# Abstract

#### Research Project: A systematic review of complex intervention evaluation studies

#### Objective

Robust evaluations of health interventions are necessary for reliable policy decisions. Meanwhile, this research exercise is highly challenging when the interventions are complex, containing different facets and mechanisms. The objective of this review is to explore evaluation frameworks and study designs employed to evaluate complex interventions in international literature.

### Methods

A systematic search was conducted through EMBASE, MEDLINE, and the Cochrane Library. We included the articles reporting evaluation studies of complex interventions, and systematic reviews of such evaluations. The search was restricted to articles published in English from January 1, 2013 to August 29, 2017. Several inclusion criteria were employed. More importantly, included article needed to be an original article that covered the evaluation of complex interventions implicitly or explicitly. Moreover, the review included a systematic review of multicomponent interventions evaluation.

### Results

In total, there were 108 eligible articles, which were categorized into three groups: outcome, process, and health economic evaluations. Sixty-one studies examined outcomes of interventions. Out of these, 13 articles used the pre-and post-intervention design. Only a small number of studies were randomized controlled trials (RCTs), even though such a research design is regarded as the "gold standard" for assessing effectiveness. Twenty-nine articles involved systematic reviews of RCTs and clustered-RCT studies, some of which reflected on the intricacies of pooling the data due to the diversity in outcome measures, and methodologies. Among the health economic evaluations reviewed (n=4), RCT was the only study design used to assess health outcomes.

Twenty-six articles reported evaluation frameworks. Most of these frameworks were developed to guide process evaluations as they explain how interventions work and why. We also found that most conceptual frameworks were underpinned by the Normalization Process Theory, which focuses on the integration of interventions into everyday service delivery practice.

## **Discussion and conclusions**

A systematic literature review indicates the problems and limitations in evaluating effectiveness, process, and health economics of complex health interventions. The first limitation is the heterogeneity of included articles, which yields difficulties in data compilation and evidence synthesis. Secondly, the evidence synthesis technique used in clinical interventions may not be appropriate for synthesizing the effectiveness of complex health interventions. Furthermore, there is no clear recommendation on method used to evaluate the effectiveness of complex interventions, especially when RCT is not applicable. The majority of articles, which we examined, do not illustrate a process evaluation of the interventions as well as an evaluation framework. Moreover, only limited number of studies on health economic evaluation guidelines have some limitations on the application for evaluating such interventions. Although the continuing effort has been put into the developing

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and improving of guidance on assessing complex health interventions, the evaluation of such interventions remains highly challenging.

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