# Evaluating a New Digital App-Based Program for Heart Health: Feasibility and Acceptability Pilot Study

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Submitted to: JMIR Formative Research
on: June 30, 2023

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## *Abstract*

**Background:** Cardiovascular disease (CVD) is the leading cause of death in the United States, affecting a significant proportion of adults. Digital health lifestyle change programs have emerged as a promising method of CVD prevention, offering benefits such as on-demand support, lower cost, and increased scalability. Prior research has shown the effectiveness of digital health interventions in reducing negative CVD outcomes. This pilot study focuses on the Lark Heart Health program, a fully digital artificial intelligence (AI)-powered smartphone application, providing synchronous CVD risk counseling, educational content, and personalized coaching.

**Objective:** This pilot study evaluated the feasibility and acceptability of a fully digital lifestyle change program called Lark Heart Health. Primary analyses assessed participant satisfaction, engagement with the program, and the submission of health screeners. Secondary analyses were conducted to evaluate weight loss outcomes.

**Methods:** This study enrolled 509 participants into the 90-day real-world, non-interventional, single-arm, observational, pilot study of the Heart Health app. Participants engaged with the app through coaching conversations, logging meals, tracking weight, and completing educational lessons. Study outcomes included participant satisfaction, app engagement, completion of screeners, and weight loss.

**Results:** On average, Heart Health study participants were 61 (40-75) years old, with average body mass index indicating class I obesity. There were 489 participants who stayed enrolled until the end of the study. Study retention, based on providing a weight measurement during Month 3, was 80.0% (407/509; CI = 76.2,83.4%). Participant satisfaction scores indicated high satisfaction with the overall app experience, with an average score of >4 of 5 for all satisfaction indicators. Participants also showed high engagement with the app, with 83% (408/489; CI = 80.1-86.7%) of the sample meeting criteria for being highly engaged in Month 3. Results indicated that participants were successfully able to submit health screeners within the app, with 89.8% (440/489; CI = 87.0, 92.5%) submitting all three screeners measured in the study. Lastly, secondary analyses showed that participants lost weight during the program, with analyses showing an average weight nadir of 3.8% (CI = 3.5,4.1).

**Conclusions:** The present results indicate that participants in this study were satisfied with their experience using the Heart Health app, highly engaged with app features, and willing and able to complete health screening surveys in the app. These acceptability and feasibility results provide a key first step in the process of evidence generation for a new AI-powered digital program for heart health.

(JMIR Preprints 30/06/2023:50446)
DOI: https://doi.org/10.2196/preprints.50446

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# Original Manuscript

## Original Paper

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**Results:** On average, Heart Health study participants were 61 (40-75) years old, with average body mass index indicating class I obesity. There were 489 participants who stayed enrolled until the end of the study, resulting in a study dropout rate of 4%. Study retention, based on providing a weight measurement during Month 3, was 80.0% (407/509; 95% $CI$ = 76.2, 83.4%). Participant satisfaction scores indicated high satisfaction with the overall app experience, with an average score of ≥4 of 5 for all satisfaction indicators. Participants also showed high

engagement with the app, with 83% (408/489; 95% $CI$ = 80.1, 86.7%) of the sample engaging in 5 or more coaching conversations in Month 3. Results indicated that participants were successfully able to submit health screeners within the app, with 89.8% (440/489; 95% $CI$ = 87.0, 92.5%) submitting all three screeners measured in the study. Lastly, secondary analyses showed that participants lost weight during the program, with analyses showing an average weight nadir of 3.8% (95% $CI$ = 3.5, 4.1).

**Conclusions:** The present results indicate that participants in this study were satisfied with their experience using the Heart Health app, highly engaged with app features, and willing and able to complete health screening surveys in the app. These acceptability and feasibility results provide a key first step in the process of evidence generation for a new AI-powered digital program for heart health. Future work can expand these results to test outcomes with a commercial version of the Heart Health app in a diverse, real-world sample.

**Keywords:** Digital health; cardiovascular disease; artificial intelligence; acceptability and feasibility; pilot study; lifestyle coaching

## Introduction

Cardiovascular disease (CVD) is the leading cause of death for adults in the United States [1] and approximately 49.2% of adults (126.9 million) are living with some form of CVD [2]. The primary type of CVD that drives CVD-related morbidity and mortality is atherosclerotic cardiovascular disease (ASCVD), which is characterized by buildup of plaque in arteries and includes conditions such as coronary heart disease, cerebrovascular disease, peripheral artery disease, and aortic atherosclerotic disease [3]. Despite effective, evidence-based strategies for preventing or managing ASCVD, millions of Americans have risk factors that place them at increased risk for having a cardiovascular event [1]. Thus, prevention and management of CVD is a top public health priority.

The primary method of preventing CVD is promoting a healthy lifestyle throughout life. The American College of Cardiology (ACC)/American Heart Association (AHA) Guidelines on the primary prevention of CVD [3] recommend that all adults should maintain a healthy weight, consume a healthy diet, engage in regular physical activity, avoid tobacco use, and practice good sleep hygiene. These lifestyle habits are also recommended for the secondary prevention of CVD. The ACC/AHA guidelines also recommend that adults who are 40 to 75 years of age and are being evaluated for CVD risk should undergo a 10-year ASCVD risk estimation at initial evaluation and at each subsequent follow-up appointment.

Despite these guidelines, maintaining a healthy lifestyle is difficult for many adults [4]. As such, a key method of CVD prevention and management is participation in behavioral interventions focused on lifestyle modifications. The US Preventive Services Task Force advises that behavioral interventions focused on diet and physical activity provide cardiovascular benefits to adults both with and without known CVD risk [5–7] interventions and lifestyle change programs can be focused on primary prevention of CVD and/or secondary prevention after a cardiac event and can be delivered by a variety of modalities (e.g., in person, by telephone, digitally), but have traditionally been delivered in person [7,8].

Although in-person programs can be very effective for increasing healthy behaviors [5,6] they also present many challenges. Such programs involve significant human-to-human contact (e.g., nurses, coaches, etc.), making them expensive to implement. Additionally, requiring in-person attendance makes it difficult or inconvenient for some individuals to attend [9]. These barriers to

implementation and participation make it challenging to scale lifestyle interventions to large populations. Given the large number of adults in the United States at risk for CVD, there is a clear need for scalable and accessible lifestyle change programs for preventing CVD.

There is a growing number of digital lifestyle change programs for primary and secondary CVD prevention [10–12] that can be delivered through a variety of digital modalities, (e.g., text messaging, smartphone apps, and web-based). Digital health programs can avoid many of the challenges posed by in-person programs, offering benefits such as on-demand support, access after standard business hours, lower cost, and increased scalability to larger populations [8]. Furthermore, digital health programs for primary and secondary CVD prevention have been shown to improve individual behaviors and show promise in delivering care that is accessible, cost-effective, and patient-focused [13].

