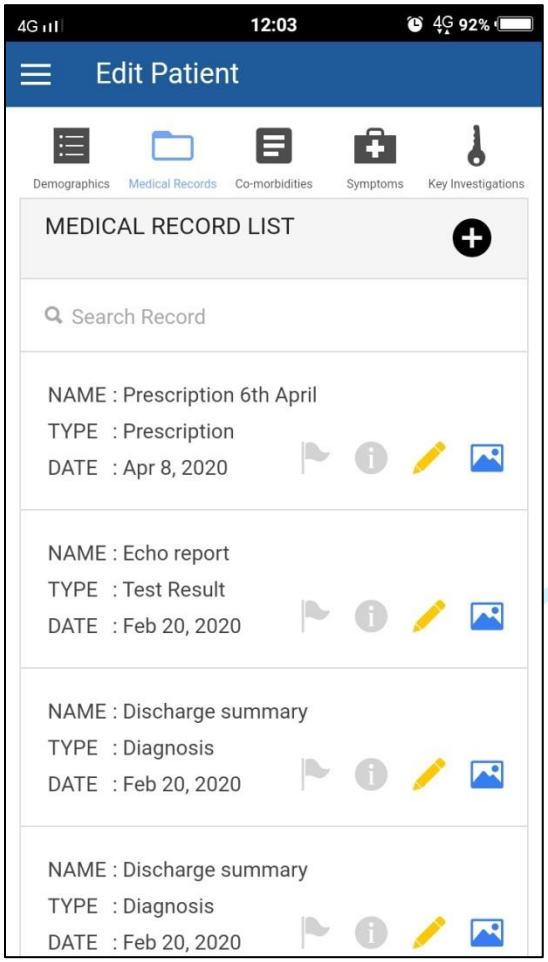
3. Add new patient



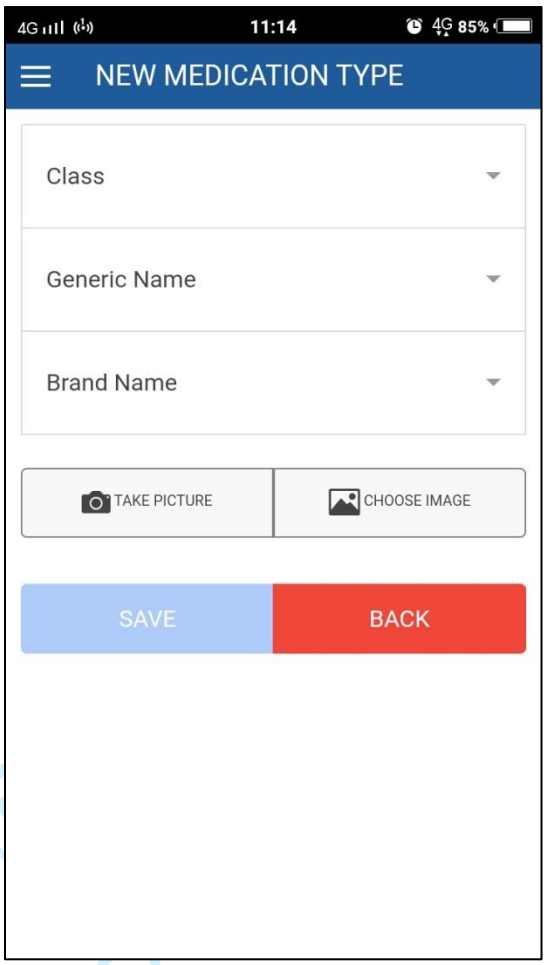
4. Patient detailed profile



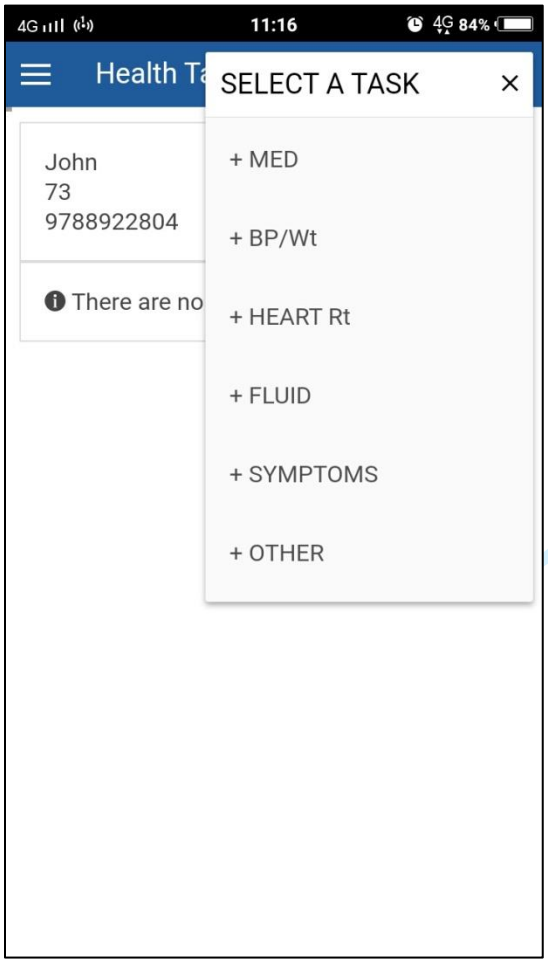
5. Patient medical records



