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## Impact of a nurse-led teleconsultation strategy for cardiovascular disease management during COVID-19 pandemic in India: A pyramid model study

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**Study title**

Impact of a nurse-led teleconsultation strategy for cardiovascular disease management during COVID-19 pandemic in India: A pyramid model study

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## ABSTRACT

**Objective.** The COVID-19 pandemic necessitated the use of telemedicine to maintain continuity of care for patients with cardiovascular diseases (CVD). This study aimed to demonstrate the feasibility of implementing a nurse-led teleconsultation strategy for CVD management during the COVID-19 pandemic in India and evaluated the impact of nurse-led teleconsultations on patient treatment satisfaction.

**Design, setting and participants.** We developed a two-stage teleconsultation strategy and tested the feasibility of implementing a nurse-led teleconsultation strategy to manage CVD in a northern state (Punjab) in India. A multidisciplinary team of experts developed the treatment protocol used for teleconsultations to manage CVD. Nurses were trained to provide teleconsultation, triaging of patients, and referrals to the physicians. Patients with CVD who had an out-patient visit or hospitalization between September 2019 - March 2020 at the Dayanand Medical College Hospital, Ludhiana, India, were contacted by phone and offered teleconsultations. Telemedicine strategy comprised of: Stage 1 nurse-led teleconsultations and Stage 2 physician-led teleconsultations. Descriptive analysis was performed to report the proportion of patients triaged by the two-stage telemedicine strategy, and patient's clinical characteristics, and treatment satisfaction between the nurse-led vs. physician-led teleconsultations.

**Results:** Overall, nurse-led stage 1 teleconsultations were provided to 12, 042 patients with CVD. The mean (SD) age of the participants was 58.9 years (12.8), and men were 65.4%. A relatively small proportion of patients (6.3%) were referred for the stage-2 physician-led teleconsultations and of these only 8.4% required hospitalizations. During stage 1 nurse-led teleconsultations, patients were referred to the physicians due to uncontrolled diabetes (24.9%), uncontrolled hypertension (18.7%) and congestive heart failure (16.2%). The patient's treatment satisfaction was similar between the nurse-led vs. physician-led teleconsultations (p value=0.07).

**Conclusion:** This study showed that a low-cost nurse-led telemedicine strategy is feasible to implement in a resource-constraint setting for triaging patients with CVD and reduces physician's burden.

## Strengths and Limitations of the study

1. To our best knowledge this is the first study to demonstrate the successful implementation of a pyramid-based healthcare delivery model i.e., nurse-led consultations to provide timely and effective cardiovascular care during the COVID-19 pandemic in India.
2. The patient's treatment satisfaction was similar between the nurse-led versus physician-led teleconsultations.
3. An important limitation of this study is that the findings are solely based on a single-centre implementation of telemedicine strategy, which may not be generalizable to other populations.

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## Introduction

The COVID-19 pandemic has led to emergence of several challenges in providing care to both chronic and newly diagnosed patients with cardiovascular diseases (CVD). In India, the first COVID-19 confirmed case was detected in the state of Kerala on 30<sup>th</sup> January 2020.<sup>1</sup> In view of its worldwide spread, World Health Organisation (WHO) declared COVID-19 outbreak as pandemic on 11<sup>th</sup> March 2020.<sup>2</sup> In the wake of COVID-19 pandemic, a nationwide lockdown was imposed on 25<sup>th</sup> March 2020 by the Indian government. During the complete lockdown for more than two months only the emergency services were allowed while maintaining the social distancing norms. Given the high prevalence of CVD in India (>54 million),<sup>3</sup> the nationwide COVID-19 pandemic related lockdowns have impacted the care by preventing both routine in-patient and out-patient care.

Furthermore, the COVID-19 pandemic related mobility restrictions, non-availability of nearby healthcare facilities especially in rural areas, need for social distancing, patients' fear of acquiring infection from healthcare facilities, necessitates the use of telemedicine strategy to provide timely care for patients with CVD. Telemedicine refers to providing remote essential medical consultations aided by the advanced technology. In India, telemedicine is not a popular mode of providing healthcare services due to physician's time constraints, less familiarity with the telemedicine principles and technology and partly due to the absence of standard guidelines on the application of telemedicine for CVD management. The pyramid model has been previously used in public health program.<sup>4</sup> Traditionally, a 4-tier pyramid is depicted by the population wide interventions with maximum impact at base followed by primary, secondary and tertiary interventions in that order tapering up to the apex of it.<sup>5</sup> We proposed a 3-tier pyramid model to deliver teleconsultations for patients with CVD during a pandemic situation within the already constraint healthcare delivery system. The base of the pyramid is represented by the nurse-led teleconsultation for screening bulk of the patients followed by the waist represented by the physician-led teleconsultation and the apex represented by the tertiary care referral. This study describes the implementation of a nurse-led teleconsultation strategy to manage CVD during the COVID-19 pandemic and related lockdowns in India and evaluate the impact of nurse-led telemedicine strategy on patient's treatment satisfaction.

## Methods

### Study setting and population

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This study was conducted in a northern state (Punjab) in India during the first wave of COVID-19 pandemic and ensuing nationwide lockdown over four weeks between 26 March 2020 to 25 April 2020. We gathered the contact information of all the patients with established CVD who attended the Dayanand Medical College (DMC) hospital, Ludhiana, Punjab, India in the past six-months, i.e., between 1<sup>st</sup> September 2019 and 24<sup>th</sup> March 2020. The patients with mechanical prosthetic valve or those receiving oral anticoagulation therapy were excluded from the study as these patients were followed up using a different treatment protocol and participated in a separate research study. Of the total 14,344 patients who had previously attended DMC hospital between Sep 2019 and Mar 2020, the full contact details of 12,042 patients could be retrieved. Of these, 7242 patients had attended the outpatient facility and 4800 patients had a recent hospital admission. The detailed medical records of all IPD patients were retrieved from the hospital database. The study design and sample selection are shown in **Figure 1**. The study was approved by the Dayanand medical college and Hospital Ethics Committee and verbal consent was obtained from the patients over the telephone prior to teleconsultation and any study related data collection.

### **Nurse-led teleconsultation strategy**

Given the ubiquitous use of mobile phones and relative paucity of video enabled smart phones or tablets, we used simple mobile phones as the tool for teleconsultation services. The real-time audio interaction was the preferred mode for care delivery. The teleconsultation-based care delivery was implemented by a team of trained health care workers (HCWs) consisting of 36 nursing staff randomly divided into three groups, and seven consultants in the field of medicine. As per the teleconsultation guidelines endorsed by the Indian Ministry of Health and Family Welfare, we conducted a one-week long teaching seminars for the physicians and nurses to standardize our treatment protocols and to improve their understanding of the teleconsultation principles used in this study.<sup>6</sup> Teleconsultation approach comprised of two stages. During stage 1, all patients (n=12042) were tele-consulted using the pre-specified questionnaire (**supplementary file 1**) by 36 nursing staff. The stage-1 questionnaire was focused on patient's demographic information, clinical symptoms, recent values of blood pressure (BP), and blood glucose, medicines related issues, exercise and patients' well being score (0-10). This stage 1 was led by nursing staff and supervised by a physician in-charge. In the next stage (stage 2), based on pre-defined cut-offs the patients shortlisted by the nursing staff were referred for teleconsultation by physicians. In stage 2, the physician-led teleconsultation focussed specifically on the clinical complaints for which the patients were referred after screening from stage 1 and were either tele-consulted as per the guidelines or were referred to nearby tertiary care centre as



per the clinical condition. This study utilised the previously described three-tiered pyramid model approach for teleconsultation: pyramid base was formed by stage 1, waist formed by stage 2, and apex formed by the patients referred for the hospital admission at tertiary care centre.

### Data collection and measurements

All the patients were equally distributed to 36 trained nurses. We administered a set of questionnaires to collect patient-reported outcomes, the response of which was recorded telephonically. Briefly, the questionnaire focused on the clinical symptoms, BP control status (BP recorded within last one week), diabetes control status (blood sugar level recorded within last two weeks), medication availability and compliance to that, medication history, and well-being score. The patients were asked to get themselves checked for BP and random blood sugar (RBS) level either by home monitors (if available) or from nearby clinic/ laboratory and provide the information to the interviewer on a follow up interview. The patient wellbeing score used was an 11-point score ranging from 0-10 that was categorised as: very high (9-10), high (7-8), medium (5-6), and as low (0-4).<sup>8</sup> A contact number of a mobile number was provided to all the patients as a 24-hour help-line number to ensure medical assistance whenever needed.

