# An introduction to the development of complex interventions

Authors: Sarah Brewster1, Richard I.G. Holt,2 Hermione Price3

1 Southern Health NHS Foundation Trust, Research and Development, Tom Rudd Unit, Moorgreen Hospital, Botley Rd, West End, Southampton, UK SO20 2RZ

2 University of Southampton, Division of Human Development and Health, Faculty of Medicine, Southampton, UK

3 Southern Health NHS Foundation Trust, West Hampshire Community Diabetes Service, Southampton, UK
Details of Corresponding Author:

E-mail- Sarah.brewster@doctors.org.uk

Telephone- 07827937619

Key words:

Complex Intervention, Research Design

Word Count: 2297

## Abstract:

Healthcare interventions are complex, but have the potential to deliver more efficient, cost-effective care and improved health outcomes. Careful attention must be paid to their early planning and development to minimise research waste or interventions that fail to deliver what they set out to achieve. The Medical Research Council provides guidance to help intervention developers, encouraging an explicit and iterative approach. This article describes the Medical Research Council’s guidance and introduces two frequently used tools that further support the process of intervention design.

## Main Messages

- Healthcare interventions are complex, consisting of several interacting and changing components.

- It is important that clear and explicit procedures are followed during the planning and development of complex interventions to reduce research waste.

- The Medical Research Council’s Framework for Complex Interventions guides intervention developers from the early planning phase, through to delivery and subsequent evaluation of complex interventions.

- Intervention Mapping and the Behaviour Change Wheel are two theory and evidence based tools that supplement the planning and development phase of the Medical Research Council’s Framework for Complex Interventions, and have both been used in a number of healthcare interventions.

## Introduction

The number of people living with one or more long-term conditions is rising worldwide creating a significant challenge for governments and healthcare systems across the globe, particularly in countries with ageing populations [1]. Furthermore, individuals living with one long-term condition are more susceptible to developing other chronic conditions that typically make up predictable clusters of disease [2]. Estimates of the prevalence of people living with two or more long-term conditions, also known as multi-morbidity, are highly variable, in part due to a lack of standardised instruments to measure it [3]. In England, 15 million people have at least one long-term condition, and the treatment and care for these is estimated to cost 70 percent of the total health and care expenditure [4]. They account for 50 percent of all GP appointments, 64 percent of all outpatient appointments and over 70 percent of all inpatients bed days.

 The rising prevalence of long-term conditions and multi-morbidity, coupled with the protean nature of health services and health policies, means that interventions to address them are increasingly complex. Targeting complex problems inevitably requires complex solutions, which typically comprise several interacting components which may or may not result in an effect.

Most long-term conditions require regular monitoring and are reliant on various self-care practices and behaviours if optimal outcomes are to be experienced by the individual. This is not always easy and the management of diabetes is a good example. Recent evaluation of national audit data has identified that people living with type 2 diabetes who have not had their care processes completed were at a significantly increased risk of morbidity and mortality [5]. As with other long-term conditions, people living with diabetes have a greater likelihood of experiencing concomitant physical and mental illnesses [6]. Such co-morbidities can have profound effects on a person’s ability to manage their self-care [7].

The UK Medical Research Council (MRC) developed a framework for developing and evaluating complex interventions to help guide intervention developers [8]. When considering an intervention to support people living with long-term conditions and multi-morbidity, it seems inherent to follow a process that considers their complexity. This article discusses the MRC framework with particular attention to the development phase. Due to the importance of behaviour in the management of long-term conditions such as diabetes, two well-described models, the Behaviour Change Wheel and Intervention Mapping are discussed, both of which guide intervention developers through the process of intervention design in accordance with the MRC framework and have been widely applied to behaviour change interventions.

## Complex Interventions and the UK Medical Research Council (MRC) Framework

It has been estimated that 85% of research activity is wasted [9]. This waste has been attributed to poor question selection, insufficient attention to previous research results, inadequate reporting, and poor intervention description [10].

Complex interventions typically have several interacting components, may necessitate new behaviours by those delivering or receiving the intervention, and can have a variety of outcomes [8]. To reduce avoidable weaknesses in the design, conduct and analysis of complex interventions, and thereby minimise research waste, several guides are available, of which the UK MRC framework for developing and evaluating complex interventions is the most cited [9] .

The UK MRC developed its first framework in 2000 to try and improve the design and reporting of healthcare interventions, with more explicit consideration of how an intervention may work during its development phase [11]. The framework introduced a systematic and phased approach to intervention design, while building evidence and testing theory before implementing an intervention or conducting a trial.

In 2008, an updated version of the UK MRC framework was published, encouraging a more iterative approach to intervention design [8]. The MRC has continued to evaluate its frameworks, and in collaboration with NIHR (National Institute for Health Research), was due to publish another update in 2019 but this is still awaited.