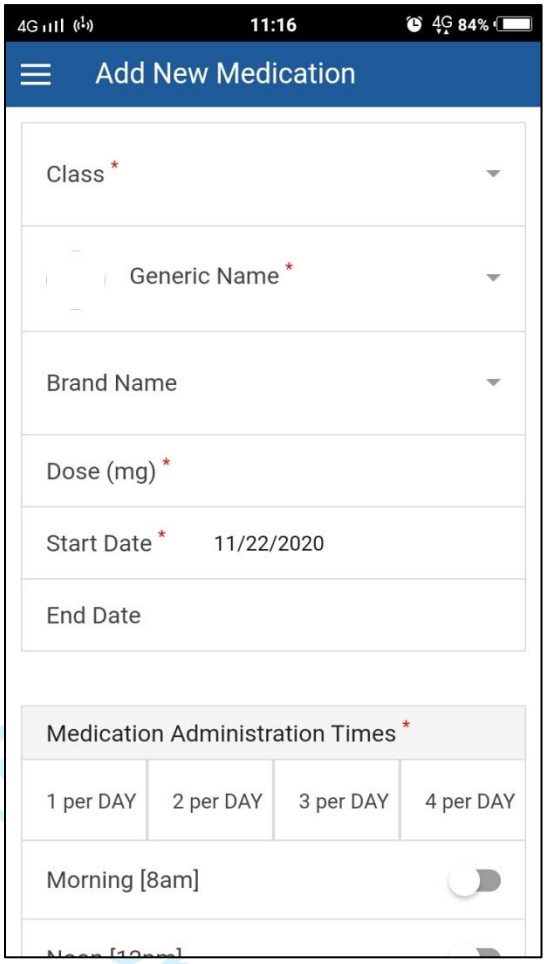
6. To create medication list



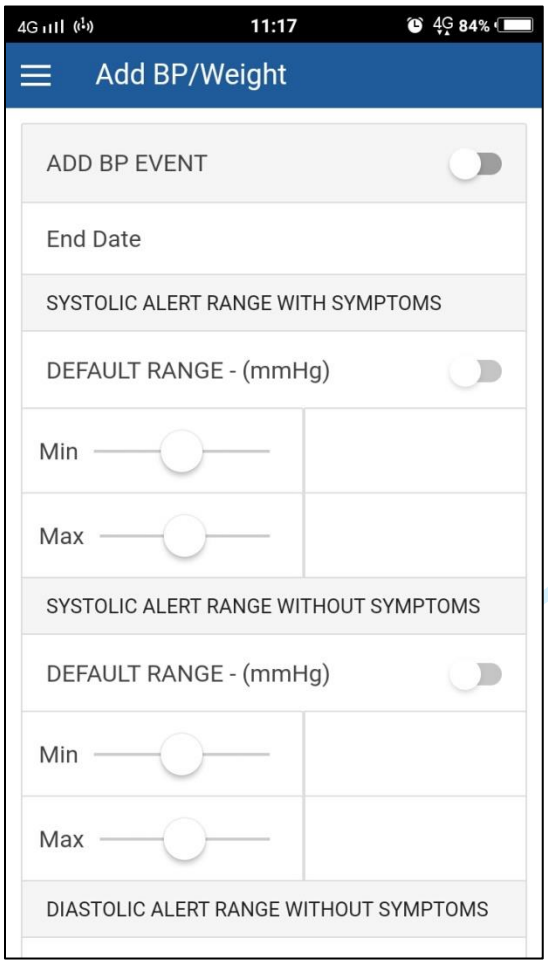
7. Assigning task



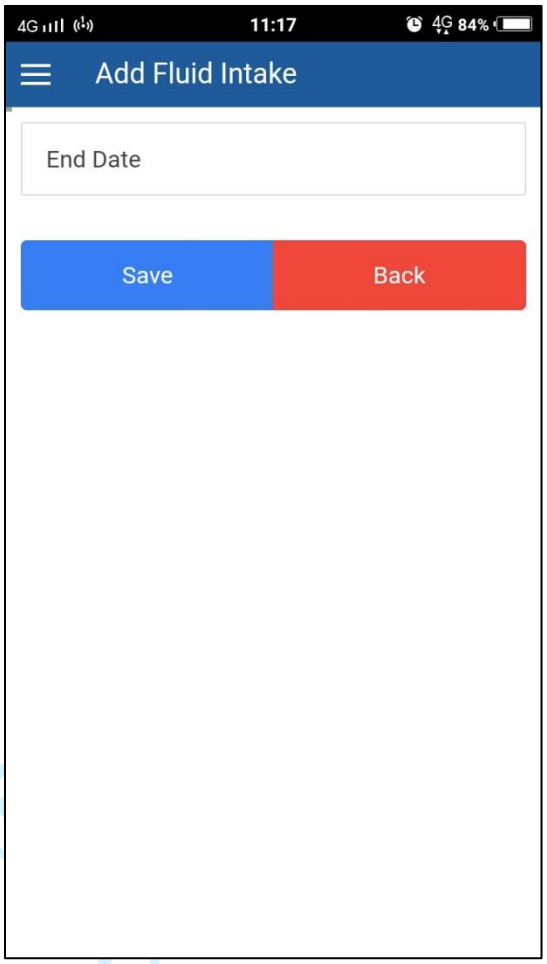
8. Assign medication reminder after filling medication details



