**Research Article**

**Cognitive Training and Mobile App Intervention Called “HM+ACT”: A Closed-Loop Assessment and Treatment for Heart Failure**

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**Abstract**

The complex nature and chronicity of heart failure with varying symptoms are challenging for patients to recognize early symptoms, resulting in delayed seeking care and poorer quality of life. In addition, patients with heart failure suffer from cognitive impairment that increases the burden of managing the disease. Therefore, this study examined a previously tested mobile app called the “HeartMapp” (HM) and auditory cognitive training (ACT) into one integrated intervention (HM+ACT) to improve heart failure outcomes. A quasi-experimental clinical trial examined the feasibility of the proposed intervention, HM +ACT. A total of 33 participants consented to participate and completed baseline data, of whom only seven (21%) completed the 12 weeks of HM+ACT training and follow-up data. The most pressing reason was the Covid-19 pandemic as we started our research. We used paired T-test and compared the baseline scores with the post-intervention scores of those who completed the prescribed training and showed significant improvement in cognitive function (p<0.05 for all) with a small to medium effect size. Self-confidence, physical health, and depression showed statistically significant improvement (p<0.05 for all) with medium effect sizes. However, quality of life and self-care management showed no significant improvement. We did not collect follow-up data on those who dropped out and did not complete ACT. Future studies must include all participants irrespective of full completion of the HM+ACT, and a well-designed larger clinical trial is warranted.

**Keywords:** Cognitive function; Cognitive training; Heart Failure; Heart Mapp; Functional outcomes

**Abbreviations**

CHF : Congestive Heart failure

COPD : Chronic Obstructive Pulmonary Disease

FSSQ : Family Support Scale Questionnaire

HF : Heart Failure

HM+ACT : HeartMapp Plus Auditory Cognitive Training

HIPAA : Health Insurance Portability and Accountability Act

IRB : Institutional Review Board

KCCQ : Kansas City Cardiomyopathy Questionnaire

MoCA : Montreal Cognitive Assessment

NINR : National Institute of Nursing Research

NYHA : New York Heart Association Classification

TAPAT : Tonic and Phasic Alertness Training

PHQ-9 : Patient Health Questionnaire-9

PROMIS : Patient-reported Outcome Measurement Information System

REDCap : Research Electronic Data Capture

SAS : Statistical Analysis System

UFOV : Useful Field of View

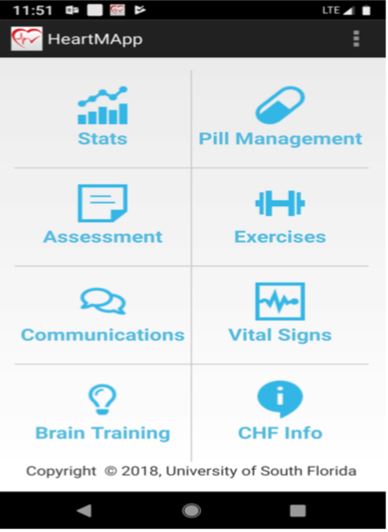
**Introduction**

Heart Failure (HF) is a debilitating, complex clinical syndrome with significant disease burden and suffering that coexists with multiple comorbidities [1]. HF prevalence is anticipated to grow by 46%, affecting approximately 8 million Americans by 2030. Patients with HF are encouraged to follow self-care management at home, including complex medications, diet, and exercise, and modify behaviors related to HF symptoms by checking daily weight and symptoms [1]. The complex nature and chronicity of the disease with varying symptoms and lack of knowledge are challenging for patients to recognize early HF symptoms, resulting in delayed seeking care and poorer quality of life [2]. About 40% to 60% of patients living with HF suffer from cognitive impairment due to reduced cerebral blood flow, inflammation, and neurohormonal activation [3]. The aging population and cognitive impairment add to the physiological and psychological burden of managing the disease [3,4]. Therefore, this current study aimed to examine a previously tested mobile app called the “HeartMapp” (HM) and Auditory Cognitive Training (ACT) into one integrated intervention (HM+ACT) to improve heart failure outcomes.

