








STUDY PROTOCOL

Addressing fidelity within complex health behaviour change interventions: A protocol of a scoping review of intervention fidelity frameworks and models. [version 1; peer review: 2 approved]

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Abstract



Intervention fidelity is crucial to facilitate accurate interpretation of research outcomes, but has been inadequately addressed within complex health behaviour change interventions. Recent research has highlighted a need for practical guidance to improve understanding and use of existing fidelity frameworks and models within complex health behaviour change intervention research. The aim of this paper is to present a protocol for a scoping review of existing intervention fidelity frameworks and models. In accordance with scoping review guidelines, the following stages will be conducted: (1) identifying the research question, (2) identifying potentially relevant studies of fidelity frameworks and models, (3) study screening and selection, (4) charting and extracting data from identified frameworks and models, (5) collating, summarising and reporting the results and (6) consultation with stakeholders. Two reviewers will independently conduct the screening and extraction stages. Identified frameworks will be collated, summarized and categorized iteratively by one reviewer in consultation with the review team.

The findings of this review will provide a useful resource by identifying and comparing existing fidelity frameworks and models. It is intended that increased clarity and understanding in this area will facilitate the appropriate selection and application of fidelity frameworks for complex health behaviour change interventions, inform areas for future research,

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Any reports and responses or comments on the article can be found at the end of the article.

and ultimately contribute towards improving how intervention fidelity is addressed in this area.

Keywords

Intervention fidelity, behaviour change, health research, complex interventions



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Introduction

Intervention fidelity refers to the degree to which an intervention is implemented as intended by its developers¹, or “the methodological strategies used to enhance and monitor the reliability and validity of behavioural interventions”². Intervention fidelity can be considered in terms of strategies to enhance or improve fidelity by using tools such as intervention manuals, as well as strategies used to assess or evaluate fidelity, such as the use of direct observations and self-reported checklists^{3,4}. Enhancing and assessing fidelity is a crucial component of complex health behaviour change intervention research, as it facilitates an accurate evaluation of research outcomes^{1,5}. Reporting fidelity is also vital in order to enable other researchers to determine the credibility of a study and replicate its results⁶. Addressing intervention fidelity in terms of enhancement, assessment and reporting becomes particularly important for complex health behaviour change interventions, where numerous interacting components are present⁷ and the exact mechanisms of action of the intervention may not always be well specified^{8,9}. Theories and frameworks have particular importance for the development, evaluation and implementation of complex health behaviour change interventions as they can facilitate a better understanding of these causal mechanisms, and of how such interventions do or do not work^{5,9}. However, the use of such theories and frameworks within behaviour change intervention research in terms of study design, measurement, implementation and interpretation is often poorly done¹⁰⁻¹².

Addressing intervention fidelity helps researchers to be more confident that study outcomes are due to the intervention that is being examined, and not due to variability in its implementation¹³. For instance, significant outcomes could be the result of an effective intervention, but could also be due to elements added to the intervention unknowingly, giving rise to a type I error (i.e. rejecting the null hypothesis when it is true). Conversely, non-significant findings could be due to an ineffective intervention, or potentially due to essential elements being omitted, leading to a type II error (i.e. accepting the null hypothesis when it is false)¹⁴. Therefore, without knowledge of intervention fidelity, potentially efficacious interventions could be discarded or potentially ineffective interventions replicated and disseminated, resulting in both financial and scientific costs^{15,16}. Another error that can also occur is a type III error, wherein the null hypothesis is correctly rejected, but for the wrong reasons¹⁴. Overall, the presence of these errors reduces the internal validity of the study, affects the overall credibility of the research, and reduces our ability to understand how and why an intervention works or not^{17,18}.

As well as being fundamental for trials testing the effectiveness of evidence-based interventions, intervention fidelity is an important element of implementation science, which has been defined as the scientific study of methods to promote the systematic uptake of evidence-based interventions into practice and policy and hence improve health¹⁹. Weakened fidelity in the implementation process may lead to an intervention that has yielded positive patient outcomes in a controlled trial producing

varied or less favourable results when applied by different healthcare professionals into clinical practice¹. Overall, enhancing, assessing and reporting fidelity across all stages of health behaviour change intervention research, including design, evaluation and implementation, will provide a better understanding of how and why an intervention works, and how adaptations and contextual factors may have affected outcomes. In addition to increasing certainty in outcomes, this also serves to facilitate the translation of effective interventions into real-life settings.