Fever was defined if body temperature was  $\geq 38^{\circ}\text{C}$ . Influenza-like illness was defined as "an acute respiratory illness with a measured temperature of  $\geq 38^{\circ}\text{C}$  and cough, with onset within the past 10 days".<sup>9</sup> For blood pressure (BP), the controlled status was defined as systolic BP (SBP) of  $\leq 130\text{mm Hg}$  and diastolic BP (DBP) of  $< 80\text{mm Hg}$  while BP cut off for physician's referral (labelled as critically high) was defined as SBP of  $\geq 160\text{mm Hg}$  and DBP  $\geq 100\text{mm Hg}$ . BP readings in between these values were defined as intermediate high. For diabetes mellitus, controlled status was defined as random blood sugar (RBS)  $< 200\text{ mg/dl}$  while the RBS cut-off for physician's referral (labelled as critically high) was defined as  $\geq 300\text{ mg/dl}$ . The RBS readings in between these values were defined as intermediate hyperglycemia. These limits were defined based on expert consensus meeting. Regular exercise was defined if the patient was doing yoga as advised at the time of discharge or at least  $> 30$  minutes of moderate activity<sup>10</sup> for at least 5 times a week (preferably daily). The compliance to medication was referred to the adherence to the medication for the last 2 weeks prescribed to the patient.<sup>11</sup>

Further, in a randomly selected sub-sample of 1200 patients from the study population we assessed the difference in patient's perceived treatment satisfaction between the nurse-led teleconsultations and physician-led teleconsultations. This sub-set of patients were distributed among the nursing staff and physicians. All these patients were tele consulted by using a pre-tested questionnaire (**supplementary file 2**) to assess: 1) patient satisfaction level with nurse-led versus physician-led teleconsultations and 2) impact of COVID-19 pandemic on CVD patients. A

1 modified version of the treatment satisfaction questionnaire for medication (TSQM) was used to  
2 assess the treatment satisfaction in the preceding 30 days<sup>7</sup>. The patient's level of satisfaction with  
3 was assessed on a scale of 0-6, where 0=very dissatisfied and 6=very satisfied. The impact of  
4 COVID-19 on the patient's mental health was assessed using a pre-tested questionnaire and it  
5 focused on the stress from work or other responsibilities, ability to cope with the ongoing pandemic  
6 stress, and overall health status on a scale of 0-100.  
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## 11 **Statistical analysis**

12 We used SPSS statistics 16.0 for windows (Chicago, USA) for data analysis. The  
13 continuous variables were expressed as mean  $\pm$  standard deviation (SD) and median  
14 (interquartile range) for normally distributed or skewed data respectively. Categorical variables  
15 were expressed as percentage (%). The statistical difference between the treatment satisfaction  
16 levels for the teleconsultation by physician and nursing staff was performed by using Mann-  
17 Whitney U-test as the data was skewed. The skewness of the given data was checked with  
18 Kolmogorov–Smirnov test. The difference between two variables was considered significant if the  
19 two-sided p-value was  $<0.05$ .  
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## 28 **Patient and public involvement**

29 Patients and community members were not directly involved in the development of the  
30 telemedicine-based treatment protocol. However, the study was explained to the participants and  
31 verbal consent obtained prior to provision of teleconsultations and study related data collection.  
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## 38 **Results**

39 Overall, 12 042 patients who previously attended either out-patient department (OPD) or  
40 in-patient department (IPD) between September 2019 – March 2020 at the DMC hospital, Punjab,  
41 were invited to participate in this study. Of these, 7242 patients (60%) were from the OPD and  
42 4800 (40%) patients were from the IPD. **Figure 1** shows the schematic flow diagram of patients  
43 screened at various stages of this pyramid-based healthcare delivery model utilizing nurse-led  
44 teleconsultations (stage 1) and physician-led teleconsultations. **Table 1** presents the study  
45 participants' demographic and clinical characteristics. The mean (SD) age of the participants was  
46 58.9 years (12.8) and 65.4% were men. The most frequently reported comorbidities were  
47 hypertension (45.8%) and diabetes (41.9%). Very few participants reported clinical symptoms or  
48 complaints such as chest pain (1.1%), breathlessness (1.2%) and palpitations (0.2%). Nearly half  
49 of the study participants (51.9%) were monitoring blood pressure at home and one-third  
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1 participants (31.9%) reported self-monitoring for blood glucose. In addition, small proportion of  
2 participants required referral to the physicians due to uncontrolled blood pressure (1.6%) or  
3 uncontrolled blood glucose (2.8%). Difficulty in access to medicines was reported by 5.3%  
4 patients with CVD during the COVID-19 pandemic. Majority of the respondents (87.8%) self-  
5 reported adherence to prescribed therapy and two-thirds (60.9%) reported performing regular  
6 physical activity. However, less than half of the participants with CVD reported taking  
7 cardioprotective drugs such as aspirin, beta-blockers, and statins. On 11-point well-being score  
8 assessment, most participants reported a relatively high well-being score between 7-8.  
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15 **Table 2.** reports the reasons for referral of patients to the next stage 2 physician-led  
16 teleconsultations. After completion of stage 1 nurse-led teleconsultations, 758 (6.6%) patients  
17 were referred to the physician-led teleconsultations. High blood sugar (24.9%), high blood  
18 pressure (18.7%) and congestive heart failure (16.2%) were the most common reasons for referral  
19 to the physicians. In addition, 64 patients (8.4%) required hospital admission. Two patients were  
20 identified via teleconsultation to have COVID-19 infection diagnosed by reverse transcription  
21 polymerase chain reaction (RT-PCR) assay.  
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27 **Table 3.** reports the impact of COVID-19 pandemic on the patients with CVD. Majority of  
28 the respondents (87.6%) did not feel the stress from work or other responsibilities during COVID-  
29 19 pandemic. Further, two-third participants (60.2%) reported that they could very easily cope  
30 with stress during the pandemic. Overall mean (SD) health status reported by the patients on a  
31 scale of 0-100 was 88.4 (6.8).  
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36 **Table 4.** demonstrates the difference in the perceived treatment satisfaction between the  
37 nurse-led and physician led teleconsultations. Large proportion of patients (92.8%) were overall  
38 satisfied with the treatment provided using the telemedicine strategy. The treatment satisfaction  
39 score did not significantly differ between the nurse-led versus physician led teleconsultations  
40 (92.8% vs. 95.2%, p value= 0.075).  
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## 47 Discussion

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49 To the best of our knowledge, this is the first study to demonstrate that nurse-led  
50 teleconsultation strategy can be successfully delivered to provide timely and effective care for  
51 patients with CVD in India during the COVID-19 pandemic. Amidst COVID-19 pandemic, there  
52 were several challenges in providing health care services like decreased availability of health care  
53 workers, shortage of resources and fear of acquiring infection. Due to the restrictions posed by  
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2 the government authorities in order to decrease virus transmission, access to both elective  
3 outpatient and emergency services were restricted.<sup>12</sup> This led on to instantaneous and  
4 unanticipated cancellation of the face to face consultation visits of the patients thereby impeding  
5 the delivery of health care services for those who needed it.<sup>12</sup> Due to lack of health system  
6 preparedness and the lack of conventional telemedicine facilities, immediate application of  
7 telemedicine which is not routinely used especially in country like India was not possible.<sup>13</sup>  
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12 In this study, despite operational difficulties we were able to rapidly create a team of  
13 nursing staff and physicians in a short time and developed standard treatment protocols to provide  
14 care for patients with established CVD. It was also important to ensure that rapid response to the  
15 COVID-19 pandemic and related lockdown, do not affect the quality of care provided by our team  
16 of nurses and physicians, therefore, we conducted appropriate training sessions for the entire  
17 team of health care workers and clinicians.<sup>14</sup> Furthermore, to expedite the process of  
18 teleconsultation, as we envisaged reaching out to large number of patients to provide health care  
19 services, we created a novel 3-tier pyramid model for teleconsultation. Pyramid model has been  
20 utilised in various fields of medicine and for public health action framework<sup>5</sup>, as well as an inverted  
21 pyramid for improving handover care.<sup>15</sup> Apart from the conventional four-tiered pyramid model,  
22 Grizzell's six tier interventional pyramid model and five-tier health impact model have also been  
23 studied in literature.<sup>4</sup> This pyramid model based study clearly demonstrated that large number of  
24 patients could be managed by a trained nursing staff, whereas a relatively small proportion of  
25 patients required physician consultation and hospital admission. By implementing this pyramid  
26 model of healthcare delivery utilizing trained and supervised nurse-led teleconsultations we could  
27 successfully triaged and provided timely care for large number of patients within a short period.  
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38 Considering the patient treatment satisfaction score, most patients (92.8%) were satisfied  
39 with the teleconsultation strategy, and the patient's treatment satisfaction level was comparable  
40 between nurse-led versus physician-led teleconsultations. These findings are consistent with prior  
41 reports that show a good satisfaction level with the use of telemedicine in various disease  
42 conditions.<sup>16-17</sup> Further, this study demonstrated that nurse-led teleconsultations during pandemic  
43 situation when health resources were already overwhelmed, could be of vital importance without  
44 compromising the efficacy of the care delivery model. Our pyramid-based model of  
45 teleconsultation also identified two confirmed cases of COVID-19 infection and both were referred  
46 to nearby tertiary care centre for appropriate care.  
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53 Due to the critical nature of CVD, associated co-morbidities, elderly patients with multiple  
54 disabilities, and with possibility of acute decompensation if left unattended, these patients need  
55 frequent and regular monitoring of various health parameters. Thus, the use of telemedicine  
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1 strategy provided the much-needed healthcare services required to manage these patients with  
2 CVD. Several systematic reviews and meta-analyses have shown a significant reduction in  
3 mortality and hospital re-admissions with the use of telemonitoring among chronic heart failure  
4 patients.<sup>18-20</sup> Utilisation of telemedicine in ST-segment elevation myocardial infarction (STEMI)  
5 care have also shown a substantial improvement in health outcomes.<sup>21</sup> The role of tele-medicine  
6 has also been studied for active surveillance of patients on anticoagulation therapy during COVID-  
7 19 pandemic.<sup>22</sup> During disaster situation and public health emergency, as imposed by COVID-19  
8 pandemic, the telemedicine strategy not only helps in remote triaging the patients and easy  
9 accessibility to routine medical care but also prevents the transmission of virus by decreasing  
10 person-to-person contact.  
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18 A major limitation of this study is that we have implemented only the audio mode of  
19 teleconsultations. Virtual teleconsultation has added advantages like reading the patients' facial  
20 expression, observing some physical signs, perceived psychological satisfaction of the patients.<sup>23-</sup>  
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### Implications of study findings

