Guidance on developing interventions to improve health and health care

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Contents

Glossary

Adaptation	Where an existing intervention is modified or tailored in order to adapt it to a new population, setting or health care context
Complex intervention	Complex interventions can have a number of interacting components, require new behaviours by those delivering or receiving the intervention, or have a variety of outcomes. [1] [2]
Context	Encompasses any feature of the circumstances in which an intervention takes place that is relevant to understanding how it is implemented, how it effects change or how it is responded to or engaged with. [3]
De novo	Creation of a new intervention, sometimes referred to as innovation. The re-use of components of existing interventions can be part of de novo intervention development
Design	The terms 'design' and 'development' are sometimes used interchangeably. The term 'design' is reserved for a part of the development process where ideas are generated about the intervention concept, content, format and delivery and creativity takes place
Delivery	How the intervention is delivered by practitioners or others during the development and evaluation phases. It may be an integral part of the intervention
Development	The term 'development' is used here for the whole process of intervention development from the idea or inception of an intervention until it is ready for formal feasibility, pilot or efficacy testing.[4] It occurs in the first of four phases in the MRC framework for developing and evaluating complex interventions

Health intervention	An intervention is something that aims to make a change and is tested through research (https://www.nihr.ac.uk/patients-and-public/why-join-in/definition-of-terms.htm). It includes programme or policy innovation
Implementation	This term can have different meanings. Implementation involves putting research findings into practice (https://www.nihr.ac.uk/patients-and-public/why-join-in/definition-of-terms.htm). The term is not used here to mean delivery of the intervention during development or evaluation
Logic model	A logic model is a diagram of how an intervention is proposed to work, showing mechanisms by which an intervention influences the proposed outcomes
Modification	This is sometimes used interchangeably with the term 'adaptation'. The term is not used in this guidance
Optimisation	A review of optimisation defines it as a process with the aim of evaluating or testing intervention components and/or draft interventions in order to identify what works and what does not work within the intervention under development.[5] The focus is often on accessibility, usability and acceptability of an intervention during the development phase.
Programme theory	A programme theory describes how a specific intervention is expected to lead to its effects and under what conditions. [6] It shows the causal pathways between the content of the intervention, intermediate outcomes and long term goals, and how these interact with contextual factors.
Published approach to intervention development	A guide to the process and methods of intervention development set out in a book, website or journal article

Refinement	The process of 'fine tuning' or making changes to the intervention once a preliminary version (prototype) has been developed. Early refinement, occurring during the intervention development phase is the focus of this guidance. Changes made during or after formal feasibility/pilot, evaluation and implementation phases of the MRC guidance on developing and evaluating complex interventions are not considered in this guidance
Scaling up	A process aimed at maximizing the reach and effectiveness of a range of actions, leading to sustained impact on outcomes. [7]
Stakeholder	"An individual or group who is responsible for or affected by health-and healthcare-related decisions that can be informed by research evidence [...] patients and the public, providers, purchasers, payers, policy makers, product makers, and principal investigators". [8]
Target population	The people who the intervention is aimed at: the general public, patients or practitioners
Theory	The term 'existing theory' is used to describe grand or mid-range theory. Grand theory has a high level of abstraction and is applicable across many domains. Mid-range theories are specific to a domain and lie between minor hypotheses and a conceptual scheme e.g. theory of diffusion of innovation, normalisation process theory. [6]

1. Introduction to the guidance

1.1 What is 'intervention development'?

The definition of intervention development used in this guidance is what happens between the idea or inception of an intervention until it is ready for formal feasibility, pilot or efficacy testing prior to a full evaluation [4]. In the 2008 MRC guidance, Craig et al. proposed four phases in the development and evaluation of complex interventions: development, feasibility and piloting, evaluation and implementation in the real world. The first phase in this framework - 'development' -is where the "intervention must be developed to the point where it can reasonably be expected to have a worthwhile effect" (p9).[1] The start and end points of this phase are not always clear. Prior to what might be termed the 'intensive development phase' there may be a variable period of preparation when members of a team undertake a series of small studies, sometimes over many years, before the point of intensively developing an intervention. This may involve assessment of the published evidence base and primary research or activities with key stakeholders and/or the target population. Alternatively, these studies may be undertaken as part of the intensive intervention development phase. The distinction between the development phase and the next phase of feasibility/piloting is not clear because some exploration of feasibility is often part of the intervention development process.[4] A helpful demarcation of the end of the development phase, and the one used in this guidance, is when a document or manual describing the intervention and how it should be delivered is produced, ready for more formal testing. [4]

In practice, intervention development never really ends, as further changes occur once an intervention is piloted, evaluated and implemented. This guidance only focuses on the intensive development phase and labels further development undertaken in feasibility/piloting and evaluation phases as 'refinement'.

1.2 Why guidance is needed

Researchers, the public, patients, industry, charities and health care providers can all be involved in the development of new interventions to improve health and health care. There is increasing recognition of the importance of carefully developing complex interventions, the argument being that attention to these tasks will increase the chance of interventions being

effective when evaluated, and being adopted widely in the real world. There is also increasing demand for new interventions as policymakers and practitioners grapple with complex challenges in health, such as integration of health and social care, risk associated with lifestyle behaviours, and the use of e-health technology. Prior to funding expensive evaluations, funders and policymakers need to be confident that any proposed intervention has the best chance of being effective, cost-effective and implementable in the real world. Poor intervention development may lead to wasted tax payers' money if expensive evaluations show that these interventions are flawed, or that effective interventions have limited impact in the real world. Poor intervention development may also create problems for patients and the public, if interventions are not fit for purpose or are not implemented as intended. Theoretical understanding and practical experience of developing interventions has accumulated over recent years. It is therefore timely to bring together learning from a variety of sources and offer overarching guidance.

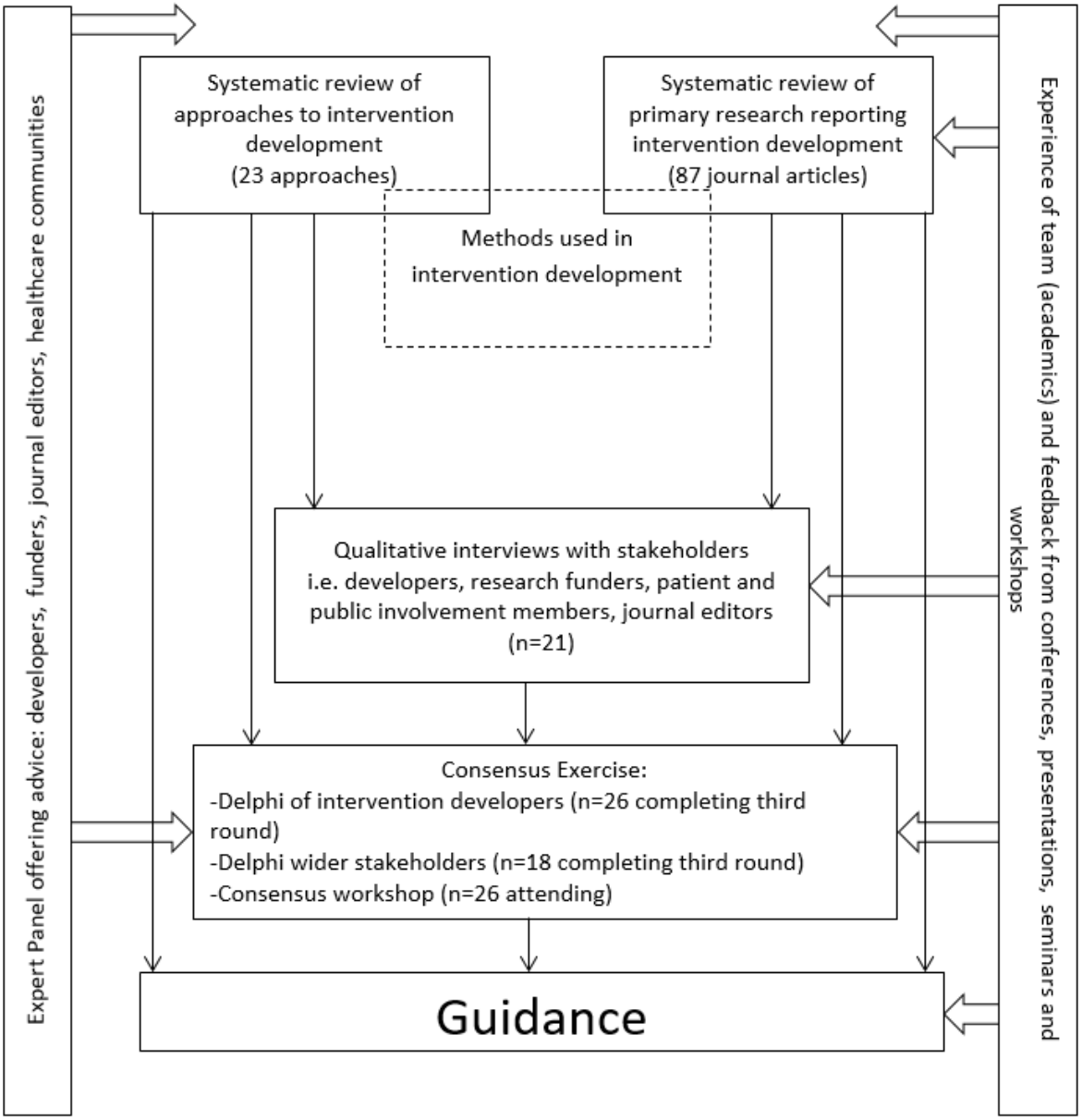
1.3 Foundations of this guidance

The guidance is based on a study funded by the NIHR –MRC Methodology Research Panel: The INDEX study – **I**de**n**tifying and assessing different approaches to **d**eveloping compl**ex** interventions (see Figure 1). It consisted of the following:

- **systematic methods overview of published approaches** to intervention development[9]
- **systematic review of primary research** reporting intervention development[10]
- **qualitative interviews** with intervention developers and wider stakeholders involved with the process, that is, funders, journal editors, public and patients [11-13]
- **consensus exercise** consisting of two simultaneous and identical e-Delphi studies distributed to intervention developers and wider stakeholders respectively, and followed by a consensus workshop. We asked experts to rate around 80 items on a five-point scale from 'very' to 'not important' using the question 'when developing complex interventions to improve health, how important is it to….' See Appendix 1 for the results of the e-Delphis and Appendix 2 for a list of experts participating in the consensus exercise.
- **expert panel** that met early in the project to guide the research and then again as part of the consensus workshop. See Appendix 2 for members.
- **experience of the authors** of this guidance who have all been involved in developing or adapting health interventions

- **discussions with researchers** attending presentations and workshops at academic conferences. See Appendix 2 for list of engagement activities.

