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Original Research Article

Assessing the effectiveness of software driven digital therapeutics in patients with coronary artery disease or post coronary intervention: real-world evidence study

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ABSTRACT

Background: Coronary artery disease (CAD) is a significant health concern worldwide. Acute coronary syndrome (ACS) is a common form of CAD that requires immediate treatment. Digital therapeutics (DTx) have emerged as a promising field for disease management, utilizing remote monitoring and promoting behavioral changes. This study aims to evaluate the effectiveness of LYFE app intervention in improving outcomes for patients with CAD, specifically those with ACS or who have undergone percutaneous coronary intervention (PCI).
Methods: This pilot, single-center, real-world evidence study evaluates the effectiveness of the LYFE in CAD and/or post-PCI patients. The primary goal was to assess adherence to medication, physical exercise, diet, and well-being of the participants. Secondary outcomes included assessing vital changes and the incidence of major adverse cardiovascular events over 6 months.
Results: Among all participants, the majority were male (93.3%) with a mean age of 53.2±12.1 years. After implementing the LYFE app, 90% adhered to regular exercise, 79.3% to prescribed diet and 79.3% reported that they had no difficulty in remembering medication over 6 months. Additionally, notable improvements were observed in the well-being of the participants using the Dartmouth COOP questionnaire. Furthermore, the intervention significantly reduced SBP (-5.52 mmHg, p=0.038), and DBP (-2.63 mmHg, p=0.044) over 6-month follow-up. By the end of the study, 88.9% of the patients had their blood pressure under control. No cardiovascular death or major bleeding events were reported.
Conclusions: LYFE has the potential to enhance cardiovascular health and well-being in CAD and/or post-PCI patients.

Keywords: Cardiovascular health, CAD, Post-coronary interventions, Digital therapeutics, Blood pressure, Quality of life

INTRODUCTION

Coronary artery disease (CAD) poses a significant challenge to cardiovascular health, leading to a high number of deaths worldwide, especially among South Asian populations, including Indians. In this demography, the risk of developing CAD is significantly higher, resulting in increased rates of hospitalization and mortality compared to other regions.[1,2]

In India, CAD has become a serious public health issue, accounting for approximately 1.2 million deaths in 2012, which represents 26.9% of medically certified deaths in 2015. However, these numbers may underestimate the true prevalence due to incomplete mortality data,

underreported cases of asymptomatic CAD, and deaths related to silent heart attacks. These statistics highlight a concerning trend, with CAD experiencing a twofold increase in rural areas and a six-fold increase in urban areas from 1960 to 2002, clearly indicating an epidemic in the country.[3]

Modifying risk factors associated with CAD can have beneficial effects on the disease, helping with prevention, regression, and slowing down its progression, to further improve the quality of life (QoL) of patients. Secondary prevention serves as a therapeutic approach to impede the advancement of the disease and minimize damage after CAD diagnosis.[4] In the treatment of CAD, PCI is the most widely used technique, showing remarkable efficacy in alleviating symptoms, especially in individuals with stable angina.[5] The integration of technology into healthcare, known as mobile health (mHealth), has given rise to a new era. Mobile applications, particularly those designed for cardiovascular disease (CVD) patients, significantly enhance medication adherence and improve clinical outcomes.[6]

However, despite advancements in smartphone-based surveillance systems, a significant question remains: Do these systems truly impact the overall well-being of end-users?[7] To answer this, we aimed to evaluate the real-world effectiveness (RWE) of software-driven digital interventions, examining their impact on vital signs, medication adherence, lifestyle changes (including diet and exercise), cardiovascular events, and dimensions of well-being such as QoL using the Dartmouth COOP questionnaire, among patients with CAD and/or post-PCI.

METHODS

This prospective, single-center, RWE study was conducted over 6 months at Cardiomet clinic, Pune, Maharashtra. The study enrolled 30 patients with CAD and/or post-PCI from October 2022 to November 2022. Ethical approval was obtained from the institutional ethics committee (ECR/233/Indt/GJ/2015/RR-21) following good clinical practice guidelines. This study aimed to pilot a clinical evidence-based software-driven therapeutic intervention and evaluate its effectiveness and applicability in the real-world clinical setting.