Given the unprecedented and rapidly evolving COVID-19 pandemic situation in India and  
the need to keep vulnerable patients (and clinicians) at home and away from the health care  
facilities to decrease risk of virus transmission, there has been a rapid increase in use of  
telemedicine. A new belief on telemedicine strategy requires many clinicians and health workers  
to develop skills to obtain objective information from these types of telephone visits. Although  
eliciting a complete medical history and adjudicating medication lists and allergies are crucial  
activities of teleconsultation visits, additional information from a telehealth physical examination  
can be useful, if virtual clinic visit can be delivered. A focussed general physical examination over  
the teleconsultation or virtual clinic visits either confirms clues suggested by the patient's medical  
history or provides data that can direct specific clinical tests or treatments. Our experience is that  
patients with CVD respond positively to these initiatives unequivocally to both the nurse-led as  
well as physician-led teleconsultations. Thus, performance of a teleconsultation strategy to  
manage patients with CVD may be considered as an essential element in the context of post

1 pandemic health care delivery models in India. Future research may also focus on evaluating the  
2 effectiveness of telemedicine on clinical outcomes in a large, randomized trial.  
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## 8 **Conclusions**

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10 This study demonstrated the feasibility to implement a pyramid model-based nurse-led  
11 telemedicine strategy during the COVID-19 pandemic and related lockdowns in India. Large  
12 number of patients with CVD were given teleconsultations in a stepwise approach with optimal  
13 utilisation of the available healthcare providers (i.e., trained, and supervised nursing staff and  
14 physicians), with comparable patient treatment satisfaction level between the nurse-led versus  
15 physician-led teleconsultations. Therefore, such a pyramid model of teleconsultation could be  
16 considered for routine care, beyond the pandemic and in post-COVID India.  
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## Authors' contribution

BM, BS, AG, GS, SA, AS, RT, STC, NA, GSW contributed to the conception and design of the study. BM, BS, KS, NN, AR, DP had a role in acquisition, analysis, or interpretation of data. KS, BS, and BM drafted the manuscript, and all authors critically revised the manuscript. All authors provided technical and material support and approved the final manuscript.

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## Conflict of interest

No conflict of interest to declare.

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**Patient consent for publication.** Not required.

**Ethics approval.** This study is approved by the institutional ethics committee of Dayanand Medical College, Ludhiana, Punjab, India Ref. No. DMcH/DrEclzozo/ 677.

**Data sharing statement.** Data are available on reasonable request. All data relevant to the study are included in the article.

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## List of Tables

**Table 1:** Characteristics of study participants during the nurse-led stage-1 teleconsultations.

	Total (%) (N= 12042)
Age (in years), mean (SD)	58.9 (12.8)
Men	7870 (65.4%)
Hypertension	5515 (45.8%)
Diabetes mellitus	5046 (41.9%)
<b>Clinical symptoms</b>	
Chest pain	137 (1.1%)
Palpitation	29 (0.2%)
Breathlessness	142 (1.2%)
Fatigue	57 (0.5%)
Fever	42 (0.3%)
Influenza like illness	99 (0.8%)
Doctor referral for clinical symptoms	231 (1.9%)
<b>Hypertension self-care</b>	
Self-monitoring of blood pressure at home	6248 (51.9%)
Critically high blood pressure* requiring physician referral	193 (1.6%)
<b>Blood sugar self-care</b>	
Self-monitoring of blood sugar at home	3843 (31.9%)
Critically high sugar level** requiring physician referral	333 (2.8%)
<b>Treatment</b>	
Medicine availability	11400 (94.7%)
Compliance to medications***	10577 (87.8%)
Regular exercises****	7330 (60.9%)
Beta blockers	4656 (38.7%)
Statins	5018 (41.7%)
ACE inhibitors/ ARBs	3937 (33%)
Calcium channel blockers	2419 (20.1%)
Antiplatelet drugs	5361 (44.5%)
<b>Wellbeing score categories</b>	
Low (0-4)	161 (1.3%)
Medium (5-6)	1379 (11.5%)
High (7-8)	9018 (74.9%)
Very high (9-10)	1482 (12.3%)

\*Critically high BP defined as SBP  $\geq$  160mm Hg & DBP  $\geq$  100mm Hg

\*\*critically high defined as RBS  $\geq$ 200 mg/dl

\*\*\*referred to the adherence to the medication prescribed to the patient.

\*\*\*\*defined if the patient was doing yoga as advised at the time of discharge or at least >30 minutes of moderate activity for at least 5 times a week (preferably daily).

Abbreviations: ACE: angiotensin converting enzymes, ARB: angiotensin receptor blocker, CCB: calcium channel blocker, SBP: systolic blood pressure, DBP: diastolic blood pressure, RBS: random blood sugar

**Table 2:** Reasons for patient referrals to the stage-2 physician-led teleconsultations.

<b>Clinical complaints</b>	<b>N= 758, N (%)</b>
Congestive heart failure	123 (16.2%)
Ischemic heart disease	51 (6.7%)
Psychiatric issues	33 (4.4%)
Medicinal issues*	122 (16.1%)
Uncontrolled Hypertension (Blood pressure $\geq$ 160/100 mmHg)	142 (18.7%)
Uncontrolled diabetes (random blood sugar $\geq$ 200 mg/dl)	189 (24.9%)
Referred for admission	64 (8.4%)

\*Issues related alteration of drug dosage, continuation or stoppage of medications, perceived side effects of drugs.

**Table 3:** Impact of COVID-19 pandemic on the patients with cardiovascular diseases.

	Overall (N=1090), N (%)
<b>Stress from work or other responsibilities</b>	
Daily	6 (0.6%)
Once in a week	49 (4.5%)
Once in a month	80 (7.3%)
Never	955 (87.6%)
<b>Ability to cope with stress during the pandemic</b>	
Very easily	656 (60.2%)
With little difficulty	59 (5.4%)
With extreme difficulty	6 (0.6%)
None of the above	369 (33.9%)
<b>Overall health status*, mean (SD)</b>	<b>88.4±6.8</b>

\*Health status assessed on a visual analogue scale of 0-100 (0=worst imagined health status, 100=best imagined health status). SD=standard deviation.

**Table 4:** Comparison of patient's treatment satisfaction between the nurse-led versus physician-led teleconsultations.

	<b>Nurse-led teleconsultation n= 801</b>	<b>Physician-led teleconsultation n= 289</b>	<b>Chi- square value</b>	<b>p- value</b>
Overall health status*, mean (SD)	88.8±6.2	87.5±8.1	0.034	0.973
<b>Treatment satisfaction</b>				
Score 0-4	64 (8%)	14 (4.8%)	3.163	0.075
Score 5-6	1012 (92.8%)	275 (95.2%)		

\*Health status assessed on a visual analogue scale of 0-100 (0=worst imagined health status, 100=best imagined health status). SD=standard deviation.