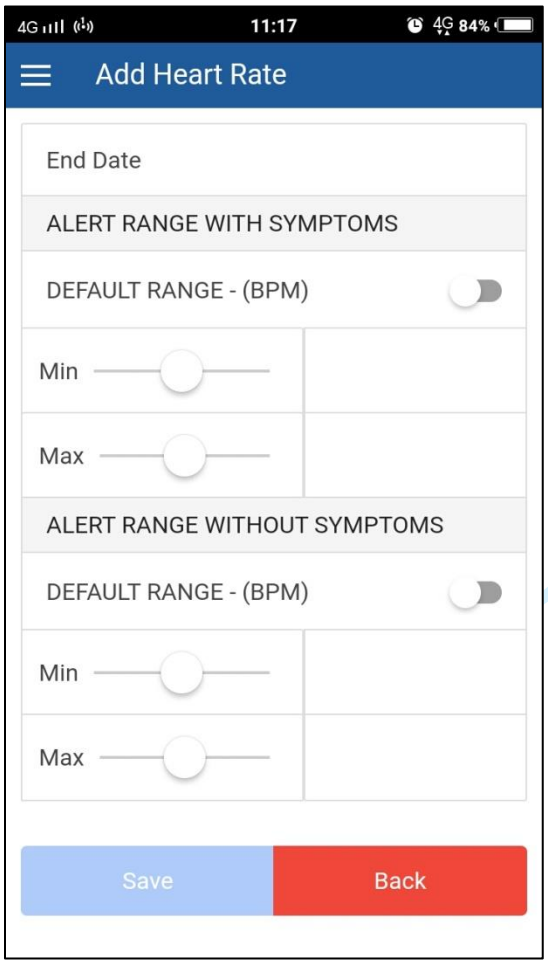
9. Assign BP/weight task



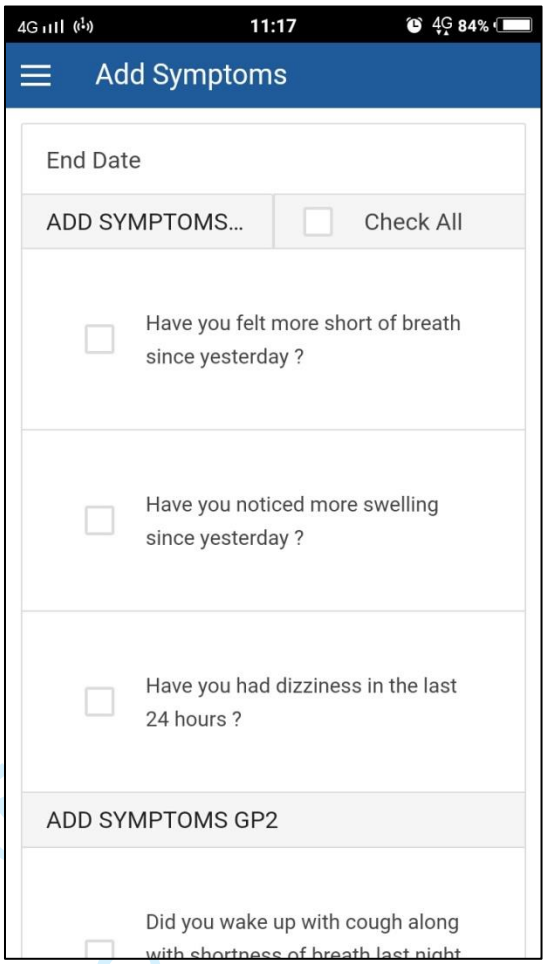
10. Assign fluid intake task



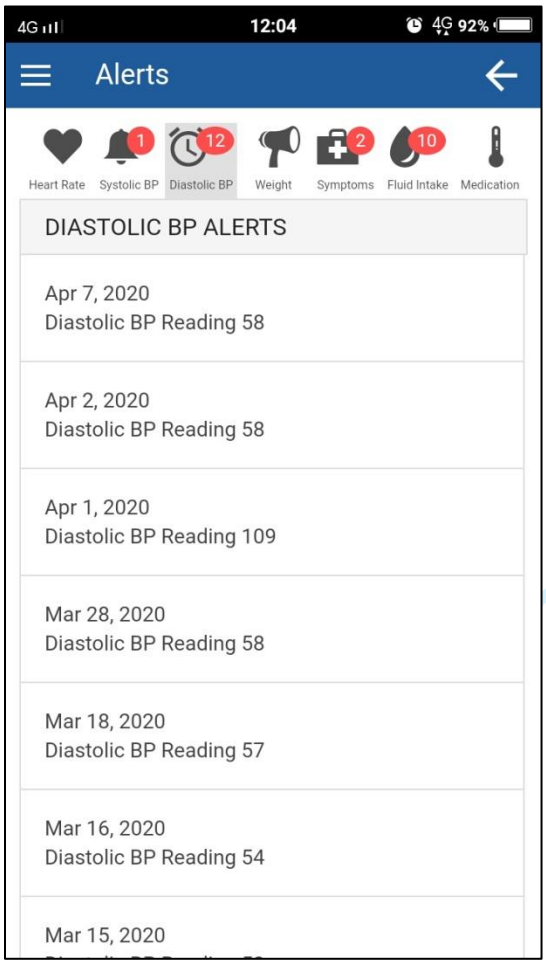
11. Assign heart rate task



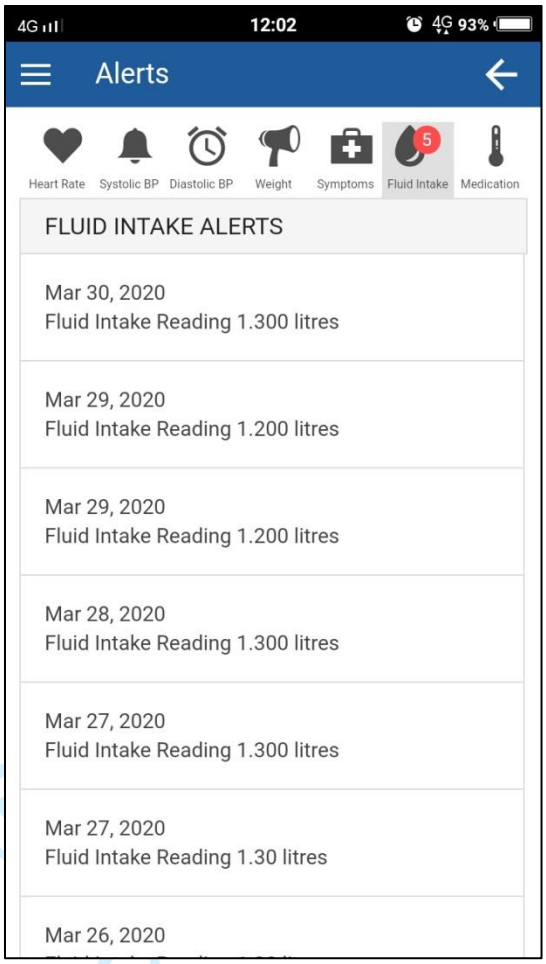
