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Follow up: Promoting self-management through adherence among heart failure patients discharged from rural hospitals: a study protocol.

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STUDY PROTOCOL

REVISED Follow up: Promoting self-management through adherence among heart failure patients discharged from rural hospitals: a study protocol [version 2; referees: 2 approved, 1 approved with reservations]

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Original article:

Relationships between activation level, knowledge, self-efficacy, and self-management behavior in heart failure patients discharged from rural hospitals [version 1; referees: 2 approved]
Van Do, **Lufei Young**, **Sue Barnason**, **Hoang Tran**

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Abstract

Background Heart failure is one of the most prevalent chronic conditions in adults, leading to prolonged morbidity, repeated hospitalizations, and placing tremendous economic burden on the healthcare system. Heart failure patients discharged from rural hospitals, or primarily critical access hospitals, have higher 30-day readmission and mortality rates compared to patients discharged from urban hospitals. Self-management improves heart failure patients' health outcomes and reduces re-hospitalizations, but adherence to self-management guidelines is low. We propose a home based post-acute care service managed by advanced practice nurses to enhance patient activation and lead to the improvement of self-management adherence in heart failure patients discharged from rural hospitals.
Objective This article describes the study design and research methods used to implement and evaluate the intervention.
Method Our intervention is a 12-week patient activation (Patient AcTivated Care at Home [PATCH]) to improve self-management adherence. Patients were randomized into two parallel groups (12-week PATCH intervention + usual care vs. usual care only) to evaluate the effectiveness of this intervention. Outcomes were measured at baseline, 3 and 6 months.
Discussion

Open Peer Review

Referee Status: ✓ ? ✓

	Invited Referees 1	2	3
REVISED version 2 published 07 May 2015			
version 1 published 30 Dec 2014	✓ report	? report	✓ report

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3 **Kevin T. Fuji**, Creighton University USA

Discuss this article

Comments (0)

This study aimed to examine the effectiveness of a rural theory based, advance practice nurse led, activation enhancing intervention on the self-management adherence in heart failure patients residing in rural areas. Our expectation is to facilitate adherence to self-management behaviors in heart failure patients following discharge from rural hospitals and decrease complications and hospital readmissions, leading to the reduction of economic burden.
Clinical Trial Registration Information: ClinicalTrials.gov; https://register.clinicaltrials.gov/ NCT01964053

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Competing interests: No competing interests were disclosed.

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REVISED **Amendments from Version 1**

Summary of main changes:

Page#3 — Study rationale: modified web link that was not working.

Page#4 — Figure 1. Patient Activated Care at Home Model: PATCH. Added "Possess confidence & knowledge to take action" under level 2 Building knowledge, Skills & Confidence.

Page#6 — Participants - Inclusion criteria: modified the referenced web link for NYHA class.

Page#6 — Participants - Exclusion criteria: modified the referenced web link for PHQ-2.

Page#6 — PATCH intervention - Added justification of using telephone instead of other telehealth delivery modalities in rural elderly heart failure patient as per reviewer recommendation, as well as 7 articles to support the argument.

Page#6 — Statistical methods, deleted "because this is an exploratory study", as per reviewer recommendations.

Page#7 — Table 1 - Added 3rd column to show test statistics per reviewers' comments.

Page#8 — Statistical methods, deleted "For the continuous outcomes (days of self-weighing and taking prescribed medication, physical activity outcomes, and level of BNP and urine Na/Cr)," as per reviewer recommendations.

Page#8–9 —Added extra references and updated reference list.

See referee reports

Study rationale

Heart failure is one of the most prevalent chronic diseases among the adult population[1] and hospitalizations account for the majority of costs related to heart failure treatment[2]. Rural hospitals had higher 30-day readmission rates for heart failure patients than urban hospitals (28% vs. 25%)[3,4] (https://ruralhealth.und.edu/pdf/umrhrc_finalreport1110.pdf). Self-management is key to improving heart failure patients' health outcomes[5] and reducing re-hospitalizations[6,7]. Non-adherence to self-management guidelines accounted for 50% of hospital readmissions in heart failure patients[8,9].

