

Evaluation of a virtual home health heart failure program: A mixed methods study

Nilufeur McKay, Rosemary Saunders, Helene Metcalfe, Sue Robinson, Peter Palamara, Kellie Steer, Jeannie Yoo, Miles Ranogajec, Lisa Whitehead, Beverley Ewens

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Abstract

Background: Heart failure is a prevalent and debilitating condition, affecting millions globally and imposing significant burden on patients, families, and healthcare systems. Despite advancements in medical treatments, the gap in effective, continuous, and personalized supportive care remains glaringly evident. To address this pressing issue, virtual healthcare services, delivered by interdisciplinary teams represent a promising solution. Understanding the outcomes and experience of remote monitoring-enabled interdisciplinary chronic disease management programs can inform resource allocation and healthcare policy decisions.

Objective: The purpose of this study was to evaluate the clinical and behavioral outcomes of patients undertaking a Virtual Home Health Heart Failure Program (VHHHFP) and explore the experiences of patients and health care practitioners.

Methods: The VHHHFP is a virtual post discharge support service for patients with heart failure that includes an intensive 3-month period followed by a maintenance period delivered by an interdisciplinary team. A mixed methods study was conducted with patients and health practitioners. Self-reported outcome data (KCCQ12, PHQ4, PAM13 and PREMS) were obtained from the records of patients (n=55) who completed the intensive phase of the VHHHFP; and interviews were conducted with patients (n= 9) and health practitioners (n= 6). Paired t- test was used to compare quantitative data before and after the three-month intervention and thematic qualitative analysis undertaken of interview data.

Results: Thirty-one (77.5%) of the n=55 patients completed the baseline and three-month follow-up KCCQ12 assessment. The mean KCCQ12 Summary Score at three months was 72.20 which was significantly higher than the mean Summary Score at baseline of 50.51 (p<.001). These findings were similar for the KCCQ12 sub-scales: Physical Limitations (47.09 and 69.43, p<0.001), Quality of Life (43.75 and 62.91, p<0.001), Symptom Frequency (60.40 and 91.70; p<0.001) and Social Limitation (50.0 and 82.50; p<0.001). The PHQ-4 measure of psychological health was completed by n=32 (80%). The median scores at baseline and follow-up for Total Distress (1.50 and 0.0; p<0.02), and the Anxiety sub-scale (1.0 and 0.0; p <0.02) reduced over time. Six hospital admissions were recorded (10.2% of n=49) within 30 days. Nine patient interviews aligned with the Value Based Healthcare (VBHC) Capability Comfort and Calm (CCC) Framework. Three themes were identified 1) Enhanced patient capability, 2) Improved patient comfort and 3) Positive influences on Calm. Six healthcare professionals shared experiences of the VHHHFP, with three emerging themes- 1) Improved patient capability through shared decision making, 2) Improving Capability through care practices and 3) Promoting Comfort and Calm through virtual coordination and collaboration.

Conclusions: The use of technologies to support the management of HF is an area of growth. This study contributes to the understanding of how remote patient monitoring with interdisciplinary chronic disease support integrated into an existing system

can improve clinical outcomes for patients.

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Original Manuscript

Title Page

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Abstract

Background:

Heart failure is a prevalent and debilitating condition, affecting millions globally and imposing significant burden on patients, families, and healthcare systems. Despite advancements in medical treatments, the gap in effective, continuous, and personalized supportive care remains glaringly evident. To address this pressing issue, virtual healthcare services, delivered by interdisciplinary teams represent a promising solution. Understanding the outcomes and experience of remote monitoring-enabled interdisciplinary chronic disease management programs can inform resource allocation and healthcare policy decisions.

Objective:

The purpose of this study was to evaluate the clinical and behavioural outcomes of patients undertaking a Virtual Home Health Heart Failure Program (VHHHFP) and explore the experiences of patients and health care practitioners.

Methods:

The VHHHFP is a virtual post discharge support service for patients with heart failure that includes an intensive 3-month period followed by a maintenance period delivered by an interdisciplinary team. A mixed methods study was conducted with patients and health practitioners. Self-reported outcome data (KCCQ12, PHQ4, PAM13 and PREMS) were obtained from the records of patients (n=55) who completed the intensive phase of the VHHHFP; and interviews were conducted with patients (n= 9) and health practitioners (n= 6). Paired t- test was used to compare quantitative data before and after the three-month intervention and thematic qualitative analysis undertaken of interview data.

Results:

Thirty-one (77.5%) of the n=55 patients completed the baseline and three-month follow-up KCCQ12 assessment. The mean KCCQ12 Summary Score at three months was 72.20 which was significantly higher than the mean Summary Score at baseline of 50.51 ($p<.001$). These findings were similar for the KCCCQ12 sub-scales: Physical Limitations (47.09 and 69.43, $p<0.001$), Quality of Life (43.75

and 62.91, $p < 0.001$), Symptom Frequency (60.40 and 91.70; $p < 0.001$) and Social Limitation (50.0 and 82.50; $p < 0.001$). The PHQ-4 measure of psychological health was completed by $n=32$ (80%). The median scores at baseline and follow-up for Total Distress (1.50 and 0.0; $p < 0.02$), and the Anxiety sub-scale (1.0 and 0.0; $p < 0.02$) reduced over time. Six hospital admissions were recorded (10.2% of $n=49$) within 30 days. Nine patient interviews aligned with the Value Based Healthcare (VBHC) Capability Comfort and Calm (CCC) Framework. Three themes were identified 1) Enhanced patient capability, 2) Improved patient comfort and 3) Positive influences on Calm. Six healthcare professionals shared experiences of the VHHHFP, with three emerging themes- 1) Improved patient capability through shared decision making, 2) Improving Capability through care practices and 3) Promoting Comfort and Calm through virtual coordination and collaboration.

Conclusions:

The use of technologies to support the management of HF is an area of growth. This study contributes to the understanding of how remote patient monitoring with interdisciplinary chronic disease support integrated into an existing system can improve clinical outcomes for patients.