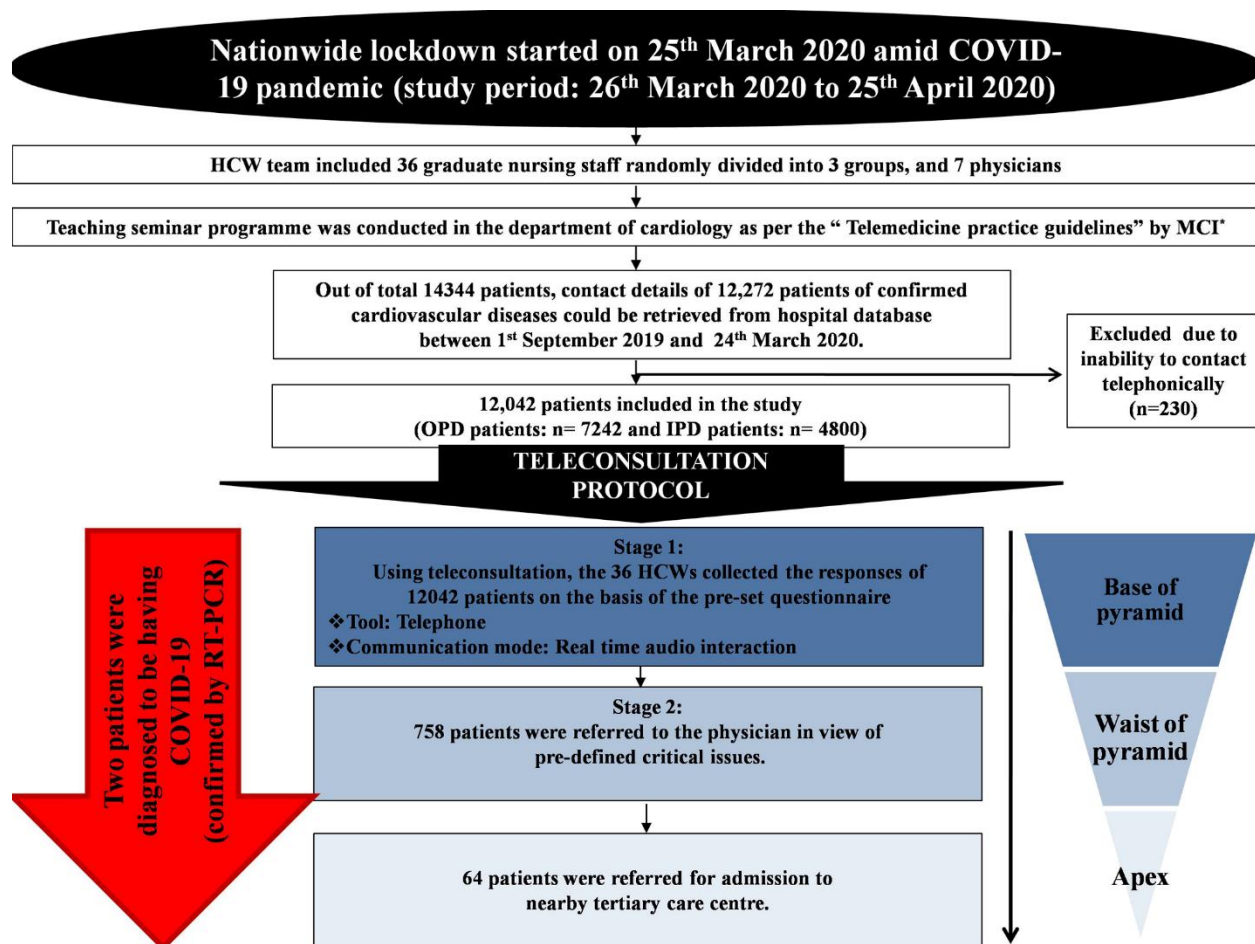
1 **Figure 1:** Flow chart of the study design.  
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8 Figure Legend.  
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10 DM: diabetes mellitus, HTN: hypertension.

11 For hypertension: critically high (SBP  $\geq$  160mm Hg & DBP  $\geq$  100mm Hg), Intermediate high  
12 (SBP 130-159mm Hg & DBP 80-99mm Hg), controlled (SBP <130mm Hg & DBP <80mm Hg)

13 For Diabetes: critically high (RBS  $\geq$ 300 mg/dl), intermediate high (RBS 200-299 mg/dl),  
14 controlled (RBS < 200mg/dl)  
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**Figure 1:** Flow chart of the study design.

DM: diabetes mellitus, HTN: hypertension.

For hypertension: critically high (SBP  $\geq$  160mm Hg & DBP  $\geq$  100mm Hg), Intermediate high (SBP 130-159mm Hg & DBP 80-99mm Hg), controlled (SBP <130mm Hg & DBP <80mm Hg)

For Diabetes: critically high (RBS  $\geq$ 300 mg/dl), intermediate high (RBS 200-299 mg/dl), controlled (RBS < 200mg/dl)



# **HERO DMC HEART INSTITUTE**

HELPLINE No.-9915322741

## **Teleconsultation in cardiovascular disease management during the COVID-19 pandemic in India**

- 1) Name:..... Age:.....
- 2) Sex:.....
- 3) MRD Number:.....
- 4) Phone Number:.....
- 5) Symptoms (tick all applicable symptoms):
- |                   |  |
|-------------------|--|
| a) Chest pain     | Patient well being scale<br>0-Worst<br>10-Good<br><br>0 1 2 3 4 5 6 7 8 9 10 |
| b) Palpitation    |  |
| c) Breathlessness |  |
| d) Fatigue        |  |
| e) Fever          |  |
| f) Cough          |  |
- 6) Blood Pressure measured within one week:
- a) No:
- b) Yes:
- i) Controlled Hypertension (Reading more than 130/80)
- |         |                 |
|---------|-----------------|
| (1) Yes | Refer to Doctor |
| (2) No  |                 |
- 7) Blood glucose measured within in the last two weeks:
- a) No
- b) Yes
- i) Controlled Diabetes (random blood sugar more than 200 mg)
- |         |                 |
|---------|-----------------|
| (1) Yes | Refer to Doctor |
| (2) No  |                 |
- 8) Available medicines:
- a) All Available
- b) Some Available
- c) Not Available
- 9) Compliance to medicines:
- a) Regular
- b) Sometimes missed
- c) No medication
- 10) Regular exercise:
- a) Yes

# **HERO DMC HEART INSTITUTE**

b) No

11) Prescribed medicines:

- a) Beta blockers
- b) Statin
- c) ACE inhibitors /ARBs
- d) Calcium channel blockers
- e) Anti-platelets

Detail of medicines on Whats app  
or text message

12) Any other complaint:

- (1) .....
- (2) .....
- (3) .....

# **HERO DMC HEART INSTITUTE**

HELPLINE No.-9915322741

## **Teleconsultation in cardiovascular disease management during the COVID-19 pandemic in India**

- 1) Name:..... Age:.....
- 2) Sex:.....
- 3) MRD Number:.....
- 4) Phone Number:.....
- 5) Frequency of stress from work/ responsibilities
  - a) Daily
  - b) Once in a week
  - c) Once in a month
  - d) Never
- 6) How are you able to manage the ongoing COVID-19 pandemic stress
  - a) Very easily
  - b) With little difficulty
  - c) With extreme difficulty
  - d) None of the above
- 7) Overall health status:  
Scale from 0-100 (%)  
Response: -----
- 8) Satisfaction score with the telemedicine  
Score:  
0 (fully satisfied), 1 ( ), 2 ( ), 3 ( ), 4 ( ), 5 ( ), 6 (unsatisfied)

# BMJ Open

## Impact of a nurse-led teleconsultation strategy for cardiovascular disease management during COVID-19 pandemic in India: A pyramid model feasibility study

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**Study title**

Impact of a nurse-led teleconsultation strategy for cardiovascular disease management during COVID-19 pandemic in India: A pyramid model feasibility study

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## ABSTRACT

**Objective.** The COVID-19 pandemic necessitated the use of telemedicine to maintain continuity of care for patients with cardiovascular diseases (CVD). This study aimed to demonstrate the feasibility of implementing a nurse-led teleconsultation strategy for CVD management during the COVID-19 pandemic in India and evaluated the impact of nurse-led teleconsultations on patient treatment satisfaction.

**Design, setting and participants.** We developed a two-stage teleconsultation strategy and tested the feasibility of implementing a nurse-led teleconsultation strategy to manage CVD in a northern state (Punjab) in India. A multidisciplinary team of experts developed the treatment protocol used for teleconsultations to manage CVD. Nurses were trained to provide teleconsultation, triaging of patients, and referrals to the physicians. Patients with CVD who had an out-patient visit or hospitalization between September 2019 - March 2020 at the Dayanand Medical College Hospital, Ludhiana, India, were contacted by phone and offered teleconsultations. Telemedicine strategy comprised of: Stage 1 nurse-led teleconsultations and Stage 2 physician-led teleconsultations. Descriptive analysis was performed to report the proportion of patients triaged by the two-stage telemedicine strategy, and patient's clinical characteristics, and treatment satisfaction between the nurse-led vs. physician-led teleconsultations.

**Results.** Overall, nurse-led stage 1 teleconsultations were provided to 12, 042 patients with CVD. The mean (SD) age of the participants was 58.9 years (12.8), and men were 65.4%. A relatively small proportion of patients (6.3%) were referred for the stage-2 physician-led teleconsultations and of these only 8.4% required hospitalizations. During stage 1 nurse-led teleconsultations, patients were referred to the physicians due to uncontrolled diabetes (24.9%), uncontrolled hypertension (18.7%) and congestive heart failure (16.2%). The patient's treatment satisfaction was similar between the nurse-led vs. physician-led teleconsultations (p value=0.07).

**Conclusion.** This study showed that a nurse-led telemedicine strategy is feasible to implement in a resource-constraint setting for triaging patients with CVD and reduces physician's burden.

