

Duncan, E., O'Cathain, A., Rousseau, N., Croot, L., Sworn, K., Turner, K. M., Yardley, L., & Hoddinott, P. (2020). Guidance for reporting intervention development studies in health research (GUIDED): An evidence-based consensus study. *BMJ Open*, *10*, [e033516].  
<https://doi.org/10.1136/bmjopen-2019-033516>

## **Reporting GUIDance for intervEntion Development in health research (GUIDED)**

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### **Abstract**

**Objective:** To improve the quality and consistency of intervention development reporting in health research.

**Design:** A consensus exercise consisting of two simultaneous and identical three round e-Delphi studies (one with experts in intervention development and one with wider stakeholders including funders, journal editors and public involvement members), followed by a consensus workshop. Delphi items were systematically derived from two preceding systematic reviews and a qualitative interview study.

**Participants:** Intervention developers (n=26) and wider stakeholders (n=18) from the UK, North America and Europe participated in separate e-Delphi studies. Intervention developers (n=13) and wider stakeholders (n=13) participated in a one day consensus workshop.

**Results:** e-Delphi participants achieved consensus on 14 reporting items. Following feedback from the consensus meeting, the final inclusion and wording of 13 items with description and explanations for each item were agreed. Items focus on context, purpose, target population, approaches, evidence, theory, guiding principles, stakeholder contribution, changes in content or format during the development process, required changes for sub-groups, continuing uncertainties, and open-access publication. They form the GUIDED checklist.

**Conclusions:** Consensus-based reporting guidance for intervention development in health research is now available for publishers and researchers to use. GUIDED has the potential to lead to greater transparency, and enhance quality and improve learning about intervention development research and practice.

### **Strengths and Limitations of this Study**

- The 14 GUIDED items were developed through a structured and transparent consensus-based process.
- Parity of opinion was given to intervention developers and wider stakeholders throughout the development of the reporting guidance.
- Despite aiming to secure an international sample this proved difficult. We acknowledge that participants in the study were predominantly based in the Global North and that the perspectives of intervention developers and wider stakeholders from the Global South is absent.

**Key words:** Intervention Development, Reporting Guidance, Delphi, Consensus

## Background

The United Kingdom Medical Research Council's (MRC) Framework for the Development and Evaluation of Complex Interventions<sup>1</sup> lists intervention development as the first of a series of interconnected phases. While the MRC complex intervention guidance has stimulated considerable methodological progress in understanding and reporting the latter phases (i.e. feasibility and piloting, evaluation, and implementation), the intervention development phase has remained relatively underdeveloped and without a comprehensive reporting guideline<sup>2</sup>. Research funders, researchers, commissioners, practitioners, the public and patients are increasingly interested in understanding and improving the intervention development process.

There are a variety of ways to develop interventions. A review of approaches include partnership (e.g. co-production; co-design), target population centred, evidence and theory-based, implementation-based, efficiency-based, step or phased-based, intervention-specific or a combination of methods<sup>3</sup>. Successful intervention development is characterised as being rigorous, scientific and resulting in effective interventions that can be implemented in real world settings<sup>4</sup>. However, a key intervention development challenge is the lack of evidence-based quality criteria on which to assess which, if any, approach is superior to another, and in which context.

The reasons why intervention development processes are currently under-reported are unclear. This may be due to research funding priorities or pressure to publish efficacy or effectiveness studies diminishing the priority of publishing intervention development studies. When intervention development studies are published, they are sometimes included as part of a feasibility or pilot study. Consequently, detail about how the intervention was actually developed can be sparse. A more systematic, comprehensive, and transparent approach to intervention development reporting is likely to enhance understanding about the intervention development process. It would help readers to understand the benefits and challenges of different intervention development approaches. It would help researchers select an intervention development approach that is relevant to their context. It would also facilitate future retrospective assessment of how different intervention development approaches can lead to either effective or ineffective interventions that do or do not translate into practice change. Potentially such assessment could provide insights into research waste. While some reporting guidance already exists that relates to intervention development, these are limited in scope. The TIDiER<sup>5</sup> guidelines are extensions to CONSORT for improving the reporting of the completed intervention that results from the intervention development process. The CREDICI guideline for reporting the development and evaluation of Complex Intervention in Healthcare does provide reporting guidance for intervention development, however this is limited to four items as CREDECI 2 also provides guidance on reporting Feasibility and Piloting and Evaluation. To date, there has been no guidance focusing in detail on reporting the whole process of intervention development.