Compared to urban residents, patients in rural communities face greater challenges in managing their heart failure[10]. Difficulties include lack of local cardiac services and heart failure specialists[3,10], lack of heart failure specific self-management guidance from providers[11,12], less hospital discharge education at critical access hospitals, lack of follow-up by providers[13,14], poor communication between the patient and providers, difficulty in traveling long distances for follow-up appointments and associated problems (time, fatigue, and cost)[11], and feeling isolated and unsupported[15,16]. Despite these identified needs, effective programs to support heart failure patients in managing this complex, chronic condition in rural communities have not been reported[10]. In addition, there is lack of reimbursement for programs that promote heart failure patients engaging in self-management behaviors over time. Innovative programs, such as the proposed PATCH program, are needed to assist heart failure patients' self-management adherence.

The effective interventions to improve adherence to heart failure self-management behaviors are primarily disease management programs[17] which require intensive resources and are mainly delivered in urban areas with comprehensive medical care centers. The limitations of existing interventions to promote self-management adherence in rural heart failure patients include: lack of theoretical guidance for the development of a rural-based intervention[18,19], unclear mechanism of intervention[8,17,20], and reliance on self-report measures of self-management adherence[21–23].

Our study will fill the gap of knowledge and evidence existing in the current literature about self-management interventions by: 1) identifying and appraising new intervention mechanisms to improve self-management behaviors; 2) testing the feasibility and efficacy of a rural theory-based intervention designed to assist rural heart failure patients in managing their chronic condition; and 3) evaluating the use of biomarkers (i.e., brain natriuretic peptide [BNP] and sodium concentration collected from a spot urine sample) to assess the adherence of self-management behaviors.

Conceptual framework

Self-management adherence is defined as the ability to follow and engage in self-management behaviors recommended in heart failure treatment guidelines (e.g., monitor daily weight, follow a restricted sodium diet, take medication as prescribed, exercise regularly, and keep follow-up appointments)[24]. We have proposed the patient activation intervention PATCH (Patient AcTivated Care at Home Model) for this study based on components of Lorig's chronic disease self-management model[25], Hibbard's patient activation theory[26,27], Bandura's conceptualization of self-efficacy[28], and Long and Weinert's rural nursing theory[19] (Figure 1). According to Long and Weinert's rural nursing theory, rural patients are more likely to accept help and care during times of crisis[19]. Therefore, the intervention is triggered by the patient's hospitalization and initiated during their hospital stay when they feel most vulnerable and receptive to the idea of making behavioral change to avoid readmission. Rural patients' belief about self-reliance (responsibility for one's own care) supports the use of Hibbard's patient activation theory[26].

In summary, the goal of the PATCH intervention is to increase adherence to self-management behaviors, leading to improved clinical biomarkers (BNP and urine sodium concentration) and fewer hospital readmissions that are considered to be threats to their health beliefs (health is to work, be productive and function in one's own role)[19]. Our central hypothesis, based upon our preliminary data, is that patients with higher activation levels, as assessed by the Hibbard patient activation measure, will have significantly better self-management adherence. Given the significant challenges of managing heart failure patients in rural settings, it is essential to examine the feasibility, acceptability, and size of the effects of PATCH on adherence to self-management behaviors and readmissions.

We test our intervention with the following aims:

Aim 1. To evaluate the immediate and extended effects of the patient activation intervention on self-management adherence,

