

Development of a Complex Intervention for Secondary Prevention of Coronary Heart Disease in Primary Care Using the UK Medical Research Council Framework

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Objective: To apply the UK Medical Research Council (MRC) framework for development and evaluation of trials of complex interventions to a primary healthcare intervention to promote secondary prevention of coronary heart disease.

Study Design: Case report of intervention development.

Methods: First, literature relating to secondary prevention and lifestyle change was reviewed. Second, a preliminary intervention was modeled, based on literature findings and focus group interviews with patients (n = 23) and staff (n = 29) from 4 general practices. Participants' experiences of and attitudes toward key intervention components were explored. Third, the preliminary intervention was pilot-tested in 4 general practices. After delivery of the pilot intervention, practitioners evaluated the training sessions, and qualitative data relating to experiences of the intervention were collected using semistructured interviews with staff (n = 10) and patient focus groups (n = 17).

Results: Literature review identified 3 intervention components: a structured recall system, practitioner training, and patient information. Initial qualitative data identified variations in recall system design, training requirements (medication prescribing, facilitating behavior change), and information appropriate to the prospective study participants. Identifying detailed structures within intervention components clarified how the intervention could be tailored to individual practice, practitioner, and patient needs while preserving the theoretical functions of the components. Findings from the pilot phase informed further modeling of the intervention, reducing administrative time, increasing practical content of training, and omitting unhelpful patient information.

Conclusion: Application of the MRC framework helped to determine the feasibility and development of a complex intervention for primary care research.

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As healthcare planners and providers work to promote efficient delivery of high-quality care, it is important that they have access to evidence provided by high-quality health services research. Within the provision of primary care, complex interventions are common: they contain separate, yet interconnected, elements or components, which may act both independently and interdependently.

Challenges arise in evaluating complex interventions through randomized controlled trials (RCTs). Complex interventions can be difficult to define, develop, docu-

ment, and reproduce; within the cocktail of components, the "active ingredient" can be elusive.

The UK Medical Research Council (MRC) published a framework for the development and evaluation of RCTs for complex interventions,¹ suggesting a phased approach that harnesses both quantitative and qualitative methodologies.² The steps include (1) exploring relevant theory, (2) modeling the preliminary intervention by selecting the main components based on the literature and qualitative research, (3) pilot-testing the preliminary intervention, (4) developing the definitive RCT, and (5) implementing and evaluating the RCT over the long term. Modeling is a key novel step within the process and refers to the development of an understanding of the intervention, its possible effects, and how its components might interact with each other and within the setting in which it is to be implemented.

Trials of complex interventions that fail to follow the MRC framework may suffer from poorly designed and inappropriately developed interventions, which may consequently fail to achieve their goals.^{3,4} There are few descriptions of the innovative methodological approach involved in applying the MRC framework in the health services literature.^{5,6}

The aim of this paper is to describe the development of a complex intervention to promote the delivery and uptake of secondary prevention of coronary heart disease (CHD) in primary care,⁷ using the first 3 steps of the MRC framework. The work reported here was done to inform the design of an intervention that is being tested currently in an RCT (see Box).

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The Secondary Prevention of Heart Disease in General Practice (SPHERE) Study⁷

- **Aims:** To design, implement, and test an intervention to improve the process of care and objective clinical outcomes for patients with established CHD in primary care in Ireland.
- **Design:** Cluster randomized controlled trial, with practice-level randomization to intervention and control groups.
- **Participants:** 909 patients with CHD (history of myocardial infarction, coronary artery bypass surgery, or angioplasty) recruited from 48 practices.
- **Primary outcomes:** Blood pressure, serum cholesterol, physical and mental well-being (as measured by the SF-12 Health Survey),⁸ and hospital readmissions at 2 years from start of study.
- **Setting:** The island of Ireland, where 2 different healthcare systems exist. In the north, in line with Britain, the National Health Service allows everyone free access to general practice and hospital services. In the south, a mixed public and private healthcare system operates, with less than 30% of the population qualifying for free general practice and hospital services. During the development of the SPHERE study, a program called Heartwatch, a national government program to encourage secondary prevention of CHD in general practice, was being pilot-tested in 20% of general practices in the south of Ireland.

tion, coronary artery bypass surgery, or angioplasty) were identified. Maximum variation sampling was used to select patients of different ages and sexes, and with different diagnoses and lengths of time since diagnosis. These patients were invited to participate in 1 of 4 focus groups; 23 patients did so between March and June 2003. Staff members (n = 29) also participated in 1 of 4 focus groups. Questions related to participants' experiences of and attitudes toward key intervention components identified from the literature and findings were used in modeling the pilot intervention.

The preliminary intervention was delivered to the same 4 practices as those involved in the modeling phase. Practitioners received training in prescribing and behavior change relevant to the management of established CHD. After each training session, they were asked to complete an evaluation sheet. After practitioner training, 27 patients attended a first consultation and 20 of these attended a second consultation. In March 2004, experiences of the intervention were explored using individual semistructured interviews (n = 10 practitioners) and 4 focus groups (n = 17 patients).

The study was approved by the ethics committees of the Irish College of General Practitioners and Queen's University Belfast.

