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Study Title: Danger Signs of Worsening Heart Failure and Self-Management of Danger Signs: The Effects of Video Education

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ABSTRACT

The most frequently cited danger signs of heart failure (HF) are new onset or worsening of fatigue, dyspnea and edema. In previous research, patients did not recognize worsening HF, due to 3 primary reasons: (1) danger signs were non-specific and misinterpreted as stress, an external force or another comorbidity, (2) danger signs were unrecognized due to the subtle nature of worsening status, or (3) when patients eliminated or minimized activities that prompted danger signs, they interpreted the results as improvement in status. Lack of recognition of HF danger signs and lack of understanding of how to control and minimize danger signs could lead to their escalation and prompt all-cause and HF-related health care resource utilization (HCRU: emergency department care, hospitalization, death/ventricular assist device/cardiac transplantation referral or placement, or an unscheduled/urgent office visit). During hospitalization, patient education is delivered, but it is assumed that patients understand the danger signs and simply need education in self-care behavior expectations. We hypothesize that patients must understand HF danger signs to have self-confidence in recognizing them and in taking steps to minimize or eliminate their occurrence post hospital discharge. Therefore, the purposes of this randomized, controlled trial are to determine if video education in HF danger signs recognition and control prior to discharge and post-discharge reduces all-cause and HF-related 30-, 60-, 90- and 180-day HCRU. Research nurses will deliver the intervention during hospitalization, and patients and family members will receive a link to a website and a DVD of content to review videos as often as desired post-discharge. The primary end-point is 30-day HF-related HCRU. A total of 732 patients (658 + 10% attrition) with decompensated HF will be enrolled. Patients will be followed by telephone or medical record review to determine HCRU post index hospitalization.

INTRODUCTION

Chronic heart failure (HF) is a costly diagnosis;[1] especially for patients who are hospitalized due to decompensation. Heart failure decompensation and hospitalization place patients at high risk for rehospitalization, exacerbating costs of care and potential penalties associated with the Patient Portability Affordable Care Act.[2]

Adherence to HF self-care maintenance (carrying out HF self-care behaviors recommended to patients with most etiologies of HF: limiting sodium intake per day, being active and exercising, managing fluids by daily weight monitoring and fluid restriction, monitoring for signs and symptoms of worsening HF, taking medications as ordered, and receiving follow-up care early after discharge) and management (calling a healthcare provider for new or worsening symptoms or taking actions to reduce sodium or fluid intake) behaviors were associated with improved clinical outcomes, including survival and fewer rehosptializations.[3-5] Of note, when researchers studied 4 self-care behaviors in 830 patients with HF (weight monitoring, low sodium diet, fluid restriction and activity) at 30 days after hospital discharge, only 48% were adherent. At 18 months, all-cause mortality or HF rehospitalization was lower among patients who were adherent to all 4 behaviors versus 0 or 1, 2, or 3 behaviors.[4]

Patients with HF may not employ self-care behavior expectations when they do not understand HF danger signs (specifically: dyspnea, fatigue and edema) or understand how HF self-care behaviors can reduce or eliminate HF danger signs. Patients with HF may not understand that eliminating behaviors that lead to worsening of dyspnea and/or fatigue does not eliminate their risk of worsening HF. Rather, elimination of activities that worsened dyspnea and/or fatigue may simply mask worsening status, as the patient no longer experiences these symptoms. If patients recognize dyspnea, fatigue and edema as danger signs of worsening HF, they could employ self-care behaviors that might minimize/reduce worsening status and create equilibrium.

Dyspnea, fatigue and edema are common in patients with HF. In 2 reports, nearly all patients reported dyspnea during decompensation,[6,7] and even when in ambulatory care,[6] and edema was present in over two-thirds of those assessed. [6,7] The symptoms of dyspnea and fatigue were often related to one another in previous research studies (r=0.40[8] and 0.43,[9] respectively). Further, patients' responses to worsening symptoms were often to go to an emergency department (92% of 87 subjects)[7] rather than to "do something" actively at home. In fact, very few called their doctor (17%; n=14) and of those, even fewer reached their doctor (6%, n=5). More patients waited for their next doctor's appointment (30%, n=25).[7] When patients were asked about self-management, very few reduced salt intake (11%, n=9) or increased diuretic doses (10%, n=8), but elevating legs was more common (48%, n=40).[7] Of note, patients took actions that would not be considered evidence-based therapies for HF; for example, patients drank more water (19%, n=16), took medications other than what was prescribed (16%, n=13) and reduced activity level (77%, n=64).[7]

