



Published in final edited form as:

*Appl Nurs Res.* 2015 May ; 28(2): 156–162. doi:10.1016/j.apnr.2014.09.006.

## Process evaluation of an exercise counseling intervention using motivational interviewing

Margaret M. McCarthy, RN, PhD<sup>a,\*</sup>, Victoria Vaughan Dickson, PhD<sup>b,1</sup>, Stuart D. Katz, MD<sup>c,2</sup>, Kathleen Sciacca, MA<sup>d</sup>, and Deborah A. Chyun, RN, PhD<sup>b,3</sup>

<sup>a</sup>Yale School of Nursing, Orange, CT 06477, USA

<sup>b</sup>New York University College of Nursing, 726 Broadway # 1085, New York, NY 10003, USA

<sup>c</sup>New York University Langone Medical Center, 530 First Avenue, New York, NY 10016, USA

<sup>d</sup>Sciacca Comprehensive Service Development for Mental Illness, Drug Addiction and Alcoholism, New York, NY 10025, USA

### Abstract

**Aim**—To describe the results of the process evaluation of an exercise counseling intervention using motivational interviewing (MI).

**Background**—Exercise can safely be incorporated into heart failure self-care, but many lack access to cardiac rehabilitation. One alternative is to provide exercise counseling in the clinical setting.

**Methods**—This process evaluation was conducted according to previously established guidelines for health promotion programs. This includes an assessment of recruitment and retention, implementation, and reach.

**Results**—Desired number of subjects were recruited, but 25% dropped out during study. Good fidelity to the intervention was achieved; the use of MI was evaluated with improvement in adherence over time. Dose included initial session plus 12 weekly phone calls. Subjects varied in participation of daily diary usage. Setting was conducive to recruitment and data collection.

**Conclusions**—Evaluating the process of an intervention provides valuable feedback on content, delivery and fidelity.

### Keywords

Exercise; Heart failure; Counseling; Program evaluation

© 2014 Elsevier Inc. All rights reserved.

\*Corresponding author at: Yale School of Nursing, 400 West Campus Drive, Orange, CT. 06516. Fax: + 203 737 2685.

margaret.mccarthy@yale.edu (M.M. McCarthy).

<sup>1</sup>Tel.: + 1 212 992 9426.

<sup>2</sup>Tel.: + 1 212 263 7751.

<sup>3</sup>Tel.: + 1 212 998 5264.

Author contributions:

*Study concept and design:* Drs. McCarthy, Dickson, Katz, Chyun. *Recruitment of patients, acquisition of data:* Dr. McCarthy. *Analysis and interpretation of data:* Drs. McCarthy, Chyun. *Drafting of the manuscript:* Dr. McCarthy. *Critical revision of the manuscript for important intellectual content:* Drs. McCarthy, Dickson, Katz, Chyun, Ms. Sciacca.

## 1. Introduction

Heart failure (HF) affects over five million adults in the United States (Go et al., 2014) and exercise intolerance is a primary symptom (Pina et al., 2003). Exercise can safely be included in the self-care regimen for patients with stable HF and improve their clinical status (Hunt, 2005). Given the many barriers to attending a formal structured exercise program like cardiac rehabilitation, including referral and cost (Shanmugasegaram, Oh, Reid, McCumber, & Grace, 2013), it has been challenging for clinicians to assist patients in achieving recommended exercise goals. One option to improve exercise habits may be for clinicians to provide routine exercise counseling during medical appointments. In fact, one of the goals of Healthy People 2020 is to increase the proportion of medical office visits that include counseling or education about exercise with patients diagnosed with heart disease, diabetes or hyperlipidemia (Centers for Disease Control and Prevention (CDC), 2013). Thus, a pilot study of an exercise counseling intervention attempted to fill that gap (McCarthy, Dickson, Katz, & Chyun, 2013).

Traditionally, most of the focus of an intervention study is on the outcome measures, examining efficacy, which is how well the intervention performs under ideal conditions (Singal, Higgins, & Waljee, 2014). But an important aspect of nursing intervention research is to clearly define the content and process of implementation so the intervention and results can be more fully evaluated. Unfortunately, these types of data are not often available from nursing interventions (Whittemore & Grey, 2002). A process evaluation documents how a program or intervention is executed and helps our understanding of the relationship between the elements of a program or intervention and its outcomes (Saunders, Evans, & Joshi, 2005). Process evaluations can lead to a rich description of a program's organization, procedures, personnel, and target audience (Devaney & Rossi, 1997) that guides future intervention development and evaluation. Therefore, the purpose of this paper is to describe the results of the process evaluation of an exercise counseling intervention using motivational interviewing (MI) in an ethnic minority sample with HF. Specifically, this paper will describe the intervention, and the following aspects of a process evaluation: 1) the recruitment and retention; 2) the implementation of the intervention according to protocol, which includes fidelity, dose, and context; and 3) reach of the intervention to the targeted population.