The MRC framework helps researchers define more clearly and transparently the research process. The four stages of the 2008 MRC framework are as follows:

1. Development of the complex intervention: reviewing the evidence base, identifying and developing theory, and modelling processes and outcomes.
2. Feasibility and piloting: testing procedures, estimating retention and determining sample size.
3. Evaluation: Assessing effectiveness, understanding the change process and evaluating cost-effectiveness.
4. Implementation: Dissemination, surveillance, monitoring and long-term follow-up.

Although the MRC framework clearly maps out the stages of evaluating an intervention, it has been criticised for lacking detail in the initial development process between the initial idea for an intervention and formal pilot testing in the next phase [12]. There are several additional frameworks and sources of guidance used in research that attempt to address this limitation, bridging the gap between ideas, theories and practice. With the different approaches available, however, the advice can be conflicting and lead to confusion. Furthermore, interventions developed using existing theory have not necessarily been shown to deliver more effective interventions than those that do not, but this may be a reflection of the current evidence base rather than a true lack of effect [13].

## The planning and development phase of complex interventions

Careful planning and development of complex interventions is important if they are to have the best chance of being effective and to be broadly adopted in the real world. Key principles can be applied and frameworks used to support this stage of the process.

### Five key principles of intervention development

Following reviews and qualitative interviews, a consensus exercise undertaken by O’Cathain et al in 2019 led to the proposition that there are five key principles to intervention development: it should be dynamic, iterative, creative, open to change and consider future evaluation and implementation [12]. The consensus recommendations include a series of suggested actions that should be considered in the development phase of an intervention, although some of these may not be relevant to every problem or context. Their suggested actions and how they relate to the underlying principles can be seen in Figure 1.

### Frameworks to instruct the planning and development of complex interventions

There are several tools available that aim to complement the MRC framework, helping to add structure and detail to the development phase. To date, no one tool has proven to be better than another or shown that its use always translates into a successful intervention [12]. In reality, developers typically select the published approach they feel best addresses the purpose of their intervention or best fits their values and beliefs. Most published approaches make reference to and include the actions recommended by O’Cathain et al, with the main difference being in the emphasis they place on some actions or subsets of actions. Although an intervention developer may decide to follow a particular approach, it should be applied flexibly to fit their specific context. In some instances a combination of approaches are used.

### Frameworks relevant to behaviour change interventions

The Behaviour Change Wheel [14] and Intervention Mapping [15] are two evidence and theory-based approaches that complement the MRC framework and incorporate models for anticipating and defining the likely influences on behaviour which can then be mapped onto appropriate behaviour change techniques. Both approaches have been widely used in healthcare intervention design, including those pertaining to long-term conditions such as diabetes [14, 16]. We will go on to describe both of these approaches in the next section below.

Other approaches to complex intervention design include the ‘Theory of Change’ [17], ‘Six steps in quality intervention development (6SquID)’ [18], ‘Realist complex intervention science’ [19] and ‘Action Research’ [20]. These approaches are less well cited in the literature for behaviour change interventions pertaining to long-term conditions and are outside the scope of this review.

To complement theory and evidence approaches including the Behaviour Change Wheel and Intervention Mapping, the Person Based Approach can also be incorporated. Through in-depth qualitative work, the Person Based Approach facilitates the understanding of an intervention’s context and the people who will use it so that evidence and theory based approaches can be more effectively applied [21]. Although most frequently used in digital interventions, it has not been designed exclusively for these. The benefits of incorporating the Person Based Approach into other evidence and theory based frameworks, is that it goes beyond describing intervention content. It considers how the content is communicated to the user, and facilitates early identification of problems with user engagement and participation, allowing issues to be addressed early and thereby minimising waste of resources.

### The Behaviour Change Wheel (BCW)

The BCW by Michie et al consist of three phases or layers, which offer a step-by-step guide to designing behaviour change interventions (Figure 2). The first layer starts with the identification of behaviour(s) that need changing, prioritising them, and then selecting the few to target. This decision is made by considering likely impact, changeability and spill-over effect of each behaviour.

Once the target behaviour(s) have been chosen, researchers are encouraged to then use COM-B, which stands for Capability, Opportunity, Motivation and Behaviour, to help identify potential personal determinants to target which drive the behaviour of interest. COM-B maps onto the Theoretical Domains Framework which divides behaviours into domains.

