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Assessment of Heart Failure Post-discharge Management Strategies, Needs and Acceptance of Mobile Application-based Remote Patient Management in South India

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Abstract

The demand for digital platforms in managing heart failure (HF) is expected to increase with promising effects on readmission and health expenditure. The study aims to explore current post-discharge management strategies and identify the need and acceptance of digital platforms, to ensure the development of a user-friendly mobile application for HF patients. Using a cross-sectional analytical research design, 90 consecutive patients diagnosed with HF who were discharged from a Tertiary Care Center were enrolled. Tele-interview was conducted using a self-developed and validated tool. The mean age of participants was 55.54 ± 10.33 years. The participants' adherence to HF management strategies was low in terms of physical exercise and weight monitoring. More than one-third were willing to self-record their measurements and use a mobile application. The common mobile application features requested were medication information/reminder (88.6%), health education (84.3%), chat with nurses (84.3%), physical activity (81.4%), symptoms (78.6%), diet (78.6%) and weight management (72.9%). The findings from this initial phase of mobile development are expected to help leverage better development of digital interventions for HF patients.

Keywords

heart failure, self-management, mHealth, telemedicine, mobile health, user-centred design, smartphone, mobile applications, cardiac rehabilitation

Introduction

Heart failure (HF) is a growing medical and economic burden worldwide. The global prevalence of HF is estimated to be 64.34 million cases (8.52 in every 1000 inhabitants) and accounts for 9.91 million years lost due to disability.[1] In India, the prevalence is 1% of the total population, which accounts for nearly 8-10 million patients as of 2016.[2] The prevalence of HF in the United States is forecasted to rise from 2.4% in 2012 to 3.0% in 2030[3]; the number of HF-attributed death was 52.8% higher in 2019 as compared to 2009.[4] The 3-month mortality for 10 851 patients under the National HF registry (NHFR) of India was 14.2%, and the readmission rate was 8.4%.[5] Even though this was lower as compared to reports from Trivandrum and Vellore HF registry 5 years earlier, the societal and economic effect in low- and middle-income country (LMIC) settings like India is unique and different from that of high-income countries.[6,7]

The application of mobile health (mHealth) in managing HF is promising to reduce readmission and health expenditure.[8] The demand for mHealth interventions is expected to further increase with the exponential growth rate in mobile

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connectivity and smartphone users.[9] However, evidence of its clinical benefits is inconsistent across studies, different in kind, and scarce, especially in an LMIC like India.[10-12] Literature review shows that only a few mobile applications meet pre-specified criteria for quality, content or functionality, which highlights the need for further refinement and mapping to evidence-based guidelines and room for overall quality improvement in HF symptom monitoring and self-care-related applications.[13] Evidence also suggests that most of the mHealth applications were designed and developed based on practical experiences, design science research approach[14] and systematic reviews[15-17] of existing cardiovascular-related mobile applications. However, prior identification of features may enhance better performance of the mobile application and improve user experience and adherence to remote patient management for HF patients. Therefore, in addition to in-hospital experiences and literature review, an extensive user-centred design is required so that actual inputs can be taken from the patients who will be the primary users of the product. The current study is the first in India that aims to explore current post-discharge management strategies and identify the need and acceptance of digital platforms, to ensure the development of a user-friendly mobile application for HF patients.

Subjects and Methods

This study is an initial phase for the development and testing of a nurse-led digital platform-based remote patient management for patients diagnosed with HF. A cross-sectional analytical research design was implemented for this phase. All consecutive patients who were discharged with a diagnosis of HF (n = 204) from a Tertiary Care Center within a period of 3 months were contacted after 6 months to participate in the tele-interview. Other eligibility criteria include patients who were between 18-80 years old, and who have access to a telephone in their household. Ninety participants who gave consent to participate by telephone were enrolled using the total enumeration method. The tele-interview method was used for data collection and was conducted in the participants' language. The researcher also collected the participants' demographic and clinical characteristics. The whole tele-interview takes 10 min on average for each participant. A tele-interview log was maintained throughout the data collection period of 1 month.