## Strengths and Limitations of the study

1. This is one of the first studies from India that evaluated the role of nurse-led telemedicine strategy for cardiovascular disease care during the COVID-19 pandemic, with a large sample size.
2. By systematically conducting telephone follow-ups with patients in a two-step approach, we were able to demonstrate a pyramid-based care delivery model, where only few patients required physician consultations, and hospitalization.
3. Another strength of this study is the use of standardized treatment protocol, and data collection instruments for all patients and rigorous training provided to the nurses and physicians involved in the implementation of telemedicine strategy.
4. An important limitation of this study is that the findings are solely based on a single-centre implementation of telemedicine strategy, which may not be generalizable to other populations.



## Introduction

The COVID-19 pandemic has led to emergence of several challenges in providing care to both chronic and newly diagnosed patients with cardiovascular diseases (CVD). In India, the first COVID-19 confirmed case was detected in the state of Kerala on 30<sup>th</sup> January 2020.<sup>1</sup> In view of its worldwide spread, World Health Organisation (WHO) declared COVID-19 outbreak as pandemic on 11<sup>th</sup> March 2020.<sup>2</sup> In the wake of COVID-19 pandemic, a nationwide lockdown was imposed on 25<sup>th</sup> March 2020 by the Indian government. During the complete lockdown for more than two months only the emergency services were allowed while maintaining the social distancing norms. Given the high prevalence of CVD in India (>54 million),<sup>3</sup> the nationwide COVID-19 pandemic related lockdowns have impacted the care by preventing both routine in-patient and out-patient care.

Furthermore, the COVID-19 pandemic related mobility restrictions, non-availability of nearby healthcare facilities especially in rural areas, need for social distancing, patients' fear of acquiring infection from healthcare facilities, necessitates the use of telemedicine strategy to provide timely care for patients with CVD. Telemedicine refers to providing remote essential medical consultations aided by the advanced technology. In India, telemedicine is not a popular mode of providing healthcare services due to physician's time constraints, less familiarity with the telemedicine principles and technology and partly due to the absence of standard guidelines on the application of telemedicine for CVD management. The pyramid model has been previously used in public health program.<sup>4</sup> Traditionally, a 4-tier pyramid is depicted by the population wide interventions with maximum impact at base followed by primary, secondary and tertiary interventions in that order tapering up to the apex of it.<sup>5</sup> We proposed a 3-tier pyramid model to deliver teleconsultations for patients with CVD during a pandemic situation within the already constraint healthcare delivery system. The base of the pyramid is represented by the nurse-led teleconsultation for screening bulk of the patients followed by the waist represented by the physician-led teleconsultation and the apex represented by the tertiary care referral. This study describes the implementation of a nurse-led teleconsultation strategy to manage CVD during the COVID-19 pandemic and related lockdowns in India and evaluate the impact of nurse-led telemedicine strategy on patient's treatment satisfaction.

## Methods

### Study setting and population

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This study was conducted in a northern state (Punjab) in India during the first wave of COVID-19 pandemic and ensuing nationwide lockdown over four weeks between 26 March 2020 to 25 April 2020. We gathered the contact information of all the patients with CVD who attended the Dayanand Medical College (DMC) hospital, Ludhiana, Punjab, India in the past six-months, i.e., between 1<sup>st</sup> September 2019 and 24<sup>th</sup> March 2020 as these patients were expected for the next clinic visit. All patients with cardiovascular diseases including coronary heart disease, heart failure, hypertension, peripheral vascular diseases, cardiomyopathies, and arrhythmic disorders were included in this study. The patients with mechanical prosthetic valve or those receiving oral anticoagulation therapy were excluded from the study as these patients attended a dedicated Valve clinic at the DMC Hospital and were followed up using a different treatment protocol conducted in a separate research study.<sup>6</sup> Of the total 14,344 patients who had previously attended DMC hospital between Sep 2019 and Mar 2020, the full contact details of 12,042 patients could be retrieved. All these patients constituted the sampling frame for this nurse-led teleconsultation-based feasibility study. Of these, 7242 patients had attended the outpatient facility and 4800 patients had a recent hospital admission. The detailed medical records of all in-patient department (IPD) patients were retrieved from the hospital database. The study design and sample selection are shown in **Figure 1**. The study was approved by the Dayanand medical college and Hospital Ethics Committee and verbal consent was obtained from the patients over the telephone prior to teleconsultation and any study related data collection.

### **Nurse-led teleconsultation strategy**

Given the ubiquitous use of mobile phones and relative paucity of video enabled smart phones or tablets, we used simple mobile phones as the tool for teleconsultation services. The real-time audio interaction was the preferred mode for care delivery. The teleconsultation-based care delivery was implemented by a team of trained health care workers (HCWs) consisting of 36 nursing staff randomly divided into three groups, and seven consultants in the field of medicine. As per the teleconsultation guidelines endorsed by the Indian Ministry of Health and Family Welfare, we conducted a one-week long teaching seminars for the physicians and nurses to standardize our treatment protocols and to improve their understanding of the teleconsultation principles used in this study.<sup>7</sup> The patients' records were retrieved and reviewed by the trained nursing staff from the hospital medical records and electronic database from the last 6 months (September 2019 – March 2020). Teleconsultation approach comprised of two stages. During stage 1, all patients (n=12042) were tele-consulted using the pre-specified questionnaire (**supplementary file 1**) by 36 nursing staff. The stage-1 questionnaire was focused on patient's demographic information, clinical symptoms, recent values of blood pressure (BP), and blood

1 glucose, medicines related issues, exercise and patients' wellbeing score (0-10). This stage 1  
2 was led by nursing staff and supervised by a physician in-charge. In the next stage (stage 2),  
3 based on pre-defined cut-offs the patients shortlisted by the nursing staff were referred for  
4 teleconsultation by physicians. In stage 2, the physician-led teleconsultation focussed specifically  
5 on the clinical complaints for which the patients were referred after screening from stage 1 and  
6 were either tele-consulted as per the guidelines or were referred to nearby tertiary care centre as  
7 per the clinical condition. This study utilised the previously described three-tiered pyramid model  
8 approach for teleconsultation: pyramid base was formed by stage 1, waist formed by stage 2, and  
9 apex formed by the patients referred for the hospital admission at tertiary care centre.

### 16 **Data collection and measurements**

17 All the patients were equally distributed to 36 trained nurses. We administered a set of  
18 questionnaires to collect patient-reported outcomes, the response of which was recorded  
19 telephonically. Briefly, the questionnaire focused on the clinical symptoms, BP control status (BP  
20 recorded within last one week), diabetes control status (blood sugar level recorded within last two  
21 weeks), medication availability and compliance to that, medication history, and well-being score.  
22 The patients were asked to get themselves checked for BP and random blood sugar (RBS) level  
23 either by home monitors (if available) or from nearby clinic/ laboratory and provide the information  
24 to the interviewer on a follow up interview. The patient wellbeing score used was an 11-point  
25 score ranging from 0-10 that was categorised as: very high (9-10), high (7-8), medium (5-6), and  
26 as low (0-4).<sup>8</sup> A contact number of a mobile number was provided to all the patients as a 24-hour  
27 help-line number to ensure medical assistance whenever needed.

28 Fever was defined if body temperature was  $\geq 38^{\circ}\text{C}$ . Influenza-like illness was defined as  
29 "an acute respiratory illness with a measured temperature of  $\geq 38^{\circ}\text{C}$  and cough, with onset within  
30 the past 10 days".<sup>9</sup> For blood pressure (BP), the controlled status was defined as systolic BP  
31 (SBP) of  $\leq 130\text{mm Hg}$  and diastolic BP (DBP) of  $< 80\text{mm Hg}$  while BP cut off for physician's referral  
32 (labelled as critically high) was defined as SBP of  $\geq 160\text{mm Hg}$  and DBP  $\geq 100\text{mm Hg}$ . BP  
33 readings in between these values were defined as intermediate high. For diabetes mellitus,  
34 controlled status was defined as random blood sugar (RBS)  $< 200\text{ mg/dl}$  while the RBS cut-off for  
35 physician's referral (labelled as critically high) was defined as  $\geq 300\text{ mg/dl}$ . The RBS readings in  
36 between these values were defined as intermediate hyperglycaemia. These limits were defined  
37 based on expert consensus meeting. Regular exercise was defined if the patient was doing yoga  
38 as advised at the time of discharge or at least  $> 30$  minutes of moderate activity<sup>10</sup> for at least 5  
39 times a week (preferably daily). The compliance to medication was referred to the adherence to  
40 the medication for the last 2 weeks prescribed to the patient.<sup>11</sup>

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2 Further, in a randomly selected sub-sample of 1200 patients from the study population we  
3 assessed the difference in patient's perceived treatment satisfaction between the nurse-led  
4 teleconsultations and physician-led teleconsultations. This sub-set of patients were distributed  
5 among the nursing staff and physicians. All these patients were tele consulted by using a pre-  
6 tested questionnaire (**supplementary file 2**) to assess: 1) patient satisfaction level with nurse-led  
7 versus physician-led teleconsultations and 2) impact of COVID-19 pandemic on CVD patients. A  
8 modified version of the treatment satisfaction questionnaire for medication (TSQM)<sup>12</sup> was used to  
9 assess the treatment satisfaction in the preceding 30 days.<sup>13</sup> The patient's level of satisfaction  
10 with was assessed on a scale of 0-6, where 0=very dissatisfied and 6=very satisfied. The impact  
11 of COVID-19 on the patient's mental health was assessed using a pre-tested questionnaire and  
12 it focused on the stress from work or other responsibilities, ability to cope with the ongoing  
13 pandemic stress, and overall health status on a scale of 0-100.