Most education materials in HF include a definition of HF and even a brief description of dyspnea, fatigue and edema. However, patients may not connect these danger signs with HF,[10] especially if they believe dyspnea, fatigue and edema are associated with external forces (stress, too much activity/not enough rest, pneumonia, chronic lung disease, anemia, worsening kidney

dysfunction, peripheral vascular disease, etc.), or if they believe there is no way to control these danger signs. In one report, of 571 patients who were assessed for understanding of HF signs and symptoms, only 38.7% had complete understanding, and of those with less than complete understanding, 22.1% had poor understanding.[11] Further, when self-care adherence was assessed, it was associated with more complete understanding of HF signs and symptoms.[11] In an integrative review of symptom perception among patients with HF, not only was symptom perception low, self-monitoring for worsening HF signs and symptoms was also low.[12] There is a need to teach patients with HF about the most common danger signs of decompensation or worsening condition (even if they believe they still feel fine), and also to provide simple, practical actions to reduce danger signs and restore equilibrium when recognized.

Media Design. In the mid-1950s, Stanford University professor Albert Bandura began to explore and establish the principles of *behavioral modeling***:** that people learn to enact behavioral skills best by observing those actions being modeled correctly and copying them. Over the next half century, thousands of experimental and field studies in refereed journal articles and the medical literature have identified and supported Bandura's *Social Cognitive Theory* principles for effecting positive behavior change.[13]

The power of modeling for behavior change was also found to be effective via media delivery – film, video, even photographic stills, called *symbolic modeling* – as long as the depicted modeling is designed and displayed according to well established social cognitive theory principles.[14]

Wellflix behavioral-modeling videos address one weak link in the HF admission / intervention / recovery process: what happens *after* patients with HF have returned home and are no longer in a controlled clinical environment. The Wellflix behavioral design, informed by social cognitive theory principles, depicts in-home self-care behaviors that are aimed at maintaining heart health, such as recognizing danger signs and taking appropriate non-pharmacological actions to minimize them.

Given that social cognitive theory principles can be successful in meeting outcomes when using media delivery and that new technologies enable easy accessibility to video in homes via digital video disc (DVD) player, computer and smartphone, this research endeavors to assess the effectiveness of symbolic modeling to promote positive heart health outcomes. Video delivery – via online and DVD – provides a 24/7 way for patients and family supporters to know how to *recognize and respond to new or worsening dyspnea, fatigue and edema danger signs*. The stimulus materials, designed by myself (the Principal Investigator) and Wellflix Inc, are not one-size-fits-all informational videos. Each video is tailored to an individual patient's gender, ethnicity, and language – one of the more than two dozen social cognitive theory design principles built into each video.

It is unknown if in-hospital video education (with repeat viewing post-discharge as desired) that uses symbolic modeling and is aimed at enhancing recognition of and HF self-care response actions to new or worsening dyspnea, fatigue and edema danger signs, (a) *reduces all-cause and HF-related healthcare resource utilization (HCRU),* (b) improves *perceptions of dyspnea and fatigue*, and (c) improves *self-efficacy for managing symptoms*. Learning the HCRU effects of

symbolic modeling video education that explains the most common HF danger signs (dyspnea, fatigue and edema) and provides practical actions to reduce danger signs is important, as the intervention is easy to deploy, uses standard HF self-care behavior expectations, and is practical to use in hospital and home environments.

It is important to learn the *time to the video intervention effect* on (a) HCRU outcomes and (b) perceptions of fatigue, dyspnea and self-efficacy for managing HF symptoms. The intervention may have an early effect (30-days) that wanes over time, have a steady effect over a 6-month period, or the effect may be slow to peak (i.e., 90 or 180 days) as patients may learn through a recognition and self-care action "trial and error" approach.