Figure 1 MRC funded study on which the guidance is based: Identifying and assessing different approaches to developing complex interventions (INDEX)



The e-Delphi was based on triangulation of findings from the different sources: the literature reviews, qualitative interview study, and expert consultation. The guidance is based on further

triangulation of the findings from the e-Delphi, consensus meeting and workshops/seminars. Details of the methods have been (or will be) reported in journal articles. [9-13] The guidance addresses where there is consensus on how to do intervention development. It also addresses where there is lack of consensus because it is important to show areas of difference and remaining uncertainty in this complex and relatively under-developed field in health.

The guidance presents key issues to consider when developing interventions rather than offering recommendations or pronouncements on actions that developers should take. This is due to two issues. First, although some research has been undertaken linking outcomes such as the effectiveness of interventions with the processes used to develop those interventions, the evidence base is limited. For example, although there is some evidence to support the relationship between using theory in intervention development and the effectiveness of the intervention,[14],concerns have been expressed about the weakness of this relationship. [15] A recent review of 9 systematic reviews of the use of theory in behaviour change interventions concluded that theory-based interventions were no more effective than those not using theory.[16] The review did, however, conclude with a cautionary note that reporting issues may not reflect the true utility of theory use. In addition, a systematic review of co-produced interventions in acute healthcare settings showed little evidence to support this approach due to a lack of rigorous evaluation.[17] Second, the process of intervention development is likely to be tailored to the specific needs of the context, health problem etc. and therefore flexibility is required when using the guidance.

1.4 Who is this guidance for?

The guidance is aimed at

- those developing complex interventions to improve health and health care
- those who lead intervention development and/or work in or with teams that undertake this endeavour. These teams may or may not be led by academics, and can include members of the public, patients, community groups, practitioners (in health, social care, schools, etc), national and local policy makers, academics, and product designers
- an international audience. It is informed by reviews, qualitative interviews and a consensus exercise that involved experts from the USA, the UK and the rest of Europe.
- a range of disciplines including clinical practice and public health. It may also be relevant to quality improvement, that is, a systematic approach that uses specific techniques to improve quality,[18] although this was not the key focus of the guidance.

This guidance is not aimed at those adapting existing interventions, where researchers take full existing interventions that have been shown to be effective at the evaluation phase, and perhaps implemented in the real world, and adapt them for a new population, health condition, or setting. At an early stage of developing this guidance it became obvious that the process of adaptation was different from development. There has been specific guidance on cultural adaptation of health promotion interventions[19] and there is ongoing research to produce guidance on the adaptation of complex population health interventions http://decipher.uk.net/research-page/adaptation-of-population-health-interventions-for-implementation-and-or-re-evaluation-in-new-contexts-development-of-guidance/

1.5 Types of interventions

The terms 'programme', 'initiative' or 'innovation' may be used as well as 'intervention'. The guidance is relevant to complex interventions that have a number of interacting components, or a number of behaviours required by those delivering or receiving the intervention. [1 2] This includes policy innovations such as introducing a new health service or public health policy nationally (e.g. smoking ban in public places). It does not include the development of medicines and any invasive interventions of an external object (e.g. pills, procedures, devices). Complex interventions to deliver health or health care outcomes can be delivered in many settings including health care facilities, social care facilities, schools, and communities and national populations. They can be delivered by a range of individuals including health care, social care and public health practitioners, as well as professionals working outside of the health care sector, such as teachers, charity workers, and peers.

This guidance relates to a range of types of interventions, including:

- De-novo, that is, novel and new. De novo interventions can include components from existing interventions. A new intervention or innovation may be "incremental (building on and improving existing practices), radical (a completely new approach to solving existing problems), or revolutionary (an innovation that creates an entirely new and unexpected market)". [20] Disruptive interventions involve complete system changes by replacing old established systems with different ways of doing things.
- Interventions working at different levels: individual, organisation, community, or national population-level (or a combination).

Some types of interventions may be associated with different practices e.g. digital interventions are more likely to feature design-based approaches, and behavioural interventions are more likely to be shaped by psychological theories.

1.6 Structure of the guidance

The guidance is divided into sections describing the key issues for developers to consider when planning and undertaking intervention development. Sections are brief to aid readability. It may help to read the guidance prior to planning an intervention development process and refer to it throughout the process of intervention development as a 'sense check'. Italicised statements reached 70% consensus amongst 57 developers and wider stakeholders in the e-Delphis described earlier.

1.7 How to use the guidance

It may not be possible or desirable for developers to address all these actions during their development process, and indeed some may not be relevant to every problem or context. The key issue is that developers consider the relevance and importance of these actions to their situation both at the start of, and throughout, the development process. In practice these actions will be undertaken in a dynamic way rather than sequentially. That is, undertaken in parallel and revisited regularly as the intervention evolves, or they interact with each other when learning from one domain influences plans for other domains.

2. Principles of intervention development

Principles are the fundamental bases for a system of thoughts or beliefs. Five principles of intervention development are proposed based on triangulation of the different sources in our study:

2.1 Being dynamic

Intervention development is unlikely to follow a linear process. Stepped or phased approaches to intervention development identify a sequence of actions for developers to follow. Other

published approaches to intervention development also usually have some sequencing of actions. Some experienced developers find any attempt to show a sequence of actions as problematic because in practice intervention development is a dynamic process, moving backwards and forwards between overlapping actions. Nonetheless, there is a direction of travel.

2.2 Using iterative processes

There was consensus on developing an intervention in an iterative way with regular stakeholder input throughout. Any prototype/draft intervention is likely to benefit from multiple cycles of assessment, feedback and refinement throughout the development process involving those using or delivering the intervention. Feedback may be from participants providing data in qualitative research or surveys, from those involved in decision making as a partner (for example through co-production approaches [21]), or through consultation with stakeholders.

2.3 Being creative

There was consensus amongst wider stakeholders but not developers that the development team use methods to enable stakeholders to be creative during the development process. It can be important to integrate creativity with the scientific methods of intervention development. Product designers and teams taking a user-centred or co-design approach value generating creative thinking when designing the content, format or delivery of an intervention. Novel activities can help creativity and may be helpful for engaging patients, public, practitioners and other stakeholders participating in intervention development.

2.4 Being open

There was consensus on being open to change, failure and unintended consequences. In particular, there was consensus that developers be open to the final intervention being different from the initial vision, be open to failure and going back a step in the development process, consider unintended consequences of the intervention, and look for and take into account that the proposed intervention may not work in the way intended. The planned intervention may not be feasible to develop, or an iteration may reveal problems that require the team to return to earlier decisions. There may be positive and negative unintended consequences of the intervention that need to be understood. This has implications for funding applications where some flexibility of protocol and budget for different scenarios can be desirable.

2.5 Looking ahead

It may be important to look ahead to evaluation. Paying attention to the later evaluation during the first phase of developing interventions may facilitate the success of both the future research and the intervention. For example, thinking about how the intervention could be evaluated, and how to recruit participants for a pilot or full evaluation, at the intervention development phase may prevent difficulties in later phases of the study.

3. Plan intervention development

3.1 Define the problem and avenue for change

Developers usually start with a problem they want to solve. They may have some initial ideas about the content, format or delivery of the proposed intervention. The knowledge about the problem and the possibilities for an intervention may be based on a published evidence synthesis, clinical practice, a political strategy, a needs assessment for a community, years of experience of working or researching in a specific field, initiatives to identify public and patient priorities for research or conversations between a person who sees a problem in practice and a person with expertise in finding a solution e.g. in theory or product design.

These early ideas about the intervention may be refined and indeed challenged throughout the intervention development process. For example, understanding of the problem and the aspects that are amenable to change is part of the development process, with different solutions emerging as understanding increases.

3.2 Decide whether to develop an intervention

Research waste is an important consideration because the cost of developing the intervention, the costs of the intervention itself, and delivery costs may outweigh its potential for benefit. So once the idea is identified, the following issues can be considered to decide whether it is worth the effort to develop an intervention:

- priority – has it been identified in a prioritisation process?
- size and cost of the problem – how many people does it affect?
- direction of travel – is the problem increasing?

- severity of problem – is it causing death, morbidity or is it a determinant of these?
- opportunity to intervene – is the context ripe for intervention?
- ability to change –are there aspects of the problem open to improvement?
- size of potential benefit- how effective and cost effective is it likely to be in future?
- stakeholder desirability for an intervention – how likely is it to be implemented if effective?
- the opportunity costs: could the effort be put to better use?
- does existing evidence suggest it is likely to be effective or cost effective?
- there may be an existing intervention that has been found to be effective or cost-effective in a different context that could be adapted.