### 21 **Statistical analysis**

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23 We used SPSS statistics 16.0 for windows (Chicago, USA) for data analysis. The  
24 continuous variables were expressed as mean  $\pm$  standard deviation (SD) and median  
25 (interquartile range) for normally distributed or skewed data respectively. Categorical variables  
26 were expressed as percentage (%). The statistical difference between the treatment satisfaction  
27 levels for the teleconsultation by physician and nursing staff was performed by using Mann-  
28 Whitney U-test as the data was skewed. The skewness of the given data was checked with  
29 Kolmogorov–Smirnov test. The difference between two variables was considered significant if the  
30 two-sided p-value was  $<0.05$ .

### 37 **Patient and public involvement**

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39 Patients and community members were not directly involved in the development of the  
40 telemedicine-based treatment protocol. However, the study was explained to the participants and  
41 verbal consent obtained prior to provision of teleconsultations and study related data collection.  
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### 50 **Results**

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52 Overall, 12 042 patients who previously attended either out-patient department (OPD) or  
53 in-patient department (IPD) between September 2019 – March 2020 at the DMC hospital, Punjab,  
54 were invited to participate in this study. The schematic flow of patients screened and provided  
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1 teleconsultations at various stages of this pyramid-based healthcare delivery model utilizing  
2 nurse-led teleconsultations (stage 1) and physician-led teleconsultations are shown in **Figure 1**.  
3 Of the total 14 344 patients eligible for the teleconsultations, contact details of 12 272 patients  
4 with CVD were obtained, and of these 12 042 consented to participate in this study. Of these,  
5 7242 patients (60%) were from the OPD and 4800 (40%) patients were from the IPD. The study  
6 participants' demographic and clinical characteristics are shown in **Table 1**. The mean (SD) age  
7 of the participants was 58.9 years (12.8) and about two-thirds were men. The most common  
8 comorbidities reported were hypertension (45.8%) and diabetes (41.9%). Very few participants  
9 ( $\leq 1\%$  each) reported clinical signs or symptoms such as chest pain, breathlessness and  
10 palpitations. Nearly half of the study participants were monitoring blood pressure at home and  
11 one-third participants (reported self-monitoring for blood glucose. In addition, relatively small  
12 proportion of participants required referral to the physicians due to uncontrolled blood pressure  
13 or uncontrolled blood glucose. Difficulty in access to medicines was reported by nearly 5%  
14 patients with CVD during the COVID-19 pandemic. The difficulty in access to medicine was  
15 attributed to multiple factors such as non-availability of the local pharmacies in the villages (most  
16 of the study participants were from villages), non-availability of few specific cardiac medicines in  
17 the nearby pharmacies, or due to the absence of a caregiver or helping hands in the family. The  
18 self-reported adherence or compliance to prescribed therapy was significantly high ( $>87\%$ ) and  
19 two-thirds of the study participants reported performing regular physical activity. However, less  
20 than half of the participants with CVD reported taking cardioprotective drugs such as aspirin, beta-  
21 blockers, and statins. On 11-point well-being score assessment, most participants reported a  
22 relatively high well-being score between 7-8.

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37 Of the total screened participants, a relatively small proportions (6.6%) required the next stage  
38 2physician-led teleconsultations. The most common reasons for the referral to stage-2 physician  
39 led teleconsultations included uncontrolled blood sugar ( $\sim 25\%$ ), uncontrolled blood pressure  
40 (19%) and congestive heart failure (16%) (**Table 2**). Of those, who received physician  
41 teleconsultations, only a small number ( $n=64$  patients, 8.4%), required hospital admission for  
42 diagnostic evaluation and management of acute coronary syndrome (ACS) or worsening heart  
43 failure symptoms. In addition, two patients were identified via teleconsultation to have COVID-  
44 19 infection diagnosed by reverse transcription polymerase chain reaction (RT-PCR) assay.

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50 Further, the analysis on the impact of COVID-19 pandemic among patients with CVD  
51 showed that majority of the respondents (88%) did not feel the stress from work or other  
52 responsibilities during COVID-19 pandemic. Also, two-third participants reported that they could  
53 very easily cope with stress during the pandemic. Overall mean (SD) health status reported by  
54 the patients on a scale of 0-100 was 88.4 (6.8) (**Table 3**).

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Lastly, our analysis focused on the difference in the perceived treatment satisfaction between the nurse-led and physician led teleconsultations demonstrated that significantly greater proportion of patients reported high satisfaction with the treatment provided using the telemedicine strategy. Importantly, the treatment satisfaction score did not significantly differ between the nurse-led versus physician led teleconsultations (92.8% vs. 95.2%, p value= 0.075) (**Table 4**). This data suggest that the nurse-led teleconsultations was very well received or accepted by the patients with CVD and was found to be feasible to implement in a resource-constraint setting.

## Discussion

To the best of our knowledge, this is the first study to demonstrate that nurse-led teleconsultation strategy can be successfully delivered to provide timely and effective care for patients with CVD in India during the COVID-19 pandemic. Amidst COVID-19 pandemic, there were several challenges in providing health care services like decreased availability of health care workers, shortage of resources and fear of acquiring infection. Due to the restrictions posed by the government authorities in order to decrease virus transmission, access to both elective outpatient and emergency services were restricted.<sup>14</sup> This led on to instantaneous and unanticipated cancellation of the face to face consultation visits of the patients thereby impeding the delivery of health care services for those who needed it.<sup>14</sup> Due to lack of health system preparedness and the lack of conventional telemedicine facilities, immediate application of telemedicine which is not routinely used especially in country like India was not possible.<sup>15</sup>

In this study, despite operational difficulties we were able to rapidly create a team of nursing staff and physicians in a short time and developed standard treatment protocols to provide care for patients with established CVD. It was also important to ensure that rapid response to the COVID-19 pandemic and related lockdown, do not affect the quality of care provided by our team of nurses and physicians, therefore, we conducted appropriate training sessions for the entire team of health care workers and clinicians.<sup>16</sup> Furthermore, to expedite the process of teleconsultation, as we envisaged reaching out to large number of patients to provide health care services, we created a novel 3-tier pyramid model for teleconsultation. Pyramid model has been utilised in various fields of medicine and for public health action framework<sup>5</sup>, as well as an inverted pyramid for improving handover care.<sup>17</sup> Apart from the conventional four-tiered pyramid model, Grizzell's six tier interventional pyramid model and five-tier health impact model have also been studied in literature.<sup>4</sup> This pyramid model based study clearly demonstrated that large number of

1 patients could be managed by a trained nursing staff, whereas a relatively small proportion of  
2 patients required physician consultation and hospital admission. By implementing this pyramid  
3 model of healthcare delivery utilizing trained and supervised nurse-led teleconsultations we could  
4 successfully triaged and provided timely care for large number of patients within a short period.  
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9 Considering the patient treatment satisfaction score, most patients (92.8%) were satisfied  
10 with the teleconsultation strategy, and the patient's treatment satisfaction level was comparable  
11 between nurse-led versus physician-led teleconsultations. These findings are consistent with prior  
12 reports that show a good satisfaction level with the use of telemedicine in various disease  
13 conditions.<sup>18,19</sup> Further, this study demonstrated that nurse-led teleconsultations during pandemic  
14 situation when health resources were already overwhelmed, could be of vital importance without  
15 compromising the efficacy of the care delivery model. Our pyramid-based model of  
16 teleconsultation also identified two confirmed cases of COVID-19 infection and both were referred  
17 to nearby tertiary care centre for appropriate care.  
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24 Due to the critical nature of CVD, associated co-morbidities, elderly patients with multiple  
25 disabilities, and with possibility of acute decompensation if left unattended, these patients need  
26 frequent and regular monitoring of various health parameters. Thus, the use of telemedicine  
27 strategy provided the much-needed healthcare services required to manage these patients with  
28 CVD. Several systematic reviews and meta-analyses have shown a significant reduction in  
29 mortality and hospital re-admissions with the use of telemonitoring among chronic heart failure  
30 patients.<sup>20-22</sup> Utilisation of telemedicine in ST-segment elevation myocardial infarction (STEMI)  
31 care have also shown a substantial improvement in health outcomes.<sup>22</sup> The role of tele-medicine  
32 has also been studied for active surveillance of patients on anticoagulation therapy during COVID-  
33 19 pandemic.<sup>23</sup> During disaster situation and public health emergency, as imposed by COVID-19  
34 pandemic, the telemedicine strategy not only helps in remote triaging the patients and easy  
35 accessibility to routine medical care but also prevents the transmission of virus by decreasing  
36 person-to-person contact.<sup>24,25</sup>  
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45 A major limitation of this study is that we have implemented only the audio mode of  
46 teleconsultations and physicians expressed some hesitancy in proving teleconsultations on  
47 audio-mode only. However, in this study, we did not collect qualitative interview data on the  
48 experiences of providers delivering care using the telemedicine strategy. Virtual teleconsultation  
49 has added advantages like reading the patients' facial expression, observing some physical signs,  
50 perceived psychological satisfaction of the patients.<sup>26,27</sup> However, due to low internet connectivity  
51 and low penetration of android based mobile phones in the study location we could not implement  
52 the video bases virtual teleconsultations. On the contrary, the use of telephone-based "audio only"  
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1 consultation has constituted most virtual visits even in the United States during unprecedented  
2 times of COVID-19 pandemic.<sup>28</sup> Virtual consultations could certainly be explored for its clinical  
3 use in urban and rural areas to further improve the efficacy and impact of teleconsultations as  
4 care delivery model.<sup>24,29</sup>  
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## 8 **Implications of study findings**