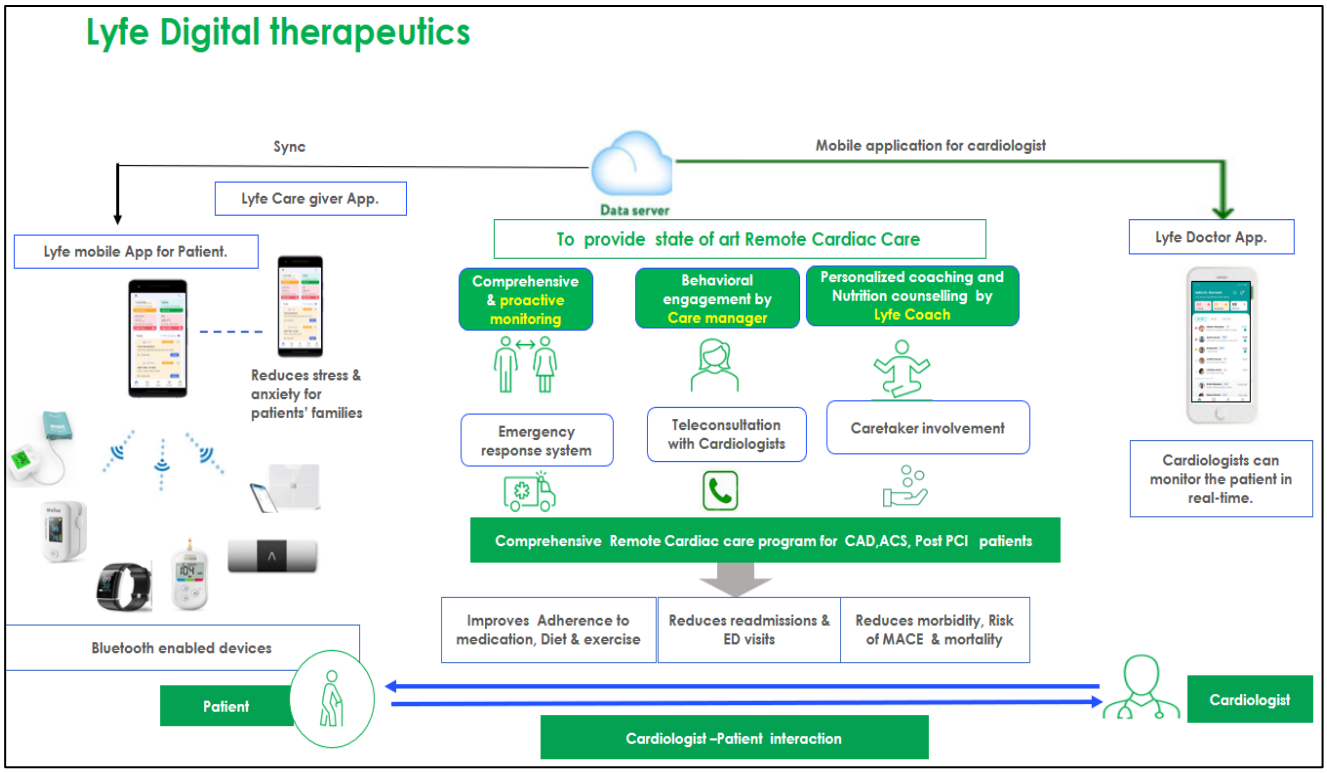

Figure 1: LYFE digital program flowchart for CAD/post-PCI patients.

Inclusion criteria

Participants aged ≥18 years with a documented diagnosis of CAD or a history of coronary intervention were eligible for enrollment. To participate, individuals were required to read and understand the informed consent form, provide authorization by signing it, and possess basic reading skills in English, Hindi, or Marathi. These criteria were implemented to ensure a suitable and representative patient population for the study.