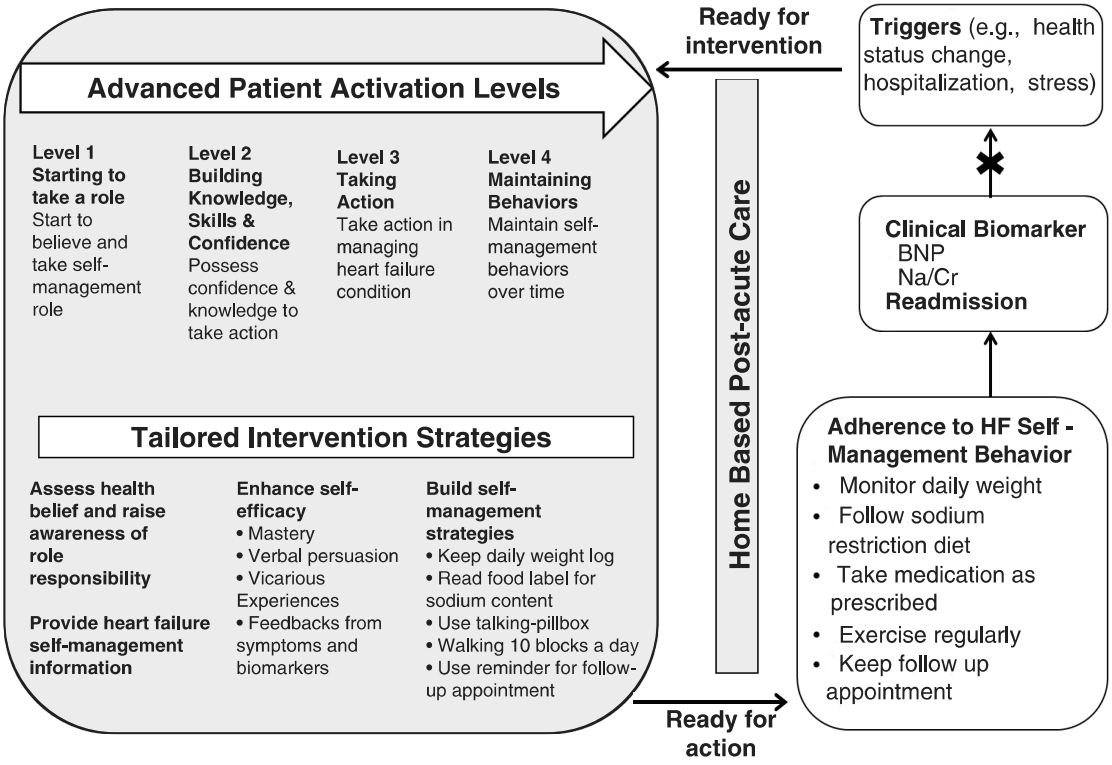

Figure 1. Patient AcTivated Care at Home Model: PATCH.

we measure adherence using clinical biomarkers and self-report of self–management behaviors. Our working hypothesis (H_1) is that subjects in the intervention group have better self-management adherence than the usual care group over time (3 and 6 months).

Aim 2. To evaluate the immediate and extended effects of the patient activation intervention on the specific health outcome, we measure hospital readmission rates. Our working hypothesis (H_2) is that subjects in the intervention group have lower readmission rate than the usual care group over time (30 days, 3 and 6 months).

Aim 3. To evaluate the mechanism of the patient activation intervention. Our working hypothesis (H_3) is that the scores on self-management knowledge, self-efficacy for self-management, patient activation, and self-management strategies in the intervention group are higher than the usual care group at the end of the intervention (3 months) when the maximum difference for each variable is expected.

Aim 4. To evaluate the feasibility of the PATCH intervention for a future larger clinical trial, which includes evaluation of enrollment (recruitment efficiency, attrition, problems and solutions), intervention fidelity (delivery, receipt, enactment), data collection, subject acceptability of the intervention, and estimation of effect sizes for sample size determination.

Methods/design

Study settings

Study participants were recruited and enrolled between October 2013 and December 2014 from two rural critical access hospitals. The principal investigator and research assistants who have ethical access at each study site were responsible to identify the potential participants, screen for eligibility and recruitment (Figure 2).

Study design

This study is a prospective, two-group, randomized experimental design with three data collection points (baseline, 3 months and 6 months). Heart failure patients discharged from the rural hospitals were randomized into two groups: the intervention or control groups.

1. **Control group** received only usual care. Usual care refers to the standardized care received after hospital discharge, including the written discharge information and the scheduled follow-up doctor appointments. Standardized discharge instructions, as recommended by CMS and the Joint Commission, include: activity level, diet, discharge medications, weight monitoring, and what to do if symptoms worsen.

2. **Intervention group** received usual care and the 12 weeks of PATCH intervention. The intervention comprised of two phases in which the in-hospital discharge education session was followed by 12 weeks of post-discharge education sessions delivered by telephone.