Data collection instrument development: With the help of an extensive literature review and expert opinion, a structured tele-interview tool was developed by the research team using the Delphi method. The tele-interview guide called 'HF Management, needs, and Acceptability of Digital Platform (HF-NADP)' is a 20-item question and has five sections: The first section consists of three questions regarding the HF patients' current health status, including New York Health Association (NYHA) functional classification.[18] The second section focuses on the patients' current HF management strategies and their adherence to important lifestyle modifications like medication, physical exercise, dietary changes and weight monitoring. The third section consists of five questions regarding HF-related hospital visits, readmissions, and patients' access to healthcare workers when the need arises. The next four questions are regarding patients' experience with healthcare monitors and their familiarity with gadgets like computers and smartphones. The last section is about the patient's willingness to use mobile applications for HF telemonitoring, as well as their suggestions on features to be included in the HF mobile application (Supplementary File 1).

The tool (HF-NADP) was translated into Tamil language by two bilingual translators and back-translated to English by two other translators, to compare and check the nuances. The face validity of the tool was checked by asking the structured questions to 10 patients diagnosed with HF, who stated that the questions were 'clear, understandable and appear appropriate' for the intended purpose. Content validity of the tool was obtained from 10 experts in the field (Department of Cardiology, Department of Medicine, and Department of Medical-Surgical Nursing). The scale-content validity index (average of all items) was 0.981, which was above the acceptable value for content validity for 10 experts.[19,20] The average proportion relevance from the 10 experts was 0.980. When assessed for reliability (internal consistency), Cronbach's alpha for the tele-interview questions was also acceptable (α-.71).[21]

Data Analysis

Data analysis was done using Statistical Package for Social Science (IBM SPSS Version 25). The distribution of categorical variables such as gender, co-morbidity, tele-interview responses, etc was expressed as frequency and percentage. Continuous variables such as age, income, etc were presented as mean with standard deviation and median with interquartile range. Data normality was checked using the Kolmogorov-Smirnov normality test. The relationship between participants' responses to the tele-interview with selected continuous participants' characteristics was assessed using Independent student t-test, Mann-Whitney U test, one-way ANOVA, Kruskal-Wallis test. Chi-square test and Fisher's exact test were used for categorical variables. All statistical analyses were performed at a 5% level of significance.

Ethical Considerations

Institutional Ethics Committee for human studies and PhD Research Monitoring Committee approved the study. The procedures followed were in accordance with the ethical standards of the institution as well as the Declaration of Helsinki revised in 2013. Informed consent was taken from each participant voluntarily before enrolment using the telephonic consent script approved by the Ethics Committee. The

participants were also ensured anonymity and confidentiality of their data.

Results

The mean age of the 90 participants was 55.54 ± 10.33 years. In terms of gender, male preponderance (81.1%) was noted, and 95.6% of the participants were married. More than two-thirds (70%) of the participants resided in the state of Tamil Nadu, while a lesser proportion of the participants resided in Puducherry (25.6%) and Kerala (4.4%). The majority of the study population (86.7%) were literate, out of which 11.5% and 5.1% completed their graduate and post-graduate level of education, respectively. One-third of the participants (64.4%) were employed, and the mean monthly family income of the participants was Rs.7394.44 ± 10 903.17. The primary caregivers were mainly the patients' spouses (67.8%) and their children (28.9%).

The median duration of diagnosis with HF was 28(26,40) months. The reported predominant aetiology for HF was ischaemic heart disease (81.1%), followed by dilated cardiomyopathy (7.8%) and rheumatic heart disease (5.60%). The median left ventricle ejection fraction (LVEF%) for all participants was 40%(30.3%,45%), and the most common presentation of HF among the participants was HF with mid-range ejection fraction (53.3%), followed by HF-reduced ejection fraction (45.6%) and HF-preserved ejection fraction (1.1%). Hypertension (38.9%) and diabetes mellitus (42.2%) were the most frequently reported comorbidities among the participants (Table 1).

Table 1. Demographic and Clinical Characteristics of Participants.