Exclusion criteria

Individuals with a history of psychiatric and neurological disorders impaired bilateral hearing, or visual impairment that limits smartphone use are not eligible to participate in

this study. Individuals who are currently participating in other clinical trials or prospective cohort studies, those with severe physical disabilities that prevent participation, and those who refuse to provide consent are all excluded. Subjects who are considered unsuitable for any reason by the investigator are also ineligible for enrollment.

Intervention

The LYFE program, developed by Lupin digital health Pvt. Ltd., was used in the study (Figure 1). This personalized digital heart care program, designed by cardiologists, consists of a mobile app and connected devices including a wireless activity and heart rate (HR) tracker, a blood pressure (BP) monitor, and a smart weighing scale. These devices allow for easy monitoring of vital parameters such as BP, HR, and physical activity. Patients also received regular reminders for medications, lifestyle changes, and appointments.

The LYFE program offers seven key components including (i) comprehensive monitoring, (ii) adherence to lifestyle changes and medication, (iii) caregiver involvement, (iv) personalized coaching, (v) educational modules, (vi) an emergency response system, and (vii) access to ambulances and pre-determined hospitals, aiding patients in monitoring and managing their cardiac health. The LYFE program aims to empower patients with a personalized approach to heart care, providing control over their health through timely interventions and support.

Study outcomes

The primary objective of the study was to assess adherence to medication, exercise, and diet. In addition, the study comprehensively assessed nine domains of well-being, including various aspects such as QoL and other relevant factors, using the Dartmouth COOP questionnaire. The secondary objective was to assess the mean changes in systolic blood pressure (SBP), diastolic blood pressure (DBP), and HR from baseline to 6 months follow-up and the incidence of major adverse cardiovascular events (MACE), and all-cause readmissions.

Statistical analysis

Descriptive statistics were used to analyze collected data, with the mean and standard deviation calculated for all variables. Paired t test was employed to determine significant mean differences between baseline and various follow-up periods. Statistical significance was defined as a $p<0.05$. Statistical analyses were performed using SPSS software (version 25.0; IBM Corp., Armonk, NY, USA), Microsoft corporation (2019), and Microsoft excel.

RESULTS

Baseline characteristics

The study included 30 patients, predominantly male (93.3%), with a mean age of 53.2±12.1 years. Their mean

height was 166.7±7.9 cm, weight 72.9±13.7 kg, and BMI 26.3±5.0 kg/m^2. Most were non-smokers (83.3%), abstained from alcohol (60%), and followed a non-vegetarian diet (60%). The results showed that 40% had no comorbidity, 30% had HTN, 20% had type 2 diabetes mellitus (T2DM), and 10% had both. Patients had an average SBP of 128.80±20.02 mmHg, DBP of 83.83±8.75 mmHg, and HR of 81.87±12.15 beats per minute (bpm). Majority (76.7%) of patients were diagnosed with STEMI.

Findings indicated that 53.3% of patients had single-vessel coronary artery lesions, 20% had double-vessel lesions, and 10% had triple-vessel lesions. Most patients (73.3%) underwent PCI, a few (6.7%) had CABG, and 1 patient (3.3%) received thrombolysis. A small percentage (16.7%) managed their condition solely with medications without specific interventions (Table 1).

Adherence to the LYFE digital program

Figure 2 illustrates adherence to a) medication, b) physical exercise, and c) diet in LYFE and SOC groups over 6 months. Of all the participants, 90% followed regular exercise, and 79.3% of them reported 'never/rarely,' indicating that they never felt difficulty remembering to take their medications and follow their prescribed diet.

Table 1: Demographics and baseline characteristics of the participant, (n=30).