## 2. Methods

This paper reports on the process evaluation of a pilot study (McCarthy et al., 2013) of an exercise counseling intervention for adults with HF (n = 20). This intervention consisted of three parts: an initial exercise counseling session; 12 weeks of telephone follow-up; and participation in a daily diary for self-monitoring. For this pilot study (a pretest-posttest design), ethnic minority adults (age 18–65) with stable HF who met inclusion criteria (stable New York Heart Association class I, II or III; age 18–65 years; diagnosed with systolic HF (EF <40%) for at least 3 months (Cameron, Worrall-Carter, Page, & Stewart, 2010); able to perform exercise; English speaking; and cleared by HF provider to participate) were invited to participate. A Mini Mental Status Exam (Folstein, Folstein, & McHugh, 1975) score of

24 was required to participate. Exclusion criteria, chosen to assure participants were medically stable and safe to exercise were: cardiac event within previous three months; severe psychiatric disorders and cognitive impairment; pulmonary disease, unstable arrhythmias or valvular disease; planned surgery in next three months; and inability to exercise. Current participant in structured exercise program was also an exclusion.

Recruitment and data collection for the pilot study took place in a HF clinic within a large urban hospital. The appropriate institutional and clinical IRB approvals were obtained and all participants provided written informed consent before participation. Research data were collected at time of enrollment and 12 weeks later after completion of the initial exercise counseling intervention using established measures of physical activity, functional status, mood, quality of life, self-care, and vascular function.

The process evaluation of the pilot study was based on previously defined guidelines for health promotion programs using mixed methods (Saunders et al., 2005). This included the data collection and analysis of the recruitment and retention, implementation (fidelity, dose, context), and reach to the target population. Table 1 lists the components of the process evaluation, method of evaluation, and results.

## 2.1. Data collection and analysis

**2.1.1. Recruitment and retention**—An evaluation of the procedures used to approach participants, and maintain them in the study, including the number of individuals screened and excluded, the number enrolled, and the number lost to follow-up.

**2.1.2. Implementation**—Implementation was evaluated by examining fidelity to the intervention, the dose, the context of intervention delivery, and adverse events. Evaluation of the fidelity to the intervention (how closely it was implemented as designed) focused primarily on the incorporation of MI principles into the counseling sessions. All 20 exercise counseling sessions conducted at the beginning of the study were audiotaped. During the recruitment phase, four audiotapes (20%) were sent to an independent expert in MI for review and assessment of the interventionist's use of MI. Specifically, each tape was scored for adherence to the principles of MI. Summary scores for each of the four audiotapes included five categories: (1) average of spirit global (use of evocation, collaboration, autonomy/support, direction, and empathy); (2) reflection to question ratio; (3) percent open questions; (4) percent complex reflections; and (5) percent MI-adherent (Moyers, Martin, Manuel, Miller, & Ernst, 2010). The independent expert in MI scored each session.

Evaluation of the dose of the intervention that was delivered consisted of examining the quantity or amount of intervention delivered to participants. This consisted of three components: the exercise counseling session, telephone follow-up, and use of the daily diary. Participation in each component was calculated. Engagement with the daily diary was tallied for each of four activities: daily step-counts, body weight, use of the hand weights, and the Borg scale. The total number of actual recorded data for each activity was divided by the number of potential diary recordings (15 participants  $\times$  84 days = 1260). This resulted in the percent adherence in each activity. The context of intervention delivery was evaluated by exploring aspects of the environment that could influence the intervention or intervention

delivery. This included the physical and social aspects of the environment and the situational issues that could affect delivery of the intervention or its outcomes. Lastly, any adverse events experienced by participants were recorded.

**2.1.3. Reach**—This assessed the percent of the target population screened that was able to participate, the ability to recruit the desired sample from the target population, and included documenting barriers to participation.

Process data on the implementation of an intervention can be both formative (feedback that helps to keep the program on track) and summative (data on how well the program was implemented)(Saunders et al., 2005). Elements of this process evaluation were established a priori and were evaluated in a summative fashion upon completion of the study. However, the use of MI in the exercise counseling intervention was evaluated during the study period to allow for formative evaluation.

## 2.2. Description of the exercise counseling intervention

The exercise counseling intervention involved brief face-to-face exercise counseling followed by 12 weeks of weekly telephone follow-up and the use of a daily diary for self-monitoring. The principles of MI were incorporated into both the initial exercise counseling session and the telephone follow-up. MI is an evidenced-based approach to assist individuals with behavior change. Miller and Rollnick (2002) identify three components that are essential to the spirit of MI. The first is the collaborative nature of the relationship between counselor and client. The second is the process of evocation, of eliciting or drawing out the client's intrinsic motivation. Lastly, there is respect for the client's autonomy; the client is responsible for the behavior change. Research supports that brief interventions using MI can lead to significant change (W. R. Miller & Rollnick, 2002). Although MI was initially used in the field of addiction, it has been used to promote different types of behavioral change, including physical activity (Cushing, Jensen, Miller, & Leffingwell, 2014).

During the initial counseling session, past exercise experience, future goals, and safety tips on exercising with HF were discussed. For example, participants were asked if they had ever exercised before, and what they might like to be able to do now. They were also asked, "Tell me what you know about exercising safely", which was then supplemented with a one-page sheet on safe exercising tips. At this initial session, participants were instructed on use of the Borg scale of perceived exertion (Borg, 1990) and were counseled to exercise at a moderate effort level. Participants were given an accelerometer to keep track of step-counts, 2-pound hand weights with instructions for upper body exercises, and a diary to record the four self-care activities. This initial counseling session was audiotaped to assess fidelity to the intervention and use of MI.