## Digital Health Solutions for CVD Prevention

There has been prior research on digital health interventions for prevention of CVD [13–15]. A meta-analysis of digital health interventions for both the primary and secondary prevention of CVD summarized many of these findings (Widmer et al., 2015) in an assessment of 24,054 participants across 51 studies. This meta-analysis found that digital health interventions significantly reduced negative CVD outcomes, such as CVD events, hospitalizations, and all-cause mortality. Widmer et al. also observed reductions in risk factors including weight, body mass index (BMI), and Framingham risk score compared to usual care. A more recent analysis focused on health behaviors also indicated that digital interventions can improve physical activity, healthy diet, and medication adherence [16]. Overall, these studies show a net benefit of digital health interventions on CVD outcomes and risk factors.

As demonstrated by these prior studies, there is evidence for the benefits of digital health interventions for primary and secondary prevention of CVD. However, there has been considerable variation in the delivery mode of available digital solutions, namely in the involvement of humans as coaches or healthcare providers. A common feature across most digital health programs is the inclusion of human coaching or care provision delivered via phone calls, text, or email [17]. Moreover, a recent review of the literature indicated that a low number (4/31 or 13%) of cardiovascular health-related digital health interventions are fully automated, requiring no specific personnel [11]. Human interaction elements in digital health, similar to in-person programs, require significant resources, limiting their scalability [18]. As a result, the present pilot study examined a fully digital solution (i.e., no human-to-human coaching) for primary and secondary CVD prevention called Lark Heart Health.

## Heart Health Program and Pilot Study

The primary purpose of the Heart Health program is to help participants make and maintain meaningful, evidence-based healthy lifestyle changes, learn about their CVD risk factors, and acquire appropriate self-management skills. Lark's Heart Health program is an Artificial Intelligence (AI)-driven mobile coaching solution that provides synchronous CVD risk counseling anytime, anywhere. The Heart Health program is for primary prevention in individuals without a major ASCVD event or secondary prevention for those in a stable condition after an ASCVD event that was ≥6 months prior. Through an ASCVD risk estimator survey, evidence-based educational curriculum, and real-time personalized coaching, Lark provides members with the tools they need to make meaningful lifestyle changes that can help them better prevent and manage ASCVD and coronary artery disease through heart health-specific digital nutrition coaching, medication adherence counseling, and personalized guidance on weight management, activity, stress, and sleep.

Additionally, one of the goals of the Heart Health program is to provide a user-friendly platform for participants to complete physical and mental health screening surveys that can be time consuming and burdensome for both patients and providers in primary care settings [5,19]. This is particularly important, as completion of health screeners is associated with improved patient outcomes and clinical care [20].

Experts designed the Heart Health program in accordance with guidelines from the AHA, ACC, and the National Heart, Lung, and Blood Institute (NHLBI). The American Diabetes Association (ADA), 2020-2025 Dietary Guidelines for Americans, American College of Sports Medicine (ACSM), and American Academy of Sleep Medicine (AASM) informed the additional nutrition, activity, and sleep recommendations. The development of the Heart Health program was a collaboration between Lark Health and Roche Diagnostics and fits within the World Heart Federation's Roadmap for Digital Health in Cardiology [21]. Full details on Lark's other digital programs have been previously reported [22,23].

Coaching in the Lark Heart Health program is completely powered by AI. The fully digital interface enables maximum program scalability and the advantage of being accessible to participants 24/7 with synchronous coaching, feedback, and encouragement delivered on-demand. Feasibility and acceptability studies are a key component of evidence generation for new programs of any kind and provide a crucial preliminary step before randomized controlled trials and/or commercialization. Similar published studies provide examples of overall scope, design, and execution of digital programs for cardiovascular health and other chronic diseases [24–26]. For example, Lunde et al. (2019) conducted a feasibility study of an app for cardiac rehabilitation, setting predefined criteria for success on participant satisfaction, recruitment rates, and app adherence to help predict possible pitfalls before conducting a large, randomized controlled trial. Despite these inherent advantages, there is little evidence supporting the feasibility and user acceptability of fully digital programs for cardiovascular health. Thus, the goal of this pilot study was to provide preliminary evidence that participants are willing and able to participate in the Heart Health program.

## Objectives

This is a real-world, single-arm, 3-month pilot study of the feasibility and acceptability of the Heart Health program. The primary objectives and corresponding success criteria determined a priori are as follows:

Objective 1: Assess participant satisfaction with the Heart Health program. Primary indicator of success: Achieve a participant satisfaction average rating of ≥4 out of 5 on participant satisfaction surveys.

Objective 2: Measure participant engagement with the Heart Health program via frequency of AI coaching. Primary indicator of success: Assess the number of coaching conversations per month and categorize them using the following: ≥5 coaching conversations per month as "highly engaged", 2-4 conversations "moderately engaged", and ≤1 conversations "minimally engaged."

Objective 3: Track submission of health screeners within the Heart Health application to demonstrate we can identify moments or events that could be used to improve patient care. Primary indicator of success: Submission of three surveys by each member. Having three completed surveys was "excellent", two was "good", and one was a "minimum improvement over usual care." This scale was based on literature indicating that there are major barriers to implementing even basic health history screeners in primary care settings [19,20,27].

Secondary Objective: In addition to the primary objectives, we also conducted secondary analyses focused on weight loss, given that a primary focus of the Heart Health program is weight management.

As a part of the Heart Health pilot study, we also evaluated predictors of recruitment and enrollment as well as changes in cardiac self-efficacy; results from these analyses are reported in separate manuscripts, as they do not focus on the acceptability and feasibility component of the study.

# Methods

## Pilot Study Design

This pilot study was a real-world, single-arm study of the digital health app-based program Heart Health that provides fully digital, AI-powered health coaching, behavior tracking, and health screeners. The active study period was 3 months (90 days) in duration for each enrolled participant. The data presented here includes participants who initiated the study between March 31 and September 15, 2022, using Lark app version 5.2.6. The target sample size for initial enrollment into this study was 500-600; rationale for this enrollment goal is described in the Supplemental Materials.

### *Study Population*

To be eligible for the Heart Health study, potential participants had to fit the following eligibility parameters: 40-75 years of age, body mass index (BMI) ≥ 25 and < 50 (indicating overweight or obesity, but excluding the most extreme cases of obesity), and English speaking. Potential participants were ineligible if they met any of the following criteria: Critically serious uncontrolled health conditions that had been active in the last six months; pregnancy or plans to become pregnant within the next six months; recent history of a medical professional telling them not to participate in a healthy lifestyle program; a medical reason preventing them from doing 10 minutes of moderate physical exercise; and not having a smartphone with an internet connection. Because the Heart Health program focused heavily on improving health behaviors (e.g., diet and exercise), the study also excluded individuals who reported at baseline that they regularly engage in strenuous physical activity in their leisure time and individuals who reported only healthy dietary behaviors. If needed, study personnel provided potential participants with telephone-based assistance in downloading the Lark smartphone app.