Participants' characteristics		N = 90 Frequency (%)
Age (in years) *Mean ± SD*		55.54 ± 10.33
Gender (Male)		73 (81.1)
Level of education (n = 78)	Primary	6 (7.7)
	Middle	26 (33.3)
	High school	25 (32.1)
	Higher secondary school	8 (10.3)
	Graduate	9 (11.5)
	Post-graduate	4 (5.1)
Employment status	Employed	58 (64.4)
	Unemployed	32 (35.6)
Marital status	Married	87 (96.7)
	Widow/Widower	2 (2.2)
	Unmarried	1 (1.1)
Relationship with the primary caregiver	Parent	1 (1.1)
	Spouse	61 (67.8)
	Children	26 (28.9)
	Sibling	2 (2.2)
Duration of heart failure (in months) *Median(IQR)*		28 (26.4)
Aetiology of heart failure	Ischaemic heart disease (IHD)	73 (81.1)
	Dilated cardiomyopathy	7 (7.8)
	Rheumatic heart disease	5 (5.6)
	Granulomatous myocarditis	1 (1.1)
	Congenital heart defect	1 (1.1)
	IHD and dilated cardiomyopathy	2 (2.2)
	IHD and non-rheumatic valvular heart disease	1 (1.1)
LVEF%	Heart failure with reduced ejection fraction (<40%)	41 (45.6)
	Heart failure with mid-range ejection fraction (40%-49%)	48 (53.3)
	Heart Failure with preserved ejection fraction (≥50%)	1 (1.1)
Comorbidity	Hypertension	35 (38.9)
	Diabetes mellitus	38 (42.2)
	Hypothyroidism	1 (1.1)
	Stroke	2 (2.2)

Abbreviations: N, total number of participants; n, number of literate participants; %, percentage; SD, standard deviation; IQR, interquartile range; LVEF, left ventricular ejection fraction.

Current Health status

When the participants were asked to rate how they are currently feeling about their general health condition (on a scale of 0-10), their mean response was 8.39 ± 1.69, with 0 being worst and 10 being health condition. The most frequently reported symptom affecting their health condition is shortness of breath on exertion (23.3%), followed by fatigue (11.1%), and chest discomfort (8.9%). Three participants experienced abdominal symptoms like nausea and vomiting, while nine participants experienced other symptoms unrelated to HF. Half of the participants (51.1%) self-reported that they have mild symptoms and slight limitations during activity when asked to categorize their physical activity tolerance level based on the NYHA functional classification. The majority of the participants (96.7%) were currently taking care of themselves at home (Table 2).

Guideline-directed Medical Therapy Followed

In response to the question regarding attending the monthly HF clinics, 34.4% of the participants have stated that they have always attended, whereas 18.9%, 36.7% and 10.0% of the participants have stated that they often, rarely, and never attended the HF clinic, respectively. However, 62.2% of the participants stated that they had always attended the HF clinic before the COVID-19 pandemic. During their hospital discharge process, 96.7% of the participants reported that they received advice from nurses or doctors regarding their medication; 78.9% of them have always followed the medications as advised. A larger portion of the participants also stated that they received advice on physical exercise (57.8%), dietary management (85.6%) and weight monitoring (57.8%). The adherence rate to these HF management strategies was however low since a great proportion of the

Table 2. Participants' Response to Questions Regarding Current Health Status.

Questions	Response	N = 90 Frequency (%)
On a scale of 0-10, with 0 being the worst and 10 being the best health condition, how are you feeling now?	1-5	4 (4.4)
	6-10	86 (95.6)
If less than 10, what are the symptoms currently affecting your health condition?	Shortness of breath on exertion	21 (23.33)
	Chest discomfort	8 (8.9)
	Fatigue	10 (11.1)
	Giddiness	3 (3.3)
	Edema	3 (3.3)
	Abdominal symptoms	3 (3.3)
	Other symptoms	9 (10.0)
What is your physical activity tolerance level?	No symptoms or limitation	33 (36.7)
	Mild symptoms and slight limitation during activity	46 (51.1)
	A significant limitation on activity and comfortable at rest	11 (12.2)
	Severe limitation and symptoms at rest	0
Where are you currently taking care of yourself?	At home	87 (96.7)
	In nursing home	1 (1.1)
	In hospital	2 (2.2)

Abbreviations: N, total number of participants; %, percentage.

participants reported that they rarely follow the advice in terms of physical exercise (31.1%) and weight monitoring (32.2%). The majority of the participants have reported that they have always followed dietary advice given to them, while 8.9% reported that they never make changes in their dietary pattern (Figure 1).