Participants were contacted weekly by telephone. The calls included a review of symptom management if needed, and barriers to exercise (exercising in the heat for example). Participants were encouraged to keep track of symptoms (like shortness of breath or fatigue) and how they responded to them. Strategies for increasing activity were also discussed. An increased step-count goal for the next week was provided if the participant was willing. The telephone calls followed the same script each week, reflecting the process of MI. The

principles of MI, including the components of collaboration, evocations and autonomy discussed earlier, continued during the telephone contact. For example, this included engaging the subject (“Tell me how things are going”), collaborative agenda setting (How do you feel about increasing your steps for next week?), evoking change talk (“Tell me how you feel about the walking you’re doing”) and summarizing the discussion (“So this week you accomplished your step goal without having any symptoms and you’ll aim to increase your steps by 600 steps per day next week. Anything else?”).

### 3. Results

#### 3.1. Assessment of recruitment and retention

Over a six-month period, the principal investigator screened 172 patients for a sample of 20 participants. The remainder (n = 144) were excluded or declined to participate (n = 8). Some of the reasons for exclusion were medical instability (n = 15), non-English speaking (n = 26), and age >65 years (n = 53). The targeted population was a sample of low-income ethnic minority adults with heart HF. Participants were recruited at the HF clinic (n = 16) where they were receiving care, or from previous research studies conducted at the site (n = 4). Flyers describing the study were distributed to potential participants at the clinic who did not want to consent immediately, but no patients contacted the principal investigator at a later time to participate in the study.

Twenty ethnic minority adults consented to participate in the exercise counseling study and to the optional outcome measure of flow-mediated dilation. Over the 12 weeks, 5 participants were lost to follow-up or withdrew consent for further participation. Three participants were unable to be contacted immediately after enrollment in week one; the remaining two were lost to follow-up during the study.

When the participants who completed the study were compared to those who did not complete the study on demographic, behavioral, and psychosocial outcomes, the only significant differences between the two groups were related to physical activity at baseline. Those who completed the study had significantly higher baseline metabolic-minutes per week (MMW) scores, compared to those who did not complete the study, on the International Physical Activity Questionnaire total physical activity score ( $2123 \pm 2472$  MMW vs.  $250 \pm 186$  MMW;  $p=.01$ ), moderate physical activity score ( $376 \pm 500$  MMW vs.  $12 \pm 27$  MMW;  $p = .01$ ) and walking score ( $1112 \pm 903$  MMW vs.  $238 \pm 181$  MMW;  $p = .003$ ).

#### 3.2. Assessment of implementation (fidelity, dose, context)

**3.2.1. Fidelity**—Consistent with the tenets of process evaluation, fidelity to the planned intervention was evaluated. As planned, all (n = 20) exercise counseling sessions conducted at the beginning of the intervention were audiotaped. Adherence to a semi-scripted exercise counseling guide assured all essential components of the exercise counseling were implemented with 100% adherence to the protocol.

Prior to study implementation, the principal investigator participated in a 3-day course in MI “Preparing People for Behavior Change: Theory and Skill Building Training Seminar”.

Following the course, the MI instructor reviewed the initial exercise counseling guide and modifications for consistency with MI were integrated into the final version. Table 2 provides a summary of the evaluation of the use of MI in the four scored exercise counseling sessions. The first two rows detail what scores are needed to achieve beginning MI proficiency and MI competency. The actual scores for each of the five categories in each of the four exercise counseling sessions are also listed.

Briefly, scoring of the tapes from subject #3 and #4 that were sent at the same time for review revealed an overall low adherence to MI principles (50% and 40%). According to the independent scorer, a level of 90% reflects beginning proficiency. In this early assessment of fidelity, the percentage of open questions, an essential element of MI, was 40% and 25%, less than beginning proficiency. Reflective listening, a process used in MI, is checking what the speaker means (Miller & Rollnick, 2002). These reflections should be more complex in nature (for example, making a guess about unspoken meaning) than simple (for example, repeating what the speaker states in similar terms). The early tapes revealed a deficiency in the percentage of complex reflections (vs. simple). The reflections-to-questions ratio is also suboptimal in tapes #3 and #4 (less than 1:1 which is considered beginning MI proficient). Lastly, a global spirit clinician rating is given as part of the process evaluation and in these early tapes this rating was also poor (2.3 and 2.7). This rating revealed a lack of beginner proficiency in the use of MI. An average rating of 3.5 is considered beginning MI proficiency. Table 2 also shows results of independent scoring of the follow up exercise counseling sessions #16 and #20, which showed mixed improvement. For example adherence to MI improved to 80–100%, but the other ratings are not all consistently higher. Based on the feedback from these formative evaluations, the exercise counseling guide was revised. This iterative process resulted in four revisions of the exercise counseling guide over the course of recruitment to improve questioning techniques and communication; however no revisions were made to the components of exercise counseling intervention.

**3.2.2. Dose**—The dose delivered of this intervention included both the initial counseling session, the telephone follow-up, and the use of the daily diary. The initial session, including data collection and the counseling session lasted approximately one hour. The mean time of the counseling session itself was  $12.57 \pm 4.84$  minutes with a range of 7.12–23.33 minutes. As previously mentioned, this session included a review of previous exercise, current exercise goals, and safety tips for exercise.

Participants were required to have some method of telephone contact and most were contacted by cell phone. Out of 180 scheduled calls (15 participants  $\times$  12 weeks), 168 calls (93%) were made successfully and step-count data were collected. Despite leaving messages, the remaining 7% of calls did not result in contact with the participant for that week. The length of each call was not timed but relatively brief, lasting approximately 5 minutes. Every subject who completed the study had to be called back at least one time. The mean number of calls over 12 weeks for each subject was  $16.3 \pm 2.9$ , with a range between 13 and 23 calls.

