

Medical Research Council framework for development and evaluation of complex interventions: A comprehensive guidance

Introduction

Complex intervention framework is extensively used in health service delivery, community, health and social policy, such as education, with important health outcomes. Such interventions are sensitive and flexible to the regional context and culture. Complex interventions introduce the use of two or more information sources or two or more research methods to answer a research question.^[1,2]

Using more than two research methods with triangulation techniques increases the validity of the research findings. Such studies are considered as mixed methods.^[2] Complex intervention framework includes the steps which are not necessarily linear and there is also no clear boundary between simple and complex interventions. Such steps include plan development, feasibility and pilot, evaluation, and implementation. These steps have no linear or cyclic order.^[3]

This framework emphasizes that any intervention should be presented to the patients tailored to the context and culture of that society (political, social, and geographical). Even if the intervention can be presented equally in different societies, the context of that society cannot be ignored in the face of the intervention because one intervention may have different effects on two different societies. In fact, this framework introduces the mechanisms which are

sufficiently relevant to that society in order to achieve some changes. In addition, the context of the society after the intervention should be considered in interpreting the findings.^[4] Meanwhile, Lakshman *et al.* considered the use of this framework to infants' nutritional behaviors in lactation with the analysis of cost-effectiveness of a complex intervention in his study as a challenging, long and costly intervention. He even suggested conducting interventional research with or without a framework to evaluate their effectiveness alongside costs.^[5]

Initial Version

In 2000, the Medical Research Council introduced a framework which could facilitate the use of appropriate methods for researchers and research support organizations. This framework was a guide for developing and evaluating complex interventions [Figure 1]. Complex interventions were introduced as the interventions with more than one component. In addition, these interventions have some other features as follows:

- The number of groups and levels of the organization which are the target group for interventions
- The number and severity of behaviors shown by intervention providers or recipients
- The number and variety of the variables are considered as estimate in the intervention
- The degree of flexibility in the permitted interventions.^[1]

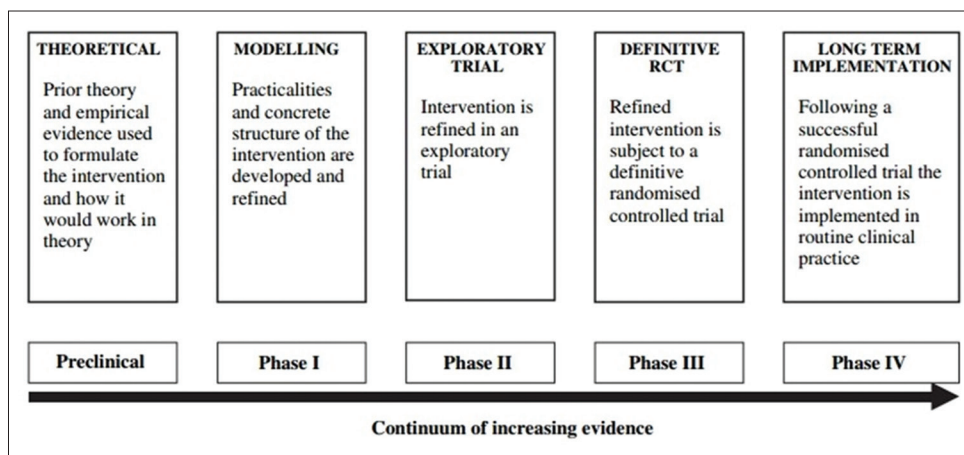


Figure 1: The steps of complex intervention framework 2000 Version

Complex Intervention Framework; 2006 Version

In 2006, 2000 version was revised due to some limitations, some were: (1) the linear form of the steps and its similarity to those which traditionally evaluate the effect of drugs, (2) there was no evidence for many of the recommendations, (3) there was little guidance on how to develop and implement a plan and (4) lack of paying attention to the geographical, political, and social context, in which interventions take place.^[1] In this version, the complex intervention framework includes the steps which are not necessarily linear and there is no clear boundary between simple and complex interventions. These steps include plan development, feasibility and pilot, evaluation, and implementation. Such steps have no linear or cyclic order [Figure 2].^[3]

The best method for developing a plan is using the current evidence and appropriate theory and then a specific approach to evaluate the plan as a pilot (aimed at clarifying the ambiguities) and then evaluate the plan. The results are extensively published to help further studies with the implementation of their interventions. It is essential for decision makers and policymakers of organizations to explain the advantages and disadvantages of the plan and then intervene in the implementation and progress of the plan. This framework emphasizes that any intervention appropriate to the context and culture of that society (political, social, and geographical) should be presented to patients. Even if the intervention itself can be presented equally in different societies, the context of those societies cannot be ignored while implementing the intervention because a constant intervention may have different effects on two different societies. In fact, this framework introduces the mechanisms which are sufficiently relevant to that society in order to achieve some changes. For interpreting the findings, the context of the society should be taken into account after using the intervention.^[4] Lakshman *et al.* considered the use of this framework to infants' nutritional behaviors in lactation with the analysis of cost-effectiveness of a complex intervention in his study as a challenging, long, and costly intervention. He even suggested conducting interventional research