Healthcare Access

Among the participants, 35 (38.9%) have visited a local health clinic or contacted a doctor near their home for their HF-related problem. The median number of visits over the past 6 months was 2 (1,2) times. The readmission rate for HF-related problems within the last 6 months was 13.30%, with the majority of them (10 participants) getting readmitted once. Among the 12 readmitted participants, 2 of them were admitted to another local hospital. 21 (23.3%) of the participants mentioned having contact details of the hospital/healthcare providers, which are not accessible when help is required, as stated by the participants. Eight (8.9%) participants have actual access to either a doctor or a nurse from their primary hospital through telephone (6.7%) or family member (2.2%) when needed. The majority of the participants (84.4%) responded that they felt the need to talk to healthcare providers regarding their medicines and treatment plan after getting discharged; 78 participants (86.7%) also stated that they would like to have easier access to doctors or nurses (either direct or through telephone) (Table 3).

Previous Use of Gadgets

When asked about previous use and ownership of gadgets, all participants have a mobile phone in their household; 69(76.7%) of the participants replied that either they or their primary caregivers own an Android smartphone in their household, and one participant owns an iPhone. Out of these 70 smartphone owners, 21(23.3%) of them belong to the actual participants, and the remaining 49 belong to the primary caregivers. Ownership of other healthcare devices and gadgets among the participants is 12.2%, 17.8% and 20.0% for blood pressure monitors, weighing machines and computers/laptops, respectively. Among the participants who own an Android smartphone, 28.6% have used their smartphones to get information about HF. However, none of the participants have used health-promoting mobile applications for the management of their condition.

Need for Heart Failure Telemonitoring Application

The majority of smartphone owners (63.3%) were willing to use a mobile application for home management of HF. Nine (10%) of the participants do not have an opinion, whereas a small proportion of the participants opined that they may not (3.3%) and not at all (1.1%) be willing to use the mobile application useful for the management of their condition (Table 3).

More than half of the smartphone owners (64.5%) also stated that they would be willing to self-record their measurements and enter their data into their phones, given that a mobile application and training on how to use it is provided to them. When 70 smartphone owners were asked about the features or type of assistance that they desire to be included in the HF mobile application, the commonly desired features reported were medication information and reminder (88.6%), health education (84.3%), chat with doctors or nurses (84.3%), physical activity (81.4%), symptoms (78.6%), diet (78.6%) and weight management (72.9%). Participants also suggested features like follow-up reminders, enabling calls to healthcare providers, video-call interactions, and other vital signs monitoring (Figure 2).

There is no statistically significant relationship between participants' smartphone ownership, willingness to use the mobile application and willingness to enter daily data with the participants' characteristics like gender, level of education, employment, income, caregiver relationship and aetiology of HF. However, the median LVEF% was significantly lower among participants who were not willing to self-measure and enter their daily data in the mobile app