This paper presents GUIDance for the rEporting of Intervention Development (GUIDED). GUIDED forms part of a larger MRC funded study to produce guidance on intervention development: the IdentifiyINg and assessing different approaches to DEveloping compleX interventions (INDEX) study<sup>6</sup>. It is the first international mixed methods consensus study to focus on reporting guidance solely for intervention development processes. In this paper we report the methods used to develop and gain consensus on the items included in the GUIDED checklist. We present each reporting item with further description and explanation. GUIDED will be of interest to research funders, researchers, journal editors, commissioners, practitioners, the public and patients, who we refer to collectively as "readers".

## Methods

### Design

We published our intent to develop intervention reporting guidance (5 July 2017) in the Equator Network Library (<http://www.equator-network.org/library/reporting-guidelines-under-development/reporting-guidelines-under-development-for-other-study-designs/#80>). The design of this intervention development consensus study involved conducting two simultaneous and identical e-Delphi studies followed by a consensus workshop. Participants included i) intervention developers and ii) wider stakeholders who were involved in the wider intervention development activities including directors of research funding panels, editors of journals that had published intervention development studies, public and patient involvement members of intervention development studies, and people working in health service implementation<sup>6</sup>. By separating intervention developers and wider stakeholders within the e-Delphi process we ensured that the perceptions of both groups were equally reported and their views given equal weight. A subset of the consensus exercise related specifically to the identification of intervention development reporting guidance, reported in this paper. We followed established methods for developing reporting guidance<sup>7</sup> (See Figure 1) and report the e-Delphi guidance in line with current best practice<sup>8</sup>. The parallel e-Delphi studies were delivered over three separate rounds. Each round lasted for 4 weeks. Non-responders were emailed a reminder after two weeks. Completion of one round was required to enter the next e-Delphi round. There was space for participants to comment beside each item and explain their responses, or (in Round 1) suggest alternative item wording. However no additional items were suggested by participants. **Items were not removed from subsequent rounds, even if they had previously passed the pre-determined threshold.**

### e-Delphi item generation

e-Delphi items were generated by triangulating three different data sources: a systematic methods overview of 87 articles, books and websites that identified 23 approaches to intervention development within 8 categories and with 18 actions undertaken across these approaches<sup>3</sup>; a systematic review of 87 international primary research articles reporting intervention development processes which describes 10 actions<sup>9</sup>; and an analysis of 21 in-depth qualitative interviews with an international sample of intervention developers (N=15) and key stakeholders (N=6)<sup>10</sup>. The research team (AO, LY, PH, ED, LC, NR, KS) met regularly to identify the potential reporting guidance items. Members of the research team worked in pairs, and one team of three, to extract potential guidance items from the three data sources. Each pair then presented potential e-Delphi items to the whole team. Each potential item was discussed, refined, and agreed. We grouped items into themes, with one theme entitled “Reporting Guidance”, which had 19 items. The full set of e-Delphi items and their ratings have been reported elsewhere<sup>6</sup>.

### e-Delphi participants

Invitations were sent to 92 individuals who had undertaken intervention development and/or published a formal approach to intervention development and 80 wider stakeholders. **Intervention developers, identified through parallel studies conducted by the research team<sup>3 11</sup>, were invited to participate if they had published at least one intervention development study, or written methodological books or journal articles about intervention development. Wider stakeholders were identified through a web search of Journal editorial boards, funding bodies, and other relevant sources. Wider stakeholders were invited if their role brought them into direct contact with the intervention development process, for example as editors, funding panel members, or**

commissioners. In addition, we convened an international expert panel with members from the UK, USA and Europe early in the project to guide the research<sup>6</sup>. Approximately one third of invited participants were from countries other than the UK. Members of this expert panel participated in the e-Delphi studies and consensus workshop alongside other participants. Individuals who responded to say they would participate in the e-Delphi were emailed a study information containing a url to an established e-Delphi platform<sup>12</sup> and a unique password to access the study.