The rate of participation with the daily diary varied by the activity recorded. Participants recorded step-counts 64% of days and body weight 52% of days. The Borg scale was

recorded 50% of days and the use of hand weights was recorded 32% of days. These data reflect compliance with the diary recordings, not necessarily what was actually done for that day.

No adverse events occurred as a result of increasing levels of physical activity. However, four participants required hospitalization during study unrelated to the intervention.

**3.2.3. Context**—Recruitment took place in the HF clinic. Data collection and the exercise counseling intervention took place in a room on the Clinical and Translational Science Institute (CTSI) research unit in the hospital. This facilitated the study since it provided privacy and the time needed for the exercise counseling and data collection without interruptions. It was also the site for the collection of vascular measure of flow-mediated dilation, which required a bed in a quiet room.

The providers in the HF clinic were receptive to identifying and referring appropriate patients for the study, which aided in subject recruitment. The CTSI staff (nurses, technicians, and clerical) fully cooperated with the investigator during data collection.

### 3.3. Assessment of reach

During recruitment, 172 adults were screened for participation and the desired sample of 20 adults in the target population of low-income ethnic minority adults with HF was recruited for the intervention. This resulted in a diverse sample of adults (60% male) from a variety of racial and ethnic backgrounds (Black, Hispanic, Mixed), who were from 10 different countries (US, Philippines, Puerto Rico, Antigua, Guyana, Grenada, Senegal, West Indies, Tobago, and Trinidad). Most (90%) were unemployed and the majority (75%) had Medicaid insurance.

## 4. Discussion

This process evaluation yields valuable information about the implementation of an exercise counseling intervention initiated during routine care at a HF clinic, which continued for 12 weeks with brief telephone contact. This evaluation shows evidence of the ability to reach the target sample of low-income ethnic minority adults with HF. The strict inclusion and exclusion criteria (designed for maximum safety of the participants in an exercise intervention in patients with HF) resulted in a large number of patients being screened and excluded. However, there was high participation in the intervention with adults who met the inclusion criteria. Future research will need to determine optimal exercise interventions for older adults with HF. This may include supervised exercise programs that provide closer monitoring and explicit guidance.

It cannot be assumed that any intervention is delivered exactly according to the protocol established. Some variability in the delivery of intervention is inherent. But there is strong evidence that the level of implementation affects outcomes (Durlak & DuPre, 2008). Evaluating the implementation processes of an intervention can help determine aspects of the protocol that may need to be revised or developed further in future testing.

The initial exercise counseling session was implemented with 100% adherence to the components of the exercise counseling protocol. One of the essential elements of this intervention was the use of MI. The American Heart Association has endorsed MI as an approach to behavior changes such as physical activity, recognizing that training of the interventionist is essential (Artinian et al., 2010).

In this study, the scoring reflects moderate fidelity to MI. The scoring also demonstrates that skills in MI may not be permanent, and frequent review may be needed to maintain efficiency. Miller and Rollnick (2014) recommend routine recording of sessions during a study to report actual fidelity, with timely remedial feedback (Miller & Rollnick, 2014). Additionally, since this was a brief intervention, there may not have been sufficient time to endorse all the principles of MI in each encounter.

MI training for health professionals generally takes the form of workshops, lasting 1–3 days (Soderlund, Madson, Rubak, & Nilsen, 2011). However, in a systematic review of MI training for health care practitioners, training varied from 20 minutes to 24 hours, with a median length of 9 hours (Soderlund et al., 2011). The shorter training may not allow for adequate practice with feedback, which is key to acquiring the necessary skills (Miller & Rollnick, 2014). The interventionist in this study attended a 3-day workshop, with feedback from the four scored counseling sessions.

The current study evaluated the use of MI over a 12-week intervention, with no long-term follow-up. However, MI has led to long-term changes in walking behavior 12 months after a counseling intervention in adults with at least one risk factor for cardiovascular disease (Hardcastle, Taylor, Bailey, Harley, & Hagger, 2013). The interventionists were given 8 hours of training in MI, with three sessions audiotaped to provide discussion and feedback from the trainer. The clear description of the training, and the analysis of the use of MI, allowed for fuller interpretation of the results in light of the MI intervention.

Another study documented the process evaluation of a program to increase physical activity in 6th and 7th grades boys utilizing MI (Robbins, Pfeiffer, Wesolek, & Lo, 2014). Two independent coders evaluated the use of MI and found the nurse achieved at least beginning proficiency on most tasks associated with MI. In the current study, only one expert coded the exercise counseling sessions and the lack of the second reviewer may reduce the reliability of the results. In both studies, however, the use of MI was clearly defined.

A recent systematic review of 10 trials examined the use of MI in improving physical activity, cardiorespiratory fitness, and functional exercise capacity (O'Halloran et al., 2014). Results indicated a small but significant effect of MI on physical activity, but not on cardiorespiratory fitness or functional exercise capacity. MI was most often delivered in a combination of face-to-face and telephone counseling. Although moderator analyses could not be calculated, there was a trend for higher effect sizes when the participation in the MI intervention was greater. Unfortunately, the majority of the physical activity trials reviewed did not confirm treatment fidelity, so it is unknown whether participants received the MI intervention according to protocol. This reinforces the need for process evaluations such as this one.