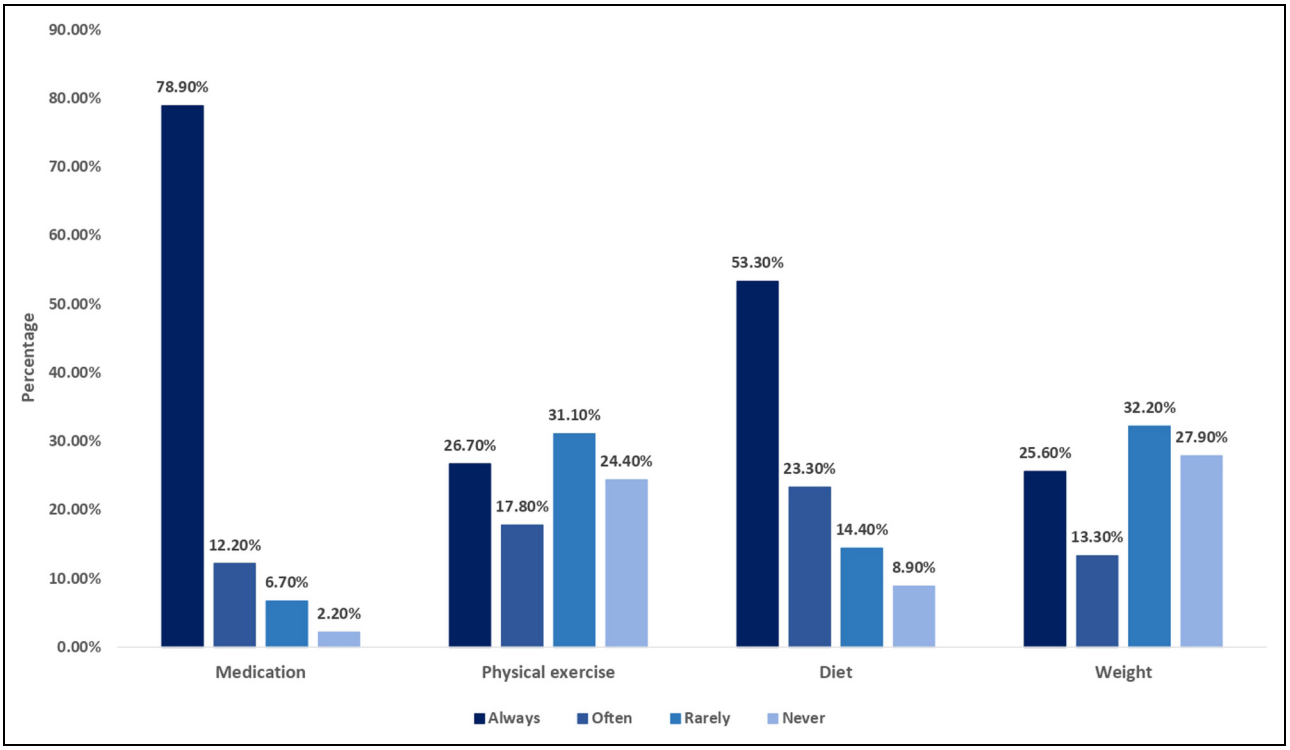

Figure 1. Participants' adherence to heart failure management advice.

Table 3. Participants' Response to Questions Regarding Current Healthcare Access and Acceptance for Mobile Application.

Questions		N = 90 Frequency (%)
Heart failure-related health clinic or doctor visit within the past 6 months		35 (38.9)
Heart failure-related readmission in the past 6 months		12 (13.3)
Any access to a doctor/ nurse from primary hospital		8 (8.9)
Need to talk to healthcare providers after getting discharged		76 (84.4)
Need easier access to doctors or nurses directly or through the telephone		78 (86.7)
Willingness to use a mobile application to help in home management of heart failure (n = 70)	Very much	40 (44.4)
	Yes	17 (18.9)
	I don't know	9 (10.0)
	Maybe not	3 (3.3)
	Not at all	1 (1.1)
Willingness to self-record measurements and enter daily data into the mobile application after proper training (n = 70)	Very much	41 (45.6)
	Yes	17 (18.9)
	I don't know	6 (6.7)
	Maybe not	5 (5.6)
	Not at all	1 (1.1)

(*P*-.041) (Figure 3). Participants who had their individual smartphones were also younger (49.8 ± 9.76 years) than those without smartphones (57.3 ± 9.92 years), which was statistically significant at *P*-.003.