Despite its importance, reviews have shown that fidelity continues to be poorly addressed in trials exploring the effectiveness of complex health behaviour change interventions^{4,13,20-23}, as well as within studies evaluating the implementation of such interventions^{24,25}. Recent research surveyed the knowledge, attitudes, practice and barriers/facilitators towards addressing intervention fidelity amongst an international sample of researchers, triallists and healthcare professionals involved with the design and conduct of trials of complex healthcare interventions²⁶. Participants identified a lack of understanding and clarity regarding intervention fidelity terminology and how fidelity is conceptualised as one of the most significant barriers towards addressing intervention fidelity in this area. In contrast, the availability of tools, models and frameworks was found to be a facilitator of the use of intervention fidelity strategies; however, the survey identified 15 different fidelity frameworks and only 26.4% of participants had actually used any of these frameworks. Underuse of existing fidelity frameworks has been similarly highlighted by several studies in this area^{3,20,27}, and has been suggested to be due to a lack of practicality or usability issues with these frameworks^{26,28,29}. Accordingly, previous research has called for more consistent use of existing frameworks and models to improve clarity of intervention fidelity terminology and conceptualisation^{24,27}, and for pragmatic guidance to improve understanding and facilitate use of these frameworks²⁶.

In order to facilitate better use of these frameworks, a systematic approach to identifying and collating all existing frameworks and their intended applications is needed. Several reviews have previously focused on collating and synthesizing fidelity definitions and conceptualisations across the literature^{1,3,30-32}, and two have also included the appraisal of existing fidelity frameworks. In 2011, Gearing *et al.* conducted a review of 24 meta-analyses, reviews and some fidelity frameworks to identify, define, and operationalize the key ingredients and components of intervention fidelity, developing the Comprehensive Intervention Fidelity Guide (CIFG) framework as a result. More recently, Ibrahim and Sidani similarly conducted an integrative literature review to identify and critically appraise existing fidelity frameworks and subsequently proposed another new framework for intervention fidelity based on this work³². However, the review by Gearing *et al.* did not refer to or include the Carroll *et al.*'s Conceptual Framework for Implementation Fidelity (CFIF), and the review by Ibrahim and Sidani did not include the National Institutes of Health Behaviour Change Consortium (NIHBCC) Treatment Fidelity Framework or the CIFG, which were the most commonly identified frameworks in the recent survey of intervention fidelity²⁶.

It is unclear from these studies why these important frameworks were not included, and highlights the possibility that other relevant frameworks may also have been overlooked. In addition, it is likely that existing fidelity frameworks and models have been developed within specific disciplines with potentially differing purposes, such as intervention design or evaluation. As such, certain frameworks or models may be more discipline-specific than others, and some may have greater relevance for different stages of research than others (e.g. design, feasibility testing, effectiveness trials, implementation); however, a systematic approach to examining the aims and intended applications of these frameworks has not yet been conducted. Accordingly, our review aims to provide a systematic overview of existing conceptual fidelity frameworks and models which address intervention fidelity³². This review will synthesise and categorise information from these frameworks and models to enable clarity around definitions, terminology and components and their intended applications. Although creation of new frameworks is important, our aim is not to generate another new framework, but to provide clarity and guidance in order to aid selection and facilitate application of existing frameworks within health behaviour change intervention research.

Specifically, the objectives of this review are:

- To identify existing conceptual frameworks or models that focus on intervention fidelity
- To describe these frameworks in terms of the fidelity terminology, definitions, components and constructs used, their provenance/disciplinary background, aims and intended applications and the methods used to develop the frameworks
- To compare and contrast these frameworks in terms of the previous characteristics and highlight any similarities or discrepancies

Methods

Reasoning for methodology

A scoping review methodology was identified as the most appropriate as this type of review is well suited to broad research questions where the aim is to map the evidence within specific research topics or areas. Scoping reviews aim to identify key concepts and gaps in the research, by systematically searching, selecting, and synthesising existing knowledge^{33,34}, and have been previously used to identify and collate frameworks relating to research dissemination³⁵, adaptation of evidence-based interventions³⁶ and knowledge translation³⁷ amongst other areas. Our scoping review will follow the framework outlined by Arksey and O'Malley³³, in addition to additional methodological guidance described by Levac *et al.*³⁴ and the Joanna Briggs Institute (JBI) 2015 scoping review guidance³⁸. The Arksey and O'Malley framework outlines six main steps, namely (1) identifying the research question, (2) identifying the relevant studies, (3) study selection, (4) charting the data, (5) collating, summarising and reporting the results and (6) expert consultation. The review will be reported in accordance with the PRISMA-ScR (PRISMA extension for scoping reviews)³⁹.