This study targeted an ethnic minority sample combining both face-to-face counseling with telephone follow-up. A systematic review of physical activity interventions examining the effect of modes of delivery and population subgroups found interventions using face-to-face counseling, as opposed to other modes of delivery (web-based or mail-mediated interventions for example) to be more effective in producing changes in physical activity (Bock, Jarczok, & Litaker, 2014). Additionally, the authors found that interventions targeting non-Caucasian samples also resulted in significantly positive changes in physical activity.

Compared with interventions that include only a single session, those that include regular follow-up are more effective in promoting lifestyle change, allowing trust to develop between provider and participant (Artinian et al., 2010). The telephone follow-up was a central component of this intervention. It was not known how this ethnic minority population would participate in a prolonged intervention where 12 weeks of telephone follow-up was required. Although 19 of 20 participants had a cell phone, some had limited minutes on their cell phone plan that might make contact challenging. The level of actual contact accounts for part of the dose of the intervention, which in turn has the potential to influence outcomes.

This study demonstrated high participation in the telephone follow-up in an ethnically diverse sample of adults. Previous interventions have used counseling and telephone follow-up to improve physical activity. The Active for Life “Active Choices” program was designed to increase physical activity in midlife and older adults through face-to-face counseling, followed by eight telephone calls over six months (Griffin et al., 2010). Participants received 5.4 calls, on average, and 31% of participants received all eight calls. The sites with the higher call completion rates and call duration tended to have higher physical activity effect sizes. Unfortunately, authors do not always report the number of calls completed in a telephone intervention. A systematic review of 25 studies of telephone delivered interventions to improve physical activity and dietary behavior found only about half of studies report the number of completed calls (Goode, Reeves, & Eakin, 2012), but there was evidence that the completion of a higher number of calls was associated with greater improvements in physical activity. This process evaluation adds to the literature by collecting data on telephone follow-up, including number of calls made and number of successfully completed calls.

In patients with HF, self-care is critical to improving outcomes and minimizing the burden of the disease, and there is evidence patients are willing to take on these self-care responsibilities (Clark et al., 2014). In this intervention, the use of the diary to record specific self-care behaviors had mixed results. The self-care activity that had the highest documentation was the daily step-counts. It is possible that wearing the accelerometer provided a daily reminder about recording activity, which was not present for the other self-care activities. In a previous study of home-based exercise, the use of a diary to record physical activity had lower adherence with only 44% of subjects having complete data (Dracup et al., 2007).

Use of a symptom diary to improve self-care was examined in a sample of adults with HF, assessing its effects on event-free survival and health-related quality of life (Lee, Lennie, Warden, Jacobs-Lawson, & Moser, 2013). Participants in the intervention arm received a symptom diary, self-care education and counseling, and follow-up telephone calls, while the control group received usual care. Those in the intervention group had a significantly longer period of event-free survival as compared to usual care, but there were no differences in health-related quality of life. In this study by Lee et al. (2013), the use of the diary, in conjunction with counseling and telephone follow-up, appears to have improved the participants' ability to monitor symptoms. This process evaluation documents the use of the daily diary, which varied depending on the activity, but may assist patients in self-monitoring.

The use of advanced technology may be one approach to improving self-monitoring. A recent meta-review on the use of text messaging to deliver self-management interventions found support for mobile phone text messaging as an effective strategy to deliver self-management interventions for individuals with chronic conditions (Jones, Lekhak, & Kaewluang, 2014).

#### 4.1. Limitations

One limitation of this process evaluation concerns the assessment of the audiotapes. The principal investigator did not send the first tapes to be evaluated (#3 and #4) immediately after the counseling sessions, which delayed feedback from the coder. Earlier feedback could have improved the use of MI in the subsequent exercise counseling sessions and may have affected the pilot study's results.

The duration of each follow-up telephone call was not recorded. Since the intervention dose delivered included these calls, the length of time of each call should have been recorded. Additionally, the use of MI in telephone follow-up was not evaluated. Although it is more difficult to assess, the use of telephone audio-recordings and following a prescribed MI telephone protocol would allow this aspect of the intervention to be evaluated.

## 5. Conclusion

Including plans for a process evaluation at the onset of an intervention study allows researchers to clearly define the essential elements of the intervention, and how they may be evaluated after completion. These process data will allow for the outcome measures to be viewed in light of the actual intervention delivered.

As a result of the process evaluation results in this study, a future intervention may consider expanding the use of technology to engage the subject in maintaining higher levels of physical activity. An accelerometer that yields more types of data (frequency and intensity) may be beneficial. Including MI text messaging in lieu of or in addition to telephone calls may be a potential intervention. Given the ubiquitous nature of smart phones in the general population, this may be one option. Smart phone applications that promote or monitor physical activity may also be included. Evaluating the use of MI during telephone follow-up would provide additional data on intervention fidelity. Tailoring the frequency of telephone

contact or text messages may be a possible option, based on the prior weeks activity counts for each subject.

The greatest challenge facing clinicians is assisting patients in behavior change to improve health. Identifying which components of an intervention resulted in significant behavior change may guide decision making in this important area of patient care. Process evaluations can provide these types of data.