3.3 Consider how much time to spend developing an intervention

There was consensus that quick intervention development is not important. There may be pressure from policy makers and service providers for a quick development process so that those who would benefit do not have to wait years for an intervention to be developed and then evaluated. A careful and, by implication, slower process may be necessary to reduce the wastage of developing flawed interventions that have no chance of being effective or implemented in the real world. However, if the intervention development phase takes a long time, there is a danger that by the time the intervention is shown to be effective it will no longer be relevant, feasible or acceptable as clinical, political, technological or social contexts change. There is no easy answer about the time required. Developers of a specific intervention can consider:

- the importance or intractability of the problem being addressed
- whether there is a history of failed interventions in the area. If so, a quickly developed intervention may also be likely to fail
- the complexity of the intervention required. Spending years developing a relatively simple intervention for a relatively simple problem may be a waste of time
- the planned method of evaluation. The intensive development phase may be reduced if adaptive designs that allow an intervention to be refined iteratively during the full evaluation are planned
- the development team's circumstances and funding. Some developers apply to funding panels for a substantial period of intensive intervention development in the context of personal fellowships or project grants, whereas others have little funding and rely on *ad hoc* development over a protracted time period.

3.4 Consider the amount of funding needed and sources of funding

There was consensus that it is important to have a funded study with sufficient resources. Development teams may be able to apply for large amounts of funding that allow for intervention development, or both development and evaluation together. However, obtaining funding for intervention development can be challenging. Teams may have no option but to undertake a series of small studies using multiple sources of small amounts of funding over time. There are pros and cons to each situation. Grants that allow both development and evaluation within the same study offer security for staff with the expertise to develop an intervention and the resource to undertake a range of actions and multiple iterations of prototypes to refine the intervention, but they can constrain researchers to a path outlined in the original grant application even when this feels wrong. Seeking a series of small grants for development can feel precarious but may offer flexibility to adapt to changing evidence over time. Developers will need to tailor their intervention development to the size of resource available.

Sources of funding may depend on the topic addressed by the intervention and the country where funding is sought. It may help to search for funders that invite applications for intervention development and look at where other researchers have obtained funding for their intervention development studies (sometimes described in the journal articles reporting the development process). Local service providers fund intervention development but they may be invested in the future intervention and shape the intervention in ways that do not necessarily fit with theory, research evidence and findings from primary data collection. Declarations of conflict within a team and wider stakeholders could help to negotiate this challenge.

There is no evidence about how much resource is sufficient to develop an intervention. It may depend on the size and complexity of the problem to be addressed, the complexity of the planned intervention, whether digital development is indicated, whether components already exist that have been shown to be effective, whether a whole existing intervention can be adapted to a different setting or population, or whether researchers have time they can spend on the endeavour without external funding.

3.5 Decide whether to use a published approach to intervention development

There was consensus amongst developers that it is important to draw on a published intervention development approach, although wider stakeholders viewed this as less important. Using a published approach offers a systematic way of developing an intervention, with the assumption that this leads to a better intervention that is more likely to work and be used in practice.

However, in a systematic review of empirical research reporting intervention development studies published in 2015-2016, 43 of 87 did not report using a published approach. [10] Instead they used what this guidance labels a 'pragmatic approach' to intervention development, where they followed a self-selected set of steps or actions. A pragmatic approach to intervention development may be used for a variety of reasons, for example the complexity, resource and time that may be needed for some approaches; not knowing that published approaches exist; or finding the lack of detail around practical issues in some approaches challenging.

There are multiple published approaches to intervention development to guide developers. [9] Researchers have published journal articles, websites and books on how to develop interventions. Approaches that show how to develop interventions may be useful to individuals new to intervention development and offer an opportunity for research communities to refine and improve those approaches for future use. A taxonomy of eight categories of published approaches is displayed in Table 1. It includes a breadth of approaches and does not claim to include all approaches. Approaches have been produced from a variety of perspectives including explicit behaviour change (11 approaches), public health and health promotion (9 approaches), digital health (6), complex interventions (5), quality or service improvement (3), clinical research (2), and social policy or innovation (2).

New published approaches, and enhancements to existing approaches, continue to be published. Sometimes authors of new approaches explicitly combine existing published approaches or present new approaches as complementary to existing approaches. Some approaches recommend taking the same set of actions as others but the weight authors give to some actions differs. For example, Intervention Mapping is a theory and evidence based approach but also addresses working with the target population and in partnership with stakeholders.[22] It is likely to give less weight to the latter than partnership approaches to intervention development such as co-production.

Table 1 Taxonomy of approaches to intervention development (adapted from O'Cathain et al 2019[9])

Category	Definition	Approach*	Contexts developed for
1.Partnership	The people whom the intervention aims to help are involved in decision-making about the intervention throughout the development process, having at least equal decision-making powers with members of the research team	Co-production, co-creation, co-design, co-operative design	Quality improvement in health and social care Social innovation in public sector services Radical innovation – as opposed to incremental –in health services
		User-driven	Information systems in health
		Experience-based co-design (EBCD) and accelerated EBCD	Service improvement specific to a single service
2.Target population-centred	Interventions are based on the views and actions of the people who will use the intervention	Person-based	Digital health-related behaviour change Self-management Behaviour change interventions
		User-centred	Innovation in organisations Improving health care delivery
		Human- centred design	Design of machines, appliances, technology for everyday use
3.Theory and evidence-based	Interventions are based on combining published research evidence and published theories (e.g. psychological or organisational theories) or theories specific to the intervention	MRC Framework for developing and evaluating complex interventions	Complex interventions in health care, public health and social policy
		Behaviour Change Wheel (BCW)	Behaviour change interventions in health
		Intervention mapping (IM)	Health promotion Public health

			Complex problems
		Matrix Assisting Practitioner's Intervention Planning Tool (MAP-IT)	Health promotion Behaviour change complex health interventions
		Normalisation Process Theory (NPT)+	Complex interventions in health and health care
		Theoretical Domains Framework (TDF)	Behaviour change complex interventions Implementation interventions to get evidence into practice Quality improvement
4. Implementation-based	Interventions are developed with attention to ensuring the intervention will be used in the real world if effective	Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM)	Health behaviour interventions
5. Efficiency based	Components of an intervention are tested using experimental designs to determine active components and make interventions more efficient	Multiphase Optimization Strategy (MOST)	Multicomponent behavioural interventions in public health
		Multi-level and fractional factorial experiments	Multi component interventions with behavioural, delivery or implementation factors where there is clustering
		Micro-randomisation trials	'Just in time adaptive interventions' (mobile health technologies) Behaviour change
6. Stepped or phased based	Interventions are developed through emphasis on a systematic overview of processes involved in	Six essential Steps for Quality Intervention Development (6SQUID)	Public health

	intervention development		
		Five actions model	Social work Social and public health program Child development
		Obesity Related Behavioral Intervention Trials (ORBIT)	Clinical Behavioural treatments for preventing and treating chronic diseases
7.Intervention-specific	An intervention development approach is constructed for a specific type of intervention	Digital (e.g. Integrate, Design, Assess and Share (IDEAS))	Digital Behaviour change Online health interventions Public Health
		Patient decision support or aids	Decision aids available in web-based versions Decision support
		Group interventions	Health improvement interventions Behaviour change
8. Combination	Existing approaches to intervention development are combined	Participatory Action Research based on theories of Behaviour Change and Persuasive Technology (PAR –BCP)	Behaviour change systems for health promotion (possibly in digital health)

+ could be considered under implementation based approaches to intervention development because the theory is about implementation

*see O'Cathain et al 2019[9] for references to different approaches

There are no systematic reviews showing that using a published approach is superior to using a pragmatic approach. There are no systematic reviews about which published approach is the best to use. Here is a set of questions that may help developers to decide which published approach to use. Ask which approaches….

- apply specifically to your setting e.g. public health?
- focus on the purpose of your intervention e.g. behaviour change?
- focus on the type of intervention e.g. digital?
- address issues you value e.g. working in partnership with the target population? (the taxonomy in Table 1 may help here)
- offer the level of detail or structure that suits your situation?
- offer credibility because they have been used by others?
- have been used in studies that gained funding?
- have produced interventions shown to be effective?
- can be delivered within the resources available to you?
- have credibility in your research community?

There was consensus that it is important to apply a published intervention development approach flexibly depending on context. The challenge is, of course, that moving too far away from the published approach may lose the potential benefits of using the approach in the first place. Some developers use a combination of approaches because of the different strengths of each approach, as well as the pragmatic approach described earlier.

3.6 Write a protocol

There was consensus that it is important to produce a protocol detailing the processes to be undertaken to develop the intervention. Intervention development can have a flexible, organic aspect to it but, at the grant application stage, funding panels like enough detail of the development process and the planned intervention to allow meaningful assessment of its quality and potential for future cost-effectiveness and implementation. Where relevant, inclusion of any work on the development of early prototypes may be useful. Producing a protocol may be helpful even if funding is not pursued so that developers can think through the necessary actions, timelines, and resources.

4. Work closely with stakeholders

4.1 Work with a range of relevant stakeholders

A variety of people may have a stake in the intervention being developed. These stakeholders can include the people who may benefit from the intervention, the people who will use the intervention, patient and community representatives, the range of people who will deliver or work with those delivering the intervention, practitioners, those funding the intervention e.g., local and national policy makers or local and national government agencies. They may have important views to share about the need for an intervention, the context in which the intervention will be used, who the intervention is best aimed at, and the characteristics of an intervention that would be feasible to implement in the real world. They can generate ideas about the content, format and delivery of the intervention and comment on early versions of intervention to refine it. Working in collaboration with stakeholders can help to build relationships that may also facilitate other issues such as recruitment of diverse and relevant samples for any primary research throughout the development and later evaluation, and ensuring the intervention is eventually implemented in the real world. The rationale for working closely with stakeholders is that this may produce a more acceptable, feasible, practical, fit-for-context intervention that key stakeholders sign up to making use of.

There was consensus on the importance of involving stakeholders who are members of the target population, that is, the group of people the intervention is aimed at. This is usually patients, service users or members of the public, but can also be practitioners. For example, the target population is GPs for an intervention to change the prescribing behaviour of GPs, although individual patients or the general population may accrue benefit.