Characteristics	N (%)/ mean ± SD	P value*
Demographics		
Age (in years)	53.2±12.10	<0.001
Weight, (kg)	72.9±13.70	<0.001
Height, (cm)	166.7±7.90	<0.001
BMI, (kg/m^2)	26.3±5.0	<0.001
Gender		
Male	28.0 (93.30)	<0.001
Female	2.0 (6.70)	
Smoking		
Never smoked	25.0 (83.3)	<0.001
Current smoker	4.0 (13.3)	

Continued.

Characteristics	N (%)/ mean ± SD	P value*
Past smoker	1.0 (3.3)	
Alcohol		
Never drinks	18.0 (60.0)	<0.001
Current drinker	11.0 (36.7)	
Former drinker	1.0 (3.3)	
Dietary preferences		
Non-vegetarian	18.0 (60.0)	0.27
Vegetarian	12.0 (40.0)	
Comorbidities		
Hypertension	9.0 (30.0)	0.11
Type 2 diabetes mellitus (T2DM)	6.0 (20.0)	
Hypertension + T2DM	3.0 (10.0)	
None	12.0 (40)	
Initial diagnosis		
STEMI	23 (76.7)	<0.001
NSTEMI	1 (3.3)	
Unstable angina	1 (3.3)	
Others	5 (16.7)	
Coronary artery lesions		
Single vessel	16 (53.3)	0.004
Double vessel	6 (20.0)	
Triple vessel	3 (10.0)	
Other	5 (16.7)	
Interventions		
PCI	22 (73.3)	<0.001
CABG	2 (6.7)	
Thrombolysis	1 (3.3)	
Neither	3 (16.7)	

*Statistically significant at p<0.05. CABG - coronary artery bypass graft; SD-standard deviation, NA-not applicable due to insufficient data; NSTEMI-Non-ST-elevation myocardial infarction; PCI-percutaneous coronary intervention; STEMI-ST-segment elevation myocardial infarction.

Patient well-being assessment

Figure 3 displays the mean differences observed in the nine well-being domains from baseline to 6 months. Social activities, health changes, daily activities, and QoL showed a slight improvement with mean changes of -0.36, -0.46, -0.55, and -0.59, respectively. Participants reported reduced pain (mean change: -0.68) and feelings (mean change: -0.72). Furthermore, overall health improved (mean change: -0.73), and the need for social support significantly decreased (mean change: 2.27) because the LYFE app does not create propagate or provide any social support groups or forums, while physical fitness showed significant improvement (mean change: -1.55).

Effects on clinical outcomes

Table 2 presents the changes in vital signs of the participants that were analyzed from baseline to 1 month, 3 months, and 6 months. At baseline, the mean SBP was 128.80±20.01 mmHg. After 1 month, the mean SBP significantly decreased to 120.69±15.80 mmHg (p<0.05). This reduction in SBP was sustained at 3 months, with a mean SBP of 118.67±16.74 mmHg (p<0.001), and at 6 months, with a mean SBP of 120.96±14.71 mmHg (p=0.038). The mean DBP at baseline was 83.83±8.74 mmHg. After 1 month, it decreased significantly to 80.24±9.19 mmHg (p<0.05). This reduction continued at 3 months, with a mean of 79.41±9.91 mmHg (p<0.01), and at 6 months, with a mean DBP of 80.52±7.25 mmHg (p=0.044). No significant changes were observed in HR during the study period. HR showed little change at 1 month (0.03 bpm increase), increased at 3 months (1.81 bpm), and decreased at 6 months (1.70 bpm).

Furthermore, Figure 4 illustrates the BP levels of the study participants evaluated over 6 months to determine the status of controlled BP. Those who achieved SBP<140 mmHg and DBP <90 mmHg were classified as being within the controlled BP range. Of all the participants, 88.9% were 'in range,' and only 10.1% had uncontrolled BP levels.

The study also examined cardiovascular events in the study participants and did not find any clear indication of major bleeding events or recorded deaths. Additionally, the majority of participants (86.7%) did not experience any cardiovascular events, except for one (3.3%) who encountered a stroke (Table 3).