Stage 1: Developing the research question

Our review aims to synthesise existing conceptual frameworks and models which address intervention fidelity. In accordance with the JBI 2015 scoping review guidance⁴⁰, which recommends the clarification of population, concept, and context in developing a research question, we clarified the following components:

Population/types of participants. For the purposes of this review, frameworks or models will not be excluded on the basis of population or participant type, and frameworks/models addressing intervention fidelity across all population or participant types (e.g. healthcare professionals, patients, policy-makers) will be eligible.

Concepts. Fidelity was defined using the National Institutes of Health Behaviour Change Consortium definition; i.e. the “methodological strategies used to enhance and monitor the reliability and validity of behavioural interventions”². We defined conceptual framework in accordance with Nilsen’s definition as ‘a structure, overview, outline, system or plan consisting of various descriptive categories, e.g. concepts, constructs or variables, and the relations between them that are presumed to account for a phenomenon’⁴¹. Model was defined according to Nilsen⁴¹ as ‘a deliberate simplification of a phenomenon or a specific aspect of a phenomenon’, or as similar to a theory, but mostly descriptive and less explanatory.

Context. The context for this review is health behaviour change intervention research; however, for the purposes of the review, it is aimed to include any frameworks that may have explored fidelity within other research fields (e.g. education, psychology) and are deemed relevant by the review team according to the inclusion and exclusion criteria.

Stage 2: Identifying the relevant studies

Information source. We will search the following eight electronic databases to identify relevant studies; MEDLINE, EMBASE, CINAHL, PubMed, ERIC, Scopus, and Psycinfo. No date limits will be applied and all databases will be searched from inception. We will also manually search the reference list of all included studies, to capture any papers potentially missed in the electronic databases.

Search strategy. The search terms and search strategy have been informed by strategies used in previous framework scoping reviews^{24,35–37,42,43} and reviews of intervention fidelity^{20,30,31}. The final search strategy was developed iteratively in conjunction with an information specialist, with input from the review team. To identify relevant papers, the following fidelity terms will be searched for (ti/abs/key: fidelity OR ‘treatment fidelity’ OR “intervention fidelity” OR integrity OR adherence OR ‘treatment differentiation’ OR ‘therapist competence’ OR ‘treatment receipt’ OR ‘treatment enactment’), combined using AND with the following framework terms (ti/abs/key: framework* OR guide* OR model* OR concept* OR approach* OR protocol*).

Stage 3: Study selection

Study selection within scoping reviews is an iterative process; therefore, at the beginning of the process, the review team will meet to discuss decisions surrounding study inclusion and exclusion. Covidence review management software will be used to facilitate screening. All references will be exported into Covidence and duplicates will be removed. Two independent reviewers will screen all articles based on title and abstract, meeting at the beginning, midpoint and final stages of the abstract screening to discuss any challenges and uncertainties. Specifically, reviewers will each conduct pilot screening of 10 studies and compare decisions. Once agreement is above 80%, reviewers will continue screening independently until 50% of studies are screened each, when another sample of 10 studies will be reviewed for agreement. Once the title and abstract screening stage is completed, full texts will be obtained and screened by two reviewers independently using the same strategy of pilot screening and discussion. Disagreement at any stage will be resolved using consensus or a third reviewer where necessary.

Inclusion and exclusion criteria. All studies that present conceptual frameworks or models which address fidelity as defined previously will be included. Our inclusion criteria will be focused to capture fidelity frameworks across multiple domains and areas of research including healthcare, education and psychology. All study designs will be eligible for inclusion, and no restriction will be put on the date, or country of origin. We will only include papers that are in English.

Stage 4: Charting the data

In this stage, we will conduct the sorting and charting of data. The research team will collectively develop a standardised data-charting form in Excel to extract the data relevant to the research question. The categories that will be extracted *a priori* will include general study characteristics such as author, publication date, framework/model title or name, fidelity terminology and definitions used and methodology of development. More detailed content such as the study aims and intended applications/users of the framework, provenance/disciplinary background, the components/constructs of fidelity described within the framework or model (i.e. delivery, receipt) and any recommendations made regarding how fidelity should be addressed in terms of enhancing, assessing and reporting will also be extracted. As recommended by Levac *et al.*³⁴, this is an iterative stage, therefore two researchers will independently extract data for the first 20% of identified studies using the data-charting form, before meeting to determine whether the data-charting form needs to be refined or updated.