Keywords: Heart failure; Patient Care Team; telemedicine, Value-Based Healthcare

Introduction

Heart failure (HF) has been acknowledged as one of the Western world's most significant public health issues[1]. This chronic condition results in reduced quality of life, creating a burden for healthcare systems in terms of resource use and financial cost[2-4]. Described as a global epidemic, affecting more than 64 million people worldwide [5], a diagnosis of HF is associated with high rates

of morbidity and mortality , particularly in low and middle income countries [6]. The percentage of the population diagnosed with HF around the world varies amongst populations [7], but globally is estimated to be between 1% and 3% of the total population [8]. In Australia, it is estimated that 1-2% of the population are diagnosed with HF, compared to a prevalence of 2.4-3% in the USA [2] and between 1.3% and 6.7% in Asia [3]. In 2017-2018 an estimated 102,000 people (0.5%) self-reported living with heart failure within Australia with around 179,000 hospitalizations in 2020-2021 attributed to heart failure or cardiomyopathy as the primary diagnosis [9]. The prevalence of HF is predicted to increase due to the ageing population, improved treatment of acute cardiac events and availability of evidence-based therapies for those with HF [2] It is estimated that by 2023, cases of heart failure in Australia will increase to 750,000 [10]. The majority of healthcare costs for people with HF, are associated with an increasing rate of hospitalizations due to poor self-care, failure of adherence to treatment or inability to access medications [4] . Research suggests that most patients (80%) living with HF are reliant on their general practitioner (GP) for ongoing management and support [11].

A growing body of evidence supports the use of digital health technology in improving patient outcomes [12-14], with telemonitoring [15] and digital health becoming central to health care [16]. Virtual healthcare has become an indispensable component of contemporary care delivery, which enables those with chronic conditions to stay connected to online supportive environments and clinicians to establish two-way communication and non-invasive monitoring for patients in remote locations [17]. The coronavirus disease 2019 (COVID-19) pandemic expedited the adoption of telehealth globally [18]. However, the evaluation of telehealth outcomes has not necessarily matched the pace of its uptake (18). In response, there has been an increase in the exploration of remote and virtual patient monitoring and care models to manage and improve the outcomes of patients with HF [12]. However, the use of virtual HF programs remains in its infancy in Australia. A recent systematic review identified that telemonitoring, remote patient management and patient self-

empowerment as an integrated approach, performed best in terms of re-admission rates and overall hospital visits [17] with further research into this approach needed [19]. The aims of this study were to evaluate the clinical and behavioral outcomes of patients undertaking a Virtual Home Health Heart Failure Program (VHHHFP), and to explore the experiences of patients and health care practitioners who participated in the program.

Methods

Research design and study population

Mixed methods study was conducted in collaboration with patients and health practitioners. Self-reported outcome data (KCCQ12, PHQ4, PAM13 and PREMS) was obtained from the records of patients (n=55) who completed the intensive phase (0- 3 months) of the VHHHFP; and interviews were conducted with patients (n= 9) and health practitioners (n= 6). A mixed methods approach was selected as it provides the opportunity to integrate quantitative findings in the analysis of the qualitative data [25]. This is particularly important in the evaluation of a chronic disease management program where there is a need to understand from a patient's perspective how programs impact or fail to impact health outcomes observed from a purely quantitative approach. This study method provides a richer level of understanding of content, processes and policies within programs [26]. The study is reported in accordance with the mixed methods reporting guidelines by Lee, et al. [27]. The study population comprised patients who were participating in the intensive phase of the program, the clinicians delivering the program, and other clinicians external to the program but involved in the care of the patients.

Virtual Home Health Heart Failure Program (VHHHFP)

The VHHHFP is a virtually delivered post discharge support service for patients with heart failure. The program aims to:

- Improve heart failure symptoms, quality of life, and physical and social limitations

- Improve heart failure self-management skills and capabilities
- Improve patient understanding of medications and therapy adherence
- Reduce signs and symptoms of anxiety and depression associated with heart failure
- Reduce preventable hospital admissions through collaborative care practices

Suitable patients who meet the inclusion criteria (Table 1) can be referred to the program by a member of their inpatient care team during a hospital admission. Services are delivered via telehealth by a clinical nurse specialist (CNS), clinical nurse or registered nurse, a dietician and a physiotherapist. Interventions provided include care coordination, remote patient monitoring of vital signs and symptoms, nurse led medication titration (as directed by the patient's cardiologist or GP), education, virtually delivered exercise (when clinically appropriate), and support for nutrition and weight management. The necessary equipment is provided to patients at no cost. The program operates during business hours, with a heart failure action plan provided to patients for out of hours concerns. The program integrates with primary and specialist care teams, with medical governance either provided by the patient's existing cardiologist, or GP, as per the specialist's preference. The program's intensive phase is delivered over a period of three months and included an initial visit by one of the VHHHFP clinical nurses who described the program to the patient and obtained consent to participate in the program. Initial screening surveys were completed, and the patient received a comprehensive description of the home monitoring equipment. Upon discharge the patient received intensive care coordination by an interdisciplinary team with remote monitoring, medication titration and self-care management support. More details of these individual components are represented in figure 1. Following this, the patient enters a 3–12-month maintenance phase based on the patient's needs to embed long term self-management behaviorist. The maintenance phase of the program was not included in this study. Upon completion, the patient is discharged to their primary care clinician with an ongoing plan of care for their heart failure. At this point the patient does not have further access to the VHHFP.

