Introduction

Generally, randomized controlled trials (RCTs) are considered to be the most rigorous method for determining cause and effect (Sibbald, 1998). Typically, they are prospective studies that compare the effects of at least 2 different interventions to determine if the intervention had a presumed effect, as well as the direction and size of such effect (Friedman, Furberg, & Demets, 1998). Interventions that are evaluated using an RCT design are standardized to control for bias and allow for replication. When appropriately designed, conducted, and reported, RCTs represent the gold standard for evaluating health care interventions (Schulz, Altman, & Moher, 2009). The conduct of RCTs is generally straightforward when they relate to interventions that contain a single component such as a drug. These types of interventions are easier to standardize by optimizing the dose of the drug and comparing it to a placebo. However, interventions that do not contain single components, such as individualized patient education programs, are much more difficult to standardize as they contain multiple components which may act independently or interdependently of each other (Conn, 2001; Seers, K, 2007; Whittemore & Grey, 2002).

The Medical Research Council (MRC) (2012) defines complex interventions as interventions that are "built up from a number of components" (p. 2). These components may include: practitioner behaviours (their expertise and skills; the guidelines or protocols they use to deliver an intervention; or the assessments they undertake), parameters of the behaviours (timing, dose, mode, and frequency of behaviours), and methods of organizing and delivering behaviours (number and type of individuals

involved in delivery, the type of technology required to deliver the intervention, and characteristics of the setting) (MRC, 2012).

Evaluating complex interventions using RCTs are challenging as their components (i.e. individualizing educational content to reflect individual learning needs) may be difficult to standardize. However, in recent years, a number of studies have examined complex interventions using RCT designs (Blackwood, 2006). Instead of replicating the components of the intervention, the function and process of the intervention delivery was standardized to allow for replication. It was reasoned that "the fixed aspects of the intervention are the essential functions, while the variable aspect is their form in different context" (MRC, 2012). Thus, in order to effectively evaluate a complex intervention, a clear description of the problem and understanding of how the intervention works (function) is needed (Blackwood; McMahon, 2002). The MRC presents a model to guide the development, evaluation and implementation of complex interventions in order to improve health (MRC). This model will be used to frame the presentation of a complex intervention developed for patients following coronary artery bypass graft and/or valve replacement surgery (CABG and/or VR) (Table 1). A brief description of the intervention of interest will first be presented.

Description of complex intervention

The intervention of interest is an individualized patient education program delivered to patients at 2 points in time, 24-48 hours and 2 weeks following hospital discharge for CABG and/or VR (Table 2). The primary outcome of interest is increase performance of self-care behaviours at 3 months following hospital discharge. The intervention has been developed and pilot tested. It consisted of an educational

component which was individualized to reflect the patient's perceived learning needs. The intervention was based on a comprehensive review of the literature regarding the patients' recovery and need for engagement in self-care, post-discharge following CABG and/or VR, as identified within the first three months of recovery. Topic areas addressed included: complications, activities, medication, symptom management and control, and psychological symptoms. The intervention was delivered by a trained research nurse prepared at the undergraduate level, via telephone. The delivery of the intervention was based on a protocol to maintain consistency in delivery. The research nurse received 2, intensive, 4 hour workshops in which cardiovascular surgical recovery content was presented, the technique for delivering the individualized patient education intervention was discussed, and the nurse was provided with the opportunity to engage in role playing with the principal investigator. The nurse researcher began the education session by introducing herself to the patient, followed by an assessment of the individual's learning needs. Patient learning needs were assessed using the Patient Learning Needs Scale (PLNS) (Galloway, Bubela, McCay, McKibbon, Ross, & Nagle, 1993). The PLNS is a self-report measure with a 6 point Likert scale, where responses range from 0 - not important to learn, to 5 - extremely important to learn. This tool was designed for use with surgical inpatients and outpatients. The topic areas identified on the PLNS are reflective of both CABG and VR patients' learning needs. Depending on the learning areas identified, the nurse used the education material to discuss the related self-care behaviours that the patient should perform to reduce the likelihood for the development of complication and hospital readmissions thus, enhancing their overall recovery experience. The educational material on self-care behaviours was derived from an

extensive and critical review of empirical evidence (Author, YYYX; Beckie, 1989; Harkness, Smith, Taraba, MacKenzie, Gunn, & Arthur, 2005; Hartford, Wong, & Zakaria, 2002; Roebuck, 1999).