Stage 5: Collating, summarising and reporting results

We will conduct a narrative synthesis of the frameworks/models and their intended applications. Descriptive statistics will be used to summarise the general characteristics of included studies. Qualitative content analysis techniques will be used to synthesise and tabulate more detailed data to facilitate comparison across frameworks/models regarding fidelity components/constructs, relevance for particular study types and

recommendations made relating to enhancing, assessing and reporting fidelity. This will be conducted by one reviewer as an iterative process in consultation with the review team.

Stage 6: Expert consultations

A multidisciplinary international review team was established to guide and conduct the review. The review team includes researchers with experience in behavioural science, health research, implementation science, intervention fidelity and scoping review methodology. In addition to this, informal consultations will be conducted individually with additional stakeholders to provide perspective and maximise the potential contribution of the scoping review for its intended audience as recommended by Levac *et al.*³⁴. This stakeholder group will comprise a sample of that intended audience, i.e. researchers and healthcare practitioners who work in the area of health behaviour change interventions with varying levels of experience in this field and in intervention fidelity research. Following Stage 5, the study purpose, research question and preliminary findings from Stage 5 will be shared with stakeholders to inform the consultations, which will focus on the potential usefulness and relevance of the content and presentation of the review findings. This information will be subsequently used by the review team to shape the final interpretation and presentation of the review findings.

Discussion

Fidelity is an integral aspect of complex healthcare interventions. Enhancing, assessing and reporting on fidelity across multiple stages of intervention research will ensure that valid conclusions about intervention effectiveness are made, and enable truly effective and evidence-based interventions to be implemented into clinical practice. While many frameworks and models have been developed to ensure that fidelity is addressed in a comprehensive and systematic manner, the use and uptake of these frameworks has been limited to date, and ambiguity regarding how best to utilize them remains^{20,26,27}. The use of frameworks and models to inform how intervention fidelity is enhanced, addressed and reported is important to enable comparisons within fidelity research and facilitate evidence synthesis, and to build towards a cumulative science in this area. Practical guidance around existing fidelity frameworks and models is therefore needed. This review will systematically identify existing frameworks and their intended applications in an attempt to increase their uptake and use, and subsequently improve how fidelity is enhanced, assessed and reported in health behaviour change intervention research. The findings will be useful across multiple stages of health behaviour change intervention research, and assist researchers, practitioners and other health professionals in evaluating, interpreting and implementing health behaviour change interventions. By highlighting the areas of overlap and discrepancies within existing frameworks, the review will also potentially inform an agenda for future theoretical development and research in this area. We hope that the application of this knowledge within complex health behaviour change intervention research will facilitate more accurate interpretation of research findings, and ultimately enable effective interventions to be more successfully implemented into practice.

Data availability

No data are associated with this article.

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Elaine Cameron 

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This protocol describes the rationale and proposed methods for a scoping review to map existing frameworks for enhancing and monitoring fidelity in complex health behaviour change interventions.

The introduction provides a clear and thorough overview of definitions of fidelity and its importance to intervention evaluation and implementation, and a concise summary of prior research in this area. The proposed methods are very detailed, supported by guidelines (e.g. Arksey & O'Malley), and are appropriate for answering the research question.

The article and research design are generally scientifically sound and the following comments are suggestions for improvement:

The inclusion of 'therapist competence', 'treatment receipt' and 'treatment enactment' in the search strategy suggests an interest in identifying frameworks for enhancing and monitoring certain aspects of fidelity (e.g. training of intervention deliverers), not just 'fidelity' as a whole concept. As such, will these three search terms be sufficient to identify papers focused on specific fidelity components? (e.g. there are likely to be many synonyms for 'therapist', 'receipt', 'enactment'). If that is not an intention of the review, are these search terms necessary and useful? If it is intended that such papers will be included, this could be made explicit.

Note that the term 'adherence' combined with [framework* OR guide* OR model* OR concept* OR approach* OR protocol*] will result in a huge number of irrelevant papers to search through given the large amount of literature on adherence to medications (e.g. a quick PubMed search shows over 67,000 results). Other terms such as approach* might also contribute to poor specificity, especially when searching abstracts. Some further testing of the search strategy might be useful.

Under 'study selection' it is stated that "at the beginning of the process, the review team will meet to discuss decisions surrounding study inclusion and exclusion". It is not clear what this will add, taking place prior to title and abstract screening, in addition to the criteria described under inclusion/exclusion criteria and the decision-making meetings of the two reviewers after pilot screening and 50% of

screening.