Finally, the video intervention effect on outcomes may differ based on *after hospital discharge viewing by patients and/or family supporters*, as repeated viewing and/or family supporter viewing of danger signs and HF self-care actions may facilitate *earlier recognition* of warning signs and/or *earlier or more accurate adherence* to HF self-care actions that lead to improved HCRU outcomes, lower perceptions of fatigue and dyspnea and improved self-efficacy for managing symptoms.

Study Purposes

The purposes of this study are to examine the effects of HF danger signs videos (1 each on dyspnea, fatigue and edema) that include 2 key features: (1) recognition of each danger sign and (2) common, simple, practical self-are actions known to reduce HF danger signs ([a] fatigue: recognizing that it may be due to dehydration and adhering to physical activity and exercise expectations; [b] dyspnea and edema: adhering to a low sodium diet and fluid intake limitations; [c] all 3: contacting a doctor when appropriate). Based on Bandura's social cognitive theory symbolic modeling, video content is meant to increase self-efficacy for independently completing self-care actions when dyspnea, fatigue and/or edema are present.

The following outcomes will be assessed:

<u>PRIMARY</u>

1. 30 ± 6 days *first occurrence of* post-discharge **HF-related** HCRU; defined as hospitalization, emergency department [ED) visits, death or cardiac transplantation/ ventricular assist device [VAD] implant-- individual components and combined),

<u>SECONDARY</u>:

2. 90- and 180-day ± 6 days *first occurrence of* post-discharge **HF-related** HCRU; defined as hospitalization, emergency department [ED) visits, death or cardiac transplantation/ ventricular assist device [VAD] implant-- individual components and combined),
3. 30-, 90- and 180-day± 6 days *first occurrence of* post-discharge **all-cause** HCRU; defined as hospitalization, emergency department [ED) visits, death or cardiac transplantation/ ventricular assist device [VAD] implant-- individual components and combined),
4. 30-, 90- and 180-day ± 6 days *time to* first occurrence of **all-cause** and **HF-related** post-discharge HCRU (individual components and combined),
5. 30-, 90- and 180-day ± 6 days *total* **all-cause** post-discharge HCRU (individual components and combined);
6. 30-, 90- and 180-day ± 6 days *total* **HF-related** post-discharge HCRU (individual components and combined);

7. Change in *functional status* from baseline to 30-, 90- and 180-days ± 6 days after hospital discharge,
8. Change in *dyspnea scores* from baseline to 30-, 90- and 180-days ± 6 days after hospital discharge,
9. Change in *fatigue scores* from baseline to 30-, 90- and 180-days ± 6 days after hospital discharge, and
10. Change in *self-efficacy for managing symptoms* from baseline to 30-, 90- and 180-days ± 6 days after hospital discharge
11. Differences in primary and secondary outcomes (1-10) among *intervention-group participants*, after creating 3 sub-groups based on post-discharge video viewing ([a] total number of times videos were watched, [b] viewed by caregivers/family in the hospital, and [c] viewed by caregivers/family post hospital discharge.

Specific aims and hypotheses:

1. Determine the effects (and time to effects) of HF danger signs education on *first occurrence*, *time to first occurrence* and *total* all-cause and HF-related HCRU after hospital discharge: hospitalization, ED visit, death, cardiac transplantation or VAD.
2. Examine if functional status, dyspnea, fatigue and self-efficacy for managing symptoms scores change over time and the direction of change.
3. Among intervention group participants, determine if post-discharge re-viewing of danger signs education by patients and/or viewing content by family supporters is associated with differences in HCRU, functional status, dyspnea, fatigue and self-efficacy for managing symptoms, including time to effects.

Hypothesis 1a: 30-day post-discharge HCRU will be lower or trend toward lower, and 90-, and 180-day *first occurrence*, and *total* HCRU will be lower in the HF video danger education group compared to the usual care group.

Hypothesis 1b: *Time to first* HCRU occurrence will be longer at 30-, 90- and 180-days in the HF video danger education group compared to the usual care group.

Hypothesis 1c: *Total* HCRU will be lower at 30-, 90- and 180-days in the HF video danger education group compared to the usual care group.