4.2 Work iteratively with stakeholders

There was consensus about developing interventions iteratively with stakeholder input throughout. There are different ways of working closely with stakeholders, from consultation through to co-production. Stakeholders may be consulted at the beginning of the process, or qualitative research may be undertaken to obtain their views, or they may belong to a stakeholder group that works in collaboration with the development team throughout the process, or they may be part of the development team. A tailored approach may need to be taken with each type of stakeholder because some stakeholders may not have time to be involved, or understand what the intervention development is trying to achieve, so extra efforts

may be required to engage them. Co-production is currently a popular approach to intervention development. [21] This goes beyond consultation or collaboration because stakeholders are involved in decision-making about the intervention throughout the development process, having at least equal decision-making powers with developers.

4.3 Address public involvement

There was consensus on the importance of developing a plan at the start of the process to integrate public involvement into the intervention development process. Different countries use different language and cultural practices for involving the public and patients/service users in their research. [23]. Public involvement members can work closely with the development team, and may be members of this team. They can help to shape the intervention development process, and any primary research undertaken, as well as participate in developing the intervention with other stakeholders.

5. Bring together a team

Interventions are usually developed by teams rather than by individuals. These teams need to make a large number of decisions during the development process. The intervention development team consists of members with decision-making rights regarding the content, format and delivery of the intervention.

5.1 Select team members

There was consensus that it is important to have a team large enough to include individuals with all the necessary expertise. There was also consensus about some key individuals to include in the team. Key team members include a behaviour change scientist when the intervention aims to change behaviour, experts in the problem to be addressed by the intervention, members with a strong track record in designing complex interventions, and people who are skilled at maximising engagement of stakeholders. There was not consensus on a product designer being part of the team but written comments made in our e-Delphi suggested that some did not know what this meant. In partnership approaches to intervention development, members of the target population and/or those delivering the intervention are part of the development team. Other

possible team members include experts in evaluation methods and economics. Team members will have different backgrounds, language and understandings, so it is important that all team members have the skills and personal qualities to contribute constructively within an interdisciplinary environment.

5.2 Think about the size of the decision-making team

There are differing views about the size of the team that makes final decisions about the intervention. The team making final decisions about the intervention content, format and delivery can be small, with these team members consulting with wider stakeholders. Alternatively, the team making final decisions may consist of a large group of people with the multiple and diverse expertise and understandings required to develop the intervention. The strengths of a diverse and inclusive team are that this promotes creativity when generating ideas about the planned intervention, includes relevant skills to design the intervention, and reduces the risk of 'group think' where people reinforce the accepted view. The weaknesses of diverse and therefore large teams include increased risk of conflicting views and difficulty making decisions. Decisions about team membership will depend on the published approach taken. Partnership approaches such as co-production value inclusion. One solution is to have a large and diverse team to generate ideas and offer opinions on decisions but a small 'editorial group' or 'sub-team' that makes final decisions about the content, format and delivery of the intervention after working closely with the diverse set of stakeholders.

5.3 Agree a process for making decisions

There was consensus about the importance of agreeing a process for making decisions within the team about the intervention content, format and delivery. Many insights will arise during generation of ideas and iterations of data collection when refining the intervention. Decisions will have to be made about the content of the prototype or first version of the intervention and then what refinements to make to future versions. Decisions may depend on the cost in terms of time and money of a component or refinement, the implications for the cost of the final intervention, and the level of agreement amongst team members about the necessity of a component or refinement. Rather than undertaking formal consensus exercises to determine the content, format and delivery of the intervention, or having equity amongst key stakeholders and researchers when making decisions, it may be more important to attend to processes that facilitate decision-making. For example, ensuring that team members understand their roles, rights and responsibilities, agreeing a process for making decisions, documenting the reasons

for decisions made, and being prepared to test different options where there is team disagreement about the content, format or delivery of key components of the intervention.

6. Review published research evidence

There was consensus that it is important to review published research evidence before starting to develop the intervention, and to consider the evidence base for each substantive intervention component. A full, scoping or rapid evidence synthesis may exist or be undertaken in preparation for the intervention development process. Published evidence can also be used iteratively for different purposes at different times during the intervention development process. It can be integrated with knowledge from other sources such as theory, public involvement, views of the target population and views of other stakeholders. Evidence can be used to:

- ***Define the health problem to be addressed***.
- ***Assess the size and determinants of the problem*** by drawing on epidemiological evidence to understand the determinants of the problem at micro, meso, or meta levels and who might benefit most from any intervention.
- ***Understand the health problem in context*** by drawing on published qualitative research about the target population's lived experiences or views of existing interventions and the context of health care. A synthesis of this evidence may exist or may be undertaken.
- ***Clarify the target population for the intervention*** because this may change as published evidence is considered, either broadening or narrowing the definition of the target population e.g. finding that a problem is particularly prevalent in older people.
- ***Identify whether effective and cost-effective interventions exist*** Randomised controlled trials (RCTs) or other quasi-experimental designs may have been used to evaluate relevant interventions. Systematic reviews may exist or, as preparation for the planned intervention development, a systematic review can be undertaken by the developers. If multiple interventions have been developed and failed for this problem and/or target population, then understanding why failure has occurred is extremely important. If a cost-effective intervention exists for another context, then consideration can be given to adapting this intervention rather than undertaking *de novo* development.

- ***Identify facilitators or barriers to delivering interventions in this context*** Feasibility/pilot and full evaluations of complex interventions often include process evaluations – either mixed methods or qualitative - that help to explain how an intervention was effective in a particular context or why it failed to be effective. Important mechanisms of action can be identified, or issues that facilitate or hinder delivery of interventions, and this evidence can be used to shape the planned intervention.
- ***Identify whether proposed components of an intervention have a published research evidence base*** When planning the development process, there may be published evidence that some intervention components are effective and could be part of a more complex intervention e.g. the evidence base on reminder prompts using mobile phones can be considered if this is a potential component of the intervention. Or, as ideas are generated about new potential components when designing an intervention, the published evidence base can be searched for any evaluation of these potential components.
- ***Look for evidence that the proposed intervention may not work as intended*** *There was consensus that developers look for and take into account that the proposed intervention may not work in the way intended.*
- ***Identify uncertainties*** *There was consensus about the importance of specifying the gaps and uncertainties in the existing evidence.* There may be published evidence about some of the questions developers have and little or no evidence about others. Developers may decide to address some of these gaps prior to starting intervention development, or during their study. Alternatively, they may move ahead regardless of uncertainties. Specifying gaps and uncertainties in the existing published evidence is good practice because it offers transparency for all stakeholders and shapes the focus of the primary research undertaken in the development process.
- ***Keep up with published evidence throughout the process*** Keeping abreast of key publications throughout the process can alert developers to issues that might impact on continuing with the development process e.g. someone else has developed a cheaper and successful intervention.

The use of published evidence may be challenging in practice because decisions need to be made about how much reviewing to do, whether it is necessary or indeed feasible to undertake formal evidence synthesis (developers may already know the key literature because they have worked in an area for many years or may lack the time, resources, or expertise to undertake a systematic review), how to do it in practice (as a one off at the start or as an ongoing iterative

process as different questions arise), and how to use it in conjunction with other sources that may conflict with it. It may also be that any review leaves developers with lots of uncertainties that they hoped it would address. The key issue is that a range of qualitative and quantitative published evidence is considered both at the start and throughout the intervention development process.

7. Draw on existing theories

Existing theories – either grand or mid-range theory such as the theory of Diffusion of Innovation - can be a source of both understanding problems and the mechanisms that can address these problems. Some published approaches to intervention development are labelled 'theory and evidence based' when they use a single existing theory, two theories, or a set of theories within a framework, to inform the intervention. The benefit of using existing theories is that they help to identify what is important, relevant and feasible to meet the intended goals.[6] There was consensus on four issues related to using theory in intervention development:

- ***Select a theory or theories at the start*** *There was consensus that it is important to identify an existing theory or theories to inform the intervention at the start of the process.* Frameworks of theories have the advantage that they bring together disparate and overlapping theories and provide a broad overview of potentially relevant factors. Individual theories can provide a more detailed and validated analysis of causal mechanisms relevant to specific contexts. Psychological theories are used for interventions focusing on behaviour change. Organisational theories are relevant to interventions aimed at a level beyond the individual and when interventions at the individual level are delivered in complex organisations. Implementation theories may be used to consider the implementation of interventions in practice. The theory can direct or inform the content and delivery of the intervention. For example, Social Cognitive Theory highlights the influence of self-efficacy on behaviour, and suggests well-validated methods of increasing self-efficacy for incorporating into the intervention. It can be helpful to others assessing the development process to see how any existing theories have shaped the content, format and delivery of the intervention. This avoids looking as if theory is used as a cloak of credibility by merely mentioning it in passing in reports of development processes. Working with existing theory(ies) may help to guide the intervention and also communicate intentions to funders and other stakeholders. However, there may be challenges involved in this in terms of finding that a selected

theory does not fit the context of the intervention and does not help developers as much as they had expected.

- ***Draw on more than one theory*** *There was consensus amongst developers (but not wider stakeholders) that it is important to draw on more than one existing theory e.g. both psychological and organisational theories.* The context in which an intervention will be used can be complex and drawing on theories from different disciplines may help to inform the intervention development.
- ***Use existing theory to guide collection of published evidence*** *There was consensus amongst developers (but not wider stakeholders) on the importance of using existing theories to inform the collection of evidence.* Theory and published evidence can be used in parallel and they can also be integrated within the intervention development process. Theory can guide which published evidence to explore.

There was no consensus on the importance of periodically considering during the intervention development process whether additional or alternative existing theories may be helpful. However, in practice the theory selected when applying for funding may not always prove to be the most appropriate one once in the field and the choice may need to be reviewed as more is known about the context in which the intervention will be used.

8. Articulate programme theory

Programme theory explains how the intervention under development is intended to produce health outcomes. [6] It shows the causal pathways between context, the content of the intervention, and intermediate and long term outcomes. Logic models are diagrams that show how components and activities within an intervention produce short and long term outcomes. They can also include contextual issues likely to impact on the success of the intervention.