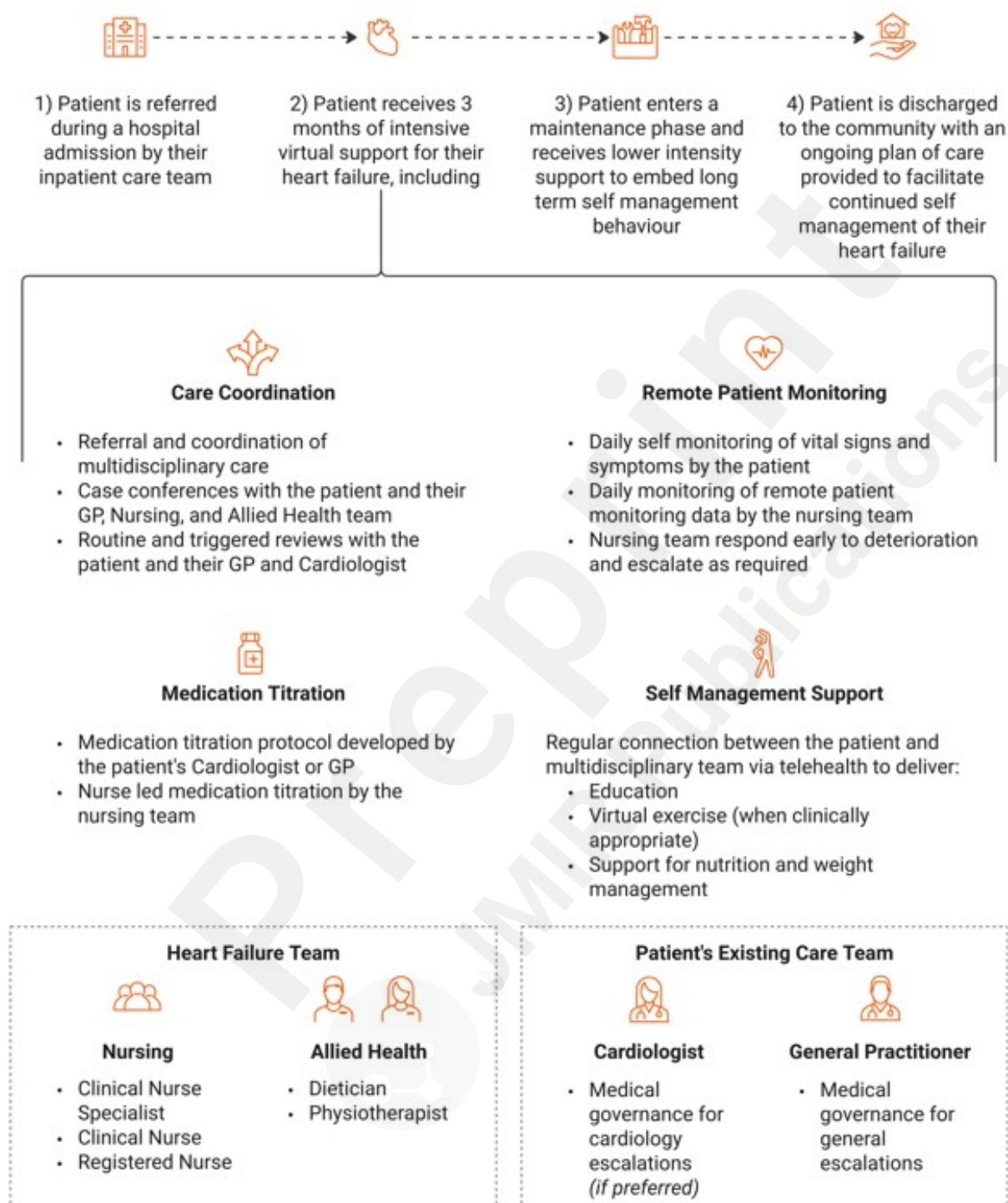


Figure 1 – The patient journey through the Virtual Home Health Heart Failure Program (3 month intensive phase followed by a maintenance period).

Several validated self-reporting assessment tools were used to monitor patient's progress

while on the program. The measures were selected to be consistent with the health outcome measures for patients with heart failure recommended by the International Consortium for Health Outcomes [20], the self-reported outcomes included the Kansas City Cardiomyopathy Questionnaire® (KCCQ12) [21], the PHQ-4 for anxiety and depression [22] and the Patient Activation Measure (PAM) [23] for assessing engagement with healthcare and self-management and a Patient Reported Experience Measure Survey (PREMS). The PREMS was adapted and modified from the Australian Hospital Patient Experience Question Set [24] to suit the context of the VHHHFP.

Table 1. VHHHFP inclusion and exclusion criteria

Patient Inclusion Criteria	Exclusion Criteria
• New or existing diagnosis of heart failure (heart failure with a reduced ejection fraction (HFrEF) or heart failure with a preserved ejection fraction (HFpEF) • NYHA Functional Class I, II or III • Patient referral to the VHHHFP from a clinician at one of the three hospital sites.	• Discharged to a residential aged care facility. • NYHA Functional Class IV • Hemodynamic instability • Recurrent arrhythmias or unstable angina requiring investigation. • Deteriorating renal function defined as eGFR<30ml/min • Continuous oxygen requirement at rest • Existing cognitive impairment

Recruitment and Consent

Patient Participants

Patients provided consent for their quantitative data to be collected for the purpose of evaluation on commencement of the program. Patients enrolled in the intensive phase of the VHHHFP were sent an email by the HF CNS, informing them about the study and the process to participate in an interview. Patients who were interested in participating in the semi-structured interview contacted the study research assistant via email and were given the opportunity to ask any questions they had. Written informed consent was obtained prior to the commencement of the interviews.

Health Practitioner Participants

Health care practitioners (HCP) (including HF CNS, physiotherapists, primary care physicians (GPs) and cardiologists) were eligible to participate if they had delivered care to the patients within the three-month intensive phase of the program. Health care participants who met the above criteria were sent an email to inform them about the study, who then contacted the research team directly. Health practitioner participants provided written consent, prior to the commencement of interviews.

Setting

Three hospital sites across Australia which varied in size from 250 to 900 beds.

Data collection

Data were collected via surveys and individual semi-structured interviews. The quantitative data was collected as part of the VHHHFP, and the qualitative data was collected to explore patients and stakeholder perspectives of the program.

Quantitative data collection

Quantitative data included baseline demographic information and patient self-reported outcome data via the home digital platform as part of the VHHHFP program. Baseline patient demographic and clinical characteristics collected included age, identified gender, HF subtype (HFrEF or HFpEF), NYHA Functional Class and the LACE Index as a measure of patients' risk of 30-day readmission [28]. This information was extracted by a program administrator and provided to the research team. Patients completed the self-reported outcomes directly on the home digital platform at various times during the intensive phase. Pretest data (baseline) and post test data (3 months after enrolment) were collected. Patients were followed up at key timepoints including enrolment (baseline) and at 12 weeks to measure health status (KCCQ12), patient reported experiences measures (PREMS), anxiety and depression (PHQ-4) and engagement with health care and self-management (PAM). Data submitted up to 14 days pre or post the expected completion date (70 – 98 days) of the 12-week program were included for analysis. A secure messaging platform was

used to transfer patient data to the research team. Data did not contain identifiable patient data and were grouped via an ID number for analysis on a per patient basis. For those participants who took part in the qualitative phase of the study, ID was linkable via a separately stored key that provided patient contact details.

Qualitative data collection

Individual interviews were conducted to obtain information about the patient and clinician perspective of the program. The Value Based Healthcare (VBHC) Capability Comfort and Calm (CCC) Framework [29], guided the development of the patient and health practitioner interview questions (Appendix 1). Patients were given a choice to complete interviews in person or virtually. The interviews were audio-recorded and later transcribed by a member of the research team. Patients were given the option to be interviewed individually or with a family member/s and permission sought to audio record the interview. One-to-one individual interviews with health care providers were undertaken by a member of the research team who did not have a professional relationship with the participants. Health care provider participants responded to eight open ended questions (Appendix 1). Interviews were audio recorded and were up to an hour in duration.