#### Definition of consensus

Following an online consent process, participants were asked to rate the importance, when conducting high quality intervention development and reporting, they would give to each potential item on a scale of 1 to 5: Not at all important (1); Slightly unimportant (2); Somewhat important (3); Fairly important (4); Very important (5). An additional option of no relevant expertise was provided for each item. Prior to commencement, we decided that an item would be included within the reporting guidance if at least 70% of participants agreed that an item was fairly important (4) or very important (5) in either e-Delphi group by the end of Round 3. Including items that reached the pre-defined threshold in either group meant that equal priority was given to participants that belonged to either the intervention development or wider stakeholder group. A similar approach to methodological guideline reporting development has been used elsewhere.<sup>13</sup>

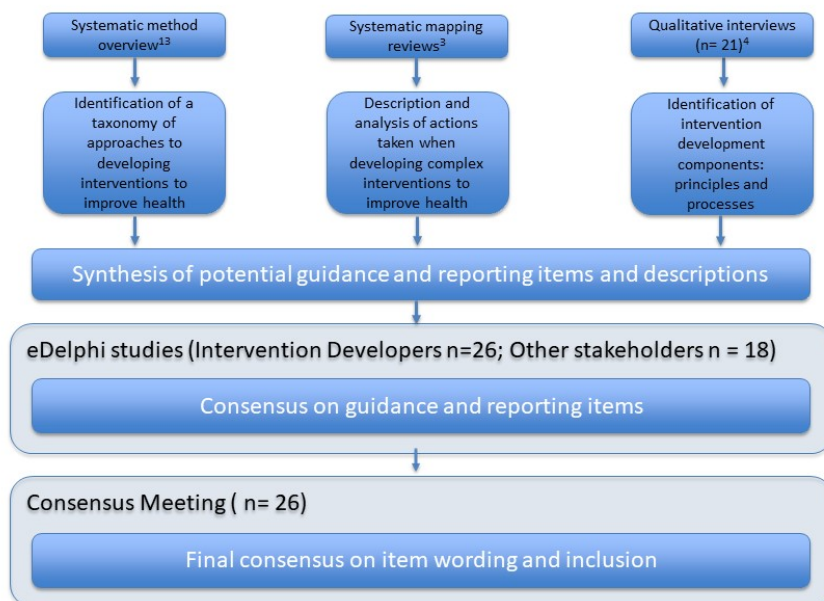
#### Consensus meeting

The results of the e-Delphi studies were discussed by participants (in person or by video link) and eight team members at a one day consensus meeting on 13 March 2018, in London, UK. The meeting began with presentations from the team: an overview of the overall INDEX study, followed by a summary overview of both systematic reviews<sup>3 9</sup> and qualitative study<sup>4</sup>. The results of both e-Delphi studies were then presented and detailed discussions were held on items that had not reached consensus, but which reflected divergence. Consensus meeting participants suggested improvements to the wording of items. Two items were merged in the final GUIDED checklist: Item 10 “Report how the intervention changed in content and format from the start of the intervention development process” and a recommendation to “report the reasons for discarding intervention components that were considered”. This was previously a separate item but was considered by the team to be appropriately covered in a single item.

#### Following the Consensus Meeting

No further changes were made to reporting guidance items. We developed supplementary files detailing the description and explanation of the item as well as a supplementary file with examples of previous studies that illustrate their use. These examples are almost completely drawn from reviews of previous intervention development literature<sup>3 11</sup>. In one instance, where an example could not be found, an example was created and is identified as a hypothetical description.

Figure 1: Intervention development guidance and reporting process.



## Results

### Description of participants

The response rates for each round were as follows: Round 1 Intervention developers (n=34), Wider stakeholders (n=22); Round 2 Intervention developers (n=27), Wider stakeholders (n=18); Round 3 Intervention developers (n=26), Wider stakeholders (n=18). Intervention development participants who completed Round 3 were based in the UK (n=16), mainland Europe (n=5), Ireland (n=4) and USA (n=1). They included people from public health (n=10), applied health research/health services research (n=8), psychology (n=7), nursing (n=6), and allied health professional (n=1) backgrounds. Wider stakeholder participants who completed Round 3 were based in the UK (n=16), mainland Europe (n=1) and USA (n=1). They included chairs or members of funding panels (n=5), editors or editorial board members of journals (n=4), commissioners of services (n=3), public and patient involvement (n=3), and other (n=3) individuals.

