

**UWS** UNIVERSITY OF THE  
WEST *of* SCOTLAND

Dr Lynsay Matthews

Lecturer in Public Health

Developing and Evaluating Complex Interventions: How to use the new MRC/NIHR  
Framework in your own research

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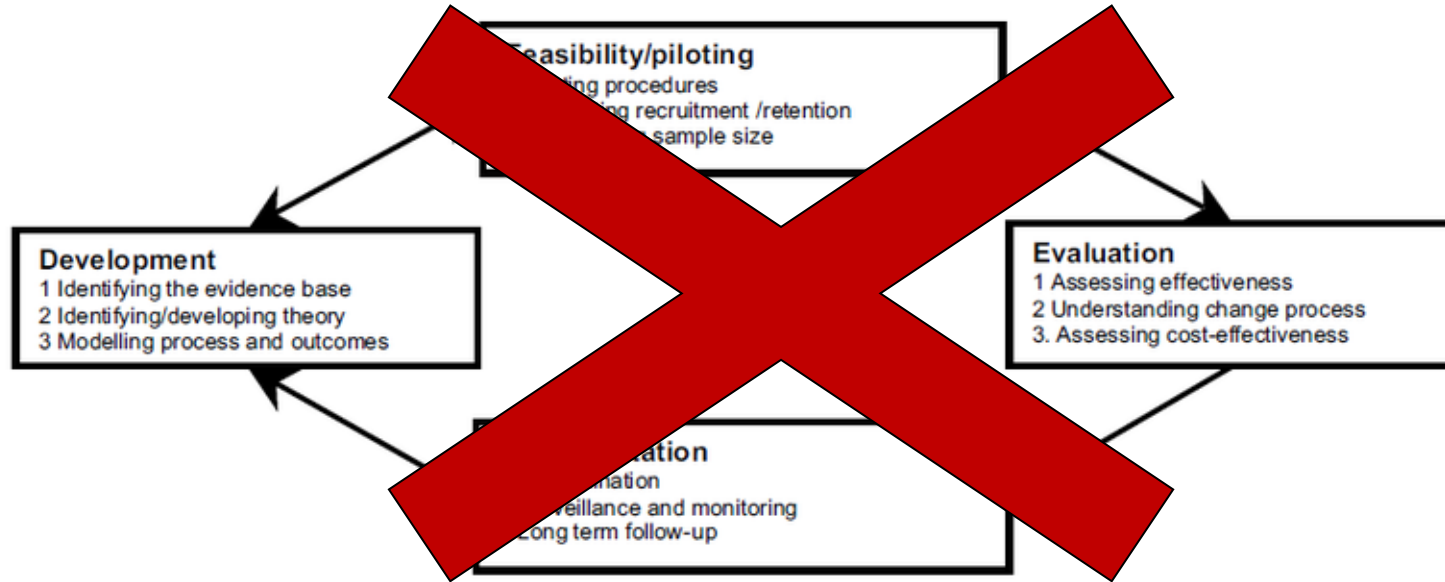
# The key publications

- The full framework
  - Skivington, K et al. Framework for the development and evaluation of complex interventions: gap analysis, workshop and consultation-informed update. Health Technol Assess 2021;25(57) <https://doi.org/10.3310/hta25570>
- The BMJ summary
  - Skivington, K et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. BMJ 2021;374:n2061 <https://doi.org/10.1136/bmj.n2061>