An analytic size of approximately 500 is recommended to produce statistics that are nearly representative of the true values in the targeted population (Bujang et al. 2018). As such, we considered a sample size between 500-600 at initial enrollment to be satisfactory for assessing primary study goals. This planned sample size at initial enrollment was larger than most published digital health interventions for the prevention of cardiovascular disease (Widmer et al. 2015)

The recruitment and enrollment flow for the Heart Health study is shown in Figure 1, starting with the number of potential participants who completed the study prescreener. After consenting to participate in the study, participants completed the enrollment process by downloading the app, completing study onboarding in an initial conversation in the app, and providing an initial weight measurement. Per study protocol, participants completing these steps were enrollees. Withdrawal rate for the study was 4%, with 20 participants withdrawing after enrollment.

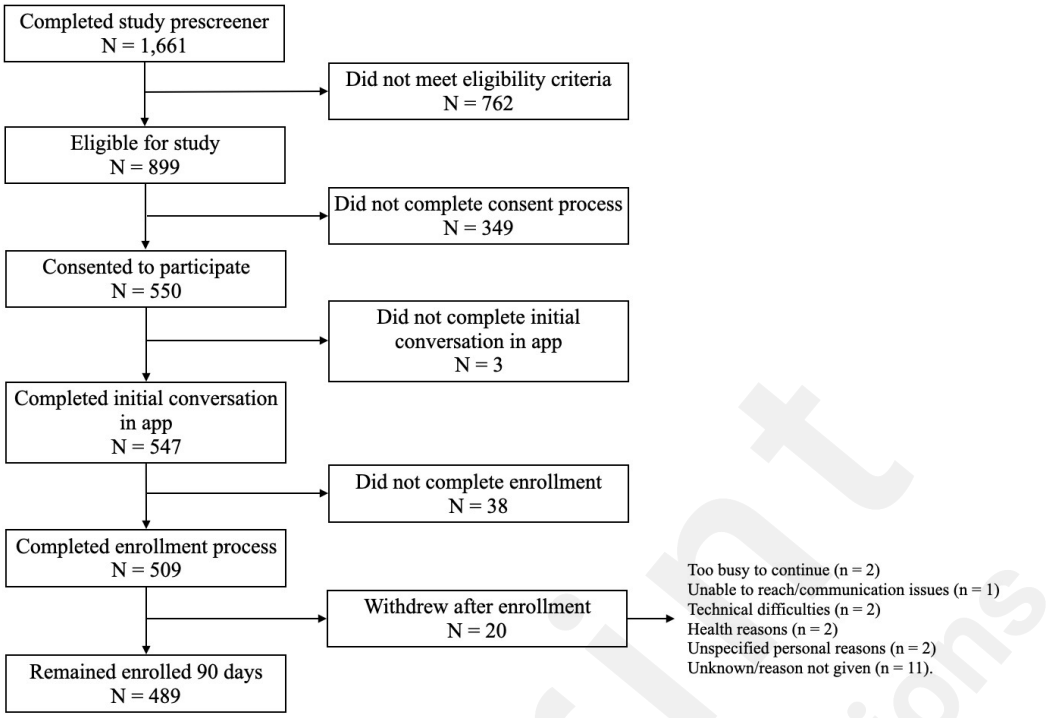


**Figure 1.** Recruitment and enrollment flow for the Heart Health study.

## Study Phases

Each participant proceeded through defined study phases: Recruitment, prescreening, eConsent, enrollment, and active participation. For recruitment, Lark partnered with a health provider in California to recruit participants from their patient population. Study personnel sent potentially eligible participants marketing emails and/or SMS messages, and printed mailers. In addition to participant recruitment via the health provider, we also recruited additional study participants using a variety of web recruitment methods. Recruitment materials provided a brief description of the program, describing the program as a way to improve heart health using digital health coaching that encourages healthier eating and getting more active. Individuals interested in participating in the study received a web link to the study recruitment site to find out more information and complete the study prescreening process.

Participants who proceeded from recruitment to prescreening completed a survey that assessed their general suitability for the study based on safety and appropriateness of the program coaching and content. Participants who passed the prescreening survey had the opportunity to complete the eConsent form to initiate study participation.

The active participation phase of the study was 90 days in duration, during which participants received coaching on heart health and lifestyle modification. Participants could engage with the Heart Health program via (1) Completing educational lessons (up to 12 lessons over 90 days), (2) Engaging in coaching conversations with Lark's conversational AI-powered digital coach, (3) Logging meals in the app, and (4) Tracking their weight using a digital smart scale that automatically synced with the app. Additional details on the Heart Health program and study design are described in Supplemental Materials.

## Ethical Considerations

All participants provided informed consent to participate in the study through an eConsent form. The pilot study received approval from Advarra Institutional Review Board (protocol Pro00061694).

Study personnel instituted appropriate safeguards to prevent any unauthorized use or disclosure of personal health information and implemented administrative, physical, and technical safeguards to protect the confidentiality, integrity, and availability of protected health information. All study data presented in this manuscript are de-identified. Lark is compliant with HIPAA Privacy and Security rules and all applicable regulations. Additionally, Lark is SOC2 and HITRUST certified.

All study participants received the Heart Health app and a cellular smart scale. There were opportunities for additional incentives throughout the study. At the start of the study, participants could receive a $50 gift card upon ordering their cellular scale; this incentive was implemented to encourage participant use the cellular scale for regular weigh-ins for higher data integrity compared to manual entry of weight data. There were two additional opportunities for participants to earn gift card incentives for completing (1) a telephone call regarding customer satisfaction and usability of the Heart Health app ($25) and (2) a telephone call about experiences taking surveys in the app ($100). Additional detail on these telephone calls is provided in the section on “Participant satisfaction surveys” below. Finally, participants could receive a Fitbit upon study completion.

## Study Measures

### Demographic and Health History Measures

We assessed participant characteristics for the study sample using a modified version of the “Non-Laboratory” Based INTERHEART Modifiable Risk Score survey [28,29]. Additional detail on this measure is described in the Supplemental Materials. Participants also completed the ASCVD Risk Estimator survey [30,31].

### Study Retention

We assessed study retention based on the proportion of participants who recorded a weight between Day 61-90 (Month 3) out of the 509 members who enrolled in the study. Study personnel determined this retention metric *a priori* as a key indicator of whether a participant was still engaging with the Heart Health program.

### Primary Objective Measures

#### Participant satisfaction surveys

Participants completed two satisfaction surveys over the course of the study. Importantly, these surveys were specific to this research study and would not typically be a part of the commercial Heart Health user experience. As such, the surveys were not built into the digital app experience but instead collected via phone call by a contract research organization (CRO) contracted by Lark Health for the purposes of this pilot study. Calls came from CRO call center employees who were specifically trained to administer these surveys; survey calls did not include human coaching that would augment the Lark app experience. This helped ensure that participation satisfaction ratings were not collected by Lark clinical research staff and reduced the impact of these survey assessments on the in-app experience.