Quantitative analysis

All data were exported from Microsoft CSV files to SPSS Version 28.0.1 for analysis. Frequency counts were used to describe data pertaining to patient demographics and clinical status, program experience, and hospital readmissions. The normality of the data on patients' physical and psychological health status and health care behaviours at each time point was assessed graphically and numerically using the Shapiro-Wilk Test for small sample sizes. For data that was normally distributed the mean and standard deviation were used as measures of central tendency and dispersion and dependent samples t-tests used to test for changes over time (Time 1, Time 2) in patient reported outcomes. For data that was non-normally distributed the median and Inter Quartile

Range and the Wilcoxon signed rank test for dependent samples were used. Frequency counts were also provided patient demographic and clinical status data. Patient data sets which had missing pre or post survey data were excluded from the analysis. Patients who died during the study were excluded as required by the organization's ethics committee.

Qualitative analysis

Thematic analysis was then undertaken using Braun & Clarke's six-step approach (familiarization with the data, generating codes, constructing themes, revising and defining themes, and producing the report) [31] to identify patterns of meaning to understand the patient and health care practitioners' experiences of the VHHHFP. The audio-recordings were transcribed verbatim and verified against the recording and the transcripts were read several times before initial coding by one researcher (HM) and then independently by two researchers (RS, NM). Following initial coding, the researchers discussed the coding and reached consensus on categories. Data were organized and managed using Microsoft Excel. Research team discussions then informed the development of themes and sub-themes using the Value-Based Health Care framework [30], comprising the concepts of Capability, Comfort, and Calm.

To ensure qualitative rigour and trustworthiness, data were collected until data saturation was achieved, which was based on the appraisal of the data collected and the rich dialogue that related to the study aim. Member checking was not possible due to the single participant interaction. Discussion and interpretations of the data ensured credibility. The presentation of the findings will guide other researchers in the transferability of the findings. The researchers maintained a clear record of the reflexive analysis process supporting the confirmability of the findings.

Ethical Considerations

The research was approved by Ramsay Health Care Human Research Ethics Committee (2022/PID/2031), and Edith Cowan University Human Research Ethics Committee (2022-03864).

Patients provided consent for their quantitative data to be collected for the purpose of evaluation on commencement of the program. Patients enrolled in the intensive phase of the VHHHFP were sent an email by the HF CNS, informing them about the study and the process to participate in an interview. Patients and staff who were interested in participating in the qualitative component of the study and participating in individual semi-structured interviews were required to contact the study research assistant via email. Participants were provided with a Participant Information Form (PIF) which detailed information about the study and the participant involvement plus it informed participants about a \$50 gift voucher as remuneration for participation. Written informed consent was obtained prior to the commencement of the interviews.

Results

Baseline Characteristics

From 1st June 2022 to 30th November 2022, n=55 patients were enrolled into the VHHHFP across three Australian hospital sites. Data for five patients were not reported in line with the ethical approval granted: three of the five patients died during the intensive phase of the program and two died during the data collection period following completion of the intensive phase of the program. In addition, one patient who enrolled in the program but failed to complete any questionnaire or biometric information was excluded. The demographic information and clinical status of the remaining n=49 patients who enrolled and engaged with the program are presented in Table 2. Of the n=49 patients, seven withdrew and did not complete the program. Three (n=3) due to hospital admission, two (n=2) patients failed to complete the intensive phase of the program within the nominated time: 98 days from the patient's date of enrolment. Data for these seven patients related to changes in physical and psychological health and health care behaviour, and their experiences of the program was subsequently excluded at analysis.

Table 2: Demographic characteristics and the clinical status of patients enrolled and engaged in the VHHHFP

Variable	n	(%)
Sex (n=49)		
Male	31	(63)
Female	18	(37)
Age in years (n=49)		
41-50 years	3	(6)
51 – 60	4	(8)
61 – 70	17	(35)
71 – 80	17	(35)
81 – 90	8	(16)
NHYA Classification (n=42)		
I	0	(0)
II	34	(81)
III	7	(17)
IV	1 ^a	(2)
Ejection fraction % (n=47)		
40% and below	38	(81)
41-49%	3	(6)
50-70%	6	(13)
LACE Score (n=34)		
0 - 4	2	(6)
5 - 9	13	(38)
10 and above	19	(56)

^a Although patients' initial evaluation was NYHA classification IV included due to cardiologist recommendations.

Patients' physical and psychological health status and health care behaviours

Descriptive statistics for measures of physical and psychological health status and health care behaviours taken at the commencement of the program (Baseline: within 0-14 days of enrolment) and at the conclusion of the intensive phase (Follow up: within 70-98 days of enrolment) are

presented in Table 3. Thirty-one (77.5%) of the n=40 patients with heart failure completed a first and follow-up KCCQ12 assessment within the intensive phase of the VHHHFP. The mean Summary Score at follow-up was found to be significantly higher than the mean Summary Score at baseline. Consistent with this, the mean baseline and follow-up scores for the KCCCQ12 sub-scale measures of Physical Limitations and Quality of Life were found to have significantly increased over time, as did the median sub-scale scores at baseline and follow-up for Symptom Frequency and Social Limitation.

The PHQ-4 measure of psychological health was completed by n=32 (80%) of program patients within the intensive phase of the VHHHFP. The median scores at baseline and follow-up for Total Distress (1.50 and 0.0; $z = -2.42$, $p < 0.02$), and the Anxiety sub-scale (1.0 and 0.0; $z = -2.53$, $p < 0.02$) significantly reduced over time, while no statistically significant change over time was found in the median sub-scale score for Depression (0.0 and 0.0; $z = -1.39$, $p = 0.16$). A total of n=28 (70%) program patients completed the PAM-13. Analysis of the mean baseline (57.40) and follow-up (68.26) scores for the PAM-13 showed a statistically significant increase in patients' self-reported knowledge, beliefs, confidence, and skills about managing their heart failure over the course of the intensive phase of the VHHHFP ($t = -4.81$, $df = 27$, $p < .001$).