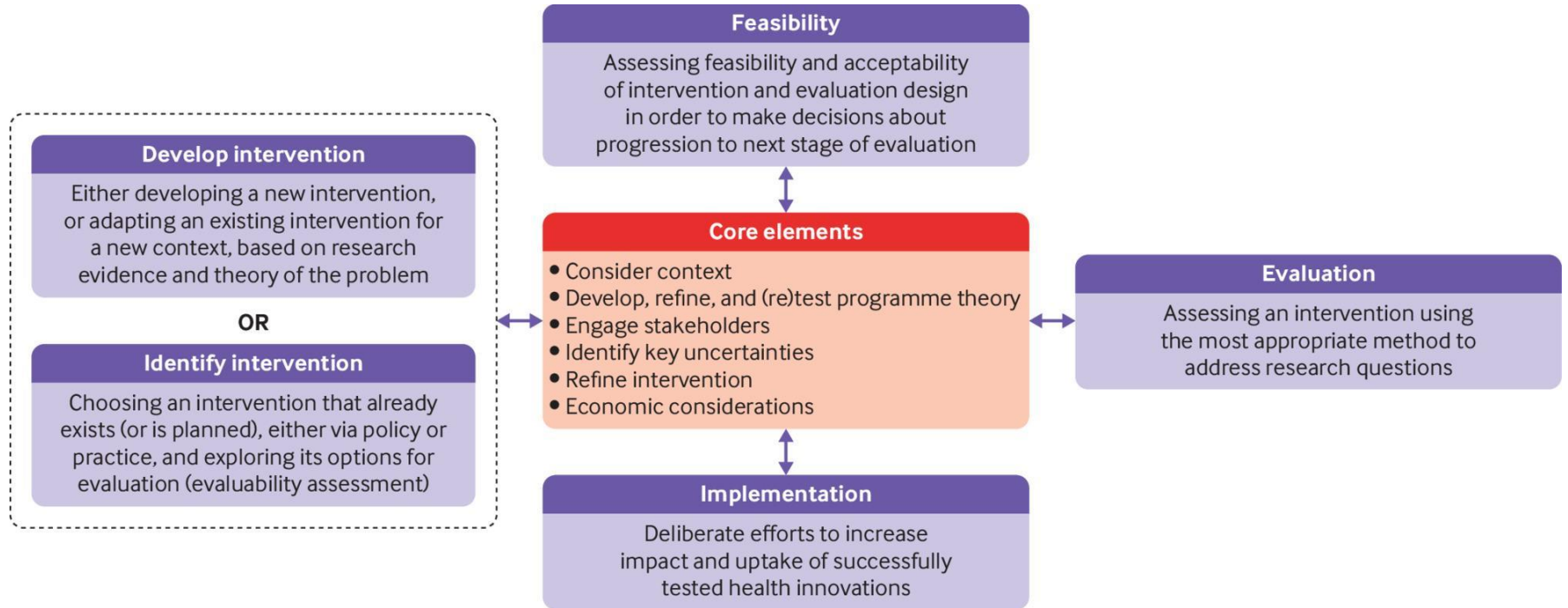
# Acknowledgements

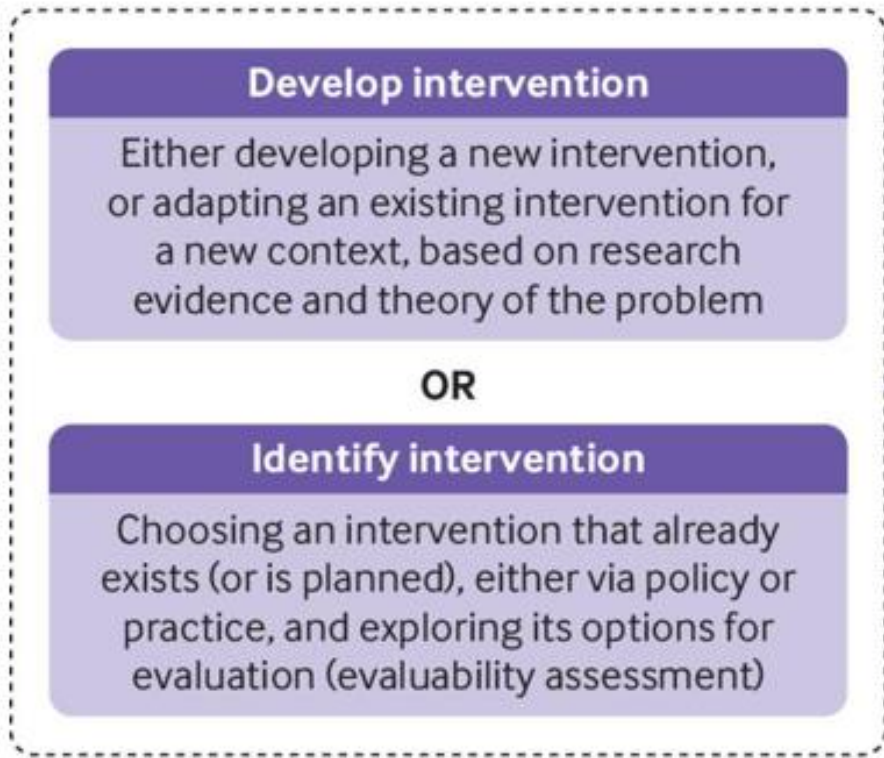
- The main project team
  - Kathryn Skivington, Lynsay Matthews, Sharon Simpson, Peter Craig, Moore
- The health economics team
  - Emma McIntosh, Kathleen Boyd, Neil Craig
- The scientific advisory group
  - Martin White, Janis Baird, Jo Rycroft-Malone, Jane Blazeby, Mark Petticrew, David French, Martin Ashton-Key
- Funded by
  - The Medical Research Council and the National Institute of Health Research