## Acknowledgments

Supported in part by grant 1UL1RR029893 from the National Center for Research Resources, National Institutes of Health; the American Heart Association Student Research Scholarship in Cardiovascular Disease; the Zeta Omega Chapter of Sigma Theta Tau International Research Grant; and the Jonas Center for Nursing Excellence. The funding sources had no involvement in the study design, in the collection, analysis and interpretation of data, in the writing of the report or in the decision to submit the article for publication. The authors would like to acknowledge and thank Robin Whittemore, PhD APRN, FAAN for her editorial assistance.

## References

- Artinian NT, Fletcher GF, Mozaffarian D, Kris-Etherton P, Van Horn L, Lichtenstein AH, et al. Interventions to promote physical activity and dietary lifestyle changes for cardiovascular risk factor reduction in adults: A scientific statement from the American Heart Association. *Circulation*. 2010; 122(4):406–441. <http://dx.doi.org/10.1161/CIR.0b013e3181e8edf1>. [PubMed: 20625115]
- Bock C, Jarczok MN, Litaker D. Community-based efforts to promote physical activity: A systematic review of interventions considering mode of delivery, study quality and population subgroups. *Journal of Science and Medicine in Sport/Sports Medicine Australia*. 2014; 17(3):276–282. <http://dx.doi.org/10.1016/j.jsams.2013.04.009>. [PubMed: 23693030]
- Borg G. Psychophysical scaling with applications in physical work and the perception of exertion. *Scandinavian Journal of Work, Environment & Health*. 1990; 16(Suppl. 1):55–58.
- Cameron J, Worrall-Carter L, Page K, Stewart S. Self-care behaviours and heart failure: Does experience with symptoms really make a difference? *European Journal of Cardiovascular Nursing*. 2010; 9(2):92–100. <http://dx.doi.org/10.1016/j.ejcnurse.2009.10.004>. [PubMed: 20441991]
- Centers for Disease Control and Prevention (CDC). [Retrieved September 12, 2014] 2020 topics and objectives. physical activity. 2013. from. <http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicid=33>
- Clark AM, Spaling M, Harkness K, Spiers J, Strachan PH, Thompson DR, et al. Determinants of effective heart failure self-care: A systematic review of patients' and caregivers' perceptions. *Heart (British Cardiac Society)*. 2014; 100(9):716–721. <http://dx.doi.org/10.1136/heartjnl-2013-304852>. [PubMed: 24548920]
- Cushing CC, Jensen CD, Miller MB, Leffingwell TR. Meta-analysis of motivational interviewing for adolescent health behavior: Efficacy beyond substance use. *Journal of Consulting and Clinical Psychology*. 2014 <http://dx.doi.org/10.1037/a0036912>.
- Devaney B, Rossi P. Thinking through evaluation design options. *Children and Youth Services Review*. 1997; 19(7):587–606. [http://dx.doi.org/10.1016/S0190-7409\(97\)00047-9](http://dx.doi.org/10.1016/S0190-7409(97)00047-9).
- Dracup K, Evangelista LS, Hamilton MA, Erickson V, Hage A, Moriguchi J, et al. Effects of a home-based exercise program on clinical outcomes in heart failure. *American Heart Journal*. 2007; 154(5): 877–883. <http://dx.doi.org/10.1016/j.ahj.2007.07.019>. [PubMed: 17967593]
- Durlak J, DuPre E. Implementation matters: A review of research on the influence of implementation on program outcomes and the factors affecting implementation. *American Journal of Community Psychology*. 2008; 41(3–4):327–350. <http://dx.doi.org/10.1007/s10464-008-9165-0>. [PubMed: 18322790]
- Folstein MF, Folstein SE, McHugh PR. Mini-mental state. A practical method for grading the cognitive state of patients for the clinician. *Journal of Psychiatric Research*. 1975; 12(3):189–198. [PubMed: 1202204]