To measure participant satisfaction with overall usability and acceptability of Heart Health, the CRO deployed a 5-item satisfaction survey at the beginning of Month 3. We adapted questions on this survey from a recent study on the acceptability of a lifestyle-based heart health risk assessment tool [32]. We also assessed participant satisfaction with taking the ASCVD Risk Estimator survey in the app to understand whether participants were capable of and comfortable with providing this type of health information without assistance in the Heart Health app. The CRO deployed this satisfaction survey at the beginning of Month 2. The primary success criterion for satisfaction with both the overall app experience and in-app ASCVD survey experience was a rating of ≥4 out of 5.

### App engagement

Participants engage with the Heart Health app primarily through personalized, interactive coaching conversations between the participant and the Lark AI coach. Participants can log in to the app at any time to engage in a coaching conversation with the coach and receive educational lessons, synchronous feedback, and encouragement. We assessed the number of days that study participants had at least one coaching conversation. We assessed the number of days with coaching conversations per month and categorized the coaching volume (primary indicator of engagement) as follows: ≥5 coaching conversations per month was highly engaged, 2-4 conversations was moderately engaged, and ≤1 conversations was minimally engaged. These engagement thresholds were determined based on expectations of the health partner for engagement with a commercial version of the program, while also accounting for individual differences in engagement and expected engagement drop-off in digital health programs.

Though we did not have specific success criteria for the other metrics of app engagement, we also tracked the number of days participants logged meals, number of days participants completed weigh-ins (i.e., weight measurements), and number of educational lessons completed. Each of these types of engagement occurs within the context of coaching conversations with the Lark coach. The Heart Health app provides a digital platform for diet tracking via a meal logging system that uses natural language processing. Participants can log meals and snacks in the app at any time, receive feedback on the nutritional content of their meals, and earn success badges for healthy meals.

The Lark coach encourages participants to weigh themselves using their cellular scale on a weekly basis. The scale automatically syncs with the app so that participants can track their progress. Participants could also enter their weight manually. In the present analyses, we assessed the number of days that study participants had at least one meal logged and the number of days with a weight measurement in the 90-days since study enrollment.

Finally, we assessed the mean number of educational lessons completed by each participant. A lesson is complete once a participant has completed all content associated with each of the required seven check-ins. Participants could complete a maximum of 12 lessons over the course of the 90-day study (i.e., one per week).

### Screener Submission

The app presented Heart Health members with several screeners throughout their participation in the study. Three key screeners occurred during Month 1 of the program: the Patient Health Questionnaire-2 (PHQ-2) depression screener [33], the Medication Adherence Questionnaire (MAQ) [34], and the ASCVD Risk Estimator [30,31]. The PHQ-2 is a two-item measure that indicates risk for depression. The MAQ has multiple sections, the first of which is a “medication check” that establishes whether the member is taking medications; members who are taking medications proceed to the “adherence” section of the MAQ. Submission values for the MAQ reflect the number of members who completed the medication check questions. Submission values for the ASCVD Risk Estimator reflect the number of members who submitted the survey; note that participants could submit the ASCVD Risk Estimator without completing all fields necessary to calculate a risk score (e.g., participants could skip cholesterol values because they may not know these values). The primary success criterion for this outcome was submission of three surveys by each participant. Having three completed was *excellent*, two was *good*, and one was a *minimum improvement over usual care*.

### *Secondary Objective Measures: Weight Loss*

To assess weight loss, we examined weight nadir (i.e., peak weight loss) among participants in the Heart Health program who provided at least two weights. Participants could complete a weigh-in at any time in the study either by stepping onto their synced cellular scale or manually entering a weight. Outlier detection algorithms ensure fidelity of all collected weight data; for details, see prior Lark publications [22,35]. The weight nadir outcome considered only valid weights and represented each member's (first weight - lowest weight)/first weight. We represent the weight nadir as the percent of initial weight lost.

Because weight nadir could occur at any point in the pilot study, we also assessed the relationship between the day in study that the weight nadir occurred and percent weight loss; a positive correlation indicates that greater percent weight loss occurred later in the study. We also assessed whether there was a significant relationship between weight nadir and baseline BMI.

## Statistical Analysis

Because this pilot study focused on feasibility and acceptability, results for primary outcomes are largely descriptive in nature and we evaluated success based on success criteria established *a priori*, described earlier in this paper. Retention rate, engagement, and screener submission were summarized using percentages and 95% confidence interval (CI) for proportions using normal approximation. Participant satisfaction was expressed using means and 95% CI. For the secondary analyses on weight nadir, we report on weight nadir across the sample, as described in the previous section. Additionally we assessed the relationships between (a) weight nadir date and weight loss and (b) baseline BMI and weight loss using Pearson correlations.

## Results

## Participant Characteristics

Table 1 contains basic descriptive statistics of the enrolled study sample. On average, Heart Health study participants were 61 years old (*median* = 62.5; *range* = 40.5-75.9) and had a BMI indicating Class I obesity (*median* = 31.3; *range* = 24.5-49.6). Approximately 61% of the sample was female, and 72% of individuals identified as White, 7% as Black, and 19% reported being a part of another racial group. Assessment of basic health history indicated that over half the sample had a history of treatment for high blood pressure and 19% had a history of type 2 diabetes. Based on reports of a cardiac event or CVD diagnosis history, 90% of the sample was in primary prevention and 10% was in secondary prevention (i.e., history of a cardiac event or CVD diagnosis). ASCVD risk scores for participants in primary prevention who provided complete surveys indicated that 64% of participants in this group were borderline risk or higher for developing cardiovascular disease or having a cardiac event in the next 10 years.

Regarding health behaviors, just over half the sample reported never smoking, while approximately a third of the sample were former smokers and 9% were current smokers. Over 77% of the sample reported being mainly sedentary or engaging in mild, low effort exercise during their leisure time. All enrolled participants reported at least one unhealthy dietary habit, including eating salty food daily, eating fried food three or more times per week, eating meat two or more times per day, not eating fruit daily, or not eating vegetables daily.