The Pew-Internet survey reported an increase in smartphone ownership of 61% among 65 years and older compared to 34% in 2010 [5]. Smartphone-based interventions are increasingly used to facilitate positive behavior change and manage chronic diseases at home [6]. With the current shortcomings in remote HF-specific digital health, our team developed and tested a novel patient-centered mobile intervention app (HeartMapp) to fill the unmet self-care needs of patients with HF [7]. In a pilot study, quality of life measured by the Kansas City Cardiomyopathy questionnaire improved by 3 points in the group assigned to HeartMapp; in comparison, the control group declined by 9.0 points, and the incidence of hospital readmissions decreased by 20% [8,9]. Similarly, a prior pilot study of Auditory Cognitive Training (ACT) in patients with HF showed a medium effect size in improving auditory processing speed (d = 0.78), speech processing (d = 0.88), and working memory (d = 0.44-0.50), as well as a small effect size functional outcomes of HF self-care (d=0.34) and 6-minute walk test (d=0.37) relative to the control group [10]. Secondary analysis of the large ACTIVE data set, including patients with HF (n=54), found that the patients randomized to ACT performed significantly better on the speed of processing composite score (p <0.001) compared to (n=31) in the control group [11]. Therefore, this two-phase pilot study aimed to integrate ACT within the HeartMapp (HM) as one integrated intervention (HM+ACT) to examine the combined application's feasibility as a point of care testing.

**Materials and Methods**

**Phase-One:** HeartMapp has 7 features with multiple HF self-care components. During the study's first phase, ACT was integrated into HeartMapp (Figure 1).



**Figure 1:** HeartMapp with Cognitive Training.

**HeartMapp and Auditory Cognitive Training (HM+ACT) Intervention**

1) **Medication Tracker:** Medication Tracker allows patients to add and edit their medications and activate reminders to take medications (e.g., SMS or push notification). This feature can also assist home health nurses in updating their patients’ medication lists collaboratively.

2) **Symptoms Tracker/Assessment:** The participants receive daily tailored prompts and are provided access to the assessment window to check weight and blood pressure and answer the short questionnaires on HF symptoms, brief cognitive assessment, and mood status. Based on data received, HeartMapp then classifies users via the HF severity index based on the New York Heart Association functional classification [12] and provides automated cues for action, a method shown to identify mild deterioration in symptoms for early medical care and assess functional improvements upon intervention [13]. Including a) Green Zone, if HF symptoms are reported as stable or no change in weight; b) Yellow Zone, if HF symptoms are reported as mild and a weight gain of three pounds in one day or 5 pounds in a week; c) Orange Zone, if symptoms are moderate and a weight gain of more than 5 pounds; or d) the Red Zone, if HF symptoms require immediate attention. HeartMapp includes a memory screener using a simple naming task to measure cognition (Boston Naming Test) with 9 items [14]. Given the higher prevalence rate of approximately 40% depression in HF [15], the symptom tracker also included Immediate Mood Scaler (IMS) that captures the *current* mood state was included under daily assessment [16].

3) **CHF Info (HF-related education):** HeartMapp includes audio-enabled HF education and reference materials with push notifications-based educational tips daily (i.e HF symptom management, low salt dietary tips, information regarding heart and brain connection, and many more). A readability analysis of the education modules showed that the education materials are at fifth-grade to eighth-grade level, as recommended by the American Medical Association [17].

4) **Exercises:** This feature includes a) deep breathing exercises for stress reduction and b) walking to enhance physical activity. The app tracks the distance walked in six minutes (6-minute Walk Test) using the accelerometer of the mobile device when they carry the device while walking*.* If they cannot walk and are wheelchair-bound, they don’t have to walk, but they can use other components of HeartMapp. Patients are encouraged to breathe as tolerated and may breathe more times initially, but the goal is to achieve 6 breaths per minute.