Here's what you're used to seeing ....



# Here's the new Framework...





Assessing  
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- Consider con
- Develop, refin
- Engage stake
- Identify key u
- Refine interve
- Economic co

Delib  
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## Feasibility

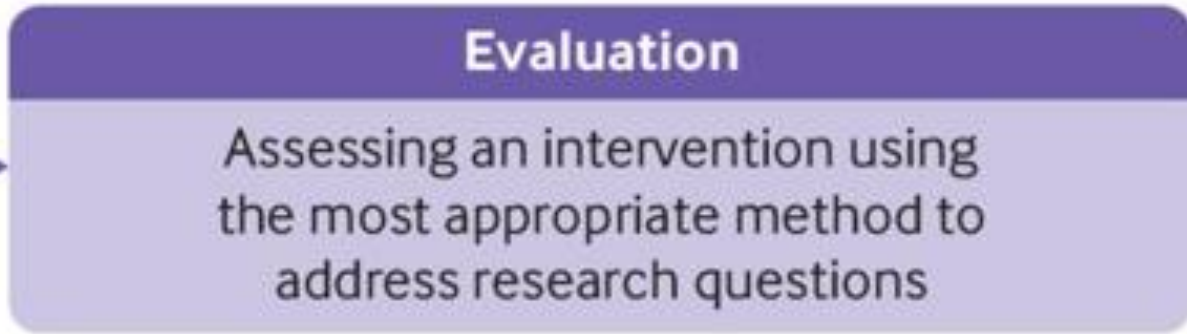
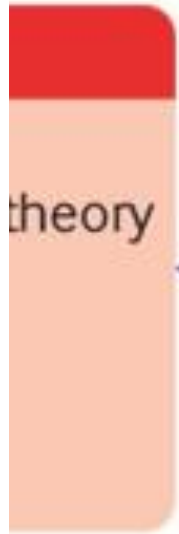
Assessing feasibility and acceptability of intervention and evaluation design in order to make decisions about progression to next stage of evaluation



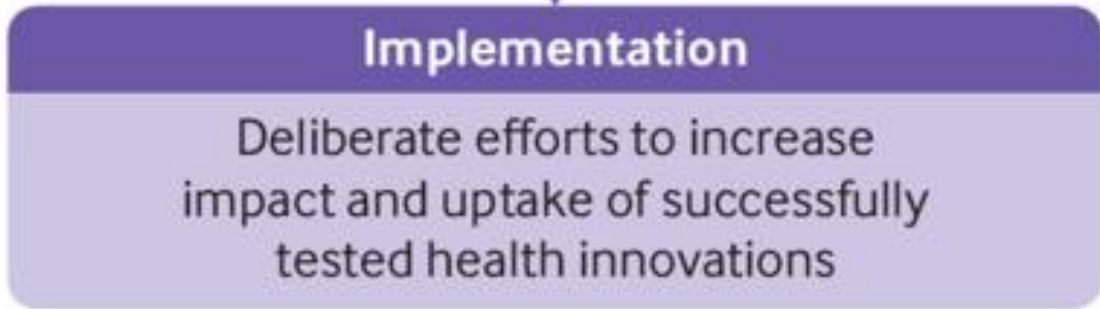
## Core elements

- Consider context
- Develop, refine, and (re)test programme theory
- Engage stakeholders
- Identify key uncertainties