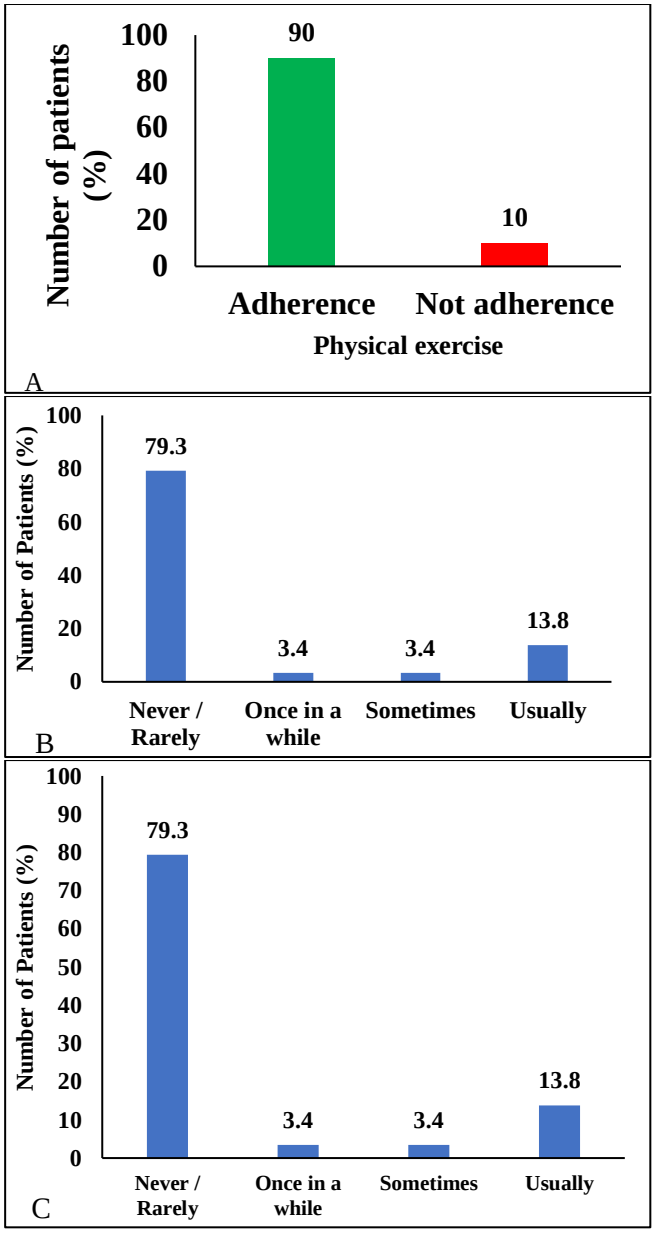

Figure 2 (A-C): Adherence to physical exercise, medication and diet in LYFE for 6-month follow-up.

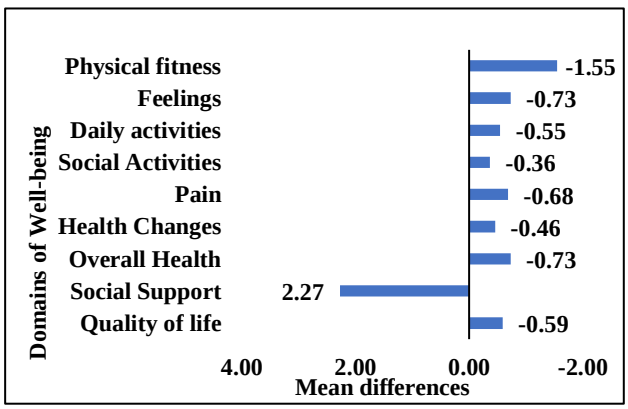

Figure 3: Well-being assessment of LYFE groups using Dartmouth COOP from baseline to 6 months.

Table 2: Mean changes in vitals from baseline to 6-month follow-up.