The 26 participants of the consensus meeting were based in the UK (n=19), USA (n=3), mainland Europe (n=3), and Ireland (n=1). They were invited due to their varied roles in the intervention development process: intervention developers (n=13), methodologists (n=4), chairs of funding panel (n=3), journal editors (n=3), public and patient representatives (n=1), commissioner (n=1), and other (n=1).

### Description of consensus from eDelphi study.

**Fifteen of a possible 18 intervention development reporting items reached our apriori threshold for inclusion<sup>6</sup>.** Table 1 presents all the reporting items included in the e-Delphi; the percentage of responses that scored 4 or 5 for each item and the mode score. **The responses to Round 3 of the full Delphi study are available in supplementary file 2 of the full guidance<sup>6</sup>.**

Table 1. e-Delphi study results for Intervention Development reporting items.

Items	Intervention Developers			Wider Stakeholder		
	Mode Score and (% Agreement by Round)					
	Round 1	Round 2	Round 3	Round 1	Round 2	Round 3
Report the purpose of the intervention	5 (97)	5 (96)	5 (100)	5 (94)	5 (100)	5 (100)
Report the target population	5 (97)	5 (96)	5 (100)	5 (100)	5 (100)	5 (100)
Report any use of components from an existing intervention	5 (84)	5 (89)	5 (100)	4 (89)	4 (93)	4 (100)
Report how evidence from different sources informed the intervention development	5 (93)	5 (96)	5 (100)	5 (83)	5 (86)	5 (100)
Report how stakeholders contributed to the intervention development process	5 (97)	5 (96)	5 (100)	4 (89)	4 (93)	4 (94)
Report important uncertainties at the end of the intervention development process.	5 (87)	5 (93)	5 (100)	5 (83)	5 (86)	5 (78)
Report the context for which the intervention was developed	5 (90)	5 (93)	5 (96)	5 (94)	5 (93)	5 (100)
Report any changes to interventions required or likely to be required for subgroups	5 (90)	5 (89)	5 (96)	5 (83)	4 (93)	4 (83)
Report how any published intervention development approach contributed to the development process	5 (83)	5 (78)	5 (92)	4 (67)	4 (64)	4 (71)
Report how existing published theory informed the intervention development process	5 (87)	5 (89)	5 (92)	4 (89)	5 (93)	4 (94)
Report any guiding principles, people or factors which were prioritised when making decisions	5 (81)	5 (85)	5 (92)	4 (72)	4 (93)	4 (83)
Report how the intervention changed in content and format from the start of the intervention development process*	5 (74)	4 (74)	5 (88)	4 (77)	4 (93)	4 (94)
Report the reasons for discarding intervention components that were considered*	5 (74)	5 (81)	5 (88)	4 (78)	4 (93)	4 (88)
Follow TIDieR guidance when describing the developed intervention	5 (76)	5 (69)	5 (80)	4 (100)	5 (100)	5 (88)
Report the intervention development in an open access format (e.g. open access journal, report chapter, website)	5 (68)	4 (67)	4 (77)	5 (77)	5 (86)	5 (89)
Report the background and contribution of those making decisions about the intervention content, format and delivery	5 (50)	3 (40)	3 (42)	4 (61)	4 (67)	4 (67)
Report the time taken to develop the intervention.	4 (52)	3 (41)	3 (27)	3 (33)	3 (21)	3 (17)
Report who, when, why and where the original idea for developing the intervention came from	3 (45)	3 (30)	3 (27)	5 (50)	4 (64)	4 (67)

\*These items were merged into one item (See Item 10 below) following the consensus meeting.



## GUIDED intervention development reporting items: Description and explanation

Below, we have ordered the items so that those which are more likely to be considered earlier in the development process are listed first. However, there is no fixed order in which the reporting items must be considered. EQUATOR reporting guidance<sup>7</sup> encourages describing and explaining the rationale for each reporting item to help researchers and others to write or appraise reports. We have therefore followed this format, in keeping with other related reporting guidelines<sup>5 14 15</sup>.