12. Assign symptom/sign monitoring task



13. Recognizing alerts, Diastolic blood pressure



14. Recognizing fluid intake alerts



15. Recognizing symptom/sign alert

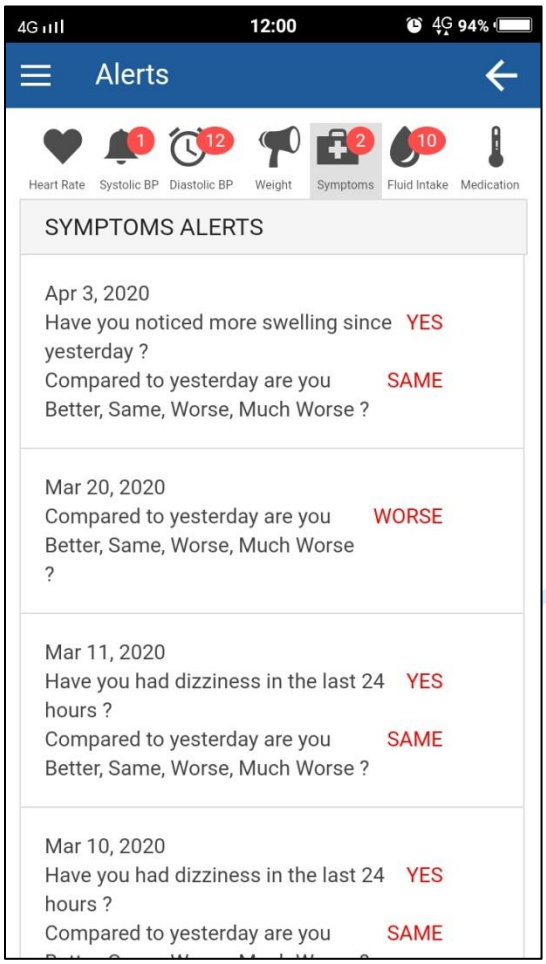
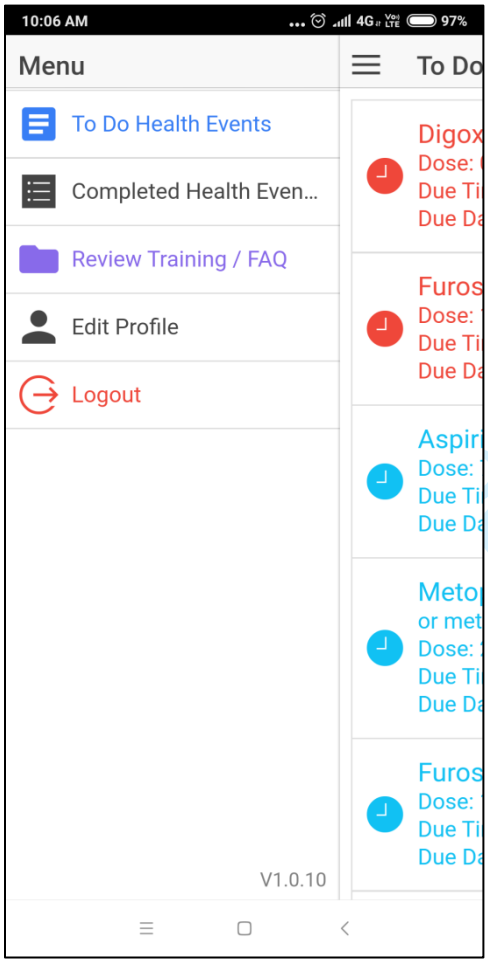