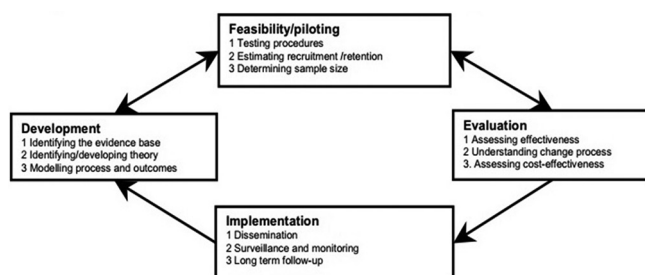


Figure 2: Complex intervention framework 2006 Version

with or without complex framework to evaluate their effectiveness alongside costs.^[5]

Sometimes, evaluation can be performed before using the interventions. Some evidence, though valid, because of political unacceptability, is better to completely deleted.^[1]

This framework has been used so far for designing and evaluating different care interventions such as infants' nutritional habits, the prevention of childhood obesity,^[5] high blood pressure control,^[6] diabetes prevention,^[7] secondary prevention of stroke, followed by transient ischemic attack^[2] and reintegration to normal life in patients with upper extremity amputation.^[8]

Step 1: Developing Complex Interventions

Introducing the current evidence

The evidence related to the subject is searched ideally as a systematic review. Even if a new quality review has been recently conducted optimistically, the researcher should carry out his/her study.^[1]

Introducing/developing an appropriate theory

Sometimes, a practical and useful theory can make a better intervention. The current evidence can be used or a new study can be conducted for this purpose.^[1] Therefore, it should be decided whether you intend to develop and evaluate the intervention yourself or evaluate an already-existing intervention.^[4]

Modeling the process and estimates

Before implementing and evaluating the intervention, it is better to model it and specify some information about the design. For example, an economic estimate can be used before the intervention begins. This should be performed at an early stage.^[1]

Step 2: Feasibility and Pilot

This step includes testing the procedure in terms of acceptance by the participants, the extent of samples' participation, and attrition rate in research and calculating the sample size. At this step, qualitative and quantitative research may be required to examine the barriers to intervention from the perspective of participants and determine the response rate.^[1]

Step 3: Evaluating Complex Interventions

Clinical trials can be used for evaluating effectiveness of the intervention. Randomization ensures the prevention of bias in selection, otherwise it cannot be ensured that the recipients of the intervention are systematically equal to those who did not receive the intervention. Clinical trials can take place at the individual or cluster levels.^[1]

In measuring the estimates, researchers should decide what estimates are more important to them and what estimates are at the second degree of importance.^[1] Useful approaches in the evaluation phase are listed in Table 1.

Understanding the intervention process

Evaluating the intervention process is highly valuable because it can understand the cause of the unexpected results of the intervention or its failure. Such an evaluation can be implicitly performed during the intervention so that the quality of the intervention can be assessed. In addition, the cultural factors which can be related to changes associated with research variables can be also introduced.^[1]

Investigating the effectiveness cost

Cost effectiveness is ideally performed during the evaluation phase. Cost effectiveness makes it possible compare cost of intervention versus its advantages.^[3,4]

Step 4: Implementation

Disseminating the intervention and the results of the study is essential. Interventions and their results should be accessible and understandable to decision makers and policymakers to be used in routine clinical care. It has become clear over time that vague strategies (actors and roles are not exactly clear) will become ineffective and inefficient in clinical care. Information should be available and informed actively.^[1]

Survival, monitoring and long-term outcomes

Clinical trials typically have a low degree of generalizability. Therefore, in interpreting the results of the trials, the characteristics of samples and the time scope should be considered in interpreting the results of the trials. Sometimes, following up the effects of interventions is made over a long period of time. Although this case is not usually conducted, sometimes, it is performed to evaluate the long-term effectiveness

Table 1: Useful approaches in the evaluation phase^[1]

Involve the stakeholders in selecting research questions and its implementation

Pay attention to the cultural context and clarify what is important to the stakeholders such as the advantages, disadvantages and the cost of the project

Present the recommendations as specialized as much as possible

In proposing the interventions, try to conduct in interventions as participatory by receiving feedback through consensus feedback instead of presenting interventions in an inflexible manner

Some degree of flexibility in the plan protocol due to the cultural context is more acceptable than the implementation of standards

Considering the key question in the evaluation phase of complex interventions: Are complex interventions effective in its daily use?

of interventions. Sometimes, unexpected results show up over time. In addition, it is studied whether the advantages are endangered by the real results of the study or not.^[3]

Due to the valuable advantages of following up the patients in the long term, it is important to think about how to follow-up them or a communication can be conducted again with them or for example follow their registered information which is accessible.^[4] Patients maybe, have chronic disease like stroke and hypertension or acute like sudden upper limb amputation.^[8]

The final goal is not to present a prescriptive guide to other researchers, decision makers and research supportive organizations, but to help them make methodological and practical choices in the clinical area. Furthermore, the editor-in-chief of magazines should emphasize the presentation of studies with a detailed reporting system.^[1]

This study attempted to use the relevant sources in complex intervention framework and its stages to help researchers, especially nurse researchers, to design more effective care plans by considering important factors like culture of the society; accompanying stakeholders collaboration for better implementation of care plan; implementing the pilot and feasibility phase to identify problems and present solutions by a panel of experts before evaluation plan in the form of randomized controlled trial; and emphasizing on the dissemination of results. Weakness points of complex framework are time consuming and cost of implementation. Calculating the cost-effectiveness and time of plan in the pilot phase can show the value of implementation of plan.

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Conflicts of interest

There are no conflicts of interest.

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