Hypothesis 2a: *Functional status* scores improve at 30-days and remain lower over time in the HF video danger education group compared to the usual care group.

Hypothesis 2b: *Dyspnea* scores improve at 30-days and remain lower over time in the HF video danger education group compared to the usual care group.

Hypothesis 2c: *Fatigue* scores improve at 30-days and remain lower over time in the HF video danger education group compared to the usual care group.

Hypothesis 2d: *Self-efficacy for managing symptoms* scores are higher at 30-days and remain higher over time in the HF video danger education group compared to the usual care group.

Hypothesis 3a: Repeat viewing of videos by patients, compared to 1-time viewing in-hospital and/or viewing of videos by family supporters/caregivers in hospital and/or post discharge, compared to viewing only by patients will be associated with *longer time to first HCRU and lower total HCRU.*

Hypothesis 3b: Repeat viewing of videos by patients, compared to 1-time viewing in-hospital and/or viewing of videos by family supporters/caregivers in hospital and/or post discharge, compared to viewing only by patients will be associated with *improved functional status* and *dyspnea and fatigue scores* (due to heightened awareness of danger signs, heightened recognition of worsening of danger signs)

Hypothesis 3c: Repeat viewing of videos by patients, compared to 1-time viewing in-hospital and/or viewing of videos by family supporters/caregivers in hospital and/or post discharge, compared to viewing only by patients, will be associated with *higher self-efficacy for HF self-care actions* (due to symbolic modeling of self-care actions)

METHODS

Design: The study will use a 2-group, randomized, placebo-controlled, single blinded, design. Healthcare providers and unit nurses will be blinded to group assignment, but may learn about HF danger signs education if they enter the patients' room during intervention delivery or discuss the intervention prior to hospital discharge.

In brief, the research intervention involves 3 novel short videos (fatigue, dyspnea and edema) that will be viewed back-to-back by intervention group patients using a DVD player. Wellflix, Inc. videos are research-informed, use behavioral-modeling, are personally-tailored and are available 24/7 online. Patients will receive a handout sheet with the web address to view the videos after discharge and will be encouraged to view them with family members.

Sample (including sample size calculation) and Setting

A total of 732 patients will be enrolled (366 per group) and consist of adults with chronic HF (diagnosis ≥ 2 months) who are hospitalized for acute decompensated HF within Cleveland Clinic Hospitals. This sample size includes a 10% attrition rate. Sample size was based on power calculations using 30-day first occurrence of HF-related HCRU (hospitalization, emergency department visit, mortality, cardiac transplantation or VAD). The current expected 30-day HF-related readmission rate is 20% among the control group. Allowing for other HCRU components, a control group HCRU rate of 28% is expected at 30 days. At 90 days, HCRU rate of 46% is expected in the control group. Sample size calculations were performed using SAS software (version 9.4; Cary, NC) and assume use of two-sided Pearson –chi square tests. With 329 patients in each group there will be 80% power to detect a 33% relative decrease (9.2% absolute decrease) in first occurrence of HF-related HCRU from a HCRU rate of 28% in the control group. With this sample size there would also be 85% power to detect a relative decrease of 25% (absolute decrease of 11.5%) from a control group event rate of 46% at 90-days. Allowing for 10% loss to follow-up, we will enroll 366 patients per group (732 total).

Patients will have decompensated HF with preserved or reduced ejection fraction when hospitalized and New York Heart Association FC III or ambulatory IV symptoms. Diagnosis and etiology of HF will be confirmed in the electronic medical record prior to enrollment.

Inclusion Criteria:

1. Not referred for cardiac transplantation or ventricular assist device placement during the index hospitalization (OK to be assessed for future placement),
2. Minimum age 18 years (no upper age limit),
3. Cognitively intact and able to view videos (adequate eyesight and hearing) with correction, if needed,
4. Discharge to home, assisted living facility or to a family member's home and can control dietary sodium and fluids as needed,
5. Willing to participate; which may require up to three (3) follow-up telephone calls post-discharge.