Discussion

A survey among the general population regarding mHealth prevention of cardiovascular diseases in South India reported that the most commonly requested mHealth advice (62.2%) was regarding self-care for chronic diseases like HF.[22] Previous literature also shows evidence that HF patients adopting self-care can reduce HF readmissions and health-care expenditures and that various non-invasive digital health telemonitoring helps improve self-care, quality of life, as well as mortality.[23,24] Identification of user capabilities is highly required for developing digital health applications since the currently available apps are not adequate for use by older adults with HF.[25] Since older adults are also increasingly using smartphones and mobile applications, personalization and patient-centred approaches for these remote health monitoring services are required.[26-28] A similar but simplified mobile application was developed for HF patients and tested using a small-scale study in AIIMS Delhi, which also shows promising results in aspects like patients' quality of life and drug compliance.[29] However, they also suggested better exploration regarding the effectiveness of the mobile application as a large-scale and multi-centre study with a longer follow-up duration.

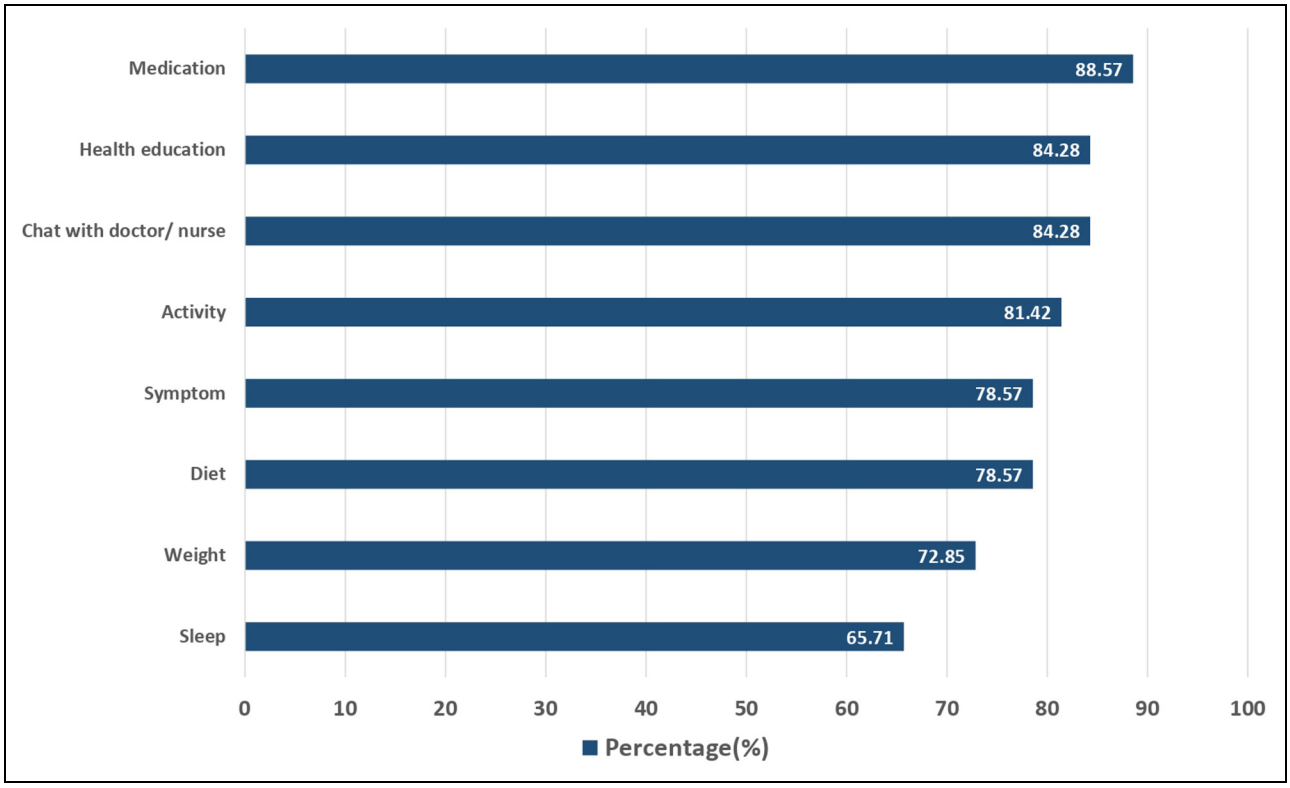

Figure 2. Participants' opinion on features required for heart failure mobile application.