5) **Vital Signs:** Data on weight, heart rate, and blood pressure entered in HeartMapp by the participants are tracked, and performance is shown as graphs under the stats menu. HeartMapp has the capability of syncing data from wearables such as Moto 360 and Fitbit, but for this study, we did not use any wearables.

6) **Communication Feature:** HeartMapp also includes a communication feature to offer social support to the participants. The communication feature allows patients to create a self-identified support circle enabling access to performance statistics of the patients and facilitating communication and support between self-identified circle members via text messages (e.g., study staff, family members, home health nurses, and health care providers). The self-identified circle member will act as a coach or companion and download HeartMapp as a coach.

7) **Performance Feedback (Stats):** This feature displays patient performance trends in weight, blood pressure, HF symptoms assessments (Zones status indicating symptom severity), medication compliance, exercise history, and vital sign statistics (i.e. weight, heart rate, and blood pressure) over time to facilitate informed communication with healthcare teams during office visits and with home health nurses for triage and decision making.

8) **Brain training, the Auditory Cognitive Training (ACT):** Neuroplasticity-based BrainHQ Cognitive Training from Posit Science Corporation, a new feature added to HeartMapp within the exercise tab, was tested in this application. The ACT includes Useful Field Of View (UFOV) and Tonic And Phasic Alertness Training (TAPAT) exercises in a 30-session training schedule delivered over 12 weeks (30 minutes per day, approximately 3 days a week, for 12 weeks). The algorithm included in the ACT program generates a continuously updated user profile derived by recording changes in the performance of each user in every exercise session, referenced to an a priori sequence of exercises identified to be the ideal sequence in which a typical user (the average of thousands of normal users) should complete this deficit-targeted exercise suite.

**Research Design and Sample**

A standard single-arm, open-label quasi-experimental clinical trial examined the feasibility of the proposed intervention, HM +ACT. A total of 33 participants, 40 years and older with a diagnosis of HF, consented to participate and completed baseline data. Data at baseline before intervention initiation was compared with data post-intervention at 3 months.

**Measures and Outcomes**

**Primary Outcome:** The primary outcome was the feasibility of using HM+ACT, which was quantified by measuring app usage and engagement. Engagement with intervention training was calculated as the percentage of participants who completed 30 sessions of assigned ACT included in HeartMapp and completed post-intervention at 3 months. App feasibility and engagement were assessed by App access by participants; accessing App components at least 80% of the days (24 days out of 30 days) and completing the 30 hours of ACT to determine app engagement.

**Secondary Outcomes:** The secondary outcomes are improvement in cognitive function. We proposed to see moderate effect sizes (Cohen’s d >0.25) or more significant for considering HM+ACT as potentially efficacious. Cognitive outcomes were measured using the subset of the Executive Abilities: Measures and Instruments for Neurobehavioral Evaluation and Research (EXAMINER) (http://memory.ucsf.edu/examiner), [18] including the Anti-Saccades, Flanker, Set-Shifting, which affect UFOV and TAPAT training and Neuro QoL cognition with 13 items questions to measure cognition (Cronbach α 0.85 to 0.97) [19].

**Exploratory Outcomes:** Exploratory outcomes include improved self-care measured using the Self-care of Heart Failure Index (Self-care management, self-care maintenance, and self-care confidence) with 15 items for a total score of 100 (Cronbach’s alpha .56 to .82). Test-retest reliability 0.90 [20]. Quality of life was measured by the Kansas City Cardiomyopathy Questionnaire, which measures clinically relevant seven domains, including symptom frequency; symptom burden; symptom stability; physical limitations; social limitations; quality of life; and self-efficacy (Cronbach’s alpha.66 to .95) [21]. depression by Patient Health Questionnaire-9 (PHQ-9) with Cronbach alphas of .86 and .89, [22] and global Physical and Mental Health measured by Patient-reported Outcome Measurement Information System (PROMIS) Global Health Short-Form (r=.81-.86, respectively) [23].

**Demographic and Clinical Data:** Demographic and clinical data were collected from patients during an in-person or online interview and confirmed by chart audit.