Table 1. Baseline characteristics of participants enrolled in the Heart Health study

| | n | Mean or % | SD |
|---|---|---|---|
| **Recruitment source (% recruited from health partner)** | 326/489 | 66.7% | |

| | | | |
|---|---|---|---|
| **Age (years)** | 489 | 60.9 | 10.3 |
| **Sex (% female)** | 298/489 | 60.9% | |
| **Race** | | | |
| White (%) | 354/489 | 72.4% | |
| Black (%) | 33/489 | 6.7% | |
| Other (%) | 95/489 | 19.4% | |
| **Baseline body mass index (kg/m$^2$)** | 489 | 32.6 | 5.9 |
| **History of treatment for high blood pressure (% yes)** | 286/489 | 58.5% | |
| **History of type 2 diabetes (% yes)** | 93/489 | 19.0% | |
| **History of cardiac event or CVD diagnosis (% yes)** | 50/489 | 10.2% | |
| **ASCVD 10-year risk score**[a] | | | |
| Low risk (<5%) | 67/185 | 36.2% | |
| Borderline risk (5-7.4%) | 15/185 | 8.1% | |
| Intermediate risk (7.5-19.9%) | 70/185 | 37.8% | |
| High risk (≥20%) | 33/185 | 17.8% | |
| **Tobacco history**[b] | | | |
| Never smoker (%) | 263/475 | 53.8% | |
| Former smoker (%) | 169/475 | 34.5% | |
| Current smoker (%) | 43/475 | 8.8% | |
| **Physical activity in leisure time** | | | |
| Mainly sedentary (e.g., sitting, reading, TV) (%) | 169/489 | 34.6% | |
| Mild exercise, low effort (e.g., easy walk, yoga) (%) | 213/489 | 43.6% | |
| Moderate exercise (e.g., walking, biking) (%) | 107/489 | 21.9% | |
| **Dietary habits**[c] | | | |
| Salty food (daily) (%) | 308/467 | 66.0% | |
| Fried food (3x/week or more) (%) | 155/451 | 34.4% | |
| Meat (2x/day or more) (%) | 278/460 | 60.4% | |
| Fruit (daily) (% yes) | 239/463 | 51.6% | |
| Vegetables (daily) (% yes) | 324/459 | 70.6% | |

[a]ASCVD 10-year risk scores only calculated for participants in primary prevention with complete surveys (n = 185) and risk categories established by Arnett et al., 2019.

[b]On the tobacco history questionnaire, 14 participants declined to report on tobacco use.

[c]Participants could indicate multiple unhealthy dietary habits. Denominator for dietary habits differs due to a technical issue that affected a subset of participants such that not all dietary habit questions were displayed on the survey.

The majority of participants in this sample were obese. Specifically, 36% (178/489) of participants were overweight, 34% (168/489) of participants were classified as obese I, 14% (70/489) as obese class II, and 13% (65/489) as obese class III. There were also eight participants (2%) who reported a BMI between 24-25 (i.e., normal weight) at baseline; we considered these individuals eligible (i.e., BMI 25+) during pre-screening because they provided a slightly higher weight on the prescreener survey.

## Study Retention

In Month 3, study retention based on providing a weigh in after Day 60 was 80.0% (407/509; 95% *CI* = 76.2, 83.4%). This Month 3 retention rate is comparable to benchmarks from non-AI, digital health programs [36].

## Primary Objective 1: Participant Satisfaction

For Objective 1, we evaluated participant satisfaction with the Heart Health program. Overall, participants were highly satisfied with the overall app experience (Table 2). On average, participants

scored Lark greater than 4 (favorable) for each question asked. Members were also highly satisfied with their experience taking the ASCVD survey in the app (Table 2). On average, participants provided high ratings of their comfort with and understanding of the survey and considered it to be an appropriate length.

Table 2. Participant satisfaction survey results

| **Satisfaction with the overall Lark Heart Health app experience**[a] | | | |
|---|---|---|---|
| On a scale of 1-5: | Mean | SD | 95% CI [LL, UL] |
| How interested are you in modifying your lifestyle choices to reduce your cardiovascular risk? | 4.7 | 0.6 | [4.6, 4.7] |
| How interested are you in using the Lark app to better understand your cardiovascular risk? | 4.2 | 1.1 | [4.1, 4.3] |
| How useful has the information provided in the app missions [lessons] been? | 4.2 | 1.0 | [4.1, 4.3] |
| How easy to understand was the information provided in the missions [lessons] in the Lark app? | 4.7 | 0.6 | [4.6, 4.7] |
| How favorably does using the Lark app compare to how you previously managed your health? | 4.2 | 1.0 | [4.1, 4.3] |
| **Satisfaction with taking the ASCVD survey in the Lark Heart Health app**[b] | | | |
| How comfortable did you feel taking this survey on your own in the app? | 4.8 | 0.6 | [4.7, 4.9] |
| How would you rate your understanding of the questions asked in the survey? | 4.9 | 0.3 | [4.9, 4.9] |
| | | 3 rating (Just Right) | 95% CI [LL, UL] |
| What is your opinion about the length of the survey? | N/A | 92.1% | [89.3, 94.4%] |

[a]n = 432 members completed the app experience satisfaction survey

[b]n = 458 members completed the ASCVD survey satisfaction survey

## Primary Objective 2: App Engagement

For Objective 2, we found that participants were highly engaged with coaching in the Heart Health app (Table 3). In Month 1, 99% of the sample met the success criteria for being highly engaged (i.e., 5+ coaching conversations). In Month 2, 91% were highly engaged, and in Month 3, 83% were highly engaged. When examining the total number of coaching conversations over the course of the program, participants averaged 129.8 coaching conversations across the 90-day study period (95% *CI* = 120.0,139.6; *SD* = 110.1; *median* = 104.0), or 1.4 conversations per day. There was substantial variability in the number of coaching conversations across participants, as indicated by the large standard deviation in total coaching conversations. The median number of coaching conversations was lower for the total number of conversations, indicating the means may be skewed by extremely engaged users. However, the median values still indicate high engagement.

Table 3: Coaching conversations during the Heart Health study by month in the study.

| | % with ≥5 | 95% CI [LL, UL] | % with 2-4 | 95% CI [LL, UL] | % with ≤1 | 95% CI [LL, UL] |
|---|---|---|---|---|---|---|
| **Month 1 coaching** | 98.8% | [97.8, 99.85%] | 1.2% | [0.3, 2.2%] | 0% (0/489) | [0, 0%] |

| | | | | | | |
|---|---|---|---|---|---|---|
| **conversations** | (483/489) | | (6/489) | | | |
| **Month 2 coaching conversations** | 91.0% (445/489) | [88.5, 93.5%] | 5.3% (26/489) | [3.3, 7.3%] | 3.7% (18/489) | [2.0, 5.4%] |
| **Month 3 coaching conversations** | 83.4% (408/489) | [80.1, 86.7%] | 8.0% (39/489) | [5.6, 10.4%] | 8.6% (42/489) | [6.1, 11.1%] |

We also tracked the number of days with meals logged, days with weigh-ins, and total number of educational lessons completed across the 90-day study period, all of which occur within coaching conversations with the Lark coach. On average, participants logged meals on 57.0 days (95% *CI* = 54.3, 59.7; *SD* = 30.1; *median* = 68.0 days), nearly two thirds of the days in the study. Regarding weigh-ins, the Lark coach encourages participants to weigh themselves at least once per week. On average, participants completed a weigh-in on 24.3 days (95% *CI* = 22.6, 26.0; *SD* = 19.1; *median* = 18.0 days), or approximately two times per week over the course of the study. Of these weigh-ins, participants provided the vast majority (88.9%; 435/489) by stepping on their cellular scale with only 11.1% (54/489) self-reported within the app. Participants completed an average of 7.1 educational lessons (95% *CI* = 6.7, 7.5; *SD* = 4.1; *median* = 9.0) during the 90-day study.