Table 3: Descriptive statistics for patients' physical and psychological health status and health care behaviours at baseline and follow-up

Measure	n	Period		Statistic (p-value)
		Baseline	Follow-up	
KCCQ12^a	31			
Summary Score		M=50.51; SD=17.59	M=72.20; SD=20.28	$t = -5.91$ (< 0.001)
Physical limitation		M=47.09; SD=29.77	M=69.43; SD=22.62	$t = -4.02$ (< 0.001)
Symptom		Md=60.40;	Md=91.70;	$z = -4.43$ (< 0.001)

frequency		IQR=20.85	IQR=35.40	
Social limitation		Md=50.0; IQR=25.0	Md=82.50; IQR=32.50	z= -4.88 (<0.001)
Quality of life		M=43.75; SD=21.71	M=62.91; SD=25.73	t= -3.94 (<0.001)
PHQ-4^b	3 2			
Total distress		Md=1.50; IQR=4.0	Md=0.0; IQR=1.0	z= -2.42 (<0.02)
Anxiety		Md=1.0; IQR=2.0	Md=0.0; IQR=0.8	z= -2.53 (<0.02)
Depression		Md=0.0; IQR=2.0	Md=0.0; IQR=1.0	z= -1.39 (0.16)
PAM-13^c	2 8	M=57.40; SD=8.53	M=68.26; SD=12.38	t= -4.81 (<0.001)

^a Kansas City Cardiomyopathy Questionnaire

^b Patient Health Questionnaire-4

^c Patient Activation Measure-13

Patient Reported Experience Measures

Of the n=34 (85%) patients who responded to the Patient Reported Experience Measures (PREMS) questionnaire, all (100%) responded 'always' or 'mostly' to questions about their treatment and care (Table 4). Most patients (94%) responded that their views and concerns were always listened to. Twenty-six patients (76%) responded that they always knew how to recognise heart failure or heart attack symptoms and what to do next. Seven (21%) patients responded that they mostly knew how to recognise heart failure, and one responded that they only sometimes knew how to recognise heart failure symptoms. In relation to the patients' experience of the technology of the VHHFP, most patients were satisfied to varying degrees. Similarly, most patients (n=33; 97%) were satisfied to very satisfied that they had the knowledge required to use the technology.

Table 4: Frequency of Patient Reported Experience Measures (PREMS) responses

Experience Items	Always n (%)	Mostly n (%)	Someti mes n (%)	Rarely n (%)	Never n (%)	Total (n (%))
My views and concerns were listened to?	32 (94)	0 (0)	1(3)	0 (0)	1 (3)	34 (100)
My individual needs were met?	30 (88)	0 (0)	4(12)	0 (0)	0 (0)	34 (100)
I felt cared for?	31 (91)	3 (9)	0 (0)	0 (0)	0 (0)	34 (100)
I was involved as much as I wanted in making decisions about my treatment and care?	30 (88)	4 (12)	0 (0)	0 (0)	0 (0)	34 (100)
I was kept informed as much as I wanted about my treatment and care?	33 (97)	1 (3)	0 (0)	0 (0)	0 (0)	34 (100)
The staff involved in my care communicated with each other about my treatment?	31 (91)	3 (9)	0 (0)	0 (0)	0 (0)	34 (100)
I knew how to recognise heart failure or heart attack symptoms, and what to do next if I experienced symptoms?	26 (76)	7 (21)	1 (3)	0 (0)	0 (0)	34 (100)
I felt confident in the safety of my treatment and care?	30 (88)	4 (12)	0 (0)	0 (0)	0 (0)	34 (100)
	Very Satisfied n (%)	Satisfied n (%)	Neither n (%)	Very Dissatisf ied n (%)	Dissatisf ied n (%)	Very Dissatisf ied n (%)
How satisfied are you that the technology operated as expected? (i.e., tablet, app, biometric devices, video	22 (65)	10 (30)	2 (6)	0 (0)	0 (0)	34 (100)

calls)						
How satisfied are you that you have the knowledge to use the technology? (i.e., tablet, app, biometric devices, video calls)	26 (76)	7 (21)	1 (3)	0 (0)	0 (0)	34 (100)

Readmission to hospital

The analysis of the patients' admission to hospital during the intensive phase of the VHHHFP was undertaken on the n=40 patients who completed the intensive phase of the VHHHFP within 70-98 days and those patients who withdrew from the program (n=7) or failed to complete the intensive phase of the program within 70-98 days (n=2). A total of six hospital admissions were recorded for five patient participants (10.2% of n=49 program participants) within 30 days of the patients' commencement of the VHHHFP (based on the patient's recorded start or enrolment date). One patient was admitted twice in three days within the 30-day period. The earliest admission within the 30-day period occurred at 7.8 days, the latest at 27.9 days.

A further eight hospital admissions for seven patients (14.2% of participants) were recorded between days 31-98 of the patients' commencement of the VHHHFP (Table 5). None of these patients had previously recorded an admission within 30-days. One patient was admitted twice in three days within the 31-98-day period. The earliest admission during this period occurred at 36.7 days, the latest at 89.9 days. In total, 14 separate hospital admissions were recorded during the intensive phase of the VHHHFP across 12 patients (24.5% of program participants). However, data provided were not complete and consistent for all hospital admissions, to determine the reason or cause for the admission, (i.e. all cause or heart failure related or otherwise) for the 14 hospital admissions.

Table 5: Frequency of all cause and 30-day readmissions to hospital during the intensive phase of the

VHHHFP

Frequency of hospital admissions	Number of patients	%	Readmitted within 30 days of commencing the VHHHFP Program	%
No admissions	37	75.5	44	89.8
1	10	20.4	4	8.2
2	2	4.1	1	2.0

Semi-structured Interviews

Nine patients participated in the interviews, four females and five males, ranging in age from 53-82 years. The VHHHFP program was described by patients as a virtual resource that facilitated clinician interaction and care and was a platform for sharing of clinical patient self-measures and communication. Three themes were identified from the analysis that described the patient experiences of the VHHHFP program, following completion of the 12-week intensive phase of the VHHHFP. The first theme described how the VHHHFP Enhanced patient capability for self-management of heart failure. Patients described recognising the need to engage in individualised self-care, and the program enhanced their ability and empowerment to confidently manage their heart failure. The second theme Improved Patient Comfort was an outcome of engagement with the Program where patients described the VHHHFP as Allaying patient fear and uncertainty regarding their heart failure condition and the Information and education (provided from the program) contributed to patient comfort, and Support from family. The third theme described Positive Influences on calm and how Calm improved through (the provision of) coordinated care and supportive environment created, the Virtual program provided a supportive environment.