**Other Covariates Measured:** Baseline cognitive impairment and family support could influence outcomes and use of the intervention. Therefore, cognitive function at baseline was measured using the Montreal Cognitive Assessment (MoCA) [24] and family support using the Family Support Scale (FSSQ) [25].

**Recruitment and Enrollment Procedure**

A diverse group of men and women aged 40 years or over from all races and ethnic groups from one Tampa Bay area HF clinic was invited to participate in this study. The study was funded by the NINR (R43NR018415-01). Institutional Review Board (IRB) approvals were obtained from the University IRB and the IRB of Posit Science Inc. After enrolling two participants; Covid-19 halted our recruitment. Thus, we pivoted from in-person data collection and intervention training to online data collection and training.

All participants completed a prescreening questionnaire after verbal consent, completed the MoCA [24], the FSSQ [25], and answered questions to ascertain their eligibility and indicate their interest in participating in the research study.All eligible participants completed the consent document that included HIPAA authorization. The data were collected and verified once a patient consented and was deemed eligible to enroll in the trial. Patients who were not eligible were referred to the primary care provider. The researchers used the common data elements to advance the science of self-management of chronic diseases [26] and a Research Electronic Data Capture (REDCap) [27] software application and workflow methodology to collect and manage data in the pilot trial.

**Intervention Training Of Participants**

Once consented and enrolled, the study staff downloaded the HM+ACT app on their mobile device or a loaner device and trained the participant. Study staff helped the participants install and configure the settings before intervention use. The study staff used teach-back methods to ensure a proper understanding of using the apps and called the participants three times during the first week to ensure a smooth transition to the mobile-delivered intervention activities. The study staff called the participants whose performance statistics demonstrated declining HF symptoms. A training manual with a link to YouTube was mailed to all participants.

**Data Collection and Follow-Up**

All data were collected online using REDCap. The study staff helped participants complete the questionnaires in REDCap on baseline outcome measures and cognitive assessments. The demographics and clinical data were confirmed by chart audit. Follow-up assessments used the same questionnaire except for demographic and clinical data at 3 months. Participants received a follow-up reminder via email a month before the schedule and a phone call 24 hours before the follow-ups. Once the participants completed the assessment visit at baseline and 3 months, they received compensation as allowed.

**Data Analysis**

The statistical software SAS 9.4 (SAS Institute) was used for the statistical data analyses in this project [28]. Univariate descriptive statistics were conducted on the subjective and objective outcomes and baseline covariates (age, sex, clinical variables, comorbidity data, MoCA score, and family support) to describe the sample characteristics of the participants. All participants had normal baseline cognitive function and family support. Outcome measures were compared using paired T-tests to understand whether the groups' post-test mean scores adjusted for pre-test scores differed from baseline. To examine the potential efficacy of HM+ACT on cognitive and functional outcomes, effect sizes were calculated utilizing Cohen’s d [29].

**Results**

A total of 33 participants completed the baseline data. As shown in (Table 1), two-thirds of the participants were male, the mean age was 62 years, ranging from 42-87 years, and 48.5% were Caucasians. About 58% were married, and others were single, divorced, or widowed. Over 90% had high school (24.4%), some college or graduates (66.6%), and two-thirds were unemployed. More than 75% of the participants were in HF stage “C,” 60% had an ejection fraction over 40% with a mean ejection fraction of 32%. Commonly reported comorbid conditions: Coronary Artery Disease, Hypertension, Hyperlipidemia, Diabetic Type 2, and COPD. The baseline MoCA score showed normal cognitive function at baseline (Mean 26.64 ± 2.10) (Table 1).