Using the MRC model for developing and evaluating an individualized patient education intervention using a RCT design

Phase 1: Development of intervention

In preparing for the design of this intervention, a review of the literature was conducted to determine patients' home recovery experience 3 months post-hospital discharge (Author, YYXX). As well, a preliminary descriptive study was conducted to describe the type of patient education programs that were delivered to patients following CABG and/or VR (Author, YXXX). Findings from these studies suggested patients were inconsistently exposed to education based interventions during their home recovery. When education was provided, it was designed in one of two formats: standard versus individual. Standardized patient education consisted of empirically based education that is provided to all patients, while individualized patient education involved the same empirically based content, however instead of all of the material being presented to patients, only portions of the content is provided based on the individual's identified learning needs at a particular point in time. Findings suggest individualized patient education interventions were more effective in producing changes in outcomes (Beckie, 1989; Harkness, Smith, Taraba, MacKenzie, Gunn, Arthur, 2005). This result supports earlier findings that suggest patient education interventions designed to reflect an individual's learning needs, and are provided on at least 2 separate occasions, are

effective in producing changes behaviour performance, symptom experience, and overall rate of recovery (Author, YYYX).

The findings also indicate, approximately, 33% of patients experienced heart failure and/or complications within the first 3 months of recovery, with approximately 20 % being readmitted (Author, YXXX). To date, the effects of individualized patient education on complications and hospital readmission rates have not been evaluated. Findings from these studies support the need to design and evaluate the effectiveness of an individualized education based intervention, delivered at 2 points in time, to patients following hospital discharge for CABG and/or VR that addresses the development of complications.

Phase 2: Pilot/Feasibility Study

The second phase of the revised MRC Model encompasses the development of the optimum intervention and study design. Thus, the testing of the feasibility of delivering the intervention and acceptability to providers and patients was implemented. The purpose of the pilot study was to examine the quality, efficiency, and feasibility of a planned large scale randomized controlled trial design that will examine the effectiveness of an individualized telephone education intervention delivered to patients following CABG and/or VR during their home recovery.

Throughout the pilot, different versions of the intervention were tested to achieve optimal effectiveness. For example, a 40, 35, 30, 25, and 20 minute version of the intervention delivered at one (24-48 hours following hospital discharge) and two (at 1 week and 24-48 hours following hospital discharge; at 2 weeks and 24-48 hours following hospital discharge; at 3 weeks and 24-48 hours following hospital discharge)

points in time were evaluated. The various time periods in which to deliver the educational intervention were selected based on the findings from a systematic review that examined the effectiveness of cardiovascular patient education interventions (YYYX, 2009). This review indicated education delivered between 20-40 minutes was most effective in producing changes in outcomes. During the conduct of the pilot, our research team sought to identify the specific length of time that was most effective in decreasing complications and hospital readmission rates. The same version of the intervention was evaluated using the same technique as outlined above.

However, the length of time was altered to reflect the proposed intensity and duration of the intervention found to be acceptable to patients. Results indicated an acceptable length of time for the intervention to be delivered while achieving optimal effectiveness was 35 minutes.

As well, the evidence of a learning curve was assessed to determine the rate of learning that would lead to improved performance of the intervention over time. The learning curve was assessed through the use of a knowledge inventory designed for use with cardiovascular surgical patients (i.e. CABG and/or vascular repair patients) (McHugh Schuster, Wright, & Tomich, 1995). The Knowledge Inventory contains 15 items, which assessed the patient's knowledge of self-care strategies to manage post-operative CABG complications: incision and chest pain, nausea, vomiting, fatigue, sleep disturbance, constipation, and edema/water retention; as well as to take medications and perform usual activity. A multiple choice response format was used. The total score represented the number of correct responses to the items. A maximum total score of 15 indicates knowledge in all areas of self-care. This inventory has demonstrated acceptable

internal consistency reliability (Cronbach's alpha = .78) in this study. Results indicated learning occurred instantly, and a learning curve did not exist, thus, a run-in period was not needed before the formal recruitment to the trial. Health literacy relates to an individual's ability to read and understand health information (MRC, 2012). It was addressed by revising the intervention content to reflect patient's feedback related to ease of use and understanding; as well as ensuring the inclusion criteria stipulated only patients who were cognitively oriented to person, place, and time were included in the study.

The feasibility study also provided an opportunity to determine the consistency with which the intervention was delivered. The PI observed the research nurse deliver the intervention at multiple points in time. They then met to discuss the consistency with which the intervention was being delivered. Furthermore, this study provided the research team with the opportunity to monitor the standard of care that was being provided to the control group, as this care may be complex and may change over time. Standard of care consisted of a patient education booklet delivered at one point in time, during the hospitalization period. Patients are asked to review materials independently. Following hospital discharge, patients are encouraged to see their family physician during the first week of home recovery. They are also asked to see their cardiologist and heart surgeon, 3 and 6 weeks following hospital discharge, respectively. Approximately 28% of patients are referred to cardiac rehab. Results from the feasibility study indicate the standard of care remained consistent over time and involved a home recovery education brochure, provide to patients during their post-operative hospitalization. There was minimal

healthcare provider-patient interaction concerning this home recovery education brochure.