Table 6: Themes and associated exemplars generated from patient interviews

Theme	Sub-theme	Exemplars
Theme 1: Enhanced patient capability	Improving capability through patient	<i>I counted every bit of fluid I put into myself, not quite so strict now, but because I counted everything for a long time, are now know exactly of what how much I can have. (P1)</i> <i>The skills that they've given me the routine that they've given</i>

	developing skills	<i>me is fantastic. I feel great, compared to what I was. (P3)</i>
	Empowered to manage self-care activities.	<i>They're all practical. It keeps me on my toes with what I've got to do at home and to make sure that I'm meeting the goals, you know, which is set. (P9)</i>
Theme 2: Improved Patient Comfort	Allaying patient fear and uncertainty.	<i>When I was in hospital and diagnosed with heart failure. I just thought crikey you know what's going to happen now when I got home, and I have to look after myself. So that thought was really quite daunting (P1)</i> <i>When they said you've got a heart failure and I and I, I looked at him and I thought, well, you know, what does that mean? It's I'm still alive. Obviously, my heart hasn't failed completely. (P3)</i>
	Information and education contributed to patient comfort.	<i>Yeah, in the beginning when I was having weekly consults with xx. He was always trying to educate me on what I had to do, what I could expect and all that sort of thing. Yeah, telling me all about it. Yeah, it's very good. (P1)</i> <i>And they're great to talk to. Any questions, not a problem. I mean, they've been fantastic. Absolutely brilliant. (P3)</i>
	Support from family.	<i>She's well aware of the whole program and supports it. (P9)</i> <i>My wife did support. ...Make sure I do the blood pressure in the morning with my measuring of vital signs regularly weight. Very proactive and person to. Help me. You know she's great. (P2)</i>
Theme 3: Positive Influences on Calm	Calm improved through coordinated care.	<i>And I think the having the virtual nurse, you can ask whatever you like cause it's you and him, or you and her. So, anything that's troubling you bothering you (P7).</i> <i>Talking to him and then explaining to me why they do it, why you're doing this when they're speaking to him once a week, then once a fortnight now, once a month, there's been fantastic. It's really answered a lot of questions. Yeah, and that's great. I would recommend it to anybody who's had this problem. (P3).</i>
	Virtual program provided a supportive environment.	<i>And I think it's very. Very appropriate. That was the word I was going to respond to. It is appropriate and it is manageable, and I think it's well directed. It's focused on. And I thought I knew it all, but I obviously didn't (P4).</i> <i>I think it sort of gives you a bit more confidence about what you're doing as well, especially when you don't have the hospital around the corner on like I have so. (P5)</i>

Six healthcare professionals (four nurses, one cardiologist and one dietician) shared their experiences and perceptions of the VHHHFP program. For the purposes of the study the term staff will be used, however in the VHHHFP, staff were either employed directly by the organisation delivering the service or as external providers. Through individual interviews the experiences and

perceptions of healthcare practitioners involved in the VHHHFP program were explored. The first theme identified health professionals Improving patient capability through a shared understanding of health needs. This theme included Creating a supportive environment of care, the Importance of guidelines for shared care, and health professionals getting Satisfaction from supporting patients in a virtual model of care. The second theme Improving capability through care practices encompassed staff perception of making a difference to patient self-care as an outcome of the VHHHFP. This was described as achieved through the Provision of care to maximise outcomes and patient capability and Empowering patients in self-care practices. The third theme Promoting comfort and calm through virtual coordinated and (a) collaborative care approach described how staff identified that the VHHHFP contributed to patient comfort and Calm. Recognition of multi-disciplinary model of care and that the virtual program enables partnership with care team and patients, were identified as critical components to the success of the program. Some participants also acknowledged that access to GPs or cardiologists presented a challenge sometimes. Tables 7 provide exemplars for the themes and sub-themes.

Table 7: Themes and Exemplars generated from Healthcare Professional interviews

Theme	Sub-theme	Exemplars
Theme 1: Improving patient capability through a shared understanding of health needs	Creating a supportive environment of care	<i>You do build up that little bit more of a rapport with them. And a bit of that connection(P2)</i> <i>You know you build with the patient that relationship that is actually I think one of the main reasons why as well that we're able to have such a successful program (P1)</i>
	Importance of guidelines for shared care	<i>I'm still getting skills in and confidence, but there is a good protocol to follow. And I've always got xxx to talk to if I need to. (P4)</i> <i>So, the protocols in place are for standard for everyone, which guides us to do what we need to do, but at the end of the day, we also correlate them with the patients' symptoms and that's how we're able to do things and that's what the protocol dictates as well. (P1)</i>
	Satisfaction from supporting patients.	<i>I am very. Happy with, you know my experience and hopefully the patients do feel the same way as well. (P1)</i> <i>I think it's a really great program and I've been loving it. I've always been a bedside nurse. But doing this virtually, ...</i>

		<i>that's a different sort of nursing that I've never done before, which is really, really interesting and rewarding. (P3)</i>
Theme 2: Improving capability through care practices	Provision of care to maximise outcomes and patient capability	<i>We can prevent, you know, patients falling unwell. (P1) I think it's amazing. I think it was something that is lacking and something a service that is usually extremely vital to all tertiary cardiology care.....But with xxx hospitals being a unique service, this has certainly filled the gap, and has in my point of view decreased morbidity and hospitalizations for all our heart failure patients. (P6)</i>
	Empowering patients in self-care practices	<i>Do these things with the patients where I can guide them and make sure to reduce their risk of readmission and giving them the skills to look after themselves much better moving forward as well. (P1) Some are super compliant, and you know adhere to their restrictions or diet and exercise regime(P4)</i>
Theme 3: Promoting comfort and calm through virtual coordinated and collaborative care approach	Recognition of multi-disciplinary model of care	<i>There's a lot on it. So, you're going to stay on your toes, but if there is an issue, you've got it to refer to so. (P3) I think they've (GP's) been excellent. That they feel like they've been very involved, I hope. The team has really tried their best to involve the GPs within the whole management team. (P6)</i>
	Virtual program enables partnership with care team and patients	<i>...patients can access, you know, expert nursing and allied healthcare and also specialist care as well from the fact that we can be that link between their treating specialists and them in wherever they are around Australia. (P2) Close communication with the cardiologist or whoever is the referring specialist, allows me to guide the patient. (P1)</i>

Discussion

Principal Findings

This study contributes to the knowledge base on the impact of a virtual health approach from both a patient and clinician perspective, and on how virtual health solutions can be integrated into existing care. A statistically significant improvement in physical health and wellbeing on completion of the intensive phase was noted as measured by the KCCQ12. Drawing on previous research as a reference point [21], a 5-point threshold for meaningful clinical change has been proposed as equivalent to a ~10% relative reduction in the risk of adverse clinical events. Using this interpretation, a mean improvement of 21.7 in KCCCQ12 patient summary scores from commencement to completion of the intensive phase of the VHHHFP could be considered to

represent a 40% relative reduction in the risk of adverse clinical events pre- and post- intensive phase of the VHHFP [21]. This highlights the beneficial effect of the program on patients' physical health and well-being. The positive impact of post discharge interventions on KCCQ-12 scores and therefore the wellbeing of patients with heart failure have also been demonstrated elsewhere. An intervention study by Stubblefield, et al. [30] comprising self-care activities, home visits and telephone calls to coach participants in the aspects of HF self-management, demonstrated a 5.4 point increase in KCCCQ12 scores in the intervention group compared to the usual structured care group. The ongoing connection with clinicians following discharge from hospital appears to contribute to the wellbeing of patients with HF. The quantitative findings reflect the qualitative themes of patients feeling "empowered to manage self-care activities", that "information and education contributed to patient comfort" and that the "virtual program provided a supportive environment".