- Go A, Mozaffarian D, Roger V, Benjamin E, Berry J, Blaha M, et al. Executive summary: Heart disease and stroke statistics–2014 update: A report from the American Heart Association. *Circulation*. 2014; 129(3):399–410. <http://dx.doi.org/10.1161/01.cir.0000442015.53336.12>. [PubMed: 24446411]
- Goode AD, Reeves MM, Eakin EG. Telephone-delivered interventions for physical activity and dietary behavior change: An updated systematic review. *American Journal of Preventive Medicine*. 2012; 42(1):81–88. <http://dx.doi.org/10.1016/j.amepre.2011.08.025>. [PubMed: 22176852]
- Griffin SF, Wilcox S, Ory MG, Lattimore D, Leviton L, Castro C, et al. Results from the active for life process evaluation: Program delivery fidelity and adaptations. *Health Education Research*. 2010; 25(2):325–342. <http://dx.doi.org/10.1093/her/cyp017>. [PubMed: 19325031]
- Hardcastle SJ, Taylor AH, Bailey MP, Harley RA, Hagger MS. Effectiveness of a motivational interviewing intervention on weight loss, physical activity and cardiovascular disease risk factors: A randomised controlled trial with a 12-month post-intervention follow-up. *International Journal of Behavioral Nutrition and Physical Activity*. 2013; 10 <http://dx.doi.org/10.1186/1479-5868-10-40> (40-5868-10-40).
- Hunt S. ACC/AHA 2005 guideline update for the diagnosis and management of chronic heart failure in the adult: A report of the American College of Cardiology / American Heart Association task force on practice guidelines (writing committee to update the 2001 guidelines for the evaluation and management of heart failure). *Journal of the American College of Cardiology*. 2005; 46(6):e1–e82. [PubMed: 16168273]
- Jones KR, Lekhak N, Kaewluang N. Using mobile phones and short message service to deliver self-management interventions for chronic conditions: A meta-review. *Worldviews on Evidence-Based Nursing/Sigma Theta Tau International, Honor Society of Nursing*. 2014; 11(2):81–88. <http://dx.doi.org/10.1111/wvn.12030>.
- Lee KS, Lennie TA, Warden S, Jacobs-Lawson JM, Moser DK. A comprehensive symptom diary intervention to improve outcomes in patients with HF: A pilot study. *Journal of Cardiac Failure*. 2013; 19(9):647–654. <http://dx.doi.org/10.1016/j.cardfail.2013.07.001>. [PubMed: 24054342]
- McCarthy MM, Dickson VV, Katz SD, Chyun DA. Exercise counseling in low-income ethnic minority individuals with heart failure: A pilot study. *Circulation*. 2013; 128:A13347.
- Miller, WR.; Rollnick, S. *Preparing people for change*. 2nd ed.. New York: The Guilford Press; 2002. Motivational interviewing.
- Miller WR, Rollnick S. The effectiveness and ineffectiveness of complex behavioral interventions: Impact of treatment fidelity. *Contemporary Clinical Trials*. 2014; 37(2):234–241. <http://dx.doi.org/10.1016/j.cct.2014.01.005>. [PubMed: 24469237]
- Moyers TB, Martin T, Manuel JK, Miller WR, Ernst D. Revised global scales: Motivational interviewing treatment integrity 3.1.1 (MITI 3.1.1) University of Mexico Center on Alcoholism, Substance Abuse, and Addictions. 2010
- O'Halloran PD, Blackstock F, Shields N, Holland A, Iles R, Kingsley M, et al. Motivational interviewing to increase physical activity in people with chronic health conditions: A systematic review and meta-analysis. *Clinical Rehabilitation*. 2014 (Epub ahead of print).
- Pina IL, Apstein CS, Balady GJ, Belardinelli R, Chaitman BR, Duscha BD, et al. Exercise and heart failure: A statement from the American Heart Association committee on exercise, rehabilitation, and prevention. *Circulation*. 2003; 107(8):1210–1225. [PubMed: 12615804]
- Robbins LB, Pfeiffer KA, Wesolek SM, Lo YJ. Process evaluation for a school-based physical activity intervention for 6th- and 7th-grade boys: Reach, dose, and fidelity. *Evaluation and Program Planning*. 2014; 42:21–31. <http://dx.doi.org/10.1016/j.evalprogplan.2013.09.002>. [PubMed: 24121658]
- Saunders RP, Evans MH, Joshi P. Developing a process-evaluation plan for assessing health promotion program implementation: A how-to guide. *Health Promotion Practice*. 2005; 6(2):134–147. <http://dx.doi.org/10.1177/1524839904273387>. [PubMed: 15855283]
- Shanmugasagaram S, Oh P, Reid RD, McCumber T, Grace SL. Cardiac rehabilitation barriers by rurality and socioeconomic status: A cross-sectional study. *International Journal for Equity in Health*. 2013; 12 <http://dx.doi.org/10.1186/1475-9276-12-72> (72-9276-12-72).

- Singal AG, Higgins PD, Waljee AK. A primer on effectiveness and efficacy trials. *Clinical and Translational Gastroenterology*. 2014; 5:e45. <http://dx.doi.org/10.1038/ctg.2013.13>. [PubMed: 24384867]
- Soderlund LL, Madson MB, Rubak S, Nilsen P. A systematic review of motivational interviewing training for general health care practitioners. *Patient Education and Counseling*. 2011; 84(1):16–26. <http://dx.doi.org/10.1016/j.pec.2010.06.025>. [PubMed: 20667432]
- Whittemore R, Grey M. The systematic development of nursing interventions. *Journal of Nursing Scholarship*. 2002; 34(2):115–120. [PubMed: 12078534]

**Table 1**

Process evaluation plan and results.