## Primary Objective 3: Screener Submission

For Objective 3, we found that participants were highly engaged with screeners in the app. Specifically, 89.8% (440/489; 95% *CI* = 87.0, 92.5%) submitted three screeners (*excellent*), 94.3% (460/489; 95% *CI* = 91.6, 96.0%) submitted two or more screeners (*good*), and 97.5% (479/489; 95% *CI* = 96.3, 99.0%) submitted one or more screeners (*minimum improvement over usual care*). Note that these groups were not mutually exclusive.

## Secondary Objective: Weight Loss

We examined peak weight loss among participants who provided at least two weights (n = 483). Across this sample, the average weight nadir was 3.8% (*SD* = 2.9; *CI* = 3.5,4.1) and occurred on day 51.9 (*SD* = 26.4; 95% *CI* = 49.5, 54.3). There was a significant correlation between day in study that weight nadir occurred and percent weight loss at nadir date ($r$ = .36, $p$ < .001). This indicates a higher percent weight loss for weight nadir dates later in the study. Across all participants, the vast majority lost or maintained weight, with only one member gaining. In Figure 2, we show the proportion of the sample in four different weight loss categories: lost weight ≥5%, lost weight between 2-4.9%, maintained weight ±2%, and gained >2% body weight [37,38]. We also examined weight loss by baseline BMI and found that peak weight loss was not significantly correlated with BMI ($r$ = .004, $p$ = .41).

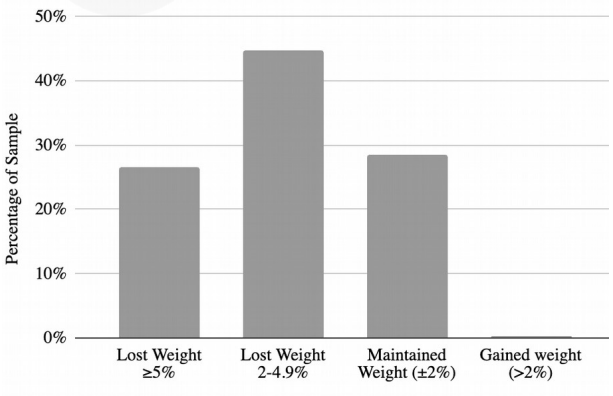

**Figure 2.** Proportion of sample across weight loss categories.

## Discussion

The present study results indicate that the fully digital, AI-powered health coaching app called Lark Heart Health had a high degree of acceptability and feasibility among this pilot study sample. In this 90-day study of the Heart Health program, we found that participants were highly satisfied with their experience using the app, showed a high degree of engagement with health coaching and other app features, and successfully completed screeners on important health indicators during their first month in the program. Secondary analyses further indicated that participants lost weight during the 90-day program. Taken together, findings from this pilot study met or exceeded all success criteria for the primary study objectives and provided key insights into weight loss as a clinical outcome that can be further examined in future clinical studies. Thus, these findings support the acceptability and feasibility of the Heart Health program. We discuss key insights from each of the primary objectives below.

## Insights from Primary Objectives

On Objective 1, the two participant satisfaction surveys indicated that participants were highly satisfied with their experience using the Heart Health program, including their experience taking the ASCVD Risk Estimator survey in the app. Mean scores on all items across the two surveys indicated participants rated their experience favorably across multiple dimensions, such as how easy it was to understand the information in the app and feeling comfortable with taking a survey in the app. The mean score on the overall app experience survey (4.4/5) also closely aligns with “high satisfaction” scores in prior feasibility studies on apps for CVD management [24].

For Objective 2, we found that participants were highly engaged with coaching in the Heart Health app. In Month 1, 99% of the sample met the success criteria for being highly engaged. In Month 2, 91% were highly engaged, and in Month 3, 83% were highly engaged. Engagement with the app far exceeded the expectations set by our success criteria. This insight indicates that engagement thresholds can be set at higher levels in future testing with the Heart Health Program. Although monthly engagement rates were higher than anticipated across all three months, the results showed a decrease in engagement over time. For instance, 8.6% of participants were “minimally engaged” at Month 3, as indicated by ≤1 coaching conversation during the final month in the study. This decrease is expected in digital health, with engagement and retention rates typically dropping over time [39,40]. Identifying this decrease in engagement also provides the opportunity to identify when engagement begins to wane and perhaps use targeted incentives at that time to mitigate drop off. Since we focused on coaching conversations as the primary engagement outcome, it is also possible that some users may have favored different features, such as weight logging and device usage (e.g., cellular scale). The descriptive results on weigh-ins support the assertion that users engaged with this feature.

Results from Objective 2 also highlight the high degree of variability in engagement between participants. As with any program or app, different individuals will have different use patterns or connect with different aspects of the program. Indeed, we have shown in previous research of other Lark programs that there are different user “personas” among individuals who engage with the app, with some users focusing more on data and tracking functionalities or device usage, rather than being highly engaged with coaching specifically [41].

In the context of this pilot study, there were some participants who had disproportionately high engagement levels. In our previous work, we refer to these individuals as “Enthusiasts” [41]. These

are individuals who log on many times per day and engage with many or all facets of the app. It is important to note that super users are not representative of most users of an app and can skew mean scores. For example, the median values for coaching conversations in this study were lower than the averages, though still indicated high engagement. That said, designers of applications can gain significant insights for program improvement from qualitative interviews with both high engagers and low engagers alike [39].

Regarding Objective 3, results showed high participant submission rates for screeners focused on important health indicators, including ASCVD risk, medication adherence, and depressive symptoms. Specifically, 90% of participants achieved the *a priori* benchmark of submitting three or more health screeners. This result indicates that participants were willing and able to complete these screeners using the app. This is a key result for feasibility and acceptability of taking screeners in the Heart Health app, as prior work has highlighted that it is important for patients in heart health prevention to show high levels of approval for risk surveys [32]. Moreover, these findings support the use of the Heart Health app as a user-friendly solution that enables patients to complete important health screeners outside of the primary care setting. This is an important usage, as there are significant barriers to screener completion during patient visits, such as short appointment times, workflow disruption, and lack of patient preparedness [19,20,27]. Moreover, screener completion has been shown to have several benefits to patients; for instance, health screeners can help increase patient awareness of and knowledge of their values on key CVD risk factors (e.g., cholesterol and blood pressure) [20].