Exclusions:

1. Chart documented psychiatric or cognitive conditions that limit ability to understand video content or adhere to self-care recommendations (Alzheimer's condition, dementia, schizophrenia, other neurological history that impairs memory or concentration),
2. Plans to discharge to skilled nursing facility or hospice care,
3. Receiving home hospice or palliative care; or has a medical condition reflecting less than 1 year of survival (cachexia, end stage liver disease or cancer or non-ambulatory New York Heart Association functional class IV HF),
4. Hospitalized but at admission, in New York Heart Association functional class I or II HF
5. Post-cardiac transplantation or ventricular assist device placement,
6. Currently enrolled in another experimental HF research study,
7. Chronic renal failure and receiving chronic hemodialysis therapy for an estimated glomerular filtration rate < 15 mL/minute/1.73 m^2,
8. A non-traditional form of HF (hypertrophic or restrictive forms of cardiomyopathy, congenital heart disease or Takotsubo cardiomyopathy).

Intervention

The fatigue and dyspnea video's will be viewed back-to-back and the edema video will be added for patients with a history of edema. There are 4 versions of each video: (1) based on race (Caucasian and African-American) and sex (male and female)—to promote symbolic modeling— by patients who look like video models (as stated in the introduction). Scripts for each video were developed jointly by Peter Orton, PhD, Director of Media and Education for Wellflix, Inc. and Nancy Albert PhD, principal investigator and clinical nurse specialist in HF. Content includes recognition and assessment of fatigue, dyspnea and edema and specific actions to take to reduce the danger signs or prevent worsening (dietary sodium and/or fluid restriction, physical activity/exercise and contacting the doctor).

Overall video viewing time for all 3 videos is 9:50 minutes; the fatigue and dyspnea videos that all intervention patients will view are 6:50 minutes:

- *Fatigue* is 2:20 minutes + end text list= 3:00 minutes;

- *Dypsnea* is 1:40 minutes + dyspnea "yes" or "no" management (2 options; patient selects the option that matches current status) = 3.50 minutes
- *Edema* is 2:40 minutes + end text list= 3:00 minutes;

During hospitalization, videos will be loaded into an iPAD and will be viewed through the iPAD.

Patients have an opportunity to view videos post-discharge as desired and able. *Post discharge*, videos can be in 2 ways: (1) via the Wellflix, Inc. site at www.wellflix.net/DangerSignsCC or (2) by DVD player (DVD created by Wellflix, Inc for this research), for patients who have DVD player capability and prefer this method.

NOTE, at/after 180-day follow up data are collected, *usual care group* patients will be offered access to Wellflix, Inc. videos used in this research study via mailing of a handout sheet developed specifically for them (that contains the web address and a note of encouragement to view the videos.

Outcomes and Measurement

HCRU. Includes all-cause and HF-related hospitalization, ED visit, death, cardiac transplantation, or VAD placement at 30-, 90-, and 180-days ± 6 days in both groups. Data will be retrieved from medical records when available or via telephone call to patients.

- Patients will receive a calendar to keep track of HCRU events in-between phone calls.
- Research nurses will use a case report form to record HCRU events

Functional status: The Duke Activity Status Index (DASI)[15] developed in a sample of people undergoing cardiac exercise testing and now routinely used to assess functional status in patients with cardiac disease. The DASI is a 12-item questionnaire using a Likert-like scale that determines a patient's ability to participate in common, everyday activities without difficulty, including self-care activities (1 item), ambulation (4 items), housework (3 items), yard work (1 item), sexual relations (1 item), and recreational activities (2 items).[15] Each item is weighted to reflect the metabolic equivalent (MET) used during the activity. A total score reflects functional status based on responses to each item. Scores can range from 0 (most severe functional impairment) to 58.20 (no functional impairment). Several investigators have investigated the reliability and validity of the DASI.[15-18] The internal consistency of the DASI measured by Cronbach's alpha has been found to be acceptable in HF patients.[16] Test-retest reliability also was examined and determined to be acceptable in patients with HF.[16] The validity of DASI was demonstrated in subjects undergoing graded exercise testing who demonstrated a high correlation (Spearman correlation coefficient from .58 to .80) with peak oxygen uptake.[15] In addition, the DASI varied in a consistent manner according to different clinical factors known to affect patient functional capacity in patients with cardiac disease.[17] When DASI results were correlated with other functional and health status measures, moderate to strong correlations were found: New York Heart Association (r, -64; $P < 0.001$); six minute walk test (r, 44; $P < 0.01$); Kansas City Cardiomyopathy Questionnaire physical limitations component (r, 68; $P < 0.001$); Kansas City Cardiomyopathy Questionnaire clinical summary (r, 60; $P < 0.001$) and estimated

metabolic equivalents calculated from peak treadmill speed and grade (r, 46; $P < 0.01$).[18] DASI will be assessed at enrollment and scores will be used as interval level data in analysis.