A blank checklist to support the use of GUIDED by authors and reviewers is provided in Supplementary File 1. Examples from papers that meet a reporting item specification are provided in Supplementary file 2.

### **Item 1.**

*Description:* Report the context for which the intervention was developed.

*Explanation:* Understanding the context in which an intervention was developed informs readers about the suitability and transferability of the intervention to the context in which they are considering evaluating, adapting or using the intervention. Context here can include place, organisational and wider socio-political factors that may influence the development and/or delivery of the intervention<sup>16</sup>.

### **Item 2.**

*Description:* Report the purpose of the intervention development process.

*Explanation:* Clearly describing the purpose of the intervention specifies what it sets out to achieve. The purpose may be informed by research priorities, for example those identified in systematic reviews, evidence gaps set out in practice guidance such as The National Institute for Health and Care Excellence or specific prioritisation exercises such as those undertaken with patients and practitioners through the James Lind Alliance.

### **Item 3.**

*Description:* Report the target population for the intervention development process.

*Explanation:* The target population is the population that will potentially benefit from the intervention – this may include patients, clinicians, and/or members of the public. If the target population is clearly described then readers will be able to understand the relevance of the intervention to their own research or practice. Health inequalities, gender and ethnicity are features of the target population that may be relevant to intervention development processes.

### **Item 4.**

*Description:* Report how any published intervention development approach contributed to the development process.

*Explanation:* Many formal intervention development approaches exist and are used to guide the intervention development process (e.g. 6Squid<sup>17</sup> or The Person Based Approach to Intervention Development<sup>18</sup>). Where a formal intervention development approach is used, it is helpful to describe the process that was followed, including any deviations. More general approaches to intervention development also exist and have been categorised as follows<sup>3</sup>:- Target Population-centred intervention development; evidence and theory-based intervention development; partnership intervention development; implementation-based intervention development; efficacy-

based intervention development; step or phased-based intervention development; and intervention-specific intervention development<sup>3</sup>. These approaches do not always have specific guidance that describe their use. Nevertheless, it is helpful to give a rich description of how any published approach was operationalised.

#### **Item 5.**

*Description:* Report how evidence from different sources informed the intervention development process.

*Explanation:* Intervention development is often based on published evidence and/or primary data that has been collected to inform the intervention development process. It is useful to describe and reference all forms of evidence and data that have informed the development of the intervention because evidence bases can change rapidly, and to explain the manner in which the evidence and/or data was used. Understanding what evidence was and was not available at the time of intervention development can help readers to assess transferability to their current situation.

#### **Item 6.**

*Description:* Report how/if existing published theory informed the intervention development process.

*Explanation:* Reporting whether and how theory informed the intervention development process aids the reader's understanding of the theoretical rationale that underpins the intervention. Though not mentioned in the e-Delphi or consensus meeting, it became increasingly apparent through the development of our guidance that this item could relate to either existing published theory or programme theory.

#### **Item 7.**

*Description:* Report any use of components from an existing intervention in the current intervention development process.

*Explanation:* Some interventions are developed with components that have been adopted from existing interventions. Clearly identifying components that have been adopted or adapted and acknowledging their original source helps the reader to understand and distinguish between the novel and adopted components of the new intervention.

#### **Item 8.**

*Description:* Report any guiding principles, people or factors that were prioritised when making decisions during the intervention development process.

*Explanation:* Reporting any guiding principles that governed the development of the intervention will help the reader to understand the authors' reasoning behind the decisions that were made. Guiding principles specify the core objectives and features of the desired intervention<sup>19</sup>. These could include prioritising patient preferences over clinician preferences, providing an engaging experience for patients, minimizing the cost of delivering the intervention, or maximising the potential for the intervention to be scaled up.

#### **Item 9.**

*Description:* Report how stakeholders contributed to the intervention development process.

*Explanation:* Potential stakeholders can include patient and community representatives, local and national policy makers, health care providers and those paying for or commissioning health care. Each of these groups may influence the intervention development process in different ways. Specifying how differing groups of stakeholders contributed to the intervention development process helps the reader to understand how stakeholders were involved and the degree of influence they had on the