Following on from the COM-B analysis, the second layer of the Behaviour Change Wheel identifies from a list of nine intervention functions, selected by expert consensus, the ones most relevant to the COM-B analysis which have shown to facilitate change in behaviour(s). Building from the COM-B analysis, its associated Theoretical Domains Framework domains and the intervention functions, the third layer of the Behaviour Change Wheel concerns identifying the relevant ‘behaviour change techniques’. An extensive taxonomy of the most frequently used behaviour change techniques for each intervention function or Theoretical Domains Framework domain can then be consulted. These are irreducible, replicable and observable or measurable. Finally, once the behaviour change techniques have been identified and chosen, the most suitable mode of delivery can be decided.

Although a useful model, particularly for those less familiar with health behaviour interventions, the Behaviour Change Wheel assumes all behaviours are a result of personal determinants that fall into ‘capability’, ‘opportunity’ or ‘motivation’. The flow from one model to the another in the Behaviour Change Wheel can be appealing, although the benefits of systemisation of intervention design has been debated, particularly with regards to the prescriptive nature of the taxonomy of behaviour change techniques [22]. It has been argued that systemisation risks creating a false sense of simplicity. There will always be variability in people, healthcare professionals, manifestations and situations, and it is this variability which contributes to the complexity of complex interventions [23].

### Intervention Mapping (IM)

Intervention Mapping comprises six steps, each of which is divided into several tasks (figure 3) [15, 16]. The Intervention Mapping approach is cumulative with each step building on the previous, but the model also encourages an iterative approach, with researchers moving in both directions as new concepts and themes evolve.

By being less prescriptive, IM is more adaptive and arguably more encompassing, relying on fewer assumptions than other approaches to intervention development such as the Behaviour Change Wheel. In a recent taxonomy of approaches by O’Cathain et al, Intervention Mapping was the most comprehensive [24]. It has also successfully been used in healthcare interventions which have led to significant increases in the uptake of disease prevention programmes [25].

### Similarities between the Behaviour Change Wheel and Intervention Mapping

Both the Behaviour Change Wheel and Intervention Mapping share many similarities. They both recommend a planning group, the use of empirical and primary data and an iterative approach to the development phase of intervention design.

Both models start by encouraging intervention developers to generate a list of target behaviours that the intervention will aim to change. To do this, they both encourage an attempt to identify all possible health behaviours contributing to the health problem of interest. Once these have been identified, both models ask that these behaviours are prioritised by considering their changeability and the likely effectiveness or suspected impact changing a given behaviour may have. The capacity of the developers and within the target population must also be part of this early decision process.

Once the target behaviour(s) are selected, the Behaviour Change Wheel and Intervention Mapping attempt to make these as specific as possible, breaking them down into their finer constituents whilst recognising that all behaviours are part of a wider ecological system. When deciding “what needs to change” in order to influence the target behaviour(s), both models consider the personal and environmental determinants that may have influence, but do so using different techniques. As the interventions developers work through the two frameworks, the determinants of the behaviour are explored and the appropriate behaviour change techniques identified.

## Conclusion

With the rising number of people living with multi-morbidity, healthcare interventions to support these individuals must be developed with an appreciation for its complexity. Although the MRC provides guidance on developing and evaluating complex interventions, a number of frameworks exist to help provide more structure during the early development phase. Two widely used frameworks used in behaviour change interventions include the Behaviour Change Wheel and Intervention Mapping. In some instances the Person Based Approach is used to supplement these models, but to date, this has typically been in relation to technology interventions. The Behaviour Change Wheel and Intervention Mapping are well cited tools in behaviour change interventions for long-term health conditions. Although they share many similarities, they also celebrate key differences, some of which have been described in this article.

By applying the MRC framework, with the addition of appropriate tools to supplement the development phase, it is hoped that complex interventions to address multi-morbidity will result in less research ‘waste.’ Following a detailed and explicit process, as outlined in this article, can help with the later identification of ‘active’ and reproducible components of an intervention, so that aspects of it may be successfully transferred to other contexts.

## Statements

### Contributorship Statement

SB reviewed the literature, wrote the first draft of the article, edited the article and submitted it. HP and R.I.G.H reviewed the first draft, provided feedback and read subsequent versions of the original article until a final version was agreed.

### Funding

No funding was received for this article.

### Competing Interests

No competing interests to declare.

### Acknowledgements

N/A

## References

1. Barnett K, Mercer SW, Norbury M, Watt G, Wyke S, Guthrie B. Epidemiology of multimorbidity and implications for health care, research, and medical education: a cross-sectional study. The Lancet. 2012;380(9836):37-43.

2. Whitty CJM, MacEwen C, Goddard A, Alderson D, Marshall M, Calderwood C, et al. Rising to the challenge of multimorbidity. BMJ. 2020;368:l6964.

3. Diederichs C, Berger K, Bartels DB. The Measurement of Multiple Chronic Diseases—A Systematic Review on Existing Multimorbidity Indices. The Journals of Gerontology: Series A. 2011;66A(3):301-11.