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11 Given the unprecedented and rapidly evolving COVID-19 pandemic situation in India and  
12 the need to keep vulnerable patients (and clinicians) at home and away from the health care  
13 facilities to decrease risk of virus transmission, there has been a rapid increase in use of  
14 telemedicine. A new belief on telemedicine strategy requires many clinicians and health workers  
15 to develop skills to obtain objective information from these types of telephone visits. Although  
16 eliciting a complete medical history and adjudicating medication lists and allergies are crucial  
17 activities of teleconsultation visits, additional information from a telehealth physical examination  
18 can be useful, if virtual clinic visit can be delivered. A focussed general physical examination over  
19 the teleconsultation or virtual clinic visits either confirms clues suggested by the patient's medical  
20 history or provides data that can direct specific clinical tests or treatments. Our experience is that  
21 patients with CVD respond positively to these initiatives unequivocally to both the nurse-led as  
22 well as physician-led teleconsultations. Thus, performance of a teleconsultation strategy to  
23 manage patients with CVD may be considered as an essential element in the context of post  
24 pandemic health care delivery models in India. Given the fragmented and heterogenous  
25 healthcare delivery system in India, with large share of private healthcare market, identifying  
26 appropriate reimbursement models to promote telemedicine strategy needs further exploration.  
27 Future research may also focus on evaluating the effectiveness of telemedicine on clinical  
28 outcomes in a large, randomized trial. Also, the costs of delivering such a nurse-led  
29 teleconsultations and pyramid-based care delivery model are currently unknown in the Indian  
30 context, so a future study should evaluate the cost of delivering such a care delivery model to  
31 inform its nation-wide expansion and scale-up if found to be successful.  
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## 48 **Conclusions**

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50 This study demonstrated the feasibility to implement a pyramid model-based nurse-led  
51 telemedicine strategy during the COVID-19 pandemic and related lockdowns in India. Large  
52 number of patients with CVD were given teleconsultations in a stepwise approach with optimal  
53 utilisation of the available healthcare providers (i.e., trained, and supervised nursing staff and  
54 physicians), with comparable patient treatment satisfaction level between the nurse-led versus  
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1 physician-led teleconsultations. Further, to optimize existing healthcare resources a hybrid model  
2 of care combining physical clinic visits for critical cardiac care and telemedicine strategy for  
3 routine follow-ups based on hub-and-spoke model could be considered, beyond the pandemic  
4 and in post-COVID India.  
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For peer review only

## Authors' contribution

BM, BS, AG, GS, SA, AS, RT, STC, NA, GSW contributed to the conception and design of the study. BM, BS, KS, NN, AR, DP had a role in acquisition, analysis, or interpretation of data. KS, BS, and BM drafted the manuscript, and all authors critically revised the manuscript. All authors provided technical and material support and approved the final manuscript.

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## Conflict of interest

No conflict of interest to declare.

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**Patient consent for publication.** Not required.

**Ethics approval.** This study is approved by the institutional ethics committee of Dayanand Medical College, Ludhiana, Punjab, India Ref. No. DMCh/DrEclzozo/ 677.

**Data sharing statement.** Data are available on reasonable request. All data relevant to the study are included in the article.

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**Table 1:** Characteristics of study participants during the nurse-led stage-1 teleconsultations.

	Total (%) (N= 12042)
Age (in years), mean (SD)	58.9 (12.8)
Men	7870 (65.4%)
Hypertension	5515 (45.8%)
Diabetes mellitus	5046 (41.9%)
<b>Clinical symptoms</b>	
Chest pain	137 (1.1%)
Palpitation	29 (0.2%)
Breathlessness	142 (1.2%)
Fatigue	57 (0.5%)
Fever	42 (0.3%)
Influenza like illness	99 (0.8%)
Doctor referral for clinical symptoms	231 (1.9%)
<b>Hypertension self-care</b>	
Self-monitoring of blood pressure at home	6248 (51.9%)
Critically high blood pressure* requiring physician referral	193 (1.6%)
<b>Blood sugar self-care</b>	
Self-monitoring of blood sugar at home	3843 (31.9%)
Critically high sugar level** requiring physician referral	333 (2.8%)
<b>Treatment</b>	
Medicine availability	11400 (94.7%)
Compliance to medications***	10577 (87.8%)
Regular exercises****	7330 (60.9%)
Beta blockers	4656 (38.7%)
Statins	5018 (41.7%)
ACE inhibitors/ ARBs	3937 (33%)
Calcium channel blockers	2419 (20.1%)
Antiplatelet drugs	5361 (44.5%)
<b>Wellbeing score categories</b>	
Low (0-4)	161 (1.3%)
Medium (5-6)	1379 (11.5%)
High (7-8)	9018 (74.9%)
Very high (9-10)	1482 (12.3%)

\*Critically high BP defined as SBP  $\geq$  160mm Hg & DBP  $\geq$  100mm Hg

\*\*critically high defined as RBS  $\geq$ 200 mg/dl

\*\*\*referred to the adherence to the medication prescribed to the patient.

\*\*\*\*defined if the patient was doing yoga as advised at the time of discharge or at least >30 minutes of moderate activity for at least 5 times a week (preferably daily).

Abbreviations: ACE: angiotensin converting enzymes, ARB: angiotensin receptor blocker, CCB: calcium channel blocker, SBP: systolic blood pressure, DBP: diastolic blood pressure, RBS: random blood sugar

**Table 2:** Reasons for patient referrals to the stage-2 physician-led teleconsultations.

<b>Clinical complaints</b>	<b>N= 758, N (%)</b>
Congestive heart failure	123 (16.2%)
Ischemic heart disease	51 (6.7%)
Psychiatric issues	33 (4.4%)
Medicinal issues*	122 (16.1%)
Uncontrolled Hypertension (Blood pressure $\geq$ 160/100 mmHg)	142 (18.7%)
Uncontrolled diabetes (random blood sugar $\geq$ 200 mg/dl)	189 (24.9%)
Referred for admission^	64 (8.4%)

\*Issues related alteration of drug dosage, continuation or stoppage of medications, perceived side effects of drugs.

^reason for admission included diagnostic evaluation and management of acute coronary syndrome or worsening heart failure symptoms.

**Table 3:** Impact of COVID-19 pandemic on the patients with cardiovascular diseases.

	Overall (N=1090), N (%)
<b>Stress from work or other responsibilities</b>	
Daily	6 (0.6%)
Once in a week	49 (4.5%)
Once in a month	80 (7.3%)
Never	955 (87.6%)
<b>Ability to cope with stress during the pandemic</b>	
Very easily	656 (60.2%)
With little difficulty	59 (5.4%)
With extreme difficulty	6 (0.6%)
None of the above	369 (33.9%)
<b>Overall health status*, mean (SD)</b>	<b>88.4±6.8</b>

\*Health status assessed on a visual analogue scale of 0-100 (0=worst imagined health status, 100=best imagined health status). SD=standard deviation.



**Table 4:** Comparison of patient's treatment satisfaction between the nurse-led versus physician-led teleconsultations.