|  |  |  |  |
| --- | --- | --- | --- |
| N =33 (%) | | | Mean & SD |
| Age in years 42-87 years | |  | 62.39 ± 10.56 |
| Gender | Male | 22 (66.6) |  |
|  | Female | 11 (33.4) |  |
| Marital Status | Married | 19 (57.6) |  |
|  | Single or Never Married | 7 (21.3) |  |
|  | Divorced | 3 (9.0) |  |
|  | Widowed | 4 (12.1) |  |
| Race | White or Caucasian | 16 (48.5) |  |
|  | Blacks | 12 (36.4) |  |
|  | Hispanics | 5 (15.1) |  |
| Education | Less than High School | 3 (9.0 |  |
|  | High school or GDE | 8 (24.4) |  |
|  | Some College/associate degree | 11 (33.3) |  |
|  | Bachelor’s or higher degree | 11 (33.3) |  |
| Employment | Currently Employed | 11 (33.3) |  |
|  | Not Employed | 22 (66.7) |  |
| Cardiac Defibrillator | Yes | 15 (45.5) |  |
|  | No | 18 (54.5) |  |
| Ejection Fraction | Less than 40% | 13 (39.4) | 32.2 ± 18.3 |
|  | 40% and over | 20 (60.6) |  |
| NYHA Class | II | 17 (51.5) |  |
|  | III | 16 (48.5) |  |
| Heart Failure Stage | B | 5 (15.1) |  |
|  | C | 25 (75.8) |  |
|  | D | 1 (3.0) |  |
|  | Not known | 2 (6.1) |  |
| Comorbid Conditions | Hypertension | 19 (57.6) |  |
|  | Coronary Artery Disease | 12 (36.4) |  |
|  | Hyperlipidemia | 16 (48.5) |  |
|  | Diabetic Type 2 | 8 (24.2) |  |
|  | Diabetic Type 1 | 1 (3.0) |  |
|  | COPD | 8 (24.2) |  |
| Montreal Cognitive Assessment Score | | | 26.64 ± 2.10 |
| Family Support Scale Questionnaire | | | 34.57 ± 8.28 |

**Table 1:** Baseline Demographic Data.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Measures | Baseline (n=7) Mean, SD | 3 Month (n=7) Mean, SD | T | Sig. P value | Effect Size Cohen’s D |
| **Cognitive Outcomes** |  |  |  |  |  |
| ANTI-Saccade | 34.43 ± 7.25 | 35.95 ± 6.50 | -2.8 | 0.01 | 0.25 |
| Flanker | 8.30 ± 0.77 | 8.83 ± 0.58 | -3.22 | 0.004 | 0.44 |
| Set-Shift | 7.02 ± 2.88 | 8.69 ± 0.56 | -2.81 | 0.011 | 0.27 |
| Executive QoL Score | 0.46 ± 0.49 | 0.65 ± 0.34 | -2.71 | 0.012 | 0.31 |
| **Functional Outcomes** |  |  |  |  |  |
| Self-care Maintenance | 30.33 ± 4.45 | 31.00 ± 3.19 | 1.78 | 0.09 | 0.17 |
| Self-care Management | 20.92 ± 2.94 | 21.92 ± 1.50 | 1.19 | 0.256 | 0.29 |
| Self-Confidence | 20.57 ± 3.04 | 22.43 ± 2.50 | -2.51 | 0.021 | 0.33 |
| Quality of Life (KCCQ) | 25.57 ± 5.17 | 26.33 ± 3.54 | -2.37 | 0.18 | 0.22 |
| PROMISE Physical Health | 45.41 ± 8.57 | 50.34 ± 6.14 | -3.34 | 0.003 | 0.67 |
| PROMISE Mental Health | 14.95 ± 2.2 | 15.81 +2.5 | -2.91 | 0.09 | 0.14 |
| Depression (PHQ-9) | 1.00 3.8 | 3.63 ± 1.9 | 3.34 | 0.03 | 0.21 |

**Table 2:** Paired-Test Comparison of Pre- and Post-Intervention Outcomes.

**Pair T-Test to Compare Pre- and Post-Intervention Outcomes**

We had a small sample of seven participants who completed the intervention and post-intervention assessment at 3 months. We used paired T-test and compared the baseline scores with the post-intervention scores of the seven participants for a head-to-head comparison. As indicated in (Table 2), there was a significant improvement in cognitive function with a small to medium effect size. Self-confidence and physical health showed statistically significant improvement with medium effect sizes. See Table 2 below. Given the small sample size, no other analyses were performed on the data.