Data Collection and Analysis

Data from training evaluation sheets were summarized. Two researchers independently analyzed qualitative data related to the modeling and exploratory phases by using audiotape transcripts of focus groups and interviews and notes on contemporaneous observations. The modeling and exploratory phases were analyzed separately.

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METHODS

Exploration of Relevant Theory

During the preclinical phase of the study, literature relating to secondary prevention of CHD was searched using Medline, PsychInfo, and Cochrane. Key words included coronary heart disease, angina, myocardial infarction, secondary prevention, lifestyle change, behavior change, primary care, and health promotion; searches started in 1985. The research team discussed key findings regarding successful interventions and identified those findings deemed appropriate to our setting.

Modeling and Pilot-testing the Intervention

Four general practices were selected from the study catchment area to capture 1 urban and 1 rural practice from each of the 2 health systems. Within these practices, patients with CHD (history of myocardial infar-

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RESULTS

The **Table** summarizes the development of the intervention through the stages of the MRC framework process.

Exploration of Relevant Theory

Secondary Prevention of CHD. The optimum mix of intervention components for secondary prevention of CHD remains uncertain.²² Key components of previous successful interventions were a structured recall system,⁹⁻¹² practitioner training,¹⁴ information for patients,^{9,10,13,23} tailoring interventions to individual patients and practices, and addressing specific barriers to change.^{13,18,19} Barriers to the provision and uptake of secondary prevention included inadequate consideration of doctors' and patients' perspectives,^{18,24} lack of patient-centeredness of the intervention,^{18,20} failure to

Intervention Development

Table. Contribution of the Stages of the MRC Framework¹ to the Development of Components of the SPHERE Study Intervention

Intervention Component	Stage 1: Preclinical Exploration of Relevant Theory	Stage 2: Modeling the Intervention	Stage 3: Pilot-testing the Preliminary Intervention	Definitive Intervention
Patient recall system	Structured system effective ⁹⁻¹² Need to tailor to individual practices ¹³	Practices welcomed support in setting up a structured recall system Lack of time and money identified as major barriers	Need for more administrative support from research staff Development of patient register and recall system possible	Structured recall system established with support from research nurse Format of system tailored to practices' needs regarding identification of patients and arrangement of appointments
Training for practitioners	Training effective ¹⁴ Need for training on behavior change ¹⁵⁻¹⁷	Training needs identified, especially with respect to behavior change and medication prescribing Training required to be focused, brief, and delivered at the practice	Training appreciated Training should be less theoretical and more focused on tasks Request for role models and opportunity for role-playing during behavior-change training	Two 90-minute in-house training sessions: (1) medication and (2) behavior change Training less theoretical and more task focused: video role models provided, along with opportunities for role-playing among practitioners Medication training focused on case-based scenarios Training tailored to participants' needs: participants invited to apply material to their personal situations
Patient information	Need to tailor to individual patients ^{18,19} Patient-centered delivery of behavior change effective ²⁰ Goal setting and action plan development effective ²¹	Need to address: <ul style="list-style-type: none"> • Influence of health beliefs on acceptance of information • Confusion among patients about their medications • Lack of motivation for behavior change • Lack of social support 	Interactive parts of booklet criticized; patients were not comfortable completing these sections Many patients forgot to bring booklet to consultation Support in developing goals and action plans appreciated	Patient-held booklet developed as resource for information only Collaborative development of goals and action plans between practitioner and patient Action plan recorded in patient's practice notes

MRC indicates UK Medical Research Council; SPHERE, Secondary Prevention of Heart Disease in General Practice.

tailor interventions to individual practices, structural factors (eg, poor access to transportation, inconvenient clinic times), patients' personal factors (eg, fear, denial of illness), social and cultural factors, past experiences, expectations, diagnostic confusion, and low knowledge and self-awareness.²⁵ Noninvolvement of practice nurses has been associated with poorer delivery of secondary prevention interventions.²⁶ Lack of time and the demands of maintaining a good doctor-patient relationship also have been identified as important barriers.²⁷

Lifestyle/Behavior Change. There is evidence from the literature to support several theories about health behavior: health education theory²⁸ (providing information about risk and benefits of behavior change); social-cognitive theory²⁹ (describing sociocognitive determinants such as self-efficacy, normative beliefs, social support, outcome expectancies, goals, and impediments as important in predicting health behavior); and the 2-stage approach, suggested by the health action process approach³⁰ and the patient-centered approach.³¹ Patients' perceptions

of feeling healthy³² or reliance on medical interventions³³ may reduce motivation to change their lifestyle. Details on the use of psychological theory to inform the development of behavior-change training have been published elsewhere.³⁴

Modeling the Intervention

Focus group findings confirmed the importance of tailoring our intervention to individual practices and patients. Practitioners indicated a need to address the factors of time and financial limitations. Their training requirements focused on medication prescribing and techniques to encourage behavioral change, and they called for training to be brief, focused, inclusive of all staff, and provided in the practice. Among both patients and practitioners, motivation to achieve behavior change needed to be improved. Patients were confused about medication and identified stress and poor social support as key issues.