There was consensus about the importance of testing and refining the programme theory, or a logic model, within the development process. Identifying at the start of the development process a programme theory that describes how and why the specific intervention should work can be used in conjunction with existing theories, and may be more relevant than using existing theories in some circumstances. The programme theory can be specified early in the intervention development process, allowing it to be tested and refined throughout the development phase.

9. Undertake primary data collection

A wide range of research methods tend to be used in intervention development, and mixed methods are common. Some activities may not be considered to be research methods, such as stakeholder workshops or the use of games to facilitate creative thinking when generating ideas about the proposed intervention. A diverse range of methods and activities are likely to be necessary, with the choice depending on the action being addressed and the published approach used:

- Primary research usually involves mixed methods.
- Quantitative methods include surveys of the target population to identify their views of the problem, or before and after measurement of change in intermediate outcomes over time when refining early versions of the intervention.
- Qualitative methods include interviews with the target population to understand their lived experience or to obtain the views of the target population or those delivering the intervention on the acceptability, feasibility and engagement with early versions of the intervention. A series of rapid iterations of the intervention may necessitate limited transcription and/or analysis in time for the next iteration.
- Verbal protocol, or think aloud, where people talk about their thoughts as they use the intervention in the presence of a researcher, may identify issues that interviewees would not explicitly raise within an interview.
- Non-participant observation of the context in which the intervention will be delivered can be undertaken early on in the development process so that the first prototype fits this context. This builds a detailed understanding of context and consideration of the relationship between context and the feasibility of the intervention, and the potential transferability of the intervention to other contexts.

10. Understand context

There was consensus that it is important to ensure developers understand the context in which the intervention will be implemented. It may be important to describe and understand the wider context of the target population and the context in which the intervention will eventually be implemented by considering context at different levels (macro, meso, micro) throughout the process. The rationale is that basing the intervention on understanding of the context may help to reduce the risk of failure in later feasibility/evaluation/implementation phases. Recent guidance on context in population health intervention research [3] identifies a breadth of features of context including: those relating to populations and individuals; physical location or geographical setting; social, economic, cultural and political features; and factors affecting implementation e.g. organisation, funding, policy.

Understanding context may not be straightforward in practice because features of context may change rapidly over time, and the context may be a system of care that the planned intervention is so embedded within that it may feel unsatisfactory to change only a small part of the system. In addition, taking context into consideration during intervention development may be challenging because interventions are often developed in a single locality. The contextual aspects of the locality in which the intervention is developed may not generalizable, resulting in challenges when the intervention is tested later in more diverse settings. In practice, where the development takes place can depend on where the lead developer is based. It usually occurs within the developers' service or locality because of convenience - developers have the contacts to undertake the necessary work, they may be more likely to get the necessary buy-in, and the need for travel is reduced. A potential problem is that the intervention may be specific to the context of that locality and the locality may be very different from others because of relationships and the work the developers have undertaken there over time. It may be important to have an awareness of this, and consider its possible impact on the intervention, the intervention-context fit, and issues such as acceptability, engagement and feasibility. It might also help if developers reflect on the relationship between the locality selected and the diversity of localities in which the intervention is intended to be implemented. A potential solution is to develop or undertake the pilot/feasibility phase in more than one locality, or in a locality with different features (environment, provider services, population) from where it was developed, including those that stakeholders suggest could be more challenging.

There was consensus that it is important to undertake qualitative data collection to understand context. A number of methods and activities can be used to understand context including

working closely with stakeholders, undertaking surveys and considering published evidence. Before designing an intervention in terms of deciding on its content, format and delivery, developers may attempt to understand the experiences, perspectives and psycho-social context of the target population rather than assume that they know enough about these issues. Qualitative research with the target population can focus on what matters most to people rather than on what is the matter with them, and why people behave as they do. Non-participant observation of the setting in which the target population lives or the intervention will be delivered, or interviews with those who will deliver and use the intervention will also be useful. Quantitative research can also be used to understand context e.g. a population survey.

11. Pay attention to future implementation

There was consensus that it is important that, at the start of the development process, interventions are developed with attention to facilitators and barriers to implementation of the intervention in the real world. Developing an intervention that is shown to be effective or cost-effective in an evaluation is not the endpoint of research. It is important that the intervention is used in the real world and improves health and health care in the long term. Therefore paying attention to factors that might affect use of the intervention, 'scaling up' of the intervention for use nationally, and sustainability in terms of long term use of the intervention at a very early stage of intervention development, may help to develop an intervention that achieves these goals. For example, consideration of the cost of the intervention at an early stage may help its future implementation. It may also be the case that lack of implementation of an existing effective intervention is the driver for developing a new intervention to promote implementation of that intervention. Or, an existing intervention may be too costly to implement so a cheaper intervention is developed to increase access. Implementation theory may help here, or consideration of RE_AIM as a published approach to follow (www.RE-AIM.org). The rationale for consideration of implementation is that it may reduce research waste in terms of interventions shown to be effective and cost–effective subsequently not being used in the real world.

12. Design and refine the intervention

There was consensus that it is important to spend time on designing the intervention. The term 'design' is sometimes used interchangeably with 'development'. Here is it is used to describe a specific action within intervention development: generating ideas about its content, format, and delivery and creating an early version or prototype to seek views on. Decisions have to be made about the key components of the intervention that will offer solutions for the health problem being addressed, the detailed content of each component, and how it will be delivered, by whom, and where. Although the TIDieR (Template for Intervention Description and Replication) Checklist was produced to help developers to describe their intervention, it is also a useful source of issues that need to be considered when designing the intervention. [24] Designing starts with the generation of ideas to address the problem. The principles of creativity and iterative working are particularly important here. Then the design process moves to creating the components of the intervention, a process that may involve creating a mock up or prototype to allow stakeholders to offer views on the intervention as it is being designed. Creating prototypes, particularly for digital interventions, helps users and those delivering the intervention to offer views of the intervention in practice rather than on possibilities. Developers can design an intervention in a range of ways and may bring in external product design expertise to help.

Once an early version or prototype of the intervention is available, undertake a series of iterations where each iteration includes an assessment of how acceptable, feasible and engaging the intervention is, resulting in refinements to the intervention in preparation for the next iteration. The first version of an intervention may need to be assessed and refined multiple times to ensure it is working as planned. The focus can be on

- aspects that users like or are frustrated with or view as important additions, relating to functionality, accessibility, acceptability and engagement
- aspects that those delivering the intervention find easy or difficult to implement
- what is needed to maximise engagement so that the intervention is used by the intended people and adhered to as planned
- whether there is support for the proposed mechanisms of action of the intervention, which may involve assessment of intermediate outcomes
- whether there are serious adverse effects

Mixed methods are likely to be used here. Sampling may start on small numbers of convenient, easy-to-reach people delivering and receiving the intervention until the intervention is refined enough to have the confidence to take it further afield, increasing the diversity of the sample in further iterations and perhaps even moving beyond the single setting where early development of the intervention took place. The focus can be on the whole intervention or on a key component only. The rationale for this iterative process of refinement is that it might produce more acceptable, feasible or engaging interventions, large refinements such as removal or addition of components, a better understanding of the mechanisms of action resulting in refinement of the programme theory and logic model, or result in a return to the drawing board to start again.

There was no consensus that formal quantitative optimisation was necessary. The process of refining an intervention is sometimes called optimisation. The term can also be used to describe a specific quantitative published approach to test different components to identify the ones that work on intermediate outcomes so that only effective components go on for testing in the feasibility and full evaluation phases (https://www.methodology.psu.edu/ra/MOST). There was no consensus that this type of quantitative optimisation is an important action to take within intervention development.

13. End the development phase

Developers need to know when to stop and move on to the next phase of feasibility/piloting, evaluating or abandoning the intervention. They also need to consider how best to describe their intervention so others can use it, and document the processes they used for developing the intervention.

13.1 Make the decision about whether or when to move to the next phases of feasibility/piloting and evaluation

There are no established criteria for stopping the intensive intervention development phase and moving on to the feasibility/pilot or evaluation phases. Developers could continue to refine an intervention within the intensive development phase for many iterations. They face the challenge of knowing when to stop, either in terms of abandoning the intervention because pursuing it is likely to be futile, or in terms of moving on to the next phase of feasibility/piloting

testing or full evaluation. They also face the challenge of convincing funders of the intervention development that enough development has occurred. The process of making this decision may be partly informed by practicalities such as the amount of time and money available and partly by the concept of data saturation (used in qualitative research) in that the intensive process stops when few refinements are being suggested by those delivering or using the intervention or those observing its use during its period of refinement.

13.2 Describe the intervention and develop a manual or documentation on how to use the intervention

It is important to address the transferability of an intervention outside the original team and location in which it was developed. Describing the content, format and delivery of the intervention in detail allows others to operationalise the intervention. Websites as well as journal articles can be used to ensure the accessibility of interventions and associated training materials. Development of documentation or a manual to help others understand the intervention, deliver or replicate it, can start early in the intervention development process so that materials can be refined over time when refining the intervention. In the case of digital interventions, it is possible to make the entire digital content available to other researchers and developers, although for the purposes of future adaptation it is useful to also have a non-digital representation of the structure and content of the intervention. Reporting guidelines for describing interventions are available .[24]

13.3 Report the intervention development process

It may be helpful to publish the intervention development process because this may: facilitate judgements about the quality of the process; allow links to be made in the future between intervention development processes and the subsequent success of interventions; and help others to learn from the development process for their future intervention development. The intervention development process may be published in a journal article, report to funder, or website. It may be important to publish failed attempts to develop an intervention, as well as successful ones, to prevent others from going through the same process. Reporting multiple, iterative and interacting processes may be challenging, particularly in the context of limited word count for some journals. Researchers have chosen to publish protocols of the planned process, summarised versions of the development process in combination with the subsequent pilot study, or detailed processes of development in a standalone journal article. Examples of the variety of publication styles can be found in a review of intervention development studies. [10]

When writing a standalone journal article, researchers will need to make decisions about where to start. Some preparatory work for intervention development is often summarised or referenced in the introduction of the article before describing the methods and findings of a more intensive process. There will also be challenges around how much to summarise the methods and findings for each action taken and how much detail to give in what can be a multi-method iterative process. There may be a temptation to attach multiple long appendices to journal articles to display the detail of the work undertaken but this may result in complex papers that obscure a clear explanation of the development process.

