CONSORT-EHEALTH Checklist V1.6.2 Report
(based on CONSORT-EHEALTH V1.6), available at [http://tinyurl.com/consort-ehealth-v1-6].

Date completed 4/28/2021 15:30:56 by Michael Dorsch

The Effects of the ManageHF4Life Mobile Application on Patients With Chronic Heart Failure: Randomized Controlled Trial

TITLE
1a-ii) Problem and the type of system/solution

"The Effects of the ManageHF4Life Mobile Application on Patients With Chronic Heart Failure: Randomized Controlled Trial"

1a-iii) Primary condition or target group in the title

"The Effects of the ManageHF4Life Mobile Application on Patients With Chronic Heart Failure: Randomized Controlled Trial"

ABSTRACT
1b-iv) RESULTS section in abstract must contain use data with Heart Failure Questionnaire (MLHFQ) from baseline to 6 and 12 weeks. Secondary outcomes were the Self-Care Heart Failure Index (SCHFI) monitoring and promoted self-management. The control group (No App) received usual care. The primary outcome was the change in Minnesota Living weeks of discharge, at day 2, 4, and 28, respectively."

Methods: A single center randomized controlled trial was performed. Participants greater than 45 years of age and admitted for acute decompensated HF or recently discharged in the past 4 weeks were included. The intervention group used a mobile application (App). The intervention prompted daily self-monitoring and promoted self-management. The control group (No App) received usual care. The primary outcome was the change in Minnesota Living weeks of discharge, at day 2, 4, and 28, respectively."

Participants were included if they were greater than 45 years of age, had a left ventricular ejection fraction (LVEF) </= 40% or a LVEF >40% (with LA size >40 mm or BNP > 200 pg/ml or NT-proBNP > 800 pg/ml) and were currently admitted or recently discharged for acute on chronic decompensated HF. Participants were excluded for any of the following: unstable coronary syndromes within 8 weeks, primary valvular heart disease, constrictive pericardial disease, uncorrected thyroid disease, dialysis or creatinine >4.0 mg/dL, a hospice candidate, active cancer, pulmonary fibrosis, discharged to a setting other than home, or required a chronic inotrope. Participants were not blinded due to the nature of the intervention. In May 2018, inclusion criteria were expanded to include HF with preserved ejection fraction in addition to HF with reduced ejection fraction and those recently discharged to increase recruitment. Eighty participants were enrolled during the index hospitalization. The remaining three of the eighty-three participants were enrolled within four weeks of discharge, at day 2, 4, and 28, respectively."
4a-iii) Information giving during recruitment

4b) CONSORT: Settings and locations where the data were collected

"The primary outcome was the change in Minnesota Living with HF Questionnaire (MLHFQ) from baseline to 6 and 12 weeks. [11] This tool consists of 21 questions regarding patients' perception of the effects of HF on their daily lives. Secondary outcomes were the change in self-management and HF readmission over time. Self-management was measured using the Self-Care Heart Failure Index (SCHFI) version 6.2, which was the most current version available at trial initiation. The SCHFI 6.2 contains 3 subscales that determine the patient's physiologic stability, response to symptoms and ability to perform self-management. The questions in each subscale are standardized to a score of 0 to 100. Each subscale is added together to give the total SCHFI score. The SCHFI was collected at baseline, 6 and 12 weeks. Both the MLHFQ and SCHFI were complete by participants using an automated online survey."* 

4b-i) Report if outcomes were (self-)assessed through online questionnaires

"The primary outcomes in the Minnesota Living with HF Questionnaire (MLHFQ) from baseline to 6 and 12 weeks. [11] This tool consists of 21 questions regarding patients' perception of the effects of HF on their daily lives. Secondary outcomes were the change in self-management and HF readmission over time. Self-management was measured using the Self-Care Heart Failure Index (SCHFI) version 6.2, which was the most current version available at trial initiation. [12] The SCHFI 6.2 contains 3 subscales that determine the patient's physiologic stability, response to symptoms and ability to perform self-management. The questions in each subscale are standardized to a score of 0 to 100. Each subscale is added together to give the total SCHFI score. The SCHFI was collected at baseline, 6 and 12 weeks. Both the MLHFQ and SCHFI were complete by participants using an automated online survey."*  

4b-ii) Report how institutional affiliations are displayed

5) CONSORT: Describe the interventions for each group with sufficient details to allow replication, including how and when they were actually administered

5-i) Mention names, credential, affiliations of the developers, sponsors, and owners

5-ii) Describe the history/development process

5-iii) Revisions and updating

5-iv) Quality assurance methods

5-v) Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used

5-vi) Digital preservation

5-vii) Access

Participants were provided access with a user generated username and password.