4. The Kings Fund. Long-term conditons and multi-morbidity 2012 [Available from: <https://www.kingsfund.org.uk/projects/time-think-differently/trends-disease-and-disability-long-term-conditions-multi-morbidity>.

5. McKay AJ, Gunn LH, Vamos EP, Valabhji J, Molina G, Molokhia M, et al. Associations between attainment of incentivised primary care diabetes indicators and mortality in an English cohort. Diabetes Research and Clinical Practice. 2021;174:108746.

6. Zghebi SS, Steinke DT, Rutter MK, Ashcroft DM. Eleven-year multimorbidity burden among 637 255 people with and without type 2 diabetes: a population-based study using primary care and linked hospitalisation data. BMJ Open. 2020;10(7):e033866.

7. Piette JD, Kerr EA. The Impact of Comorbid Chronic Conditions on Diabetes Care. Diabetes Care. 2006;29(3):725.

8. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ. 2008;337:a1655.

9. Bleijenberg N, de Man-van Ginkel JM, Trappenburg JCA, Ettema RGA, Sino CG, Heim N, et al. Increasing value and reducing waste by optimizing the development of complex interventions: Enriching the development phase of the Medical Research Council (MRC) Framework. International Journal of Nursing Studies. 2018;79:86-93.

10. Ioannidis JPA, Greenland S, Hlatky MA, Khoury MJ, Macleod MR, Moher D, et al. Increasing value and reducing waste in research design, conduct, and analysis. The Lancet. 2014;383(9912):166-75.

11. Campbell M, Fitzpatrick R, Haines A, Kinmonth AL, Sandercock P, Spiegelhalter D, et al. Framework for design and evaluation of complex interventions to improve health. BMJ. 2000;321(7262):694.

12. O'Cathain A, Croot L, Duncan E, Rousseau N, Sworn K, Turner KM, et al. Guidance on how to develop complex interventions to improve health and healthcare. BMJ Open. 2019;9(8):e029954.

13. Dalgetty R, Miller CB, Dombrowski SU. Examining the theory-effectiveness hypothesis: A systematic review of systematic reviews. British Journal of Health Psychology. 2019;24(2):334-56.

14. Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. Implementation science : IS. 2011;6:42-.

15. Bartholomew LK, Markham, C.M, et al,. Planning health promotion programs: an Intervention Mapping approach. Fourth Edition ed. Hoboken, NJ: Wiley; 2016.

16. Kok G, Peters LWH, Ruiter RAC. Planning theory- and evidence-based behavior change interventions: a conceptual review of the intervention mapping protocol. Psicologia: Reflexão e Crítica. 2017;30(1):19.

17. De Silva MJ, Breuer E, Lee L, Asher L, Chowdhary N, Lund C, et al. Theory of Change: a theory-driven approach to enhance the Medical Research Council's framework for complex interventions. Trials. 2014;15(1):267.

18. Wight D, Wimbush E, Jepson R, Doi L. Six steps in quality intervention development (6SQuID). Journal of Epidemiology and Community Health. 2016;70(5):520.

19. Fletcher A, Jamal F, Moore G, Evans RE, Murphy S, Bonell C. Realist complex intervention science: Applying realist principles across all phases of the Medical Research Council framework for developing and evaluating complex interventions. Evaluation. 2016;22(3):286-303.

20. Dick B. Action research literature: Themes and trends. Action Research. 2004;2(4):425-44.

21. Yardley L, Morrison L, Bradbury K, Muller I. The person-based approach to intervention development: application to digital health-related behavior change interventions. J Med Internet Res. 2015;17(1):e30.

22. Ogden J. Celebrating variability and a call to limit systematisation: the example of the Behaviour Change Technique Taxonomy and the Behaviour Change Wheel. Health Psychology Review. 2016;10(3):245-50.

23. Peters G-JY, Kok G. All models are wrong, but some are useful: a comment on Ogden (2016). Health Psychology Review. 2016;10(3):265-8.

24. O’Cathain A, Croot L, Sworn K, Duncan E, Rousseau N, Turner K, et al. Taxonomy of approaches to developing interventions to improve health: a systematic methods overview. Pilot and Feasibility Studies. 2019;5(1):41.

25. Garba RM, Gadanya MA. The role of intervention mapping in designing disease prevention interventions: A systematic review of the literature. PLOS ONE. 2017;12(3):e0174438.

## Figures

Figure 1 Principles and actions to consider in the development phase of a complex intervention- adapted from the logic model published by O'Cathain et al 2019 [12].

Figure 2- The Behaviour Change Wheel [14]

Figure 3 Intervention Mapping [15]