Table 1: Alerts reported by patients/ caregivers:

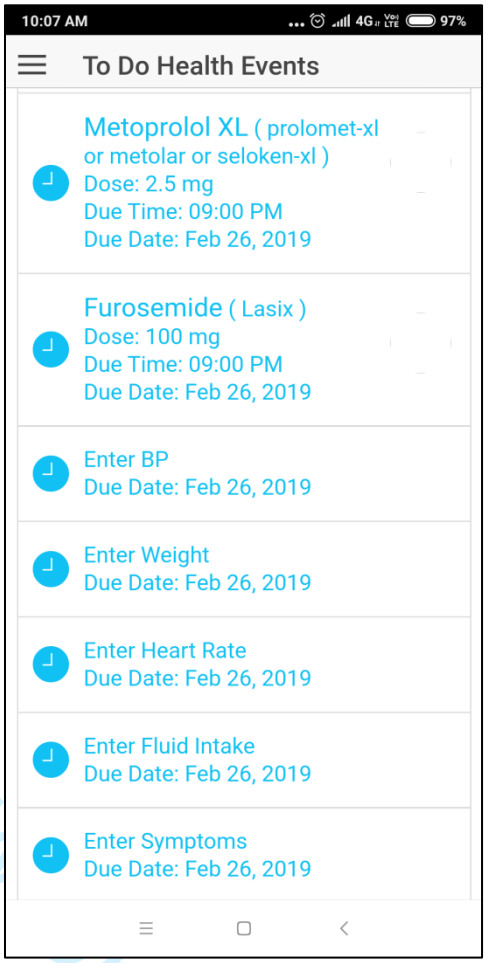
Alerts reported, N = 62	**No. of alerts** n (%)
Fluid intake	36 (58.1)
Variance in diastolic BP	12 (19.4)
Symptom worsening	10 (16.1)
Variance in systolic BP	4 (6.5)

