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Increasing value and reducing waste by optimizing the development of complex interventions: Enriching the development phase of the Medical Research Council (MRC) Framework

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ABSTRACT

Background: In recent years there has been much emphasis on 'research waste' caused by poor question selection, insufficient attention to previous research results, and avoidable weakness in research design, conduct and analysis. Little attention has been paid to the effect of inadequate development of interventions before proceeding to a full clinical trial.
Objective: We therefore propose to enrich the development phase of the MRC Framework by adding crucial elements to improve the likelihood of success and enhance the fit with clinical practice
Methods: Based on existing intervention development guidance and synthesis, a comprehensive iterative intervention development approach is proposed. Examples from published reports are presented to illustrate the methodology that can be applied within each element to enhance the intervention design.
Results: A comprehensive iterative approach is presented by combining the elements of the MRC Framework development phase with essential elements from existing guidance including: problem identification, the systematic identification of evidence, identification or development of theory, determination of needs, the examination of current practice and context, modelling the process and expected outcomes leading to final element: the intervention design. All elements are drawn from existing models to provide intervention developers with a greater chance of producing an intervention that is well adopted, effective and fitted to the context.
Conclusion: This comprehensive approach of developing interventions will strengthen the internal and external validity, minimize research waste and add value to health care research. In complex interventions in health care research, flaws in the development process immediately impact the chances of success. Knowledge regarding the causal mechanisms and interactions within the intended clinical context is needed to develop interventions that fit daily practice and are beneficial for the end-user.

What is already known about the topic?

- To prevent research waste, little attention has been paid to the effect of inadequate development of interventions before proceeding to a full clinical trial.
- The MRC Framework for developing and evaluating complex interventions is the most cited guidance using an iterative approach.
- A misfit between the intervention and the implementation context often hampers resulting in suboptimal treatment success.

What this paper adds

- A comprehensive development approach is proposed by combining the elements of the MRC development phase with elements from

Abbreviations: MRC, Medical Research Council

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existing guidance to enhance the fit with clinical practice.
- The proposed elements will improve the development of complex interventions, strengthen the internal and external validity, minimize research waste and add value to health care research.

1. Background

Much of the cause of 'research waste', estimated at 85% of research activity, has been attributed to poor question selection, insufficient attention to previous research results, inadequate reporting, and poor intervention description (Ioannidis et al., 2014). Moreover, many biomedical and public health research studies can be regarded as wasteful due to avoidable weakness in their design, conduct and analysis (Ioannidis et al., 2014; Chalmers and Glasziou, 2009). In complex intervention studies in health care, preventing these weaknesses is challenging. Complex interventions are defined as interventions with several interacting components that impact the length and complexity of the causal chain from intervention to outcome and the influence of features of the local context (Craig et al., 2008). Some argue that definitions of simple and complex interventions evolve from the question being asked in the research project rather than the intervention itself (Petticrew, 2011).

In recent years, much emphasis has been placed on better reporting of evidence-based complex interventions in health care (Glasziou et al., 2014, 2010a; Hoffmann et al., 2014). Report guidance such as the Template for Intervention Description and Replication[6] (TIDieR) and CReDECI (Mohler et al., 2015; Möhler et al., 2012) have been developed to assist authors, editors, peer reviewers, and readers enhance transparency, replication, and the potential impact. Less attention, however, has been given to enhancing the development process of complex interventions and how the intervention can be improved before proceeding to a full clinical trial. This too often ends in trials showing results that tend to be negative or inconclusive, as demonstrated in a comprehensive analysis of treatment success of 51 funded pragmatic trials (Dent and Raftery, 2011). This could possibly be prevented when the intervention was carefully designed and tested in a feasibility or pilot study.