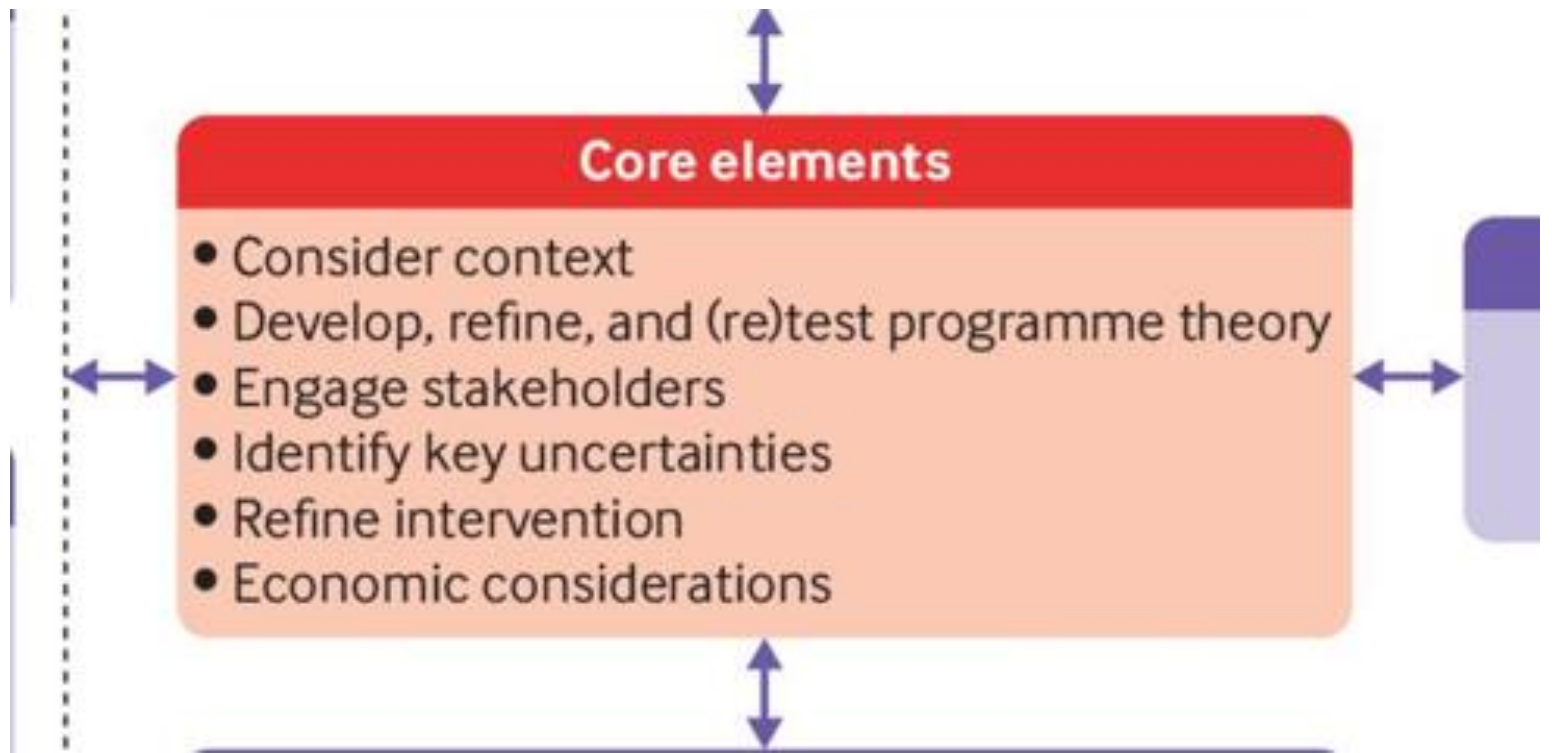






Unit  
rsity





# The key changes



**Pluralistic  
approach**

(no single optimal  
method)