Dyspnea: The Patient-Reported Outcomes Measurement Information System® (PROMIS®) Dyspnea Functional Limitations – Short Form 10a has been used in patients with idiopathic pulmonary fibrosis[19] and systemic sclerosis.[20] The tool was able to discriminate health-related quality of life deficits and cough severity[19] and when traditional dyspnea measures were compared with PROMIS dyspnea short form results, significant correlations were found.[20] The tool measures dyspnea by asking 10 questions about difficulty in completing activities in the past 7 days. Response options use a Likert-type scale from 0, *no difficulty* to 3, *much difficulty* and there is an option for "*I did not do this in the past 7 days*".

Fatigue: Fatigue is a hallmark symptom of HF that may decrease energy and reduce the patient's desire to exercise. The *Fatigue Assessment Scale* is a 10-item self-rated measure of fatigue with 5 answer categories; 1 = *never* to 5 = *always*, that has been assess in patients with end-stage heart failure,[21] as well as in patients with stroke and in working adults. In factor analysis, this tool correlated strongly with 4 other fatigue scales; however, this tool had the highest factor loading on a clear one-factor solution.[22]

Self-efficacy for managing symptoms. Validation of the PROMIS Self-Efficacy for Managing Symptoms forms were completed among 1087 subjects that included patients with chronic neurologic conditions (epilepsy, multiple sclerosis, neuropathy, Parkinson disease, and stroke) and general chronic conditions and compared with a traditional self-efficacy measure and 5 PROMIS short forms that measured physical and mental global health, physical function, fatigue, depression, and anxiety.[23] Researchers found strong correlation between all forms of the PROMIS and the traditional self-efficacy measure (*rhos,* 0.56 to 75).[23] In this research study, the PROMIS Self-Efficacy for Managing Symptoms Short form 8a will be used.[23] The 8-item tool uses a Likert-type scale from 1, I am *not at all confident* to 5, *I am very confident*.

Patient characteristics and medical history at baseline. Standard patient characteristics that are used in many research studies of patients with HF, will be used in this research as they span themes of interest and provide global information about participants. Items include height and weight, highest education, comfort living on current household income, current signs and symptoms of HF, comorbid conditions and billing data retrieved from Cleveland Clinic billing database (age, race, gender, marital status, discharge disposition, and length of hospital stay). The *Charlson Comorbidity Index* will be used to collect medical comorbidity history. This index was developed to classify comorbid conditions which might change the risk of mortality.[24-29] The score will be categorized into 3 groups (score of 1-2 = 1; 3-4 = 3; 5 or more = 5). In one study with 33,940 patients with ischemic heart disease, the grouping demonstrated a strong relationship with mortality rate.[29] In 2011, the tool was reduced from 19 items to 12 items and each item was re-scored based on morbidity and mortality of medical conditions in the current era of medical therapies.[30] This data will also be used to describe the sample groups for similarity in acuity.

Video Watching Experiences in-hospital and at 30 day follow-up (intervention group only). A 3-item, investigator-developed survey will assess video watching characteristics: total number of watching's, caregiver/family member video watching *in the hospital*, and

caregiver/family member video watching *in the post discharge* period, up to 30 days. Items use choose-the-best-response options.

Data Collection

Medical records will be assessed for inclusion and exclusion criteria before approaching patients. Research personnel will explain the study in a patient's room (in non-private rooms, a curtain will be drawn to separate beds and enhance confidentiality). After received verbal informed consent, patients will complete baseline data that includes assessment of functional status, dyspnea, fatigue and self-efficacy for managing symptoms immediately before hospitalization. Administration of the functional status, dyspnea and fatigue questionnaires will be randomly changed for each participant to allow for counterbalancing, since there item themes may have overlap/be similar. Baseline data collection should take 10 minutes or less.