It is also stated that descriptive statistics will be used to summarise general characteristics of included studies. It is unclear what statistics would be presented given the general characteristics listed under 'charting the data'.

Aside from the points raised above, the protocol has obviously been thoroughly researched and well thought out. I look forward to seeing the finished article, in particular the comprehensive approach (to avoid 'missing' frameworks), the inclusion of 'intended applications' which the authors have pointed out as lacking in earlier reviews, and the focus on producing guidance for framework selection and application which survey respondents have observed is lacking and much needed.

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Yes

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Behaviour change interventions; fidelity evaluation

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 17 December 2018

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Christopher Carroll 

School of Health and Related Research (SchARR), University of Sheffield, Sheffield, UK

This is an excellent, well-researched protocol outlining very clearly the process to be undertaken in, what will be a challenging but ultimately very interesting and useful scoping review of existing frameworks and models.

There are, indeed, many such published frameworks / models, but there remains little guidance on how they might best be used. This represents a genuine gap in the field, and this work a robust first step in

creating something rather more practical and useful. I'll be fascinated to see the results and whether the creation of guidance for researchers, in the selection and use of relevant frameworks, is possible.

The field is rather heavy in conceptualisations, but rather less well-served in empirical and practical research.

My only other comments on the protocol are:

p.4: PsyclINFO not Psychinfo - a common error

p.4: Re: the search string: 'fidelity OR 'treatment fidelity' OR "intervention fidelity" - the use of the first 'fidelity' by itself as a search term renders redundant the subsequent use of the alternative terms, 'treatment fidelity' OR "intervention fidelity".

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Yes

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Systematic review and evidence synthesis, implementation fidelity

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Author Response 17 Dec 2018

Elaine Toomey, National University of Ireland, Galway, Galway, Ireland

Dear Dr Carroll,

Thank you very much for reviewing our protocol and for such positive comments. We will address both of those comments before we run our searches. Thank you again.

Best wishes,
Elaine

Competing Interests: No competing interests were disclosed.

Comments on this article

Version 1

Author Response 17 Dec 2018

Elaine Toomey, National University of Ireland, Galway, Galway, Ireland

Hi Elizabeth,

Thanks so much for your comment - really interesting and insightful! With our review, we are hoping to find any framework that explores fidelity, so very much open to finding and including any from a realist perspective if they meet our criteria.

I wholeheartedly agree with you around the importance of adaptation and exploring fidelity to different aspects e.g. theoretical fidelity v content fidelity for example. I think this flexibility is sometimes addressed in some of the frameworks (e.g the Borrelli 2011 updated version of the NIHBC framework pays specific attention to the importance of exploring theoretical fidelity), but may not be in others. This is definitely something we will be cognisant of in doing this review, and will hopefully be able to shed more light on this issue by the end. Thank you for the RAMESES link, a very interesting project!

All the best,
Elaine

Competing Interests: No competing interests were disclosed.

Reader Comment 12 Dec 2018

Elizabeth Sturgiss, Australian National University, Australia

Thank you for sharing this well-written protocol for a scoping review exploring conceptual frameworks for the fidelity of intervention delivery. It will focus on complex interventions that aim to change behaviour of the participants.

I am interested in your review as I have recently been exploring how realist evaluation looks at complex interventions and the way they work. I note that your review does not include any of the literature from realist evaluation that views intervention fidelity in a very different manner.

In a realist evaluation paradigm, researchers embrace the complexity that surrounds all complex interventions. Rather than aiming for uniformity in how parts of an intervention are delivered, they consider the underlying program theory and whether this is triggered in the participant.

As an example, patients with obesity may need support around lifestyle change, but it is unlikely that each participant would benefit from exactly the same intervention around nutrition and activity due to the complexity of these behaviours and the different types of contexts that patients live in.

A good summary of the realist approach to intervention delivery is found from the RAMESES group, where they summarise "Fidelity should instead be re-articulated in terms of programme theory: fidelity to underlying causal processes, context sensitivity, and adaptation."

(http://ramesesproject.org/media/RAMESES_II_Realist_understanding_programme_fidelity.pdf)

Would you consider looking at alternative paradigms for thinking about intervention fidelity in your scoping

review? Or if you are not considering alternative paradigms, like realist evaluation, it might perhaps be worth outlining in your protocol the ontology that is informing your review?

Thank you again for sharing your work.

Competing Interests: I have no competing interests to declare.