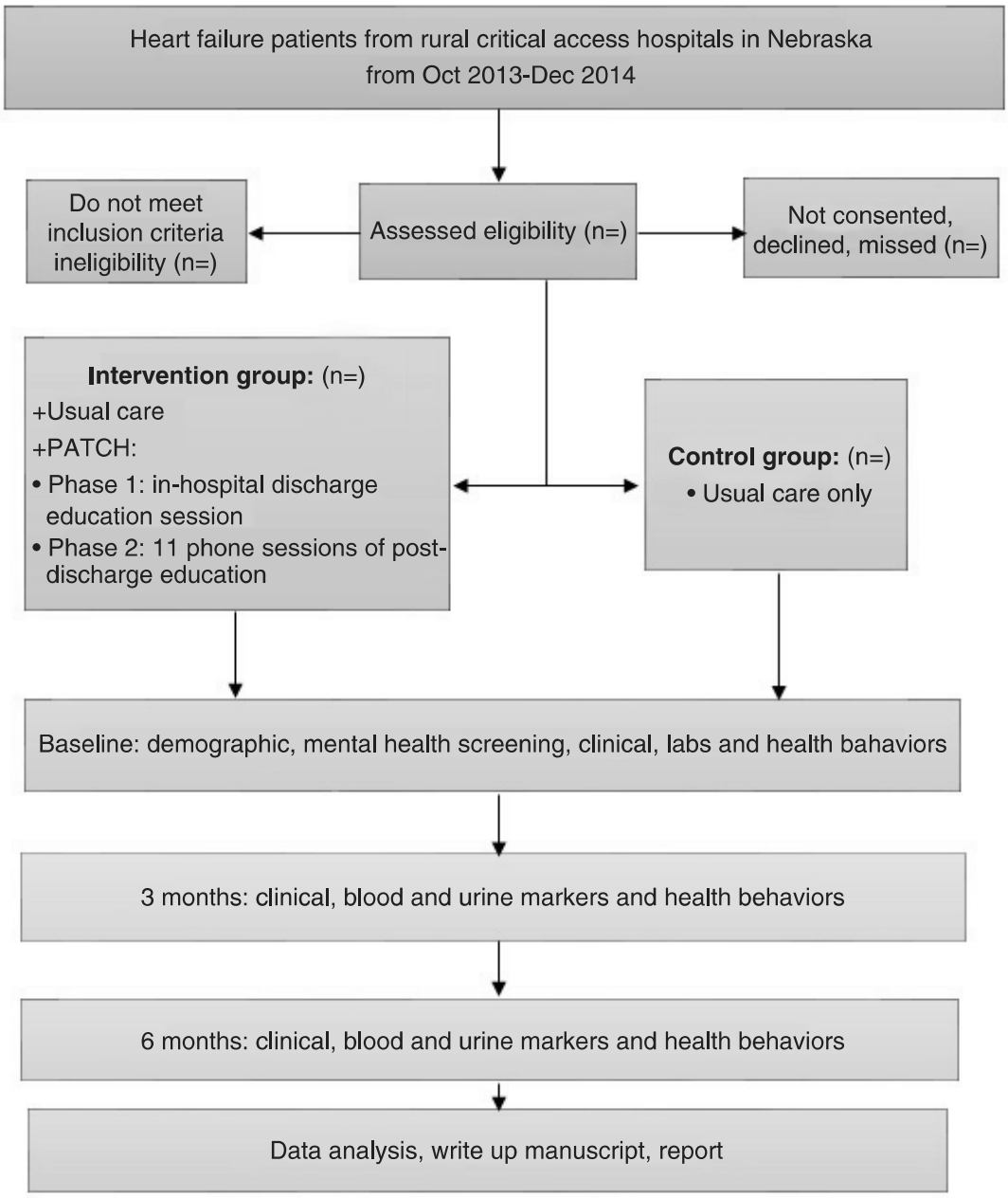

Figure 2. Promoting Self-management through Adherence among Heart Failure Patients Discharged from Rural Hospitals- Flow Chart of Study Design.

Sample size

Because this is a preliminary study, sample size was estimated for two-sided statistical tests using a liberal α level of .10. For Aim 1, a repeated-measures ANOVA with an average between-group difference of Cohen's f=.25 (a medium effect) and a within-subject correlation of ≤.6 would require 41 patients per group to have power=.80. With this sample size, a z-test of independent proportions would have power=.79 if the group proportions meeting guidelines differed by approximately .25, a value reached or exceeded by medication, diet, and weighing adherence in most of the intervention trials reviewed[29]. The sample of 82 also would be large enough to estimate proportions ± .07–.13 with 90% confidence (the precision depends on the value of the proportion and whether it was calculated within-group or for the entire sample). Allowing for 15% attrition, 48 patients per group (total N=96) are recruited.

Participants

Inclusion criteria. Patients were eligible for the study if they: 1) were age 21 or older; 2) had heart failure as one of their discharge diagnoses; 3) had New York Heart Association (NYHA) class II to IV (http://www.heart.org/HEARTORG/Conditions/HeartFailure/AboutHeartFailure/Classes-of-Heart-Failure_UCM_306328_Article.jsp) or had NYHA class I symptoms and at least one other heart failure-related hospitalization or emergency department visit in the year prior to the study; 4) were discharged to home; 5) passed a mini-cognitive screen[30]; 6) understood English; and 7) had access to a phone.