**Choice of 4  
research  
perspectives**



**Consideration of 6  
core elements**



**Includes 24 case  
studies and a  
checklist**

# What is 'complexity'?

Complexity arises from the properties of:

1. the intervention itself e.g. number of groups, intervention components etc.
2. the context in which an intervention is delivered e.g. political, social, economic context etc.
3. and the interaction between the two e.g. 'events in systems'.

# **The 4 Research Perspectives**

Perspective	Questions
Efficacy	Does the intervention work, in a tightly controlled experimental setting?
Effectiveness	Does the intervention work, in the kind of setting(s) where it is expected to be implemented in practice?
Theory based	How does the intervention achieve impact, given its interactions with the context in which it is implemented?
Systems	How do system and intervention adapt to one another? Does the intervention change the system in which it is implemented and vice versa?



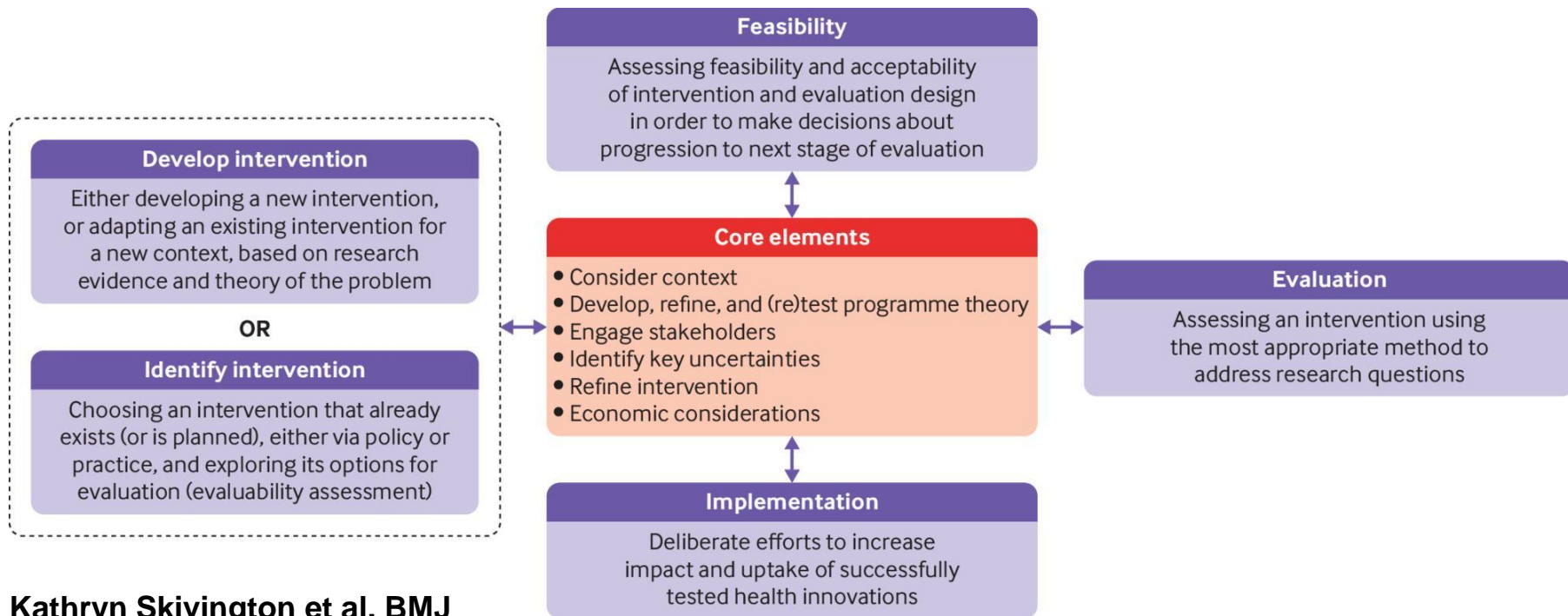
# Choice of perspective

- There is no one method of undertaking an evaluation; considerations include:
  - Who is the evaluation data for? – involve them in the design of the evaluation. The data needs to be ‘useful’.
  - What perspective is the evaluation taking? – this helps us define the questions that need answered, which in turn informs the choice of design and methods.
  - What is the evaluation data hoping to impact? – ensure appropriate outcomes are included to capture and inform this.

# **The 6 core elements**



# Framework for developing and evaluating complex interventions



**Kathryn Skivington et al. BMJ  
2021;374:bmj.n2061**

# Core Element 1: Consider context

**Context:** any feature of the circumstances in which an intervention is conceived, developed, evaluated, and implemented.

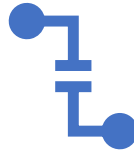
Context is dynamic and multi-dimensional

Effects of an intervention may be highly context dependent

# If we don't consider CONTEXT



Lack of understanding of context may result in an intervention that works in one setting, but may be ineffective elsewhere



Failure to understand how the intervention interacts and/or interrupts the system in which it is located



Interventions implemented in contexts in which they are unlikely to work

# Core Element 2: Programme Theory

- ***Programme theory***: describes how an intervention is expected to lead to its effects and under what conditions. The programme theory should be tested and refined at all stages and used to guide the identification of uncertainties and research questions.