App at patient interface:

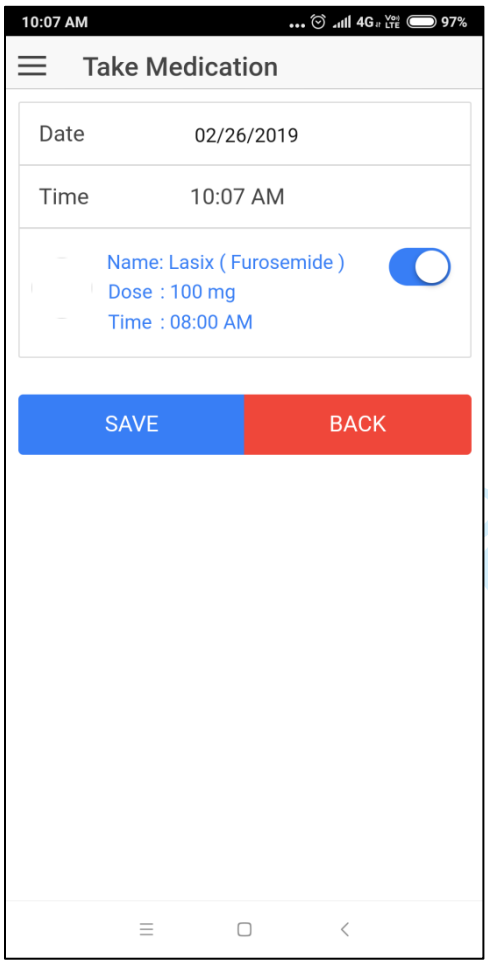
1. **Menu**



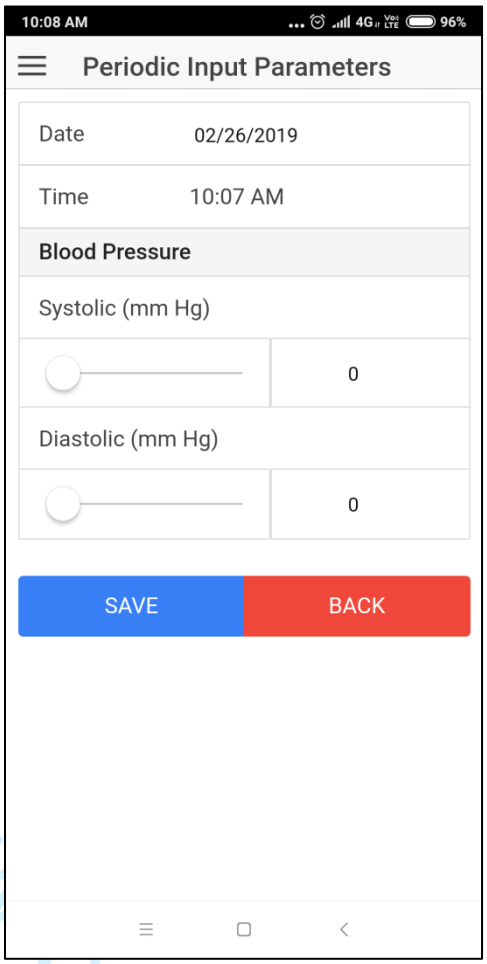
2. **To do health events**



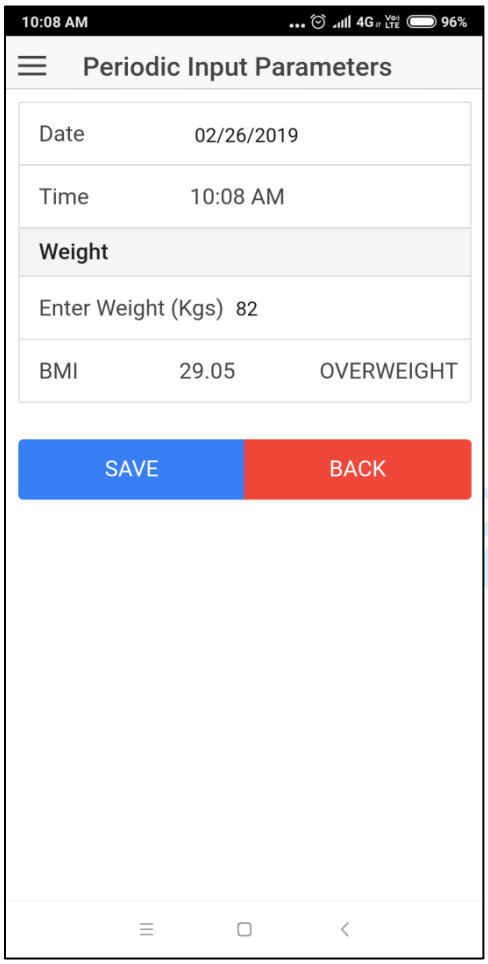
3. Medication taking & acknowledgement



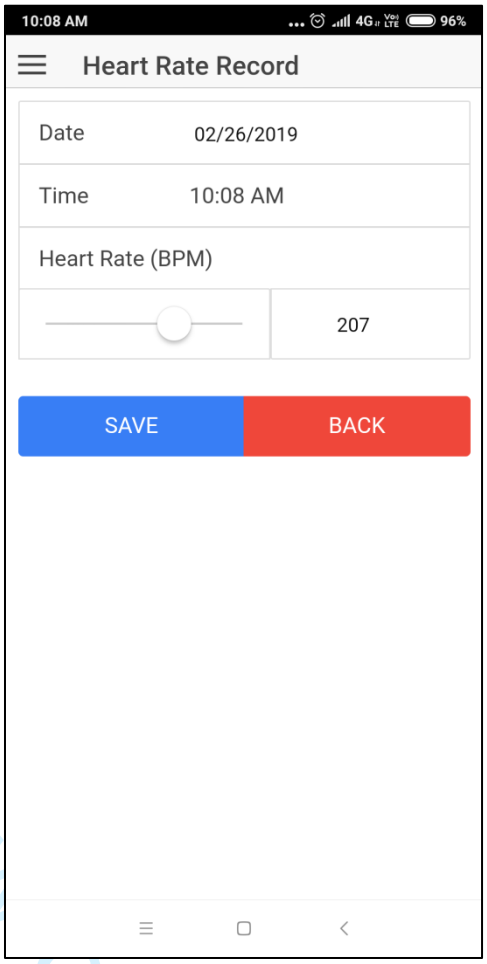
4. Completing task of entering