Exclusion criteria. Patients were not eligible for the study if they: 1) had depressive symptoms (received a score of 3 or above on the Patient Health Questionnaire-2 (PHQ-2))[31] (http://www.commonwealthfund.org/usr_doc/PHQ2.pdf); 2) had documented medical diagnosis or diagnostic evidence of liver cirrhosis; 3) had documented medical diagnosis or diagnostic evidence of renal failure defined as serum creatinine greater than 2.0mg/dl; and 4) had documented medical diagnosis or diagnostic evidence of end stage and/or terminal illness (e.g. cancer) affecting their abilities to perform self-management behaviors.

PATCH intervention

The intervention group received usual care and the PATCH intervention. The intervention was comprised of two phases in which the in-hospital discharge education session was followed by 12 weeks of post-discharge education sessions delivered by telephone. The telephone delivery mode was a reliable method to reach patients living in rural counties where internet service was often unreliable and costly. In addition, telephone contact was preferred by many elderly patients because of the complexity of navigating and manipulating other communication platforms[32].

In addition to the complexities, burden and costs, other telehealth delivery modalities presented the following limitations: 1) challenge with recruitment and retention; 2) wide range of variation in intervention administration (i.e., various single dose strength and dosing frequency); and 3) recruitment bias. Previous web-based behavioral interventions reported having low recruitment rate (<11%)[33], high attrition rate (>65%)[34], and inconsistent intervention administration[33]. Compared to non-participants, the participants of web-based interventions were predominantly white[34], younger[34,35], well-educated[34,35], with greater engagement in seeking health information[36] and fewer risk factors (e.g., smoking, obesity)[35]. Previous studies indicate participants of an intervention study delivered by internet or other similar methods are more likely to have higher baseline activation level and have already engaged in self-management behaviors, leaving little to no room for the intervention to work. It has been reported that the barriers for elderly HF patients using advanced interactive technology are low energy from chronic fatigue[37] and inadequate health and computer literacies[38,39]. Thus the telephone platform is used to deliver the intervention so that we can reach the HF patients who are more likely to have low levels of patient activation and refuse to participate in the study if the intervention delivery methods are perceived to be too complex or burdensome.

During **Phase I (in-hospital discharge education session)**, the intervention was delivered in the hospital to capture a "teachable moment" when patients had recently experienced deteriorated health and recognized the need to better manage their heart failure. The intervention was focused on assessing the patient's intent and readiness to assume a self-management role or encouraging the patient to assume this role (patient activation level 1) and building knowledge, skills and confidence specific to areas of knowledge deficit identified by the patient (patient activation level 2). The teaching materials included: 1) an educational workbook developed by Dr. Darren DeWalt at the Cecil G. Sheps Health Services Research Center for heart failure patients (http://www.nchealthliteracy.org/comm_aids/Heart_Failure_Intervention_eng_v1.pdf), 2) the Agency for Healthcare Research and Quality (AHRQ) guide book for patients discharged from hospitals (http://www.ahrq.gov/qual/goinghomeguide.pdf) and 3) the personal stories about living with heart failure posted on the American Heart Association webpage (http://www.heart.org/HEARTORG/Conditions/HeartFailure/HeartFailureToolsResources/Heart-Failure-Personal-Stories_UCM_306386_Article.jsp). The overall goal was to establish the initial patient-provider relationship and encourage patients to take an active role in self-management. At discharge, each participant from the intervention group received an intervention toolkit containing the heart failure self-management workbooks, an electronic talking pillbox and a digital scale.

During **Phase II** (**post-discharge phone education sessions**), a total of 11 phone contacts were made with the patient (twice a week for the first 2 weeks, once a week for weeks 3–6, and every other week for weeks 7–12). Each session focused on 1–2 topics and confirmed the patient's understanding of the knowledge and skills delivered during their hospital stay. The goals for the **Phase II** intervention were to establish a therapeutic patient-provider relationship and to monitor and reinforce self-management behaviors. Each session started with an informal assessment of the patient's activation level and the intervention strategies were modified based on the results. The length of the intervention and number of sessions were similar to Wolever's study that showed effects of a telephone delivered patient activation intervention on the improvement of self-management behaviors in type 2 diabetic patients[40].

Outcome measures and data collection

Table 1 describes the outcome variables specified in the study aims, the study instruments used, their psychometric characteristics, and data collection points.