Reporting guidelines are being produced from our work, based on the results of the e-Delphis.

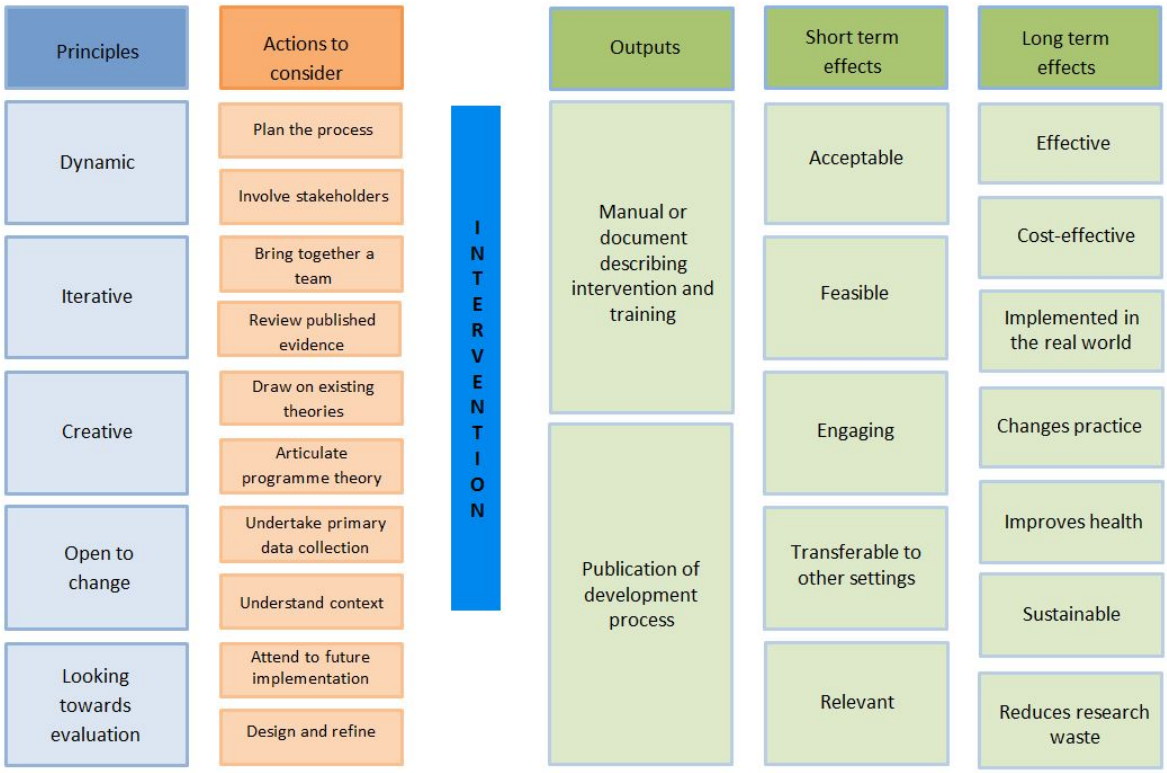
14. The value of taking each action in intervention development

A logic model for intervention development is presented in Figure 2. An important question is whether the actions specified in this model/guidance will result in interventions that are more likely to be successful in terms of producing interventions that are acceptable, feasible, engaging, effective, cost-effective and implemented in the real world.[11] As stated earlier in the guidance, the evidence linking specific actions tends to conclude that the few actions tested have no effect but that this may be due to problems with how actions are reported or how evaluations of actions are undertaken. More evidence is needed on which actions are more likely to lead to successful interventions. Before this evidence can be produced, developers will need to pay attention to how they report their intervention development, and evidence synthesisers will need to set the bar high for identifying that an action actually occurred within a study. Additionally, developers may place different weights on each action during their development process so attention will need to be paid to how developers have undertaken each action rather than simple whether they have taken it or not.

Three recently published examples are presented in Appendix 3, chosen to highlight three very different approaches to intervention development rather than as exemplars of good practice. Some of the principles and actions described in this guidance were not followed in some of these examples, or are very briefly described compared with descriptions in the other examples. The authors of these examples may have attended to these actions in other papers, not

described them in detail due to a lack of space within their journal article, or not undertaken them.

Figure 2 Logic model for intervention development



15. Conclusions and recommendations

This guidance is based on expert opinion of intervention development drawn from reviews of published approaches and practical examples, interviews with developers and wider stakeholders, and a consensus exercise. It sets out principles and actions for developers to consider to help them reflect on their practice.

It is based on the expert opinion of developers from a range of high income countries, and wider stakeholders from the UK, undertaken in 2017. The outcomes of consensus exercises may be dependent on who participates in the exercise[25] and the time at which consensus is sought. Views of experts from low and middle income countries could be sought to build on this

guidance. Future guidance could be based on evidence linking specific actions with successful interventions if researchers produce this evidence in the next few years.

Funders of intervention development may wish to assess the extent to which those applying for funding have *considered* the principles and actions within this guidance, recognising that not all actions may be relevant to all contexts.

This guidance will contribute to updated MRC guidance on developing and evaluation complex interventions that adopts a systems perspective within which complex interventions are used and evaluated. The updated guidance is due to be published this year, along with new guidance on feasibility and pilot studies.

This guidance has been summarised and published in BMJ Open.[26]

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Appendix 1 Delphi results

The stem question was 'When developing complex interventions to improve health, how important is it to…' with options of very important=5, fairly important=4, somewhat important=3, slightly important=2, not at all important =1, and I do not know. Numbers stating 'I do not know' are not reported here.

The column '% agree' presents the percentage ticking very important=5 or fairly important=4; the denominator was all respondents except those ticking I do not know.

Consensus was set at 70% agreement for 'very or fairly important' or 'slightly or not important at all'.

The items are listed in order of highest to lowest consensus (%agree) for developers.

The dark shaded cells are the most frequently ticked options.

No.	Item	Mode score	% Agree	Developers (numbers ticking each option)					Mode score	% Agree	Wider stakeholders (numbers)				
				Not at all important	Slightly important	Somewhat important	Fairly important	Very important			Not at all important	Slightly important	Somewhat important	Fairly important	Very important
1	Be open to the potential that the final intervention may be different from the initial vision	5	100	0	0	0	0	26	5	100	0	0	0	2	16
2	Report the purpose of the intervention	5	100	0	0	0	0	26	5	100	0	0	0	1	16
3	Report the target population	5	100	0	0	0	1	25	5	100	0	0	0	1	17
4	Clearly define the health problem to be addressed	5	100	0	0	0	1	24	5	100	0	0	0	1	17

5	Review the published evidence before starting to develop an intervention	5	100	0	0	0	1	24	5	100	0	0	0	1	17
6	Be open to failure and going back a step	5	100	0	0	0	2	24	5	100	0	0	0	4	13
7	Ensure team members understand the context in which the intervention will be implemented	5	100	0	0	0	3	23	5	100	0	0	0	3	15
8	Report any use of components from an existing intervention	5	100	0	0	0	4	22	4	100	0	0	0	14	4
9	Report how evidence from different sources informed the intervention development	5	100	0	0	0	5	21	5	100	0	0	0	5	13
10	Report how stakeholders contributed to the intervention development process	5	100	0	0	0	6	20	4	94	0	0	1	14	3
11	Report important uncertainties at the end of the intervention development process.	5	100	0	0	0	7	19	5	78	0	1	3	0	14
12	Look for and take into account evidence that your proposed intervention may not work in the way you intend	4	100	0	0	0	17	9	5	89	0	0	2	2	14
13	Consider the evidence for each substantive intervention component	5	100	0	0	0	11	15	4	94	0	0	1	17	0
14	Have a plan to guide how you will use evidence during the design process	4	100	0	0	0	13	13	4	89	0	0	2	16	0
15	Develop the intervention in an iterative way with regular stakeholder input throughout	5	96	0	1	0	0	25	5	82	0	1	2	3	11
16	Report the context for which the intervention was developed	5	96	0	0	1	0	25	5	100	0	0	0	2	16
17	Ensure the team includes experts in the problem to be addressed by the intervention	5	96	0	1	0	1	24	5	94	0	0	1	1	16
18	Consider facilitators and barriers to future use of the intervention in the real world	5	96	0	1	0	1	24	5	94	0	0	1	1	16