5-viii) Mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework

"The App group used a mobile application, ManageHF4Life version 1, along with a Fitbit physical activity monitor (Fitbit Charge 2) and scale (Fitbit Aria and Aria 2). The mobile application was developed by using user centered-design. Accurate self-monitoring, feedback and self-efficacy are essential components of the self-regulation cycle and are critical for managing HF. The application prompted active daily self-monitoring, provided a health status indicator to promote self-management, and included standard education on HF. The daily prompt for active self-monitoring was done with a 9:00 a.m. push notification to complete an 8-question survey within the application. If they did not complete the survey by 12:00 p.m., a reminder push notification was sent to the user. The health status indicator was a stop light (green, yellow, and red) and was generated from a rule-based model calculated from an equation based on the eight survey questions and the difference between the daily weight and dry weight that was recorded in the application. The stop light colors represented the participant's health status. The green color represented stable status. Yellow and red represented a clinical worsening state. The text below the health status indicator changed based on the color with recommendations on self-management. An example health status indicator screen is shown in figure 1 and the full mobile application layout is presented in the supplement. All intervention participants were provided a 30-minute educational session on how to use the application. The control group received usual care upon discharge from the hospital. At Michigan Medicine, usual care is a two week follow up appointment with an advanced practice provider and periodic phone calls from a telehealth HF nurse."*  

5a) Describe use parameters

5-x) Clarify the level of human involvement

5-xi) Describe any prompts/reminders used

"The App group used a mobile application, ManageHF4Life version 1, along with a Fitbit physical activity monitor (Fitbit Charge 2) and scale (Fitbit Aria and Aria 2). The mobile application was created from the theory of self-regulation and developed using user centered design. Accurate self-monitoring, feedback and self-efficacy are essential components of the self-regulation cycle and are critical for managing HF. The application prompted active daily self-monitoring, provided a health status indicator to promote self-management, and included standard education on HF. The daily prompt for active self-monitoring was done with a 9:00 a.m. push notification to complete an 8-question survey within the application. If they did not complete the survey by 12:00 p.m., a reminder push notification was sent to the user. The health status indicator was a stop light (green, yellow, and red) and was generated from a rule-based model created by the investigators. The rule-based model was calculated from an equation based on the eight survey questions and the difference between the daily weight and dry weight that was recorded in the application. The stop light colors represented the participant's health status. The green color represented stable status. Yellow and red represented a clinical worsening state. The text below the health status indicator changed based on the color with recommendations on self-management. An example health status indicator screen is shown in figure 1 and the full mobile application layout is presented in the supplement. All intervention participants were provided a 30-minute educational session on how to use the application. The control group received usual care upon discharge from the hospital. At Michigan Medicine, usual care is a two week follow up appointment with an advanced practice provider and periodic phone calls from a telehealth HF nurse."*  

5-ii) Describe any co-interventions (incl. training/support)

"The App group used a mobile application, ManageHF4Life version 1, along with a Fitbit physical activity monitor (Fitbit Charge 2) and scale (Fitbit Aria and Aria 2). The mobile application was created from the theory of self-regulation and developed using user centered design. Accurate self-monitoring, feedback and self-efficacy are essential components of the self-regulation cycle and are critical for managing HF. The application prompted active daily self-monitoring, provided a health status indicator to promote self-management, and included standard education on HF. The daily prompt for active self-monitoring was done with a 9:00 a.m. push notification to complete an 8-question survey within the application. If they did not complete the survey by 12:00 p.m., a reminder push notification was sent to the user. The health status indicator was a stoplight (green, yellow, and red) and was generated from a rule-based model created by the investigators. The rule-based model was calculated from an equation based on the eight survey questions and the difference between the daily weight and dry weight that was recorded in the application. The stop light colors represented the participants' health status. The green color represented stable status. Yellow and red represented a clinical worsening state. The text below the health status indicator changed based on the color with recommendations on self-management. An example health status indicator screen is shown in figure 1 and the full mobile application layout is presented in the supplement. All intervention participants were provided a 30-minute educational session on how to use the application. The control group received usual care upon discharge from the hospital. At Michigan Medicine, usual care is a two week follow up appointment with an advanced practice provider and periodic phone calls from a telehealth HF nurse."* 

6) CONSORT: Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed

"The primary outcome was the change in Minnesota Living with HF Questionnaire (MLHFQ) from baseline to 6 and 12 weeks. [11] This tool consists of 21 questions regarding patients' perception of the effects of HF on their daily lives. Secondary outcomes were the change in self-management and HF readmission over time. Self-management was measured using the Self-Care Heart Failure Index (SCHFI) version 6.2, which was the most current version available at trial initiation. The SCHFI 6.2 contains 22 questions and has 3 subscales that determine the patient's physiologic stability, response to symptoms and ability to perform self-management. The questions in each subscale are standardized to a score of 0 to 100. Each subscale is added together to give the total SCHFI score. The SCHFI was collected at baseline, 6 and 12 weeks. Both the MLHFQ and SCHFI were complete by participants using an automated online survey. All admissions were reviewed in a blinded fashion for the potential to be a HF readmission. An unscheduled hospitalization was defined as a HF readmission if the primary diagnosis was HF and the length of stay either exceeded 24 hours or crosses a calendar day. [12] Outcome ascertainment was done blinded to randomization group. The study team contacted participants at 6 and 12 weeks to confirm the study outcomes and prompted participants to complete any survey tasks. At the completion of the clinical trial, each participant in the App group received an online survey about the mobile application. The survey focused on the perceived usefulness and ease of use for the mobile application."* 