With regards to identifying threats to the effectiveness of the intervention, the participant's use of other resources to obtain information was monitored. In particular, five questions were mailed to patients at the end of the final data collection time period. These questions identified if patients received teaching other than the intervention during their recovery; the type of teaching that was received; and which education, the additional teaching, standardized teaching, or individualized telephone intervention they found to be useful. The responses to these questions were controlled for during data analysis. Results suggested the study participants found the individualized teaching intervention to be useful because of the opportunity it provided for them to speak directly to a nurse (Bosak, Pozehl, & Yates, 2012; Resnick, 2009).

Furthermore, findings from the feasibility study suggested on average 2 phone calls, lasting approximately 3 minutes, were required to contact patients during the home follow-up data collection period at all intervals. However, from mid-June to the end of July, the number of calls/time interval increased to 4. The majority of study participants indicated that they were either on holidays or out, resulting in an increase number of calls. In preparing for the main trial, additional time will be allocated for data collection during holidays (Easter, Christmas), long week-ends, and over the summer. As well, during the baseline data collection, study participants will be asked to identify whether or not they will be away during the times in which the data collection phone calls are scheduled.

In addition, the feasibility study was randomized to allow for testing procedures, estimate of recruitment and retention values, determining sample size, power of trial, resources, and commitment, identifying data collection strategies, testing components of the intervention, and documenting the process involved in the delivery of the individualized telephone education intervention and the conduct of the planned RCT. Based on the findings of the feasibility study, the script used to guide how the data were collected and the procedures used to deliver the intervention were revised to reflect common phrases and terms easily understood by patients. A recruitment rate of 95%, and retention rate of 85% were obtained, which was incorporated in the calculation of sample size for the main study. Resources in the form of research staff, supplies, and databases were estimated based on the conduct of the feasibility study. Data collection strategies, such as use of flow charts and checklists were created and are being used as a template for the management of the study in the main trial.

Finally, outcome measures for the main trial were piloted to demonstrate the change in complications and hospital readmission rates were in fact due to the intervention and not other variables. These measures included: A complications scale designed by the research team; a Revised Self-Care Behaviour Scale (RSCB) (Artinian, Magnan, Sloa, Lange, 2002), and an inventory to determine the number of times individuals accessed the health care system designed by the research team. Adequate content validity indices of.86 (complications scale), .79 (RSCB), and .8 (accessing health care resources) were obtained for each instrument; while internal consistency reliability coefficients of.80 (complications scale), .8 (RSCB), and .72 (accessing health care resources) were identified.

Outcome data were collected via self-report. T-test and ANCOVA analyses were used to determine effectiveness of intervention in producing outcomes of interest.

Phase 3: Evaluation

The definitive RCT is the next phase in the framework. Using the findings from the pilot/feasibility study a randomized controlled trial has been designed in which the primary research question is: does the rate of complications and hospital readmissions at 3 months following hospital discharge for CABG and/or VR equivalent in adults who receive an individualized telephone patient education intervention to those who receive standardized patient education intervention? A conventional, 2-arm parallel, prospective randomized, partially blinded, controlled trial will be used to determine the superiority of an individualized telephone intervention to usual patient education in decreasing the rate of complications and hospital readmissions, 3 months following hospital discharge for CABG and/or VR. Two hundred and seventy patients will be recruited from a university-affiliated hospital that has an active cardiovascular surgical program. Patients who are literate in English; cognitively oriented to person, place, and time; underwent their first coronary artery bypass graft and/or valve replacement; and have access to a working phone following hospital discharge will be considered for inclusion in this study. Individuals who underwent emergency or transplant procedures will not be considered for inclusion in this study. This study is presently in the final stages of its design, and it is anticipated will begin in the coming months.

Phase 4: Implementation

The final phase of the MRC Model is to establish the long-term and real-life effectiveness of the intervention. This phase would encompass assessments and surveys

following the implementation of the intervention into the clinical setting to determine the reason for effectiveness of the intervention (i.e. ease of use, adaptable to cardiovascular programs, or easily understood and valued by patients). The implementation phase of designing and managing interventions can only be performed following the definitive RCT.

Conclusion

In summary, the design of an individualized patient education intervention is being optimized so that it can be evaluated using an RCT design. The use of trained research assistants and research nurses, protocols for intervention delivery and data collection; and having a clear understanding of the key processes, outcomes, and mechanisms by which the patient education enhance self-care behaviour performance, while reducing complications and hospital readmission rates served to standardize some of the key processes associated with the intervention delivery. Furthermore, using an intervention that is empirically based and valid minimizes the fluidity associated with the process involved in delivering the patient education content. Finally, the intentions to conduct a pilot test that will mirror the larger RCT to determine potential difficulties; having clear inclusion and exclusion criteria; and including the best achievable combinations of the intervention into the design and delivery of the patient education intervention serves to further standardize the intervention, allowing for a certain degree of replication.

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