Statistical methods

A two-sided, alpha level of 0.10 was used to identify trends in the group differences on outcomes. Descriptive statistics are reported at baseline, 3 months and 6 months. Chi-square tests were used to evaluate the difference between proportions. We used t-tests to compare the averages of continuous variable between groups.

Linear mixed model methods are used to compare the groups across the 6-month period, adjusting for baseline levels on the respective outcome. We used ANOVA analysis for repeated measures.

Table 1. Data Collected in the Study.

VARIABLE	MEASURES AND DATA COLLECTION TIME POINTS	Data analysis
BASELINE SCREENING (PRIOR TO ENROLLMENT)		
Cognition	Mini-cog Screen: to screen for cognitive impairment in older adults. Score ranges from 0 for cognitive impairment to 3 for no impairment[30]	
Depression	Patient Health Questionnaire-2 (PHQ-2): to screen for depression, providing a 0 to 6 severity score (cut score of 3 for depression)[31] (http://www.commonwealthfund.org/usr_doc/PHQ2.pdf)	
BACKGROUND VARIABLES (BASELINE)		
Demographic and Clinical variables:	Demographic and Clinical Variables Tool: demographic (e.g., age, gender, race/ethnicity) and clinical data (e.g., comorbidity, ejection fraction, NYHA score, medications, medication changes, previous admissions).	T-test Chi-square
Monitoring daily weight	One question on the Follow-up Data Collection Survey: How many days per week do you weigh yourself?	T-test
Following low sodium diet	One question on the Follow-up Data Collection Survey: How many days per week do you follow a low-sodium diet?	T-test
Taking prescribed medications	• Medical Outcome Study (MOS) Medication Adherence Scale: During the past 7 days (including last weekend), how many days have your missed taking ANY of your doses? • Medication Adherence in Heart Failure Patients[41]: 32-items measuring factors influencing adherence to the prescribed medication regimen.	T-test
Exercise regularly (Physical Activity)	• Physical activity is measured using the GT3X: ActiGraph accelerometer[42] Data obtained include average daily activity counts, average expended energy (kcal/kg/day, Estimated Energy Expenditure [EEE]), and average activity intensity (kcal/day) • One question on the Follow-up Data Collection Survey: How many days per week do you exercise (e.g., walking)?	T-test
Attending the scheduled appointment	One question on the Follow-up Data Collection Survey: In the last month, did you go to the scheduled follow-up appointment with your primary care provider (or heart doctor) after dismissal from the hospital? Yes or No	Chi-square
Clinical Biomarkers	Serum BNP level: the whole blood specimen is collected and BNP Fragment (nt-proBNP 8–29) ELISA (Triage® BNP test, ALPCO Diagnostics, Inc. Salem, NH)	T-test
	Urine sodium (Na) and creatinine (Cr) level: the urine sample is used to determine the urine Na and Cr levels (http://www.questdiagnostics.com/testcenter/BUOrderInfo.action?tc=8514X&labCode=SJC)	T-test
OTHER FOLLOW-UP DATA COLLECTION SURVEY ITEMS (3, AND 6 MONTHS)		
Re-admission rate	• Follow-Up Data Collection Survey Tool (i.e, healthcare utilization, work status, current medications) • Medical records to validate healthcare utilization including readmission rates	KM analysis
INTERVENTION COMPONENT MEASURES (BASELINE, 3 MONTHS)		
Self-management Knowledge	Atlanta Heart Failure Knowledge Test (AHFKT-V2)[43]: 27-item multiple-choice questions to measure HF self-management knowledge. Total scores range from 0 to 27.	Repeated ANOVA (rANOVA)
Self-efficacy	Self-Efficacy for Heart Failure Self-management: Self-care of HF Index Section C, 6 items (questions 17–22). Scores are standardized to range from 0 to 100, with higher scores indicating higher self- efficacy.	rANOVA
Patient Activation	Patient Activation Measure (PAM)[26]: 13 items with a 5-point Likert response scale. The raw scores are summed and transformed to 0–100 metric (0 = lowest activation level, 100 = highest).	rANOVA
Self-management Strategies	Heart Failure self-management strategies: 29-item Revised Heart Failure Self-Care Behavior Scale (RSCB)[44] asks patients to rate how often they performed a behavior in the last few days: on a scale from 0=none of the time to 5=all of the time.	rANOVA

Kaplan-Meier method is used for survival analysis to estimate the difference of hospital readmission occurrence between groups.