Few studies on the acceptability of mHealth applications were reported; however, these studies are conducted after prototype development as a part of validation and usability testing of the mobile application.[14,26,30-32] However, the current study also focuses on the development of a standardized tool for pre-assessment of acceptability among the target population, which is the first of its kind in India.

More than two-thirds of the participants have always followed their HF medications as advised, and the majority of the participants have reported that they have always followed dietary advice given to them. On the other hand, the current participants' adherence rate to some HF management strategies was low, since a great proportion of the participants reported that they rarely follow the advice in terms of physical exercise and weight monitoring. Weight monitoring has been identified as a pivotal component of HF self-care, as weight gain was previously found to be independently associated with a poor post-discharge prognosis, considering it is the last common step before the worsening of clinical outcomes (Hazard ratio per kg increase 1.16; $P < .001$).[8,33]

The current study reported a significant difference in participants' age concerning smartphone ownership and a significantly reduced LVEF% among participants who were not willing to self-measure and enter their daily parameters into the mobile application. A study by Portz et al[26] found that there were no differences in mobile application acceptability by race, ethnicity or gender. However, older age was significantly associated with a self-identified need for help in the ongoing use of the HF app (*P*-.010). A smartphone application was recently tested for usability and feasibility for HF self-care remote monitoring at St. John's Medical College Hospital, India. The authors also reported that despite the high level of usability, variations in age, gender and socioeconomic status among patients, and their caregivers were found to be important factors in users' engagement with a mobile application.[10]

A systematic review shows that mHealth applications with tailored content based on users' preferences and interests have higher retention rates.[17] A few participants in the study also suggested physical activity and other features to be individualized as per their data entry. A study by Alnosayan et al[14] reported patients' and providers' experiences in using a mHealth system for HF patients. The study suggested that a logging mechanism for abnormal readings, immediate alerts to the healthcare providers, and trend charts for the nurses are some of the most valuable features in their mHealth application. IMS healthcare analytics reported that only one-fifth of consumer-targeted healthcare applications provide information and also track/capture user data. This further reiterates the importance of developing multi-functional digital platforms with improved user interactions.[31]

Taking such features into consideration, the later stages of the current study will include the development of a user-centred mobile application for HF patients, in addition to incorporating the current findings. The development