Comparison to prior work

Anxiety and depression are known to be significant issues in patients with HF [31], impacting on many areas of a patient's life including adherence to treatment plans. Anxiety and depression are also associated with reduced quality of life [32], reduced exercise capacity [33], increased hospitalisations and mortality [34]. In this study there was a statistically significant reduction in self-reported levels of anxiety and improvement in self-reports symptoms on the distress scale during the program, highlighting the importance of routinely monitoring mood in patients with HF. Enabling patients to self-report symptoms of anxiety and depression in a safe way, provides the opportunity for early recognition and management, which in turn may improve the management of HF and improve patient outcomes. This was reinforced in the qualitative data of this study where patients reported feeling reassured when they had a clinician to contact if, and when, they had an exacerbation of their symptoms. Studies of patients with cardiac conditions have traditionally measured easily accessible outcomes such as hospitalisations and mortality, a strength of this study is the focus on patient reported outcomes which provides clinicians and researchers with an accurate report of health status

directly from the patient, leading to the capture of meaningful data of the patient experience [35].

Enhanced patient “Capability” is an important outcome for the program given the centrality of self-management in heart failure. This was highlighted in the qualitative results relating to patient experiences after engaging with the VHHHF program. The availability of staff to ask questions and allay concerns were described by patients as important and to also contribute to their Comfort, providing reassurance that someone was monitoring their measurements. This highlights the value of the availability of support beyond scheduled consultations. The CCC framework highlights the component of “Calm” which from a patient’s perspective reiterates the important benefits of having services designed around them, rather than around the health practitioner, reducing the stress of accessing care and minimising disruption to their lives. These qualitative findings could potentially be linked to the positive change in PHQ-4 Total distress score which was statistically significant. Virtual programs such as the VHHHFP promote outcomes related to “Calm” for post-acute support services. The impact and importance of care integration has been evidenced in other studies and populations where continuity and availability of healthcare providers was recommended [36]. The findings from this study highlighted the need to ensure all health practitioners involved in the patient’s care were familiar with the program’s services to ensure smooth communication processes. The impact of communication processes on Calm has also been reported in other populations. In a study with people diagnosed with bipolar disorder, participants reported that their sense of Calm was enhanced by increased engagement time and improved communication with healthcare providers [37] and in young adults diagnosed with cancer [38].

The qualitative data supports a clinically significant improvement in self-reported knowledge, beliefs, confidence, and skills about managing heart failure over the course of the intensive phase of the VHHHFP. Similar effects were reported in a study of patients with atrial fibrillation undertaking a virtual program during the COVID-19 pandemic. Improvements in self-monitoring abilities and self-management behaviours, and statistically significant reductions in anxiety and depression were

also findings from this study [39]. Patients with HF are particularly vulnerable in the immediate post hospital discharge period whilst transitioning to their home environments.

The up-titration of guideline directed medications is a cornerstone in patients with HF, particularly in the context of reduced ejection fraction [40] and is an essential strategy to fill the gap in care during the early discharge period [41]. Evidence based clinical guidelines recommend that each medication be titrated as tolerated to the target dose which was supported by landmark clinical trials to achieve maximum benefits [42]. Medication up titration had limited uptake in this study despite processes for this being in place, including the availability of medication up titration request forms. The qualitative data did not directly identify why the opportunity for up-titration was not readily taken up, but this could be related to the references to challenges in accessing GPs or cardiologists where any changes to a titration plan required a GP or specialist oversight. The qualitative data indicates that nursing staff reported the need to titrate medications but did not have the protocol or scope to do so without contacting the patients' GP or specialist. In a study exploring the barriers to up-titration of beta blockers in patients with HF in the community, barriers identified included physicians' concerns about medication side effects and polypharmacy, existing healthcare system barriers, comorbidities, patient communication/involvement, and physician's knowledge and or experience [43]. The lack of uptake and potential missed opportunity to improve patient outcomes is an area for further exploration. An extended scope of practice for nurses to up titrate and initiate guideline directed medications could be an option for future iterations of the VHHHF program [44].

Data on hospital admissions were not collected from time of discharge from hospital, but from time of enrolment into the program which is a limitation of this study. However, the rate of hospital admissions within 30 days of enrolment into the VHHHFP was 10.2% which does compare favourably to 30 day all cause readmission rates in a previous study which demonstrated 20% [45]. Whilst a direct comparison cannot be made due to potential delays from discharge from hospital to onboarding to the program, the results are still promising in that readmission was well below 20%.

The finding is also in line with previous research that demonstrated a reduction in readmission rates in similar, virtually delivered, remote monitoring programs for patients with heart failure [14].

Strengths and Limitations

A strength of this study was the exploration of self-reported patient outcomes and patient and clinical staff perceptions of the VHHHFP. The exploratory qualitative process evaluation provided valuable insights into the acceptability and usability of the intervention from the perspectives of the participants. The qualitative data allowed a deeper understanding of how participants responded to the program and the contextual factors that influenced the study outcomes. Trials in the study of patients with cardiac care routinely report outcomes such as hospitalizations and mortality. However, a significant strength of this study was the focus on patient reported outcomes, an approach that could be more widely adopted in virtual health programs and beyond.

It is important to acknowledge the limitations that may affect the validity and generalizability of the research findings. Firstly, the service was set up as a pilot to assess feasibility and as such, the sample size was not powered to detect change with a level of statistical certainty. Secondly, the evaluation commenced after the commencement of the service and as such it was not possible to create a control group minimising the opportunity to assess selection or detection bias. The variation in the time taken to complete the intensive phase and the submission of data associated with key time points made comparisons between participants in the current evaluation challenging. To include as many participants as possible in the study, the parameters relating to the time taken to complete the intensive phase and the submission of data associated with a given time point were extended. Thirdly, the number of patient participants who agreed to be interviewed post completion of the 12-week intensive program was low and there may have been a self-selection bias among patients who chose to participate in the qualitative component of this evaluation. Additionally, direct comparisons with data on readmission rates could not be made where the date of discharge from hospital (the admission which led to the initial referral to the program) was not collected.