	<b>Nurse-led teleconsultation n= 801</b>	<b>Physician-led teleconsultation n= 289</b>	<b>Chi- square value</b>	<b>p- value</b>
Overall health status*, mean (SD)	88.8±6.2	87.5±8.1	0.034	0.973
<b>Treatment satisfaction</b>				
Score 0-4	64 (8%)	14 (4.8%)	3.163	0.075
Score 5-6	1012 (92.8%)	275 (95.2%)		

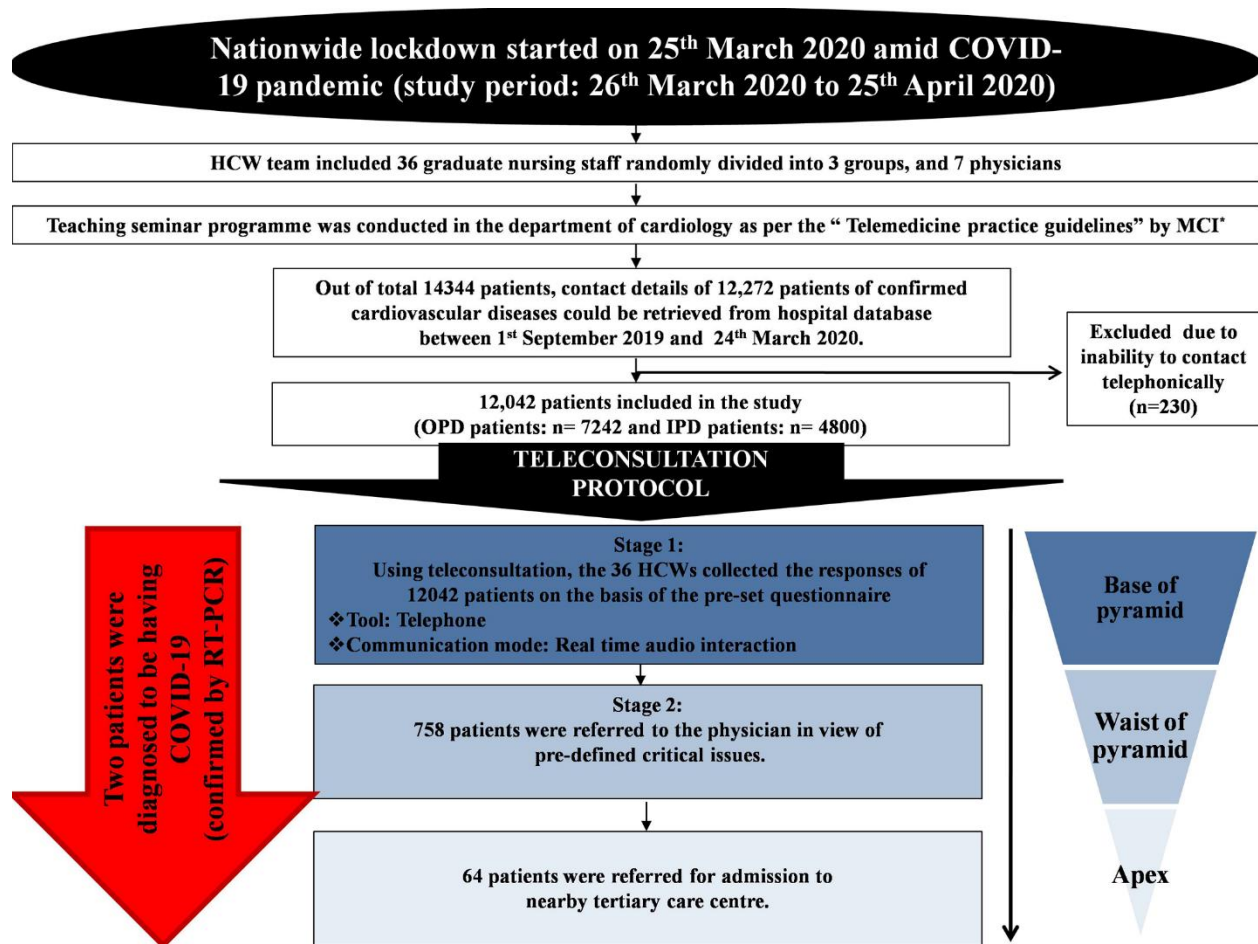
\*Health status assessed on a visual analogue scale of 0-100 (0=worst imagined health status, 100=best imagined health status). SD=standard deviation.

1  
2 **Figure 1:** Flow chart of the study design.  
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8 Figure Legend.  
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10 DM: diabetes mellitus, HTN: hypertension, SBP=systolic blood pressure, DBP=diastolic blood  
11 pressure, mmHG=millimoles of mercury, mg/dl=milligram per deciliter, RBS=random blood  
12 sugar  
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14 For hypertension: critically high (SBP  $\geq$  160mm Hg & DBP  $\geq$  100mm Hg), Intermediate high  
15 (SBP 130-159mm Hg & DBP 80-99mm Hg), controlled (SBP <130mm Hg & DBP <80mm Hg)  
16 For Diabetes: critically high (RBS  $\geq$ 300 mg/dl), intermediate high (RBS 200-299 mg/dl),  
17 controlled (RBS < 200mg/dl)  
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**Figure 1:** Flow chart of the study design.

DM: diabetes mellitus, HTN: hypertension.

For hypertension: critically high (SBP  $\geq$  160mm Hg & DBP  $\geq$  100mm Hg), Intermediate high (SBP 130-159mm Hg & DBP 80-99mm Hg), controlled (SBP <130mm Hg & DBP <80mm Hg)

For Diabetes: critically high (RBS  $\geq$ 300 mg/dl), intermediate high (RBS 200-299 mg/dl), controlled (RBS < 200mg/dl)

# **HERO DMC HEART INSTITUTE**

HELPLINE No.-9915322741

## **Teleconsultation in cardiovascular disease management during the COVID-19 pandemic in India**

- 1) Name:..... Age:.....
- 2) Sex:.....
- 3) MRD Number:.....
- 4) Phone Number:.....
- 5) Symptoms (tick all applicable symptoms):
- |                   |  |
|-------------------|--|
| a) Chest pain     | Patient well being scale<br>0-Worst<br>10-Good<br><br>0 1 2 3 4 5 6 7 8 9 10 |
| b) Palpitation    |  |
| c) Breathlessness |  |
| d) Fatigue        |  |
| e) Fever          |  |
| f) Cough          |  |
- 6) Blood Pressure measured within one week:
- a) No:
- b) Yes:
- i) Controlled Hypertension (Reading more than 130/80)
- |         |                 |
|---------|-----------------|
| (1) Yes | Refer to Doctor |
| (2) No  |                 |
- 7) Blood glucose measured within in the last two weeks:
- a) No
- b) Yes
- i) Controlled Diabetes (random blood sugar more than 200 mg)
- |         |                 |
|---------|-----------------|
| (1) Yes | Refer to Doctor |
| (2) No  |                 |
- 8) Available medicines:
- a) All Available
- b) Some Available
- c) Not Available
- 9) Compliance to medicines:
- a) Regular
- b) Sometimes missed
- c) No medication
- 10) Regular exercise:
- a) Yes

# **HERO DMC HEART INSTITUTE**

b) No

11) Prescribed medicines:

- a) Beta blockers
- b) Statin
- c) ACE inhibitors /ARBs
- d) Calcium channel blockers
- e) Anti-platelets

Detail of medicines on Whats app  
or text message

12) Any other complaint:

- (1) .....
- (2) .....
- (3) .....

For peer review only

# **HERO DMC HEART INSTITUTE**

HELPLINE No.-9915322741

## **Teleconsultation in cardiovascular disease management during the COVID-19 pandemic in India**

- 1) Name:..... Age:.....
- 2) Sex:.....
- 3) MRD Number:.....
- 4) Phone Number:.....
- 5) Frequency of stress from work/ responsibilities
  - a) Daily
  - b) Once in a week
  - c) Once in a month
  - d) Never
- 6) How are you able to manage the ongoing COVID-19 pandemic stress
  - a) Very easily
  - b) With little difficulty
  - c) With extreme difficulty
  - d) None of the above
- 7) Overall health status:  
Scale from 0-100 (%)  
Response: -----
- 8) Satisfaction score with the telemedicine  
Score:  
0 (fully satisfied), 1 ( ), 2 ( ), 3 ( ), 4 ( ), 5 ( ), 6 (unsatisfied)

STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation	Page No
<b>Title and abstract</b>	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1, 2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
<b>Introduction</b>			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any prespecified hypotheses	3
<b>Methods</b>			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	4, 5
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6
Bias	9	Describe any efforts to address potential sources of bias	6
Study size	10	Explain how the study size was arrived at	5,6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6, 7
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	7
		(b) Describe any methods used to examine subgroups and interactions	NA
		(c) Explain how missing data were addressed	NA
		(d) If applicable, describe analytical methods taking account of sampling strategy	7
		(e) Describe any sensitivity analyses	NA
<b>Results</b>			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	8
		(b) Give reasons for non-participation at each stage	8
		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8
		(b) Indicate number of participants with missing data for each variable of interest	8
Outcome data	15*	Report numbers of outcome events or summary measures	8
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	9

		(b) Report category boundaries when continuous variables were categorized	9
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA
<b>Discussion</b>			
Key results	18	Summarise key results with reference to study objectives	9
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	11
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	11
Generalisability	21	Discuss the generalisability (external validity) of the study results	11
<b>Other information</b>			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	13

\*Give information separately for exposed and unexposed groups.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at [www.strobe-statement.org](http://www.strobe-statement.org).