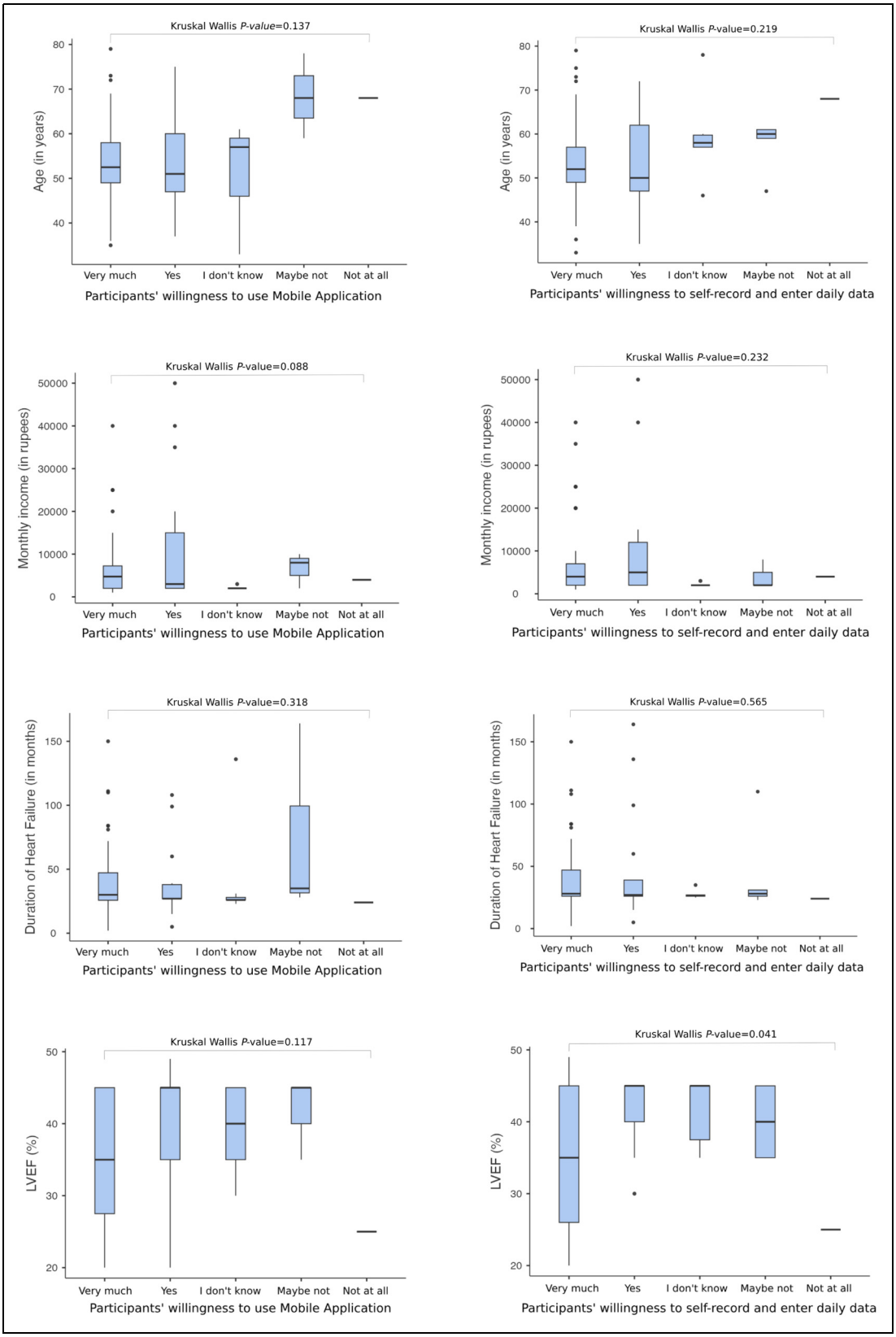

Figure 3. Relationship between selected participant's characteristics and their willingness to use mobile application, self-measure and record daily data.

process, validation and testing of the HF mobile application will further be reported.

Limitations

The major limitation of the current study is the small sample size. A formal sample size calculation was not performed, since we expect personalized opinions from all available patients who were discharged during the mentioned timeline. Other studies can be conducted in different HF clinics using the same tool (HF-NADP) to generalize the participants' responses based on regional preferences. Since the English and Tamil versions of the tool are available and validated, the tool may be used for other HF studies with permission from the authors. A multi-centre assessment of healthcare workers' preferences on features to be included in the HF mobile application could also be included as an extension to the ongoing project.

Conclusion

It is understood that 'One size does not fit all' and all the features identified in this phase may not be integrated into the HF mobile application. However, it is expected that the findings from this initial phase of HF mobile development help to leverage better development of digital interventions for HF patients, to enable effective monitoring of their health outside of the hospital setting.

Author Contributions

The manuscript has been read and approved by all the authors; the requirements for authorship as stated earlier in this document have been met, and each author believes that the manuscript represents honest work.

Data Availability Statement

The data set used in the current study is available on request from College of Nursing, JIPMER through the corresponding author.

Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethical Policy and Institutional Review Board Statement

Institutional Ethics Committee (JIP/IEC/Ph.D/2020/01) for human studies and Ph.D Research Monitoring Committee approved the study. The procedures followed were in accordance with the ethical standards of the institution as well as the Declaration of Helsinki revised in 2013.

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Informed Consent

Informed consent was taken from each participant voluntarily through telephone before enrolment. The participants were also ensured anonymity and confidentiality of their data.

Presentation of the Study Findings

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Supplemental Material

Supplemental material for this article is available online.

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