Discussion

This study will examine the effectiveness of a rural theory based, advance practice nurse led, activation enhancing intervention on the self-management adherence in heart failure patients residing in rural areas. The findings of this study could fill the gap of knowledge in self-management research in rural heart failure populations.

The long-term goals of this research are to: 1) test this patient activation intervention in other rural patient populations with multiple chronic conditions; 2) develop a rural based patient activation conceptual framework to guide the design and implementation of interventions to promote life-long self-management adherence in rural and underserved communities; and 3) develop a point of care tool kit for heart failure patients to provide timely feedback about their performance in managing their chronic conditions.

Our expectation is to facilitate adherence to self-management behaviors in heart failure patients following discharge from rural hospitals and decrease complications and hospital readmissions, leading to the reduction of economic burden.

Author contributions

As the principle investigator (PI) of the study, Dr. Young contributed the essence part of this manuscript from study's conception and design; acquisition of data and preparation of the manuscript. Other authors contributed extensively to the work presented in this paper. Dr. Barnason, as co-PI, contributed to the development of conceptual framework, intervention protocol, outcomes and their instrument selection, manuscript revisions, as well as other essential part of manuscript preparation. Dr. Do contributed in analysis of data, literature search, citation and reference editing, table and figure editing.

Competing interests

No competing interests were disclosed.

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Ethical approvals

The study protocol was approved by the Institutional Review Board at the University of Nebraska Medical Center. The written informed consent was obtained from all study participants prior to enrollment. In analyzing data and reporting, all participants will be anonymized.

Registration number and name of trial registry

Clinical Trial Registration Information: ClinicalTrials.gov; https://register.clinicaltrials.gov/ NCT01964053

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Referee Report 18 March 2015

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Kevin T. Fuji
Center for Health Services Research and Patient Safety, Creighton University, Omaha, NE, USA

This is a well-written and well thought-out protocol for an exploratory (or pilot) approach to the use of the PATCH intervention in critical access hospitals. There are just a few additional points of clarification that would further strengthen the paper.

During Phase II (post-discharge phone education sessions), what happens if patients cannot be reached? How many attempts are made to reach each patient? At what point of non-contact is the patient excluded from the study?

The authors might consider adding a third column to Table 1 – “Data Analysis” which could describe the data analysis procedures used to analyze each variable.

In Figure 1, where is the description for “Level 2 Building Knowledge, Skills & Confidence” that matches the other Levels in the figure?

I have read this submission. I believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Competing Interests: No competing interests were disclosed.

Author Response 27 Apr 2015

Lufei Young, University of Nebraska Medical Center, USA

"During Phase II (post-discharge phone education sessions), what happens if patients cannot be reached? How many attempts are made to reach each patient? At what point of non-contact is the patient excluded from the study?"

Author Response: During Phase II, we tried to reach patients 3 times. If we fail to reach patients after 3 attempts, the patient will be excluded from the study. Fortunately, we haven’t had to exclude any patient during Phase II

"The authors might consider adding a third column to Table 1 – “Data Analysis” which could describe the data analysis procedures used to analyze each variable."

Author Response: Author added analysis procedures will be used for each variable as suggested.

"In Figure 1, where is the description for "Level 2 Building Knowledge, Skills & Confidence" that matches the other Levels in the figure?"

Author Response: We added the description for level 2 of patient activity level in the figure.

Competing Interests: None

Referee Report 28 January 2015

doi:10.5256/f1000research.6416.r7154

Huo Yong
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This manuscript by Young *et al.* does an excellent job aiming to propose an intervention and evaluation of it for self-management among heart failure patients discharged from rural hospitals. With the prevalence of heart failure, self-management of patients plays a critical role in their improvement of quality of life, relief of exacerbation of symptoms and readmission to hospitals. Patients discharged from rural hospitals especially need education and guidance to improve adherence. The authors tried to solve this needs and described in detail the innovative intervention of a 12-week patient activation (Patient AcTivated Care at Home [PATCH]). And this paper is well-organized in clarifying the rational and design of the study to evaluate feasibility and efficacy of PATCH. Moreover, the authors showed us a vision of implementation of this intervention.

The genesis of this study based on solid nursing and patients' activation theories. And a prospective, two-group, randomized experimental design with three data collection points (baseline, 3 months and 6 months) were chosen to assess the feasibility and efficacy of the intervention. Sample size was carefully estimated. Also, different measures on biomarkers, outcomes and self-management were designed. In order to prevent the possible cognitive or psychotic confounding factors, simple screening tests were required to conduct prior to enrollment. The article was well constructed, the study was well designed, and interpretation was prudent.