19	Ensure the team specifically includes a behaviour change scientist when the intervention aims to change behaviour.	5	96	0	0	1	2	23	5	83	0	0	3	3	12
20	Document key reasons for decisions made throughout the process	5	96	0	0	1	3	22	5	82	0	0	3	2	12
21	Clearly define the target population: the group of people that will receive the intervention	5	96	0	0	1	3	22	5	100	0	0	0	1	17
22	Ensure high levels of collaboration with stakeholders throughout the development process	5	96	0	1	0	3	22	5	94	0	0	1	2	15
23	Engage all relevant stakeholders	5	96	0	0	1	4	21	5	100	0	0	0	4	13
24	Generate a programme theory/ logic model for how the intervention will have an effect	5	96	0	0	1	4	21	4	94	0	0	1	13	3
25	Identify existing interventions and consider whether they could be adapted	5	96	0	0	1	4	21	5	100	0	0	0	2	15
26	Seek stakeholders' perspectives on several possible versions of the intervention at a very early stage	5	96	0	0	1	4	21	5	89	0	1	1	5	11
27	Carry out feasibility research throughout the intervention development	5	96	0	0	1	5	20	4	89	0	1	1	15	1
28	Consider interactions between parts of the intervention	4	96	0	0	1	20	5	5	94	0	0	1	7	9
29	Develop a plan to integrate patient and public involvement (PPI) into the intervention development process	5	96	1	0	0	5	20	5	83	0	0	3	2	13
30	Stay open minded about the structure, content and delivery of the intervention	5	96	0	0	1	5	20	5	94	0	0	1	6	11
31	Report any changes to interventions required or likely to be required for subgroups	5	96	0	0	1	6	19	4	83	0	1	2	9	6
32	Focus on designing the content, format and delivery of the intervention as much	4	96	0	0	1	17	8	4	78	0	0	4	13	1

	as on gathering or synthesising the evidence to inform it														
33	Have a team large enough to include individuals with all the necessary expertise.	4	96	0	1	0	17	8	4	100	0	0	0	9	9
34	Evaluate important components where there has been team disagreement about aspects of content, format or delivery	4	96	0	0	1	15	10	4	72	0	0	5	13	0
35	Do intervention development quickly	1	96	13	12	0	1	0	2	94	2	15	1	0	0
36	Ensure the team includes members who are skilled at maximising engagement of stakeholders	5	96	0	0	1	12	13	4	83	0	0	3	11	4
37	Involve stakeholders who are members of the target population.	5	92	0	0	2	0	24	5	100	0	0	0	4	14
38	Identify an existing published theory or theories to inform the intervention at the start	4	92	0	1	0	21	3	4	100	0	0	0	17	1
39	Report how any published intervention development approach contributed to the development process	5	92	0	0	2	3	21	4	71	0	0	5	11	1
40	Report how existing published theory informed the intervention development process	5	92	0	0	2	3	21	5	94	0	0	1	5	12
41	Check that the proposed mechanisms of action are supported by early testing	4	92	0	1	1	18	6	5	94	0	0	1	3	14
42	Undertake qualitative data collection to understand the context in which the intervention will be delivered	5	92	0	1	1	8	16	4	83	0	0	3	12	3
43	Consider unintended consequences of the intervention	5	92	0	0	2	9	15	5	94	0	0	1	8	9
44	Ensure all members of the team have the skills and personal qualities to contribute constructively in an interdisciplinary environment	5	92	0	1	1	9	15	4	78	0	1	3	14	0

45	Report any guiding principles, people or factors which were prioritised when making decisions	5	92	0	0	2	11	13	4	83	0	1	2	13	2
46	Collect data from a diverse sample of those who will deliver and receive the intervention	5	92	0	1	1	10	13	4	94	0	0	1	15	2
47	Consider the different levels that the intervention may target and impact (patients, professionals, communities, services)	5	88	0	0	3	2	21	4	94	0	1	0	11	6
48	Draw on a published intervention development approach	4	88	0	2	1	20	3	3	6	0	1	16	1	0
49	Test and refine the programme theory, or logic model, within the development process	5	88	0	0	3	5	18	4	94	0	1	0	14	2
50	Specify gaps and uncertainties in the existing evidence	4	88	0	0	3	16	7	5	94	0	0	1	6	11
51	Ensure the team includes individuals with a strong track record in designing complex interventions	5	88	1	0	2	8	15	4	88	0	0	2	14	2
52	Report how the intervention changed in content and format from the start of the intervention development process	4	88	0	3	0	15	8	4	94	0	1	0	13	4
53	Report the reasons for discarding intervention components that were considered	5	88	0	0	3	9	14	4	88	0	0	2	15	0
54	Use the term 'intervention development' in the title and abstract of any report or publication.	4	85	1	2	1	18	4	3	24	1	2	10	2	2
55	Identify sub-populations that the intervention may need to be adapted for or tailored to	4	85	0	0	4	14	8	4	83	0	1	2	14	1

56	Produce an intervention development protocol detailing the processes to be undertaken to develop the intervention	5	85	0	2	2	10	12	4	88	0	0	2	15	0
57	Apply a published intervention development approach flexibly depending on context	5	84	0	1	3	7	14	4	83	0	0	3	14	1
58	Follow TIDieR guidance when describing the developed intervention	5	80	3	0	2	7	13	5	88	0	0	2	6	9
59	Collect evidence using a diverse range of methods	5	80	0	0	5	9	11	4	100	0	0	0	17	1
60	Draw on more than one existing published theory e.g. both psychological and organisational theories	4	77	0	2	4	19	1	4	50	1	0	8	9	0
61	Have a small sub-team that makes final decisions about the intervention	4	77	1	1	4	19	1	4	61	1	0	6	10	1
62	Use the existing published theories that you have identified to inform the collection of evidence	4	77	1	1	4	16	4	4	67	0	0	6	12	0
63	Agree a process for making decisions within the team about intervention content, format and delivery	5	77	0	0	6	5	15	4	94	0	0	1	15	1
64	Report the intervention development in an open access format (e.g. open access journal, report chapter, website)	4	77	1	1	4	13	7	5	89	0	0	2	5	11
65	Have a funded study with sufficient resources	4	73	0	0	7	14	5	5	88	0	0	2	1	14
66	Establish a set of guiding principles to facilitate decision making about intervention content, format and delivery	4	73	0	1	6	12	7	4	76	0	0	4	11	2
67	Ensure the intervention development team members know their specific roles, rights and responsibilities	5	73	0	0	7	8	11	5	83	1	1	1	2	13
68	Follow every step in a published intervention development approach	2	69	3	15	6	1	1	3	59	5	5	7	0	0

69	Include all stakeholders when making final decisions about the intervention	4	58	0	2	9	12	3	4	83	0	1	2	13	2
70	Ensure the team includes a commissioner or purchaser of health care	2	54	1	13	8	3	1	3	33	1	5	10	1	1
71	Try to design the intervention for use in a wide range of settings	2	52	1	12	7	5	0	3	17	0	1	14	3	0
72	Periodically consider whether additional or alternative existing published theories may be helpful to inform the intervention development.	4	50	1	2	10	13	0	4	67	0	1	5	12	0
73	Have a formal consensus exercise to finalise the content, format and delivery of the intervention	2	50	1	12	7	4	2	3	22	1	3	13	1	0
74	Have equity of decision making amongst key stakeholders and researchers	2	50	2	11	9	2	2	3	22	3	1	10	2	2
75	The team uses methods to enable stakeholders to be creative	3	46	0	1	13	6	6	4	78	0	2	2	12	2
76	Ensure the team includes someone with a background specifically in product or pathway design	4	46	0	3	11	12	0	4	65	0	3	3	11	0
77	Undertake statistical and economic modelling to consider whether an intervention is likely to be worthwhile	2	46	3	9	3	8	3	4	56	0	3	5	9	1
78	Report the background and contribution of those making decisions about the intervention content, format and delivery	3	42	0	4	11	6	5	4	67	1	0	5	10	2
79	Consider the potential cost of several possible versions of the intervention at a very early stage	3	35	0	2	15	8	1	3	0	0	0	18	0	0
80	Have a clear plan of how evidence, data and opinions from different sources will be prioritised and inform the final intervention	3	35	0	2	15	7	2	4	94	0	0	1	16	0
81	Report the time taken to develop the intervention	3	27	1	1	17	4	3	3	17	0	3	14	1	0

82	Consider intellectual property (IP) issues	3	27	3	1	15	4	3	3	39	0	5	6	6	1
83	Report who, when, why and where the original idea for developing the intervention came from	3	27	3	1	15	5	2	4	67	2	1	3	9	3
84	Undertake a quantitative optimisation process to ensure only the strongest components of the intervention are included in the final version	3	27	2	5	15	4	0	3	19	1	2	13	0	0
85	Ensure the team includes someone who has developed a similar intervention	3	23	1	5	17	3	0	3	22	1	3	14	0	0

Appendix 2 Acknowledgements

Expert panel attendees

Dr. Lou Atkins
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Prof. Michael Donnelly
Prof. Russell Glasgow
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Dr. Deirdre Harrington
Dr. Lisa Hinton
Prof. Paul Little
Prof. Christine Markham
Ms. Karen Macpherson
Dr. José Merino
Dr. Ceri Phelps
Dr. Carol Sinnott
Prof. Michel Wensing
Prof. Danny Wight

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Ms. Sonja Beckmann
Dr. Andrew Booth
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Mrs. Val Bryant
Dr. Marian Carey
Dr. David Chandler
Ms. Hannah Collacott
Prof. Neil Coulson
Dr. Mieke Deschodt
Dr. Diane Dixon
Mr. Hiten Dodhia
Dr. Omara Dogar
Prof Lisa Dolovich
Dr. Charlotte Edwardson
Prof. Gene Feder
Prof. Kevin Fenton
Prof. Chris Fife-Schaw
Prof. Paul Flowers
Prof. David French
Dr. Tara French
Prof. Russell Glasgow
Dr. Kara Gray-Burrows
Mr. Dave Green
Prof. Diana Greenfield
Prof. Ingalill Rahm Hallberg
Prof. Graham Hart
Ms. Gemma Heath
Prof. Marie Johnston
Prof. Marian Knight
Dr. Niina Kolehmainen
Dr. Antje Koller
Prof. Gill Lancaster
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Dr. Ira Madan
Prof. Christine Markham
Prof. Maureen Markle-Reid
Dr. Karen Matvienko-Sikar
Dr. Rosie McEachan
Dr. Sheena McHugh
Dr. Jennifer McSharry
Dr. José Merino
Ms. Carol Namutebi
Dr. Helen Noble
Dr. Nicki O'Brien
Ms. Rosemary Phillips
Dr. Cath Quinn
Mr. Michael Reddington
Prof. David Richards
Prof. Glen Robert
Prof. Kathryn Rowan
Prof. Chris Salisbury
Prof. Walter Sermeus
Mr. Ed Sipler
Ms. Bernie Stribling
Ms. Gemma Teal
Dr. Elaine Toomey
Mr. James Turvill

Prof. Marjon Van der Pol
Dr. Oonagh Ward
Prof. Richard Watt
Prof. Michel Wensing
Prof. Danny Wight
Prof. Scott Wilkes
Prof. Claire Wilkinson
Prof. Rob Wilson

Consensus meeting participants

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Dr. Laura Asher
Dr. Kat Bradbury
Dr. Omara Dogar
Prof. Chris Fife-Schaw
Prof. Paul Flowers
Prof. Russell Glasgow
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Dr. Cath Quinn
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Prof. Michel Wensing
Prof. Danny Wight

Feedback on the developing guidance

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Contributors

AOC led the study on which the guidance is based, wrote the first draft of the guidance, and integrated contributions from the author group into subsequent drafts. All authors contributed to the design and content of the guidance and subsequent drafts. The guidance is based on reviews and primary research. AOC led the review of different approaches to intervention development working with KS. LC led the review of primary research working with KS. PH led the qualitative interview study working with NR, KT and ED. ED led the consensus exercise working with NR. Vera Fibisan was the Administrative Assistant.

