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Preparing for a Randomized Controlled Trial: Strategies to Optimize the Design of an Individualized Cardiovascular Surgical Patient Education Intervention

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ABSTRACT

Randomized controlled trial (RCT) designs are standardized to control for bias and allow for replication. Conducting RCTs is generally straightforward when dealing with interventions that contain a single component, such as a drug. However, interventions that do not contain single components, such as a patient education programs, are more difficult to standardize, as they contain multiple elements, which may act independently or interdependently of each other. The purpose of this discursive clinical methods paper is to describe and explain a methodology that can be used to optimize the design of a complex intervention prior to its evaluation in a randomized control trial.

1. 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, Rantz, Wipke-Tevis, & Maas, 2001; Seers, 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.

2. 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

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Table 1
Components of Intervention linked to MRC Model.

MRC Model	Components of Intervention
1) Development Phase:	
✔ Identifying the evidence base	✔ Systematic review preliminary study - to assess learning needs of individuals and type of education to provide
✔ Identifying/Developing theory	to patients during home recovery
✔ Modelling process and outcomes	✔ Post-operative patient education: A systematic review
2) Feasibility/Piloting	
✔ Testing procedures	✔ Pilot testing of intervention to determine the quality, efficiency, and feasibility of a planned large scale randomized
✔ Estimating recruitment/retention	controlled trial design that will examine the effectiveness of an individualized telephone education intervention
✔ Determining sample size	delivered to patients following CABG and/or VR during their home recovery
	❖ Testing procedures, estimate of recruitment and retention values, determining sample size, power of trial, resources, and commitment, identifying data collection strategies, test components and feasibility of the intervention, and to assess its acceptance in practice
	❖ Determine whether the intervention is delivered in a standardized fashion by all
	❖ To document the process involved in the delivery of the individualized telephone education intervention and the conduct of the RCT
3) Evaluation	
✔ Assessing effectiveness	✔ Definitive RCT to determine the effectiveness of an individualized telephone patient education intervention in reducing
✔ Understanding change process	complications and hospital readmissions at 3 months following hospital discharge for CABG and/or VR
✔ Assessing cost-effectiveness	
4) Implementation	
✔ Dissemination	✔ To determine the long-term and real-life effectiveness of the intervention
✔ Surveillance and monitoring	❖ Conduct observational studies to explain the observed success or failure for replication of the intervention and provide
✔ Long term follow-up	a realistic means of assessing the long-term outcome beyond the 3 months evaluated in the original RCT

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 3 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 et al., 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 et al., 2005; Hartford, Wong, & Zakaria, 2002; Roebuck, 1999).

Table 2
Individualized education delivery protocol.

Activity	Time
Confirm subject eligibility, recruitment, consent, randomization, baseline demographic data collection	24–48 hours following admission to CVS unit
First delivery of intervention	24–48 hours post-hospital discharge
First data collection	1 week post-hospital discharge
Second delivery of intervention	2 weeks post-hospital discharge
Second data collection	3 weeks post-hospital discharge
Third data collection	8 weeks post-hospital discharge
Fourth data collection	12 weeks post-hospital discharge

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

3.1. 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 that 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 that individualized patient education interventions were more effective in producing changes in outcomes (Beckie, 1989; Harkness et al., 2005). This result supports earlier findings that suggest that 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 in behaviour performance, symptom experience, and overall rate of recovery (Author, YYYX).

The findings also indicate that, 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