Characteristics	1 month, (n=30)	3-month, (n=30)	6-month, (n=30)
Systolic blood pressure, SBP (mmHg)			
Baseline, mean ± SD	128.80± 20.02	128.80 (20.02)	128.80 (20.02)
Follow-up, mean ± SD	120.69 (15.81)	118.67 (16.74)	120.96 (14.71)
95% CI	1.53-14.60	3.516-12.11	0.34-10.70
P value	0.01	<0.001	0.04
Diastolic blood pressure, DBP (mmHg)			
Baseline, mean ± SD	83.83 (8.75)	83.83 (8.75)	83.83 (8.75)
Follow-up, mean ± SD	80.24 (9.20)	79.41 (9.91)	80.52 (7.25)
95% CI	0.96-6.49	1.50-5.99	5.19-2.11
P value	0.01	0.001	0.04
Pulse rate, PR (bpm)			
Baseline, mean ± SD	81.87 (12.15)	81.87 (12.15)	81.87 (12.15)
Follow-up, mean ± SD	82.03 (9.82)	83.15 (11.09)	79.63 (10.19)
95% CI	-2.30-2.23	-5.41-1.78	5.243-0.99
P value	0.49	0.15	0.33

*Statistically significant at p<0.05. SD=standard deviation; CI=Confidence interval.

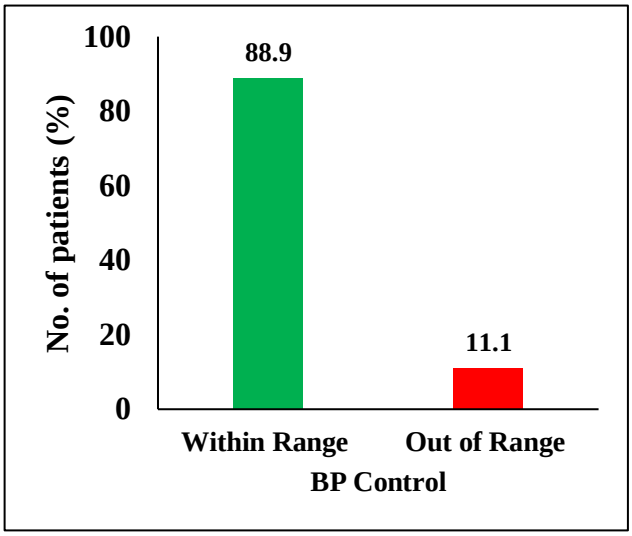

Figure 4: BP control at 6-month follow-up.

Table 3: Status of cardiovascular events, (n=30).

Cardiovascular events	N (%)
Cardiovascular death	0 (0)
Major bleeding events	0 (0)
Stroke or TIA	1 (3.3)
None	26 (86.7)

DISCUSSION

Recent studies have emphasized the potential of software-driven digital interventions in reducing cardiovascular risk factors. However, there is a lack of research on how these interventions impact health outcomes in managing CVD.[8] Our study aimed to fill this gap by investigating how the 'LYFE' digital program affects key outcomes in people with CAD and/or those who underwent PCI. We assessed the program's impact on BP, medication adherence, well-being, and overall clinical outcomes, revealing some positive results.

In a study investigating the impact of gender on clinical outcomes in patients with CAD and/or post-PCI, a total of 1,032,828 patients were included. Of these, 774,115 were male and 258,713 were female.[9] This observation aligns with the present study, which also had a significant proportion of male participants. The median age for the onset of the first heart attack in Indians is reported to be 53 years.[10] In a previous study that examined stable or unstable CAD patients who underwent successful PCI, the majority of the participants were male (63%) and the mean age of the study population was 56.65±9.65 years.[11] Similarly, in our study, we observed a similar trend with a significant number of participants having a mean age of 53.2±12.1 years. This indicates that the study population primarily consisted of middle-aged individuals, which is consistent with the previously reported median age for first heart attacks in Indians. In another prospective study, patients with proven CAD were recruited, and among the participants, the mean BMI was found to be 27.4±4.4 kg/m^2.[12] Likewise, in the present study, the mean BMI of the participants was 26.3±5.0 kg/m^2.[13] While smoking and alcohol consumption are known to be associated with CVD occurrence, surprisingly most of the participants in the current study were non-smokers and did not consume alcohol. These findings contribute to our understanding of the demographic and clinical characteristics of CAD and/or post-PCI patients.