**Feasibility of HM+ACT**

Although we recruited 33 participants, only seven (21%) completed the 12 weeks of HM+ACT training and follow-up data. The most pressing reason was the Covid-19 pandemic as we started our research. We did not collect follow-up data on those who dropped out and did not complete ACT. Future studies must include all participants irrespective of full completion of the HM+ACT.

**Discussion**

The results from this pilot study demonstrate that the intervention with HM+ACT is likely to improve cognitive performance. Conventionally medium to large effect sizes (d> .0.5) are considered meaningful with practical implications. Research in psychology supports using effect sizes independent from sample sizes to express the size of an effect regardless of the sample size [30]. Thus, a small to medium effect size identified in this study demonstrated a meaningful impact of the intervention with potentially meaningful improvement using HM+ACT.

Prior cognitive training studies have shown similar results when examining older adults with some degree of initial cognitive impairment [10,11,31-33]. On the contrary, participants in our study who completed the training all had normal scores on the MoCA, indicating normal cognitive function at baseline. A study with a larger sample size is warranted to really demonstrate the practical implication of the combined intervention of HM+ACT.

Prior cognitive training studies have supported functional improvement among older adults [34,35], and patients with HF [11,36], which has been supported in our prior pilot study [10]. Although the current results showed improvement in physical function with a moderate effect size, the results showed negligible effect sizes with no significant improvements in HF-related self-care and quality of life. The participants in this study (75%) were in HF stage C with possible functional limitations; we also hypothesize that the influence of the pandemic may have limited their physical activities.

The large Jackson Heart Study of 2,651 individuals reported high depressive symptoms among 20.3% of the participants with a 43% greater risk of HF (*P*=0.035) [37]. This was supported in a systematic review with meta-analysis with the global pooled prevalence of depression based on clinical diagnosis (N=2,62,815) of HF patients was 42.0% (95% CI: 36.9, 47.1; I2 = 98.9%) [38].

Although the effect size was small, among a small number of participants, our results showed significant improvement in depression measured using PHQ-9. This result is encouraging that the intervention with HM+ACT potentially improves multiple outcomes, including depressive symptoms warranting future well-designed research to test the efficacy of HM+ACT.

Our prior pilot studies demonstrated 80% or more compliance with the intervention with a similar completion rate when delivered alone as cognitive training [10] and the HeartMapp [9]. The current study showed an intervention and study completion rate of 21%. The exit survey of our study demonstrated that these patients with HF were very fearful and did not want to learn something new despite their interest. A meta-analysis indicates that at least 10 hours of cognitive training are needed to receive benefits [39]. However, in the current study, we did not collect data at the exit to examine if fewer training hours could influence outcomes. This warrants future study to mitigate this limitation we had in this study.

**Limitations**

One of the most contentious limitations of the study is that the study had no comparison group. This study was initially proposed and approved as a pilot randomized clinical trial with intervention training and data collection in person; we had to pivot due to the pandemic to an online study. This had a major impact on our completion rate. The other significant limitation of this study was the small sample size recruited from one facility. This pilot study included many cognitive and functional outcome measures, and the sample size was not adequately powered.

The study aimed to examine the feasibility and explore the potential efficacy of the combined HM+ACT, which was novel to inform future research. The trends demonstrated in this pilot feasibility study warrant further exploration of using HM+ACT to improve cognitive and functional outcomes in patients with HF.

**Conclusion**

Cognitive impairment negatively affects the patient’s ability to carry out self-care, potentially resulting in higher hospital readmission rates. Improvement in cognition can potentially enhance HF outcomes, including self-care, quality of life, and hospital readmission rates. Further exploration in a larger, well-designed clinical trial is warranted to test the feasibility of utilizing HeartMapp over time to improve short-term and long-term HF outcomes.

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**Conflict of Interest**

The authors declare no conflict of interest.

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