Component of study	Method of evaluation	Results
Recruitment and retention		
Recruitment	<ul style="list-style-type: none"> <li>• Number approached</li> <li>• Duration of recruitment</li> <li>• Ability to obtain and retain desired number of subjects</li> <li>• Compare completers to non-completers</li> </ul>	<ul style="list-style-type: none"> <li>• Able to recruit 20 subjects of 172 approached</li> <li>• 6 months</li> <li>• Loss of 5 subjects during 12-week follow-up</li> <li>• Completers had significantly higher levels of total and moderate physical activity and walking</li> </ul>
Recruitment methods <ul style="list-style-type: none"> <li>• Onsite</li> <li>• Flyers</li> <li>• Previous research participants</li> </ul>	<ul style="list-style-type: none"> <li>• # of participants recruited via each method</li> <li>• Assess barriers to each method of recruitment</li> </ul>	<ul style="list-style-type: none"> <li>• Onsite (16); Flyers (0); Previous research (4)</li> <li>• No-show patients and high traffic in clinic impeded recruitment</li> </ul>
Implementation		
Fidelity		
Initial counseling session	<ul style="list-style-type: none"> <li>• Session fully audiotaped</li> <li>• Essential elements covered according to interview guide</li> <li>• Adherence to principals of MI as assessed by independent auditor familiar with MI techniques</li> </ul>	<ul style="list-style-type: none"> <li>• 100% audiotaped</li> <li>• All essential elements covered as planned</li> <li>• MI tapes reviewed (n = 4) during study period. Adherence to principles of MI was 40–50% in subject 4 and 5 and increased to 100% and 80% in subject 16 and 20.</li> </ul>
Weekly phone calls delivered	<ul style="list-style-type: none"> <li>• % of weekly calls successfully made/step counts obtained</li> </ul>	<ul style="list-style-type: none"> <li>• 168/180 calls with collected data (93% of calls successfully made/step data collected)</li> </ul>
Phone call assessment of adverse events as part of data safety monitoring plan	<ul style="list-style-type: none"> <li>• % of participants who have adverse events assessed</li> <li>• % of participants who report an adverse event (include type of event)</li> <li>• % of participants hospitalized</li> </ul>	<ul style="list-style-type: none"> <li>• Patients were assessed weekly for adverse events (except for missing phone contact: 7%)</li> <li>• No adverse events related to intervention occurred during study period.</li> <li>• 4 subjects required hospitalization during study: one for HF symptoms; one for a stroke; one for electrolyte imbalance; one for elective catheterization and post-catheterization arrhythmia.</li> </ul>
Phone call assessment of concerns or barriers related to exercise	<ul style="list-style-type: none"> <li>• % of calls that include assessment of exercise concerns or barriers to exercise</li> </ul>	<ul style="list-style-type: none"> <li>• 100% of calls with successful contact reviewed concerns/barriers. Subjects were able to identify symptoms and barriers which were discussed</li> </ul>
Dose		
Counseling Session	<ul style="list-style-type: none"> <li>• Duration of session (minutes)</li> </ul>	<ul style="list-style-type: none"> <li>• Mean duration of initial session = 1 hour; mean interview time: 12.57 ± 4.84 minutes</li> </ul>

Component of study	Method of evaluation	Results
Successful phone contact Phone call duration	<ul style="list-style-type: none"> <li>Percentage of calls that result with contact with participant</li> <li>Assess length of each call in minutes</li> </ul>	<ul style="list-style-type: none"> <li>93% phone call contact successful</li> <li>Approximate length of each call: 5 minutes</li> </ul>
Phone call content	<ul style="list-style-type: none"> <li>Notes taken during each call regarding content areas</li> </ul>	<ul style="list-style-type: none"> <li>Notes taken during each call: content focused on activity conducted in prior week; symptoms experienced; plan for following week to maintain or increase step count according to subjects' willingness; symptom management</li> </ul>
Adherence to daily diary <ul style="list-style-type: none"> <li>Step count</li> <li>Corresponding Borg scale</li> <li>Daily weight</li> <li>Use of hand weights</li> </ul>	<ul style="list-style-type: none"> <li>Assess % of days each component is documented for 15 subjects (of 84 days total)</li> </ul>	<ul style="list-style-type: none"> <li>Step count recorded: 801/1260 = 64% of days</li> <li>Borg scale: 628/1260 = 50% of days</li> <li>Daily weight: 651/1260 = 52% of days</li> <li>Hand weight use: 400/1260 = 32% of days</li> </ul>
Context		
Ability to conduct intervention at site during clinic hours	<ul style="list-style-type: none"> <li>Qualitative assessment of site, staffing, logistics</li> </ul>	<ul style="list-style-type: none"> <li>Use of CTSI research unit was essential in collecting data since private area was need for data collection and long hallway was required for functional capacity data</li> <li>Providers varied in their referral of potential subjects</li> <li>The majority of subject data was collected on the day of visit. Some subjects chose to return to clinic for data collection</li> </ul>
Reach		
Reach Participation rate	<ul style="list-style-type: none"> <li>Ability to recruit in target population</li> <li>% of patients who agreed to participate</li> <li>Collection of data regarding why subjects were excluded + age and gender collected</li> </ul>	<ul style="list-style-type: none"> <li>20 low-income ethnic minority adults with HF recruited</li> <li>Demonstrated ability to recruit in HF clinic</li> <li>n = 172 approached; n = 152 excluded per criteria or declined to participate</li> <li>Data collected on all patients approached but excluded; age and gender collected</li> </ul>

Note. CTSI = Clinical and Translational Science Institute; HF = heart failure; MI = motivational interviewing.

Author Manuscript

Author Manuscript

Author Manuscript

Author Manuscript

**Table 2**

Process evaluation of the use of motivational interviewing (MI).

	Length of interview (m:s)	Global spirit clinician rating	Reflection to question ratio	Percent open questions	Percent complex reflections	Percent MI-adherent
<i>Beginning MI proficiency</i>	— — —	<i>Average of 3.5</i>	<i>1:1</i>	50%	40%	90%
<i>MI competency</i>	— — —	<i>Average of 4</i>	<i>2:1</i>	70%	50%	100%
Interview #3	10:46	2.3	9:10* (0.9:1)	40%	44%	50%
Interview #4	8:56	2.7	5:12* (0.4:1)	25%	30%	40%
Interview #16	21:48	4.2	24:9* (2.7:1)	33%	54%	100%
Interview #20	23:14	3.7	21:9* (2.3:1)	89%	42%	80%

Note: (m:s) = minutes:seconds;

\* = actual behavior counts of reflections and questions.