Effectively managing CVD patients with comorbidities is important. This group faces higher mortality, reduced QoL, and increased healthcare service utilization compared to those without comorbidities. In a cross-sectional study, a strong association was found between CAD and arrhythmias [odds ratio (OR): 2.55, 95% CI: 2.30-2.82]. Diabetes mellitus also significantly correlated with CAD (OR: 2.22, 95% CI: 2.02-2.45).[14] Furthermore, another study emphasized HTN as the most common risk factor for CVDs, showing its association with the development and progression of various atrial and ventricular arrhythmias.[15] HTN was also found to have a strong association with arrhythmias (OR 2.05; 95% CI, 2.30-2.82).[14] Our study confirmed that HTN is the most common comorbidity among participants, and diabetes, either alone or with HTN, is frequently observed. These findings enhance our understanding of the connection between HTN, diabetes, and CAD. In the study comparing PCI in STEMI and NSTEMI patients, 417 individuals underwent coronary intervention. Of these, 175 (42.0%) were diagnosed with acute myocardial infarction (MI). The analysis included 168 patients, with 104 (61.9%) having STEMI and 64 (38.1%) diagnosed with NSTEMI.[16] The present study results were consistent with the findings with the majority of the participants having STEMI, further supporting the existing body of evidence.

In our study, a substantial number of patients underwent PCI for CAD management, which is considered the preferred initial treatment for individuals experiencing STEMI within 12 hours of symptom onset.[17] Previous studies have shown that PCI could be as safe and effective as CABG, particularly in a select group of patients with left main CAD.[18] The DELTA registry further supports this, demonstrating that PCI for ostial/mid-shaft lesions is associated with better clinical outcomes (propensity-score adjusted hazard ratio: 1.68, 95% CI: 1.19 to 2.38; p=0.003).[19]

With the widespread use of the internet and communication, electronic health technologies are now common, even among older adults. A particularly popular and rapidly growing aspect of this technology is mHealth.[20] According to a systematic review on the prevention or management of non-communicable diseases, the included mHealth apps had an average adherence score of 56.0%.[21] Additionally, a cross-sectional study focusing on patients with CVD found that 68.0% of them showed interest in using mHealth solutions to manage their condition.[22] Similarly, in our study, a significant number of participants were actively engaged, while a few had delayed responses. The high acceptance and adherence to our LYFE digital program, as demonstrated, highlight the effectiveness of our digital intervention, attributed to an array of in-app features such as nudges, notifications, regular reminders, and dietitian support.

A thorough review and meta-analysis of mHealth on secondary prevention of CVDs revealed that patients in the mHealth group had significantly increased adherence to medical therapy (OR, 4.51; p<0.00001) and both pharmacologic and non-pharmacologic therapy (OR, 3.86; p<0.00001). Additionally, they were more likely to meet recommended BP targets (OR, 2.80; p<0.001) with a tendency towards reaching the exercise goals (OR, 2.55; p=0.07).[23] In a systematic review and meta-analysis of randomized clinical trials (RCTs) that aimed to investigate the effects of mHealth on BP management, the pooled effects of mHealth interventions on BP control were estimated. When compared to the control group, the mHealth group was associated with significant reductions in both SBP (-3.85 mm Hg; 95% CI, -4.74 to -2.96) and DBP (-2.19 mm Hg; 95% CI, -3.16 to -1.23).[24] Over the 6-month study period, we observed similar outcomes, with significant improvements in both SBP and DBP in the study population might be due to the improved adherence to physical exercise, diet and medication.