- Programme theory should be developed at the beginning of the project with involvement of diverse stakeholders, and based on evidence and theory from relevant fields
- Visual representation of programme theory
- A refined programme theory is an important evaluation outcome

# If we don't consider PROGRAMME THEORY



Unable to advance theory



Key contextual dependencies are neglected resulting in an intervention that fails to operate as designed



Failure to identify harms, side effects or potential wider, long-term effects that were not assessed in the evaluation

# Core Element 3: Stakeholders

- ***Stakeholders***: those who are targeted by the intervention or policy, involved in its development or delivery, or more broadly those whose personal or professional interests are affected, i.e. who have a stake in the topic.
- **Meaningful** engagement
- Broad thinking and consultation is needed to identify a diverse range of appropriate stakeholders.
- The purpose of stakeholder engagement will differ depending on the context and phase of the research

# If we don't consider STAKEHOLDERS



Lack of useful and convincing data to inform progression to the next phase of evaluation and/or implementation



Planning and progression to the next phase will not meet stakeholders' needs or benefit from their critical insights



Risk of proceeding with a full-scale definitive trial for an intervention that is highly unlikely to be implemented in practice

# Core Element 4: Identify the key uncertainties





# If we don't consider UNCERTAINTIES



Unanticipated contextual and implementation factors undermine the intervention



Evidence of effectiveness may not translate as the intervention is implemented outside research conditions



Failure to continue to learn about how the intervention can best be implemented to maximise effects

# Core Element 5: Refinement

**Refinement:** The process of ‘fine tuning’ or making changes to the intervention once a preliminary version (prototype) has been developed.

- It benefits all stakeholders for the optimal version of an intervention to be evaluated and/or implemented
- Ongoing refinement can improve the potential implementability of the intervention
- Acceptable boundaries of refinement should be agreed from the outset

# If we don't consider REFINEMENT



Intervention failure owing to unnecessarily rigid adherence to intervention as evaluated



Risk of proceeding to the next phase of evaluation with a suboptimal intervention and/or evaluation design



Waste of resources

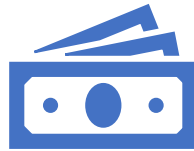
# Core Element 6: Economic considerations