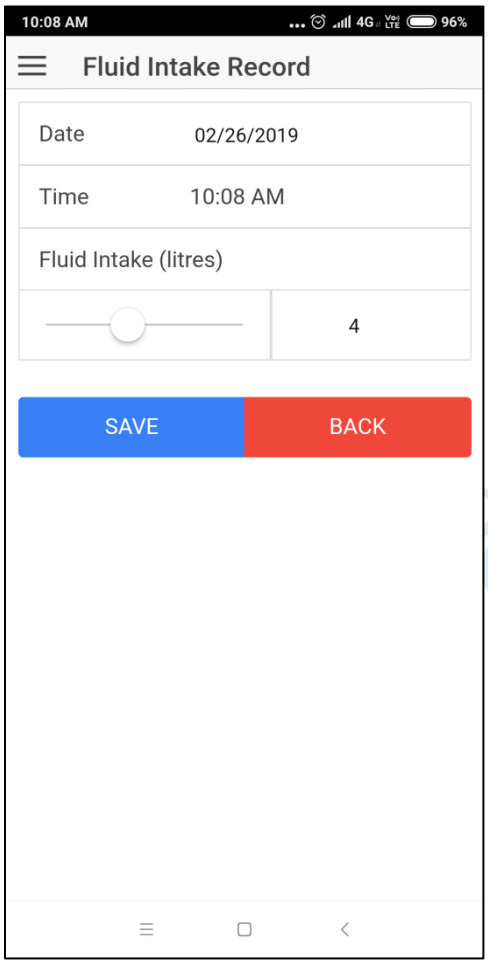
5. Completing task on entering weight



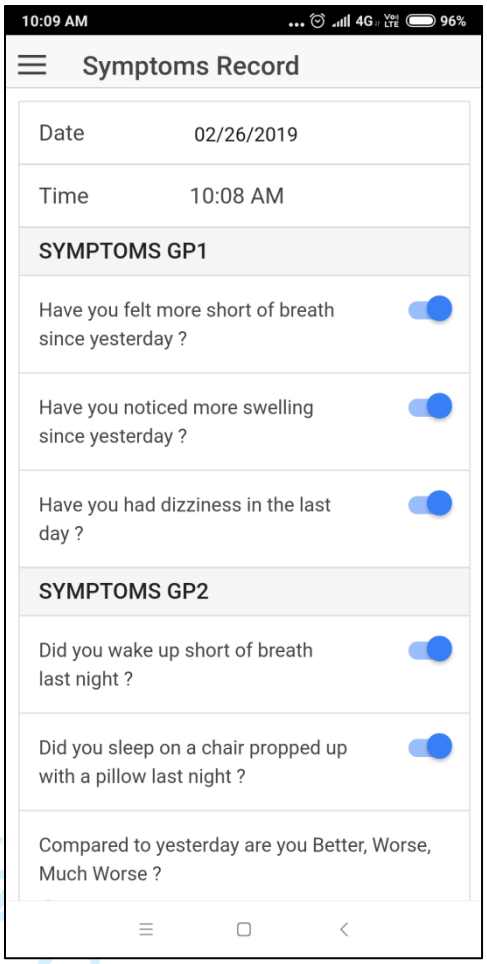
6. Completing task on heart rate



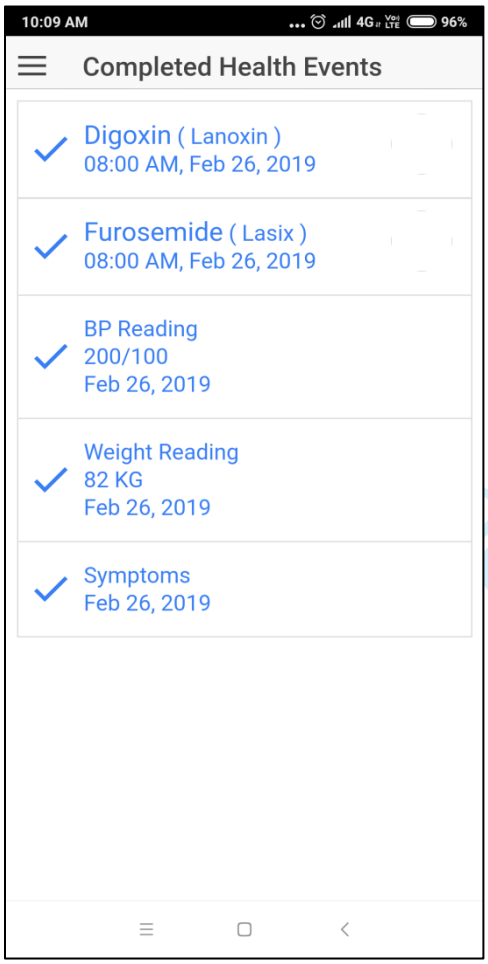
7. Completing task on entering fluid intake



8. Reporting symptoms/signs task



9. Completed health events



10. Viewing uploaded medical record