After completing baseline paperwork, patients will be randomly assigned to the usual care or usual care plus HF danger signs video education group using block randomization; with blocks of 20, to decrease the influence of external factors that could alter outcomes. The randomization assignment will be made by a QHS statistician.

After randomization to groups:

- Intervention group patients will receive usual hospital care and also, HF danger signs education via iPad by research personnel. Danger signs education can be administered at the time of enrollment. There is no need to wait until day of discharge, since HF danger sign messages are not individualized and discharge is a very busy time. Immediately prior to discharge, patients' focus may be on preparing to leave the hospital and not on education about HF, especially if patients believe that they have accurate perceptions of HF danger signals, even though in previous research, most subjects did not.
- Usual care group patients will be educated by their healthcare providers (including nurse/other caregivers). Education may include Elsevier HF videos that are shown on Cleveland Clinic hospital televisions.

A research nurse will use telephone calls or mailing methodologies to have the following 4/5 tools (40/43 items in total for usual care and intervention groups, respectively) completed at 30 ± 6 days: functional status, dyspnea, fatigue, self-efficacy for managing symptom and video watching experiences. Administration of functional status, dyspnea, and fatigue questionnaires will be randomly ordered (counterbalanced). The intervention-only group survey on video watching experiences will be administered last. It is expected that data collection will take ~ 10 minutes or less.

A research nurse will review EMRs of enrolled patients after the index (baseline) hospital discharge and at 30-, 60-, 90- and 180-days (± 6 days) for HCRU events.

- If not found in the EMR, telephone calls will be made to gather data.
- At baseline, research nurses will obtain home telephone number and the telephone number of a close relative or friend that can provide patient contact information, as needed.

Analyses

Patient characteristics will be summarized overall and by randomized group using frequencies and percentages for categorical factors and means and standard deviations for continuous measures. First occurrence HCRU use (all-cause and HF-related) will be compared using Pearson chi-square tests. Time to first HFCU use will be summarized using Kaplan-Meier estimates, and compared using log-rank tests and Cox proportional hazards models. Total HCRU use will be compared using Poisson regression models. Linear mixed effect models will be used to evaluate trends in functional, dyspnea, fatigue, and self-efficacy measures over time and, if trends significantly differ, comparisons within time point will be performed. Secondary analyses will use similar methods to compare patients in the video group, stratified by video viewership, on the same outcomes. If appropriate, exploratory analyses will also be performed, comparing the above outcomes between treatment groups, adjusting for any patient characteristics that differ between randomized groups. Analyses will be performed using SAS software (version 9.4; Cary, NC), and an overall significance level of 0.05 will be assumed for all endpoints. Comparisons between the 3 subgroups of patients in the video group will use Bonferroni corrected significance criteria to preserve the overall error rate when making multiple comparisons.

Feasibility

The main campus of Cleveland Clinic has a high volume of HF discharges each year. Other hospitals in the system have moderate volumes of HF discharges, and are less likely to have patients who meet exclusion criteria due to enrollment in another research study or non-ambulatory NHYHA FC IV (advanced) HF. Electronic medical records allow for review of data on events that occur in *all* system hospitals and regional medical practice ambulatory care sites; decreasing the need to rely on patient recall of HCRU.

The HF danger signs videos provide information that patients should understand, but that may not have been explicitly explained previously; therefore, it may be considered an extension of usual care education. Ideally, no new information is presented; as patients receive content about HF signs and symptoms and HF self-care actions via CC video education (in-hospital, when attentive) and via the HF handbook, which is sent home and can be re-given in ambulatory care. Danger signs video content was based on symbolic modeling; and has a *repeatable format*, if patients in the intervention group choose to utilize the on-line 24/7 viewing option post discharge. Patients do not need to be able to read and if they are forgetful or have mild memory impairment that was not documented at enrollment, they can replay videos multiple times.

Research personnel from the Office of Nursing Research and Innovation will recruit subjects, apply the intervention and collect data (at all sites). The main campus has multiple research projects in place, led by physicians, myself and other RNs. Research team personnel are accustomed to working with cardiology research nurses, as needed, to ensure patients are not approached for more than 1 research study.