- Inclusion of economic considerations helps with understanding the problem and shaping the design of future studies
- Comparative analysis of alternative courses of action in terms of both costs (resource use) and consequences (outcomes and effects)
- Key to economic evaluation is the identification, measurement and valuation of the resources and outcomes
- Complex interventions are likely to have costs and outcomes across different sectors

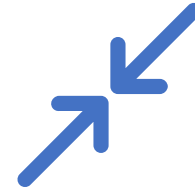
# If we don't consider ECONOMIC ISSUES



Decision-makers  
misunderstanding economic  
results and what that means  
for their practice/budgets



Cost-effective interventions  
not implemented in practice



Cost-effectiveness of large-  
scale implementation  
underestimated or  
overestimated

# 27 individual case study examples

TABLE 9 Case studies referred to in the report

Case study	Description
<b>Core elements</b>	
Case study 1	Travel through the main phases of complex intervention research
Case study 2	Considering context
Case study 3	Developing, refining and testing programme theory
Case study 4	Complex logic model
Case study 5	Dark logic model
Case study 6	Realist matrix
Case study 7	System map to develop programme theory
Case study 8	Engaging stakeholders (service users)
Case study 9	Refining the intervention
Case study 10	Economic considerations
<b>Phases of the research process</b>	
Case study 11	Intervention development and example systems map
Case study 12	Feasibility trial
Case study 13	Feasibility: evaluability assessment
Case study 14	Evaluation: effectiveness perspective - cluster RCT with theory-informed process evaluation
Case study 15	Evaluation: efficacy perspective
Case study 16	Evaluation: effectiveness perspective with individual RCT

# Signpost boxes

## SIGNPOSTS TO FURTHER READING 11 Implementation

- Implementation fidelity: the MRC guidance on process evaluation of complex interventions.<sup>5</sup>
- The Context and Implementation of Complex Interventions (CICI) Framework.<sup>70</sup>
- *Development of a framework and coding system for modifications and adaptations of evidence-based interventions.*<sup>145</sup>
- *Unintended outcomes evaluation approach: a plausible way to evaluate unintended outcomes of social development programmes.*<sup>136</sup>
- *Standards for reporting implementation studies (StaRI) statement.*<sup>273</sup>
- The Implementation Research ('ImpRes') tool.<sup>289</sup>
- An introduction to implementation science.<sup>290</sup>
- *Making sense of implementation theories, models and frameworks.*<sup>291</sup>
- *Normalisation process theory: a framework for developing, evaluating and implementing complex interventions.*<sup>130</sup>
- *Implementation research: new imperatives and opportunities in global health.*<sup>271</sup>
- *Diffusion of innovations in service organizations: systematic review and recommendations.*<sup>292</sup>
- *The quality implementation framework: a synthesis of critical steps in the implementation process.*<sup>293</sup>

# Checklist

## Appendix 6 Checklist for developing and evaluating complex interventions

This checklist is intended as a tool to help researchers prepare funding applications, research protocols and journal publications. It may also help reviewers to assess whether or not the recommendations have been followed.

Item	If NO, please justify, If YES, briefly describe how this has been addressed	Reported on page number(s)
<b>Addressing uncertainties</b>		
<ol style="list-style-type: none"><li>1. Have you determined the aim(s)/purpose(s) of the intervention?</li><li>2. Have you identified the key uncertainties given existing evidence about the intervention and the context in which it will be tested or implemented?</li><li>3. Do the research questions and methods address the key uncertainties?</li><li>4. Does the choice of research perspective (efficacy, effectiveness, theory-based, systems) reflect the key uncertainties that have been identified?</li></ol>		
<b>Engaging stakeholders</b>		
<ol style="list-style-type: none"><li>1. Have you engaged stakeholders in the design/identification of the intervention and the development of the research protocol?</li><li>2. Have you engaged stakeholders in the conduct of the research and the dissemination of findings?</li><li>3. Have all stakeholders declared any potential conflicts of interest?</li></ol>		
<b>Considering context</b>		
<ol style="list-style-type: none"><li>1. Have you identified all the dimensions of context that may</li></ol>		



# Any questions?

Please ask or pop your questions into the chat box



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