Several guides for developing and evaluating complex interventions have been published to enhance the performance and design of an intervention before studying its effectiveness (Conn et al., 2001a; van Meijel et al., 2004; Whittemore and Grey, 2002; Bartholomew et al., 2011) and some emphasize the importance of studying the modifiable causal or contextual factors (Wight et al., 2016; Card et al., 2011). The Medical Research Council (MRC) Framework for developing and evaluating complex interventions is well known and cited in the literature and guides the process in making appropriate methodological and practical decisions. By working with the MRC Framework and other intervention development guidance over the years, we have learned that when designing interventions using these existing models, the fit with the actual context often hampers. Additional knowledge is often needed to successfully develop a complex intervention that has a strong evidence and theoretical base and fits within the delivery context (Wight et al., 2016; Richards and Hallberg, 2015a; Wells et al., 2012).

Designing interventions that fit into practice and increase the chance of success, data are needed regarding 1) the causal mechanism between the intervention ingredients and outcomes, 2) the interactions between the proposed intervention ingredients, and 3) how the context, i.e. the receiver (recipient) and provider (professional) interact with the intervention. Thus far, to our knowledge, none of the existing guidance systematically addresses the abovementioned elements in the development or design phase. However, there are few examples, such as the process evaluation guidance by Moore et al. (2015), describing various elements that should be considered when developing interventions, although this is seldom the case. Therefore, based on published reports and our own experience, we propose a comprehensive approach by combining the elements of the development phase of the MRC Framework with elements of existing development models to enhance the intervention design, increase value and minimize the risk of subjects being exposed to ineffective interventions. This approach may facilitate researchers, research funders, and reviewers when developing a complex intervention in a broad domain of health care research. To illustrate the methodology that can be used within the development phase, we use published examples.

2. Methods

2.1. Design

a methodological approach consisting of reviewing the literature combined with using published examples and experience to enrich the MRC development phase to enhance the design of complex interventions. This approach was chosen to illustrate the different methodological approaches that can be used to address one element within the development phase of complex interventions.

2.2. Essential principles throughout the development process

When synthesizing existing guidance, a commonality of existing models is that they aim to systematically map the path from the recognition of a relevant need or problem to the identification of a therapeutic solution (Appendix A) (Craig et al., 2008; van Meijel et al., 2004; Whittemore and Grey, 2002; Wight et al., 2016; Conn et al., 2001b; Corry et al., 2013). Essential common principles is that the intervention should be evidence-based, have a strong conceptual basis or solid theoretical rationale, and match the individual needs, capacities, and preferences of both recipients and providers as well as fit into the context of routine practice (van Meijel et al., 2004; Bartholomew et al., 2011; Conn et al., 2001b). However, different models address distinctive elements and activities that contribute to enhancing the intervention development process. In Table 1, we outline the elements within the developmental phase of several existing development models.

An iterative development approach rather than a linear-stepwise approach has been recommended (Craig et al., 2008; Richards and Hallberg, 2015a), because of the reciprocal relation between the elements in the development phase. In this reflective approach, literature reviews as well as quantitative and qualitative research are considered to be of major importance to optimizing the prototype of the intervention design (Craig et al., 2008; Lewin et al., 2009; O'Cathain et al., 2014). During this iterative process, important feedback-loops can be incorporated and researchers are challenged to consistently seek answers to fill in the knowledge gaps within each element. Considering the sustainability of the intervention a priori, and the likelihood of adoption and implementation in daily practice is crucial in the development phase (Richards and Hallberg, 2015a). A user-centred approach consisting of an interdisciplinary team of researchers and experts together with recipients and providers may enhance the feasibility, efficacy, and effectiveness of the intervention. (van Meijel et al., 2004) Multiple stakeholders can be invited to participate in the development phase and consulting them frequently regarding the when, how, what, and why of the intervention can provide important information (Glasziou et al., 2010a). An example that covers these elements and is based on our experience is provided in Box 1.

2.3. Proposed elements added to the MRC development phase

The MRC Framework describes three, non-linear elements consisting of a systematic approach of '*identifying the existing evidence*', '*identifying or developing theory*', and '*modelling process and outcomes*' in the development phase before proceeding to feasibility and piloting phase. These elements focus primarily on gathering the existing evidence for the proposed intervention using systematic reviews and