To develop the preliminary intervention, findings from the exploratory qualitative work were used to add detail to 3 intervention components identified from the literature: structured recall system, training for practitioners, and patient information. These components are discussed below.

Structured Recall System. This component involved identifying patients, creating a register, contacting patients, and scheduling appointments. The qualitative findings indicated that variation in each of these aspects was to be expected.

Training for Practitioners. In response to the findings, all staff were invited to attend two 90-minute training sessions provided in the practice: 1 concerning medication prescribing and adherence and the other concerning facilitation of lifestyle change. In the session on medication training, the latest guidelines on secondary preventive medication were presented for discussion and application to clinical cases. The session on behavior change summarized behavior-change guidelines and outlined the theories of behavior change. Practitioners were encouraged to discuss the application of the guidelines to their practice and share in tailoring the training to their experience.

Patient Information. A patient-held booklet was developed, containing information about CHD, medication, behavioral risk factors for CHD, and a list of community support organizations. This booklet was to be used to facilitate consultations, during which the patient would be asked to select an area of behavior, if any, in which the patient would like the practitioner's support to achieve change. The booklet contained sections in which patients could record diary-type information, goals, action plans, and a self-monitoring

record, and was designed to be adapted to individual needs.

Pilot-testing the Preliminary Intervention

Structured Recall System. Patient registers were established and invitation letters were posted to patients, followed by a phone call from a practice staff member. The implementation of this recall system varied among practices according to existence of preestablished registers, and the availability and willingness of practice staff. Support provided by the SPHERE research nurse during this process was valued by practitioners. However, practices in the south of Ireland that were participating in the Heartwatch program (see the Box) reported being overburdened by administrative work.

Training for Practitioners. Most participants found the training to be useful, clear, delivered at the right pace, and of satisfactory duration. However, participants specified that they wanted less theory and more specific guidance about what they should do during consultations.

Patient Information. There was positive feedback about the patient-held booklet: It was seen as a useful resource, containing clear and easy-to-understand information. However, patients disliked completing the interactive sections, and several forgot to bring the booklet along to the consultation.

The Definitive Intervention

The RCT protocol was developed and has been published. The definitive SPHERE intervention contains the following components:

Structured Recall System. The SPHERE research nurse supports practice staff in developing and maintaining a register and recall system for all patients with CHD attending the practice. Identification in the pilot version of the problem among practices participating in the Heartwatch program resulted in exclusion of these practices from the definitive RCT and emphasized the need for the intervention to involve minimal administration.

Training for Practitioners. The behavior-change training contains less theory and more explicit guidance regarding implementation, using video materials and opportunities for role-playing of skills. Specific skills included are (1) patient-centered selection of behavior for focus, (2) patient identification of facilitators and barriers, (3) goal setting, (4) action planning, and (5) monitoring. The medication training session contains less presentation of factual information and more opportunity for discussion of case-based scenarios.

Patient Information. The patient-held booklet has been transformed into a document that provides infor-

mation only; interactive sections have been removed. Patient care plans, goals, and action plans are recorded in charts in the practice.

DISCUSSION

This study provides an example of the application of the MRC framework to the development of a complex intervention for an RCT in primary care. The relevance of adapting interventions in light of theory and context has been emphasized by others,³⁵ but there are few examples of this application in practice.

A significant number of barriers to the implementation and uptake of secondary prevention were identified in the literature. The qualitative work during the modeling phase enabled us to investigate how these barriers affected practitioners and patients in 2 different health systems in which the intervention was to be tested. As a result, we could alter design details of the intervention components to make them more acceptable to our study population. For example, focus groups indicated that training would be welcomed by staff, but it should be brief, focused, and delivered on the premises of the practice. Specific areas in which training was required were identified. Some previous trials of interventions relating to CHD management in primary care have included staff training,^{12,14} but we are not aware of previous attempts to identify participants' needs in this area. Modeling also helped us to identify key issues for patients (stress management, poor motivation, perceived lack of support) and allowed us to address these in our information booklet.

The pilot phase was useful in testing practical aspects of our intervention protocol, including the feasibility of creating registers and implementing recall systems. Evaluation of the training sessions indicated that they were perceived as useful and acceptable, and allowed us to refine their content (eg, provide less theory) and style of delivery (eg, include video and role-playing) to try to increase their effectiveness.

Although this development process enabled us to make a number of improvements to our intervention, and to achieve a design that is likely to be accepted in the setting in which it is to be delivered and tested, the process has some disadvantages. It was time-consuming (the process described took 18 months to complete). Also, the focus groups and pilot work included small numbers; it must be acknowledged that this work was limited by time and resource restraints.

Because the intervention was refined and tailored to local settings, generalizability of findings from the RCT may be compromised. However, linking the intervention components to a theoretical framework may provide an

effective way to allow our findings to be generalizable and avoid duplicating efforts for subsequent research.³⁶

The effectiveness of this intervention in improving care for patients with CHD is being evaluated currently in an RCT. This innovative approach of using the MRC framework to develop the intervention has made the intervention more likely to be acceptable and deepens understanding of how such a complex intervention performs in primary care.

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