6a) Describe whether and how "use" (including intensity of use/dosage) was defined/measured/monitored

6a-ii) Describe whether, how, and when qualitative feedback from participants was obtained

6b) CONSORT: Any changes to trial outcomes after the trial commenced, with reasons

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7a) CONSORT: When applicable, explanation of any interim analyses and stopping guidelines

7b) CONSORT: When applicable, explanation of any interim analyses and stopping guidelines

8a) CONSORT: Method used to generate the random allocation sequence

8b) CONSORT: Type of randomisation; details of any restriction (such as blocking and block size)

9) CONSORT: Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned

10) CONSORT: Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions

11a) CONSORT: For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome

11b) CONSORT: If relevant, description of the similarity of interventions

12a) CONSORT: Statistical methods used to compare groups for primary and secondary outcomes

12b) CONSORT: Methods for additional analyses, such as subgroup analyses and adjusted analyses

Subgroup analyses and adjusted analyses were not performed in the data analysis for this trial.

RESULTS

13a) CONSORT:  For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome

Eighty-three participants were enrolled and completed all baseline assessments. Baseline characteristics were similar between groups except for the prevalence of ischemic HF. Participants were 60.2 years of age in the App group and 62 years of age in the No App group (P=0.379). The average ejection fraction (EF) was 37.2% in the App group and 38.2% in the No App group (P=0.725). Most of the participants were Caucasian (81% App vs. 83% No App, P=0.559) and NYHA class III (55% App vs. 66% No App, P=0.409) at study enrollment. The median number of days the App group performed self-monitoring within the application was 63 [IQR 28, 84] of the 84 days (74%). Table 1 demonstrates the baseline characteristics for the participants in both groups. Figure 2 represents the consort diagram for this clinical trial.

13b) CONSORT: For each group, losses and exclusions after randomisation, together with reasons

Eighty-three participants were enrolled and completed all baseline assessments. Baseline characteristics were similar between groups except for the prevalence of ischemic HF and 62 years of age in the No App group ([P=0.725). The average ejection fraction (EF) was 37.2% in the App group and 38.2% in the No App group (P=0.725). Most of the participants were Caucasian (81% App vs. 83% No App, P=0.559) and NYHA class III (55% App vs. 66% No App, P=0.409) at study enrollment. The median number of days the App group performed self-monitoring within the application was 63 [IQR 28, 84] of the 84 days (74%). Table 1 demonstrates the baseline characteristics for the participants in both groups. Figure 2 represents the consort diagram for this clinical trial.

14a) CONSORT: Dates defining the periods of recruitment and follow-up

This was an open label study so concealment was not an issue.

10) CONSORT: Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions

Participants were randomized to the intervention (App) or control (No App) group in a 1:1 fashion using the Trial Randomize (https://trial-randomize.appspot.com/) application created by the University of Michigan Consulting for Statistics, Computing and Analytics Research (CSCAR). The randomization methodology uses the minimization approach to reduce covariate imbalances by using non-uniform assignment probabilities for the two groups.[10]

8a) CONSORT: Method used to generate the random allocation sequence

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11a) CONSORT: Attrition diagram

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16a) CONSORT: For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups

17a) CONSORT: For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)
Yes, this was provided in the results section of the manuscript.

17a-i) Presentation of process outcomes such as metrics of use and intensity of use
Yes, this was provided in the results section of the manuscript.

17b) CONSORT: For binary outcomes, presentation of both absolute and relative effect sizes is recommended
Yes, this was provided in the results section of the manuscript.

18) CONSORT: Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory
Yes, this was provided in the results section of the manuscript.

18-i) Subgroup analysis of comparing only users
Yes, this was provided in the results section of the manuscript.

18-ii) Highlight unanswered new questions, suggest future research

19) CONSORT: All important harms or unintended effects in each group
Yes, this was provided in the results section of the manuscript.

19-i) Include privacy breaches, technical problems

19-ii) Include qualitative feedback from participants or observations from staff/researchers

DISCUSSION

20) CONSORT: Trial limitations, addressing sources of potential bias, imprecision, multiplicity of analyses

20-i) Typical limitations in ehealth trials

20-ii) Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use)

20-iii) Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence

22) CONSORT: Registration number and name of trial registry
ClinicalTrials.gov: NCT03149510 https://clinicaltrials.gov/ct2/show/NCT03149510

24) CONSORT: Where the full trial protocol can be accessed, if available
ClinicalTrials.gov: NCT03149510 https://clinicaltrials.gov/ct2/show/NCT03149510

25) CONSORT: Sources of funding and other support (such as supply of drugs), role of funders
"The study was funded by the National Institute on Aging at the National Institutes of Health."

X26-ii) Outline informed consent procedures

X26-iii) Safety and security procedures

X27-i) State the relation of the study team towards the system being evaluated