Future Directions

The growth in virtual health programs such as VHHHP, have demonstrated a range of benefits to

patients regarding improved access to advice and guidance on their medical condition without the need to visit healthcare facilities. This approach has led to the re-allocation of much needed healthcare resource provision [46], especially within the high-resource area of heart failure management. The virtual nature of the intervention creates the opportunity to scale within and across health care services. However, this service sits in what can be termed the “missing middle” of healthcare, with the service spanning a gap between care provided in the acute care and community settings. One of the key barriers to further implementation in the Australian context relates to funding mechanisms. Ongoing support for services that do not meet existing healthcare funding mechanisms can be uncertain, limiting their increased uptake and opportunity for further translation of benefits to a broader section of the community. Further research into enhancing the adoption of such models is needed. The use of technologies to support the management of HF is growing internationally. Understanding how virtual healthcare that uses remote patient monitoring can be integrated into existing systems and models of care is a challenge that requires multilevel collaboration. The findings of this study support the need to develop and adoption virtual healthcare solutions for chronic disease management including and beyond HF.

Conclusion

The evaluation of the Virtual Home Health Heart Failure program (VHHHFP) demonstrates improvements in both clinical and behavioural outcomes, directly addressing our primary study aim. Patients completing the program showed statistically significant improvements in all KCCQ12 domains, including Physical Limitations, Quality of Life, Symptom Frequency and Social Limitations. Psychological health measures similarly improved with reduction in Total Distress and Anxiety scores. Our second aim, exploring participant experiences revealed enhanced Capability, improved Comfort and positive influences on Calm according to the Value Based Healthcare Framework. Clinician experiences identified benefits in patient Capability through

shared decision making and care practices, while also noting virtual coordination promoted patient Comfort and Calm. This evaluation, utilizing both quantitative and qualitative methods, provides evidence for the effectiveness of the VHHHFP model in HF management.

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Data Availability

The data that support the findings of this study are available from the corresponding author on reasonable request.

Conflicts of Interest

JY and MR are employees of Home Health, Australian Unity and KS of Ramsay Health Care (Ramsay Connect) which are the companies involved in the development and delivery of VHHHFP. The authors have no other conflicts of interests to declare.

Author Contributions

NM, BE, RS, LW, KS, JY and HM designed the study. NM, HM, BE, LW and RS developed the semi structured guiding questions for the qualitative interviews. HS and SR completed the qualitative interviews. HM, RS, LW and NM completed the qualitative analysis and initial coding. PP and SR completed the quantitative data analysis. KS, MR and JY were involved in the program design that was evaluated by the study. All authors approved the final manuscript. Conflicts of Interest JY and MR are employees of Home Health, Australian Unity and KS of Ramsay Health Care (Ramsay Connect) which are the companies involved in the development and delivery of VHHHFP. The authors have no other conflicts of interest to declare.

References

Supplementary Files

Untitled.

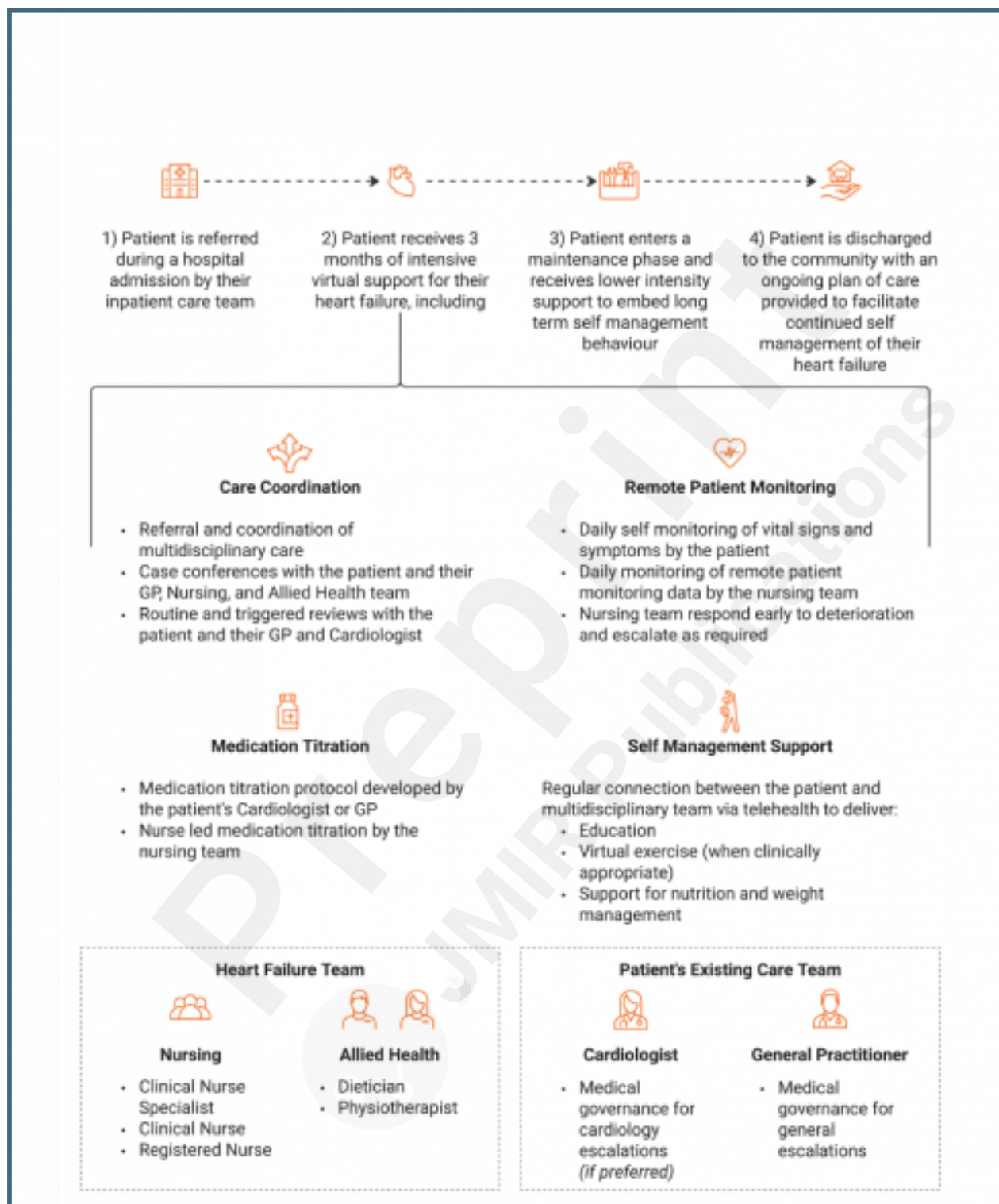
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URL: <http://asset.jmir.pub/assets/0961cf0f968caebd3fe4fc6fd003c16f.docx>

Figures

Virtual home health heart failure program patient journey.



CONSORT (or other) checklists

Mixed methods reporting checklist.

URL: <http://asset.jmir.pub/assets/f51ed910b00b53fe7c3c0961c9d0b810.pdf>