Instruments that will be completed at baseline may be self- or research nurse-administered (patient demographics, HF characteristics, danger signs [dyspnea and fatigue], functional status and self-efficacy for managing symptoms). The patient demographics and HF characteristics instruments have been used many times in previous HF research and are short, simple and quick

to complete. Patients may become fatigued when completing baseline data collection forms; however, all 6 tools have only 71 items (in total) and all tools are short (12 or less items; each one should take about 3 minutes to complete).

- At baseline, all 6 tools should take and take under 20 minutes to complete. In previous research, patients were NOT burdened by data collection that included similar length instruments.
- At follow-up, telephone calls are only made when HCRU data is not available in medical records at 60-, 90- and 180-days. Data obtained from electronic medical records is consistently present, minimizing the occurrence of missing data.
- At 30-day follow-up, there are 2 options to collect data on 4 tools with 40 items in total, that will take ~ 10 minutes or less to complete (usual care group) or 5 tools with 43 items in total, that will take ~ 10 minutes to complete (intervention group) and include functional status, dyspnea, fatigue self-efficacy, and a 3-item video viewing experience survey for the intervention group, by telephone or mail. As a secondary method, patients who are hospitalized during the follow-up period may receive tools in person by a research nurse.

Limitations and Anticipated Problems

Patients and caregivers may never view the Wellflix, Inc. HF danger sign videos after discharge, and/or forget content viewed during hospitalization. Patients may view/hear, but ignore, message content. Patients may drop out before the 180-day follow-up data collection. Analyses will be completed using "intent to treat" methods. In this way, we will be able to learn the effect size of the intervention among all patients randomized to the intervention group.

No adverse effects are anticipated, as the intervention in this research are HF danger signs videos that cannot create harm to patients. Video scripts provide messages that may be available in commercially available videos and or written materials used in usual HF care education and discharge instruction materials. There are no risks of adverse events from the intervention itself.

Human Subjects Protection

Approval by the Cleveland Clinic Institutional Review Board will be sought prior to study initiation. We believe this study is minimal risk as the intervention is composed of back-to-back video viewing of 3 HF danger signs (fatigue, dyspnea and edema). Video self-care messages delivered through demonstration, imitation and modeling are part of usual heart failure post-discharge care, but are delivered using principles of Bandura's social learning theory, to enhance ability to complete independently after viewing videos.

One data collection form will use a research number and CCF medical record number; as it will also contain names and phone numbers; however, all other baseline and follow-up data collection forms contain only research numbers. Only the research number will be recorded in the electronic database. Paper forms will be kept in a locked cabinet, in a locked office of the principal investigator and will be destroyed upon assurance that data in the electronic database is high quality, after enrollment is completed. Electronic data for analysis will use a research number; no patient identifiers will be used. All study results will be reported in aggregate.

SPSS will be the electronic database used to capture paper data. The electronic database will be maintained for 6 years after study completion. Paper documents will be destroyed once the initial analysis is complete.

This research project will be registered in www.clinicaltrials.gov.

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Timeline*													
	2018									2019			
Work	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr
Startup work**													
Patient enrollment, data collection and data entry into database													
Patient follow-up													
Data entry													

**, secure video links/iPADs to play videos; secure web link for post discharge video viewing (Wellflix to do); identify/train research nurses; prepare randomization cards/envelopes; obtain IRB approval; develop database

Timeline*, continued														
	2019								2020					
Work	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun
Patient enrollment and data collection														
Patient follow-up														
Data entry														

Timeline*, continued												
	2020						2021					
Work	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun
Patient follow-up												
Data Cleaning												
Data Analysis												
	2021						2022					
Work	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	
Abstract shared w **stakeholders**												
Abstract submission at Nat'l Mtg; 2021†												
Publication develop/ submit												

*, Timeline subject to change based on number of sites participating and cases enrolled/month. The prepared timeline *is conservative*; timeline may be shortened to 1.5 years if multiple sites; † i.e. late breaking clinical trial at HFSA or AHA, or submit to a 2022 annual meeting (i.e., ACC).