However, there are some comments and suggestions for authors to consider. First, is it practical for a rural heart failure patient to complete so many questions on measurements of self-management knowledge, self-efficacy, patients' activity and strategies at one visit? Suggest simplified measurable scales. Second, for measurements of adherence of self-management, only data at 3 months were collected. Will it help to analyze extended effects of the intervention by record data at 6 months?

Finally, this work is a good reminder for all the cardiologists to pay more attention to the management and education of heart failure patients. The novel intervention of PATCH might acts as an example to help more and more heart failure patients.

I have read this submission. I believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Competing Interests: No competing interests were disclosed.

Author Response 27 Apr 2015

Lufei Young, University of Nebraska Medical Center, USA

"First, is it practical for a rural heart failure patient to complete so many questions on measurements of self-management knowledge, self-efficacy, patients' activity and strategies at one visit? Suggest simplified measurable scales."

Author Response: We greatly appreciate your suggestion and will use objective measures for activity level, adherence and knowledge in the larger scale study.

"Second, for measurements of adherence of self-management, only data at 3 months were collected. Will it help to analyze extended effects of the intervention by record data at 6 months?"

Author Response: This is a feasibility study aimed to examine the magnitude of intervention on variable of interest. To determine the mechanism of intervention, the group comparison was made at 3 months when the 12-week intervention was just completed so the maximal differences would be expected between intervention and control groups in self-management knowledge, self-efficacy for self-management, patient activation, and self-management strategies. Another reason to assess 3-month only is to reduce subject burden. The population studied is characterized as elderly living with heart failure and other debilitating chronic conditions. Fatigue and functioning declination are primary symptoms in this population.

"Finally, this work is a good reminder for all the cardiologists to pay more attention to the management and education of heart failure patients. The novel intervention of PATCH might acts as an example to help more and more heart failure patients."

Author Response: We really appreciate your recognition of the practice implication of this study. Thank you so much.

Competing Interests: None

Referee Report 19 January 2015

doi:10.5256/f1000research.6416.r7376

Pascale Salameh
Faculty of Public Health, Section II, Lebanese University, Beirut, Lebanon

This is an excellent work, well justified and adequately addressed. However, some points should be met:

Study design: References are needed for interventions. More details are particularly needed for the

major PATCH intervention.

Figure 2: Why not add the number of patients for each step, since the study is already over?

Statistical analysis: Why adjust over baseline value of the measure in question only? Adjustment over other baseline variables may also be needed in case randomization did not succeed to equilibrate them. For readmission, we think that Cox regression model would be more adequate than KM analysis.

One more point: In several locations in the manuscript, the authors say it is an exploratory work. Why? What is lacking?

I have read this submission. I believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Competing Interests: No competing interests were disclosed.

Author Response 27 Apr 2015

Lufei Young, University of Nebraska Medical Center, USA

"Study design: References are needed for interventions. More details are particularly needed for the major PATCH intervention."

Author Response: Thank you for your suggestion. We added the reference and more detail for our intervention.

"Figure 2: Why not add the number of patients for each step, since the study is already over?"

Author Response: Our study is still collecting data for 3 months and 6 months so we haven't gotten the data for these steps yet. Moreover, given that our manuscript is a research protocol, we think the data result is not mandatory

"Statistical analysis: Why adjust over baseline value of the measure in question only? Adjustment over other baseline variables may also be needed in case randomization did not succeed to equilibrate them. For readmission, we think that Cox regression model would be more adequate than KM analysis."

Author Response: Thank you for valuable comment. We will adjust all relevant baseline variables in case randomization did not succeed to attenuate the differences between groups. The aim of the study is to examine the effects of 12-week patient activation enhancing intervention on self-management adherence. Identifying the potential predictors of readmission and assessing how intervention affecting the identified predictors of readmission are not the main aim of the study, which was not designed to examine predictors of readmission. Therefore, Kaplan-Meier method is preferred due to its simplicity. In the future manuscript, we may use Cox regression model with multiple predictors for readmission if our survival analysis need to adjust for the other risk factors.

"One more point: In several locations in the manuscript, the authors say it is an exploratory work. Why? What is lacking?"

Author Response: The purpose of this study is to evaluate the feasibility of the PATCH intervention and gather initial data to support a larger investigation. But in order to avoid misunderstanding, the author will remove the word, “exploratory" as suggested.

Competing Interests: No competing interests were disclosed.