Appendix 3 Examples of intervention development

Here are some examples of intervention development studies reported in journal articles. We present them within our framework. These summaries are based on our reading of the information researchers reported in their journal articles, information that is always limited by the need to attend to word count. Researchers may have reported other details in different articles or reports.

Domain	**Highfield L, Valerio MA, Fernandez ME and Eldridge-Bartholomew LK (2018). Development of an Implementation Intervention Using Intervention Mapping to Increase Mammography Among Low Income Women. Front. Public Health 6:300. doi: 10.3389/fpubh.2018.00300**
Principles: Dynamic, iterative, creative, open to change, forward looking to future evaluation and implementation	There is evidence of a dynamic movement between actions, as existing theory is used at different times in the process. The authors do not consider planning for future evaluation in this paper because it is step 6 of Intervention Mapping and is outside the scope of the paper. The authors state that the intervention is being evaluated in a stepped wedge non-randomised trial which was planned as part of the wider intervention development process.
Plan the development process	The aim was to develop an implementation intervention to deliver the Peace of Mind Program (PMP) to increase mammography rates for underserved women. PMP had already been found to be effective, and an implementation strategy had been developed, but there were concerns about whether implementation could occur successfully at scale. PMP had been tailored to a specific local community but there was heterogeneity in the provision of mammography so an 'implementation at scale' intervention was needed. The authors focus on step 5 of the published approach Intervention Mapping. They use it because it is a systematic process and has been used to develop similar interventions.
Involve stakeholders, including those who will deliver, use and benefit from the intervention	The authors state that the development of effective implementation strategies should include participatory approaches. They decide which stakeholders to include based on experience within the team and a literature review. The process of stakeholder involvement started with a brain storming workshop to ask who would implement PMP, who would ensure maintenance of PMP and who needed to do what. The theory used to develop the intervention (see later) was discussed in facilitator-led sessions with stakeholders. A participatory stakeholder group including clinical staff met with the research team during implementation of the intervention to trouble shoot problems.

	The authors describe needing to limit the amount of time community partners spent on intervention development because they had other priorities so the academic members of the research team went away and did work after the meetings with community partners.
Bring together a team and establish decision making processes	The authors described forming an intervention planning group consisting of the academic team, community partners, and community health workers with experience in the field. A Powerpoint presentation was developed to keep a record of decisions made during planning meetings and the evolving design of the intervention. This offered a complete record of the process available to all team members.
Review published research evidence	The authors described reviewing relevant research and practice literature on potential components of the intervention to confirm, refute or modify their list of components.
Draw on existing theories	The authors used the Consolidated Framework for Implementation Research (CFIR) to guide the development of the intervention because of their focus on implementation. They also drew on Social Cognitive Theory and Diffusion of Innovation. The authors remark on the utility of CFIR in this context.
Articulate programme theory	A logic model was not constructed but throughout the paper the authors articulate the links between intervention components and outcomes.
Undertake primary data collection	It was unclear whether research methods were used.
Understand context and systems	The theory CFIR was used to identify potential contextual factors affecting implementation and sustainability of PMP
Pay attention to future implementation of the intervention in the real world	Future implementation was the aim of the intervention so paying attention to implementation was central to the whole process. The use of CFIR reflected this.
Design and refine the intervention	The team designed the scope of the intervention and the sequence of the components of the intervention. The group started with a list of determinants of the problem and the change objectives. Members met over a period of two months to consider evidence on potential components and the set of three theories. Intervention materials were produced including training curricula. The stakeholder group was used to trouble shoot problems when the intervention was implemented.
End the development phase	The authors describe their reasons for writing this paper: because of the lack of description of how such interventions are developed, to help replication of developing these types of interventions, and to show how CFIR was used to develop the intervention.

Domain	**Birken M, Henderson C, Slade M. The development of an occupational therapy intervention for adults with a diagnosed psychotic disorder following discharge from hospital. Pilot and Feasibility Studies (2018) 4:81 https://doi.org/10.1186/s40814-018-0267-7**
Principles: Dynamic, iterative, creative, open to change, forward looking to future evaluation and implementation	There is some evidence of a dynamic approach as members of focus groups undertaken early in the process are used to offer feedback on the intervention manual. Feasibility studies were undertaken, with the intention that they would be reported separately. The authors state that the next step is to write a protocol for an RCT to measure effectiveness.
Plan the development process	The authors identify the need to use a more proactive approach to reduce the impact of mental health problems on people discharged from hospital and reduce costs to the health service. They describe the process of developing GLOW (Graduating Living skills Outside the Ward) for people diagnosed with a psychotic disorder and discharged from hospital. The development phase of the UK MRC framework for developing and evaluating complex interventions was used to guide the process. The three stages of this were followed and outlined in a diagram. The justification was to ensure the intervention was empirically defensible and developed sufficiently prior to testing in a feasibility study.
Involve stakeholders, including those who will deliver, use and benefit from the intervention	There was no stakeholder involvement reported. Instead focus groups were undertaken with clinicians and service users (see later).
Bring together a team and establish decision making processes	No details reported.
Review published research evidence	Stage one of the published approach used is to identify the evidence base. Three studies were conducted to address this: a systematic review of interventions to improve occupational performance following discharge from hospital (no studies found); a mixed review of occupational performance for people with psychosis (no relevant studies found); and new data collection because no relevant studies were found.
Draw on existing theories	Stage two of the published approach used focuses on identifying/developing theory. A literature review of theory relating to occupational performance was undertaken and 8 theoretical models identified. The Model of Human Occupation was selected and the Intentional Relationship Model was also used to guide the therapeutic relationship with the clinician.
Articulate programme theory	Stage three of the published approach used is modelling. Causal modelling was used to show how the intervention components would produce outcomes based on the theoretical model underpinning the intervention. This was articulated clearly within a figure.

Undertake primary data collection	Focus groups with service users and clinical staff were undertaken as part of stage one 'identifying the evidence base'. This was used to identify the problems people face.
Understand context and systems	Attention to understanding context may have occurred in that the focus groups helped to identify context.
Pay attention to future implementation of the intervention in the real world	Attention to implementation may have occurred in that the focus groups helped to identify issues relevant to implementation.
Design and refine the intervention	The findings of all the sub-studies were synthesised and the content, structure and format of the intervention identified.
End the development phase	The intervention was formally manualised to ensure consistent delivery and replication in different settings. Also standardised training for using the intervention was documented to enhance fidelity. The manual was shared with some of the focus group participants and amended based on feedback. TIDieR was used to describe the intervention.

Domain	**Hochstenbach LMJ et al. Co-creative development of an eHealth nursing intervention: Self-management support for outpatients with cancer. Applied Nursing Research 36 (2107) 1-8. painhttp://dx.doi.org/10.1016/j.apnr.2017.03.004**
Principles: Dynamic, iterative, creative, open to change, forward looking to future evaluation and implementation	The authors describe a three phase approach, with iteration within each, to consider the research, generate ideas, make a prototype, evaluate the prototype and document the final intervention. Financial and practical issues are considered early in the process to ensure the intervention can be used in the real world.
Plan the development process	A problem is identified for intervention: patients receive inadequate care for pain when being treated as outpatients. The approach taken to intervention development is described as co-creation* and is based on the principles of user-centred design using a multidisciplinary team. Iterative processes ensure the intervention fit with the needs and desires of health professionals and patients.
Involve stakeholders, including those who will deliver, use and benefit from the intervention	The authors describe how health professionals and patients were actively involved in the development process to ensure their wishes and needs guided the process from an early stage. Health professionals and patients were consulted throughout in consultation sessions. The authors report that they could have involved patients more throughout and document this as a limitation of their study. The team used easy-to-understand language to describe activities to support stakeholders involvement.
Bring together a team and establish decision making processes	Attention was paid to bringing together a team with different perspectives and expertise in cancer pain, palliative care, e-health, self-management, software development and design.
Review published research evidence	Authors report that a review of the literature identified important aspects of self-management (no details given).
Draw on existing theories	Authors report that theories about self-management for chronic conditions and educational interventions were taken into account (no details given).
Articulate programme theory	A conceptual framework was described in a table, linking broad components of the intervention and outcomes.
Undertake primary data collection	Documentary analysis and interviews with health professionals and patients were used to identify problems, and this information was then discussed in team brain-storming sessions. Usability and desirability of prototypes (paper drafts of the software applications) were tested with patients. The authors note that a limitation was that feasibility as well as usability should have been considered.

Understand context and systems	Phase one of the development process was to explore context through documentary analysis and interviews with health professionals and patients.
Pay attention to future implementation of the intervention in the real world	Phase three of the development process was to focus on organisation of care and consider the integration of the intervention into routine clinical practice. Practical and financial issues were considered when deciding on the content of the intervention.
Design and refine the intervention	Prototypes were used to support the creative process, help visualise ideas and solutions, and obtain feedback on the intervention.
End the development phase	The authors describe the intervention within the paper. The authors report writing the paper on intervention development to justify the intervention, help interpret the outcomes of the future evaluation, and facilitate reproduction of the intervention in other settings.

*terms like co-creation, co-production are used in our guidance to describe power sharing when making decisions about the intervention. The term co-creation may have been used differently in this example because the development team made decisions after consulting stakeholders.