The acceptability of screener submission in the app also has important implications for future delivery of the Heart Health program. In a commercial version of the program, participants would complete health screeners, such as the PHQ-2, MAQ, and ASCVD Risk Estimator approximately every 60-90 days. Longitudinal self-monitoring has many benefits for self-management of CVD, such as enabling participants to track changes in their symptoms over time [42] and improve medication adherence [43]. Further integration of the Heart Health app with health partners would also enable participants' health providers to track their patients' changes over time and potentially support clinical decision making [20,44].

## Weight Loss and Study Retention

Beyond the primary acceptability and feasibility study results, secondary analyses also revealed initial insights into weight loss during the program. Specifically, participants showed an average peak weight loss of 3.8% during the study and weight loss percentage was not correlated with baseline BMI. This percent weight loss compares favorably to prior studies examining weight loss in digital health interventions [45]. These results should be considered preliminary, as the pilot study was not developed with the intention of testing weight loss or other clinical outcomes. However, these results support future consideration of weight loss as a clinical outcome for the Heart Health program.

We observed an 80% retention rate in Month 3 of the study. This retention rate is on par with target benchmarks from non-AI, digital health studies that are higher-touch than Heart Health [36]. Additionally, withdrawal rate for the study was low: 20 participants withdrew after enrollment (4% withdrawal rate). Withdrawal rates for digital health apps with frequent survey content range from 15-51% [46]. It is important to note that retention rates reported here should be interpreted as *research study* retention rates; study retention rates are typically higher than retention rates in programs that are commercially released to real-world populations. Indeed, it is well established that retention is one of the biggest challenges with digital health solutions, and there are often high attrition rates with health programs delivered via mobile apps [39,40]. Improving retention rates in

real-world populations is a major focus in the digital health space [47] and will be a focal point in a commercial version of the Heart Health program.

## Limitations and Future Directions

There are several limitations to the present results. First, this was a pilot study examining feasibility and acceptability as a first step in the evidence generation process; the findings presented here are not meant to show clinical efficacy of the Heart Health program and should not be interpreted as such. Future studies could examine the impact of the Heart Health program in a controlled trial. For example, a key next step in evidence generation is to examine clinical outcomes (e.g., weight loss) between program participants and a control group receiving usual care and/or a control group that involves human coaching. As a second limitation, the sample used for this study contained individuals recruited to participate in a research study rather than real-world participants of a commercial version of the product. As such, an important future direction for generating evidence for the Heart Health program will be examining these objectives and other study outcomes in a commercial version of the product with a real-world sample. Additionally, the present study included opportunities for incentives throughout the Heart Health program that are similar to incentives provided in existing Lark programs but may not be identical to incentives provided in the commercial implementation of the Heart Health program. Importantly, only one incentive was directly tied to any type of app engagement: the Fitbit incentive provided for completing the 90 day program. It is common for research studies to provide an incentive for study completion, and it is also common for Lark's existing healthcare partners to provide members with a Fitbit for reaching a major program milestone. As a result, we do not believe that this incentive had any undue impact on participant engagement that would differ significantly from commercial implementation of the program. Differences in incentive structure may have an impact on participant engagement in future program implementation and this will be dependent on healthcare partners.

A third limitation is that the sample in this study came primarily from a single health partner in California, and participants tended to be older, White adults from that region. Future work should examine the impact of the program among diverse samples; indeed, this is a key limitation and future direction in the broader digital health space [12,40]. Lastly, a key next step in improving the program is to gain a deeper understanding of the user experience with the app; this could include qualitative or interview-based studies with individuals who show different engagement patterns (e.g., low engagers, average engagers, and super users) to gather detailed feedback on features that could be improved.

## Conclusions

These acceptability and feasibility results provide a key first step in the process of evidence generation for a new AI-powered digital program for heart health. The present results indicate that participants in this study were satisfied with their experience using the Heart Health app, highly engaged with app features, and willing and able to complete health screening surveys in the app. While digital health solutions are increasingly common, many have not been tested using formalized evidence generation strategies that are traditionally used for new therapeutics, such as pharmaceuticals [13]. As such, results from this pilot study provide one example blueprint for early-stage evidence generation for new digital health offerings in the prevention and management of CVD.

## Acknowledgements

All authors contributed to the conception of the work and made critical revisions to the content of the manuscript. Additional contributions are listed by author. KGL contributed to data collection and

management, led data analysis, and drafted and revised the manuscript. PRK and SAG provided critical review and interpretation of all statistical analyses. JP, LSB, MC, and ECS contributed to study design and outcomes reporting. OLHB was principal investigator of the pilot study, supervised data collection and management, and supported analyses and interpretation of the data. The Heart Health pilot study was supported by funds from Roche Information Solutions and Lark Health. KGL, JP, LSB, SAG, and OLHB received salary from Lark Health. PRK, MC, and ECS received salary from Roche Information Solutions.

## Data Availability

The dataset referenced in this manuscript cannot be made publicly available. The data used for these analyses include sensitive, potentially identifiable information that was obtained through a collaboration between Lark Health and its healthcare partners. Please end any data-related requests to the Lark Health Clinical Advisory Council via email to clinicalquestions@lark.com.

## Conflicts of Interest

KGL, JP, LSB, SAG, and OLHB were employees of Lark Health at the time of manuscript development. PRK, MC, and ECS are employees of Roche Information Solutions.

## Abbreviations

CVD: cardiovascular disease
AI: artificial intelligence
BMI: body mass index
ASCVD: atherosclerotic cardiovascular disease
ACC: American College of Cardiology
AHA: American Heart Association
PHQ-2: Patient Health Questionnaire-2
MAQ: Medication Adherence Questionnaire