Medication nonadherence has long been a challenge for CVD patients and has been repeatedly recognized as a major contributor to adverse cardiovascular events.[25-27] However, the use of app-based interventions for medication adherence has shown promising results in addressing this issue.[28] The Text4Heart RCT, which had a 6-month intervention period, demonstrated significantly higher medication adherence scores [mean difference (MD): 0.58, 95% CI, 0.19-0.97; p=0.004). The SimCard trial, which lasted for 1-year, revealed that the intervention group had a 25.5% (p<0.001) higher net increase in the primary outcome-the proportion of patient-reported antihypertensive medication use pre- and post-intervention in comparison to the control group.[29,30] Our study showed similar results with almost all patients demonstrating medication adherence that can be attributed to in-app reminders and notifications, which help create habits and improve overall adherence. A review of activity trackers in CAD patients found a significant 0.51 risk ratio decrease in MACE (95% CI: 0.31-0.86; p=0.01).[31] The MiCORE multicenter unrandomized controlled trial showed a 52% lower risk of all-cause 30-day readmissions [hazard ratio (HR) 0.48; 95% CI, 0.26-0.88] in the DHI group compared to the historical control group receiving standard of care.[32] A population-wide analysis of managed care after acute myocardial infarction (MC-AMI) presented a 38% reduction in 1-year mortality, and the effect continued even after the completion of the program.[33] Interestingly, our study experienced no such adverse events, which is reassuring and suggests that the use of digital interventions may have a positive impact on secondary prevention in CAD patients.

The evaluation of mHealth-based interventions to reduce CVD risk factors revealed that 4 of 7 RCTs focusing on enhancing physical activity demonstrated significant improvements.[34] Home-based cardiac telerehabilitation programs showed a favorable outcome, with the intervention group showing an increase in the 6 WMT (MD: 16.59 meters, 95% CI:7.13-26.06, p=0.0006).[35] Moreover, smartphone-based interventions in CAD patients resulted in a noteworthy improvement in exercise capacity (20.10 meters, 95% CI:7.44-33.97, p<0.001, I^2=45.58) and a review of RCTs highlighted that mHealth interventions improved QoL for patients post-coronary event, as evidenced by significant changes in the physical [standardized mean difference (SMD): 0.26, 95% CI, 0.09-0.44; p=0.004] and mental (SMD: 0.27, 95% CI, 0.06-0.47; p=0.01) aspects.[36,37] Furthermore, mHealth interventions for CR and HF management demonstrated equal efficacy as traditional center-based CR (TCR), resulting in significant QoL improvements.[38] Similar to the above mentioned study results, our LYFE digital intervention, with the help of the Dartmouth COOP questionnaire, which has been widely used to assess the QoL of heart patients, achieved remarkable improvements in most of the well-being domains within our study population.[39,40]

This study, while valuable, has limitations. The small sample size may limit generalizability. The absence of a control group hinders comparing the intervention's effectiveness and short follow-up might not capture long-term effects. Self-reported data on outcomes like medication adherence may introduce bias. Despite these limitations, our study offers insights into the LYFE digital program's potential benefits for CAD and/or post-PCI patients. Future research with larger samples and longer follow-ups is needed for broader validation in diverse clinical settings.

CONCLUSION

In conclusion, our study aimed to fill the research knowledge gap regarding the impact of digital health interventions by analyzing our 'LYFE' digital program and its effects on CAD and post-PCI patients. The program provides a wide range of benefits for users, including comprehensive monitoring, encouragement of adhering to lifestyle changes and medications, caregiver involvement, personalized coaching and support, disease education modules, an emergency response system, and access to ambulances and hospitals. The results of the study were highly encouraging, revealing positive outcomes in various aspects, including improved medication adherence, better BP control, enhanced patient well-being scores, and overall clinical improvements. These findings highlight the significant potential of software-driven digital interventions in effectively managing CAD and/or post-PCI patients, thereby reducing cardiovascular risks. Implementing such digital health programs can pave the way for more efficient and personalized patient care, ultimately contributing to better health outcomes for these patients.

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