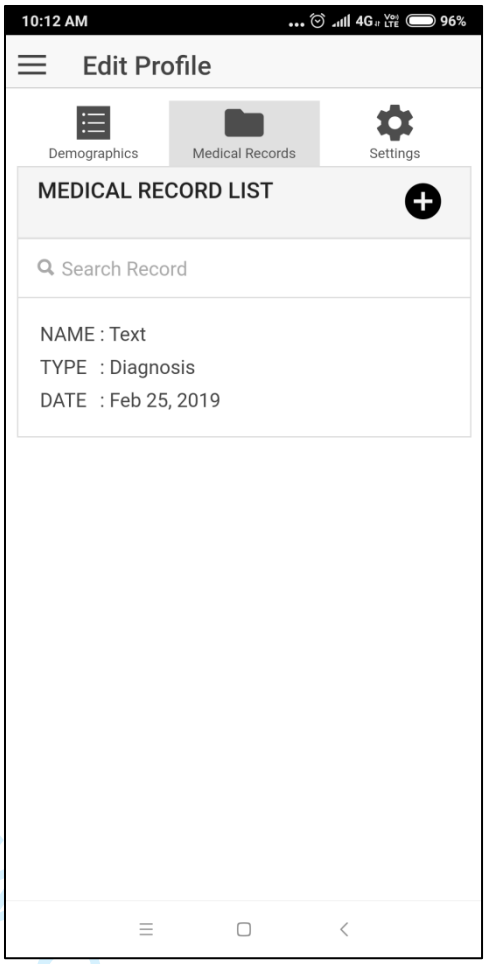


Table 2: App issues at patient/caregiver interface:

Technological issues at patient interface	No. of issues
App download issue	3
Log in issue	1
Medication swipe issue	1
Translations missing (drug names and symptom questions)	1
Non-reflection of medication/ task lists	3
Total	**9**