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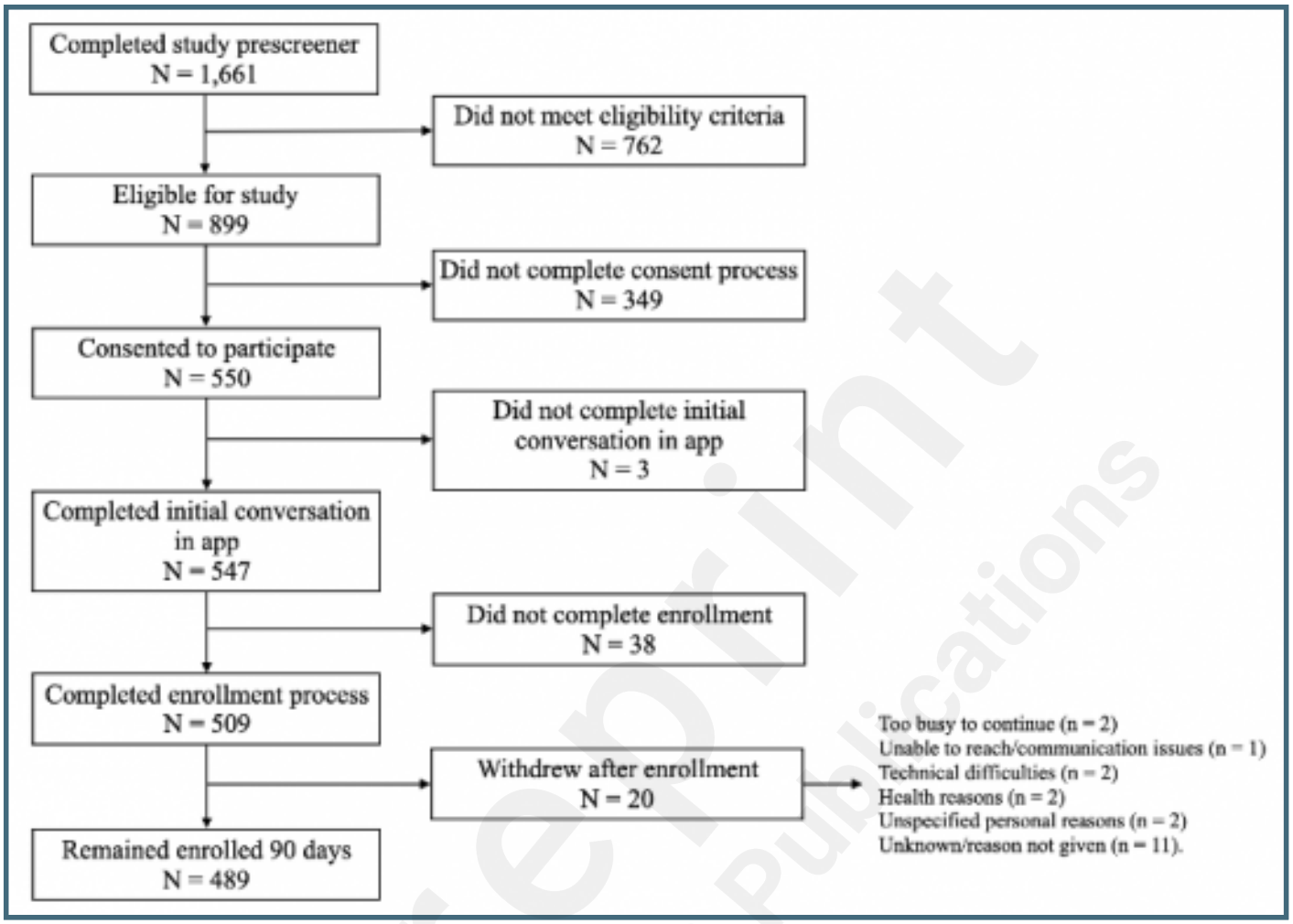
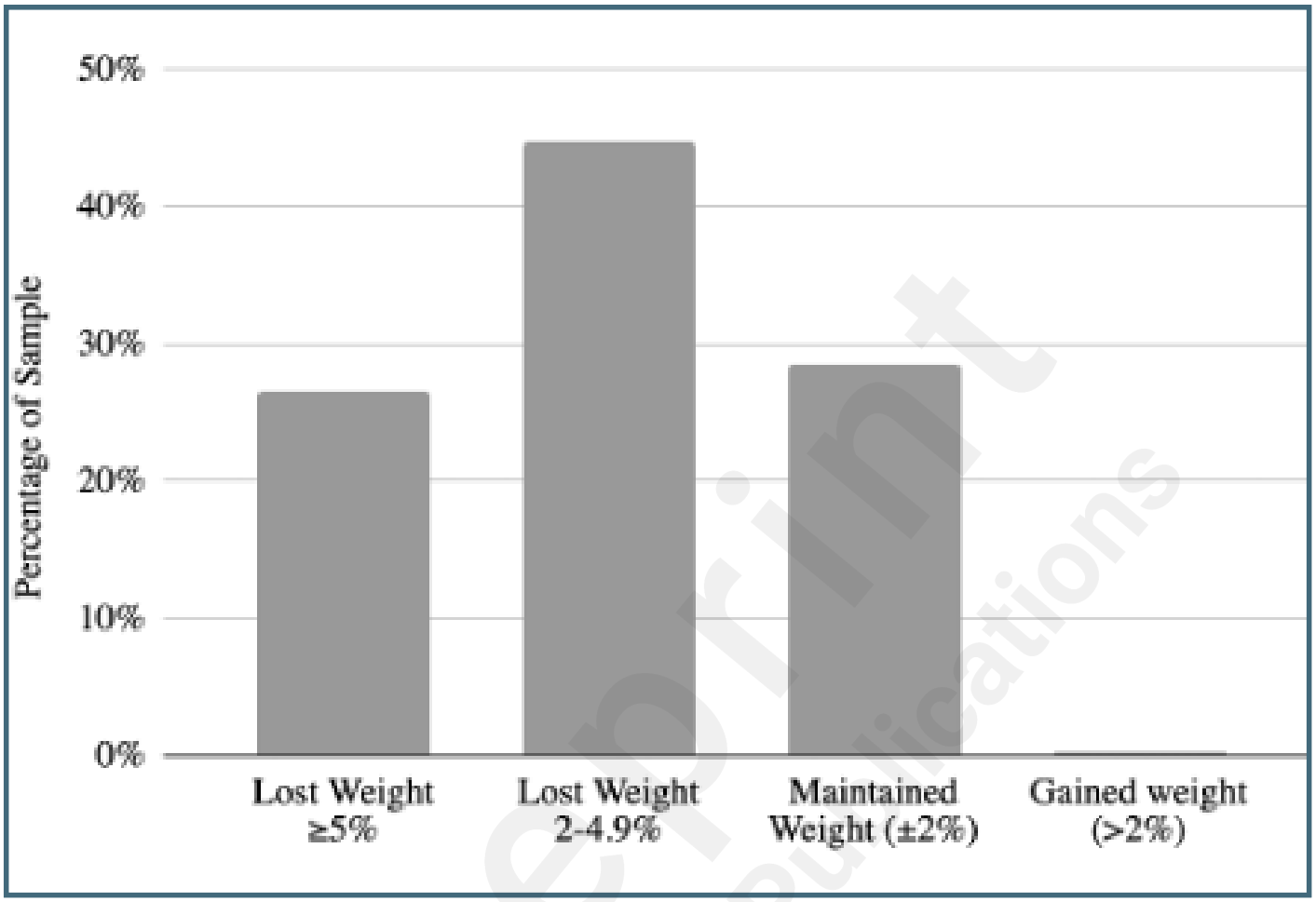
# Supplementary Files

# Figures

Recruitment and enrollment flow for the Heart Health study.



Proportion of sample across weight loss categories.



# Multimedia Appendixes

Supplementary methods information including additional details on the program, study design, and participant characteristics measurement.
URL: http://asset.jmir.pub/assets/db7ec881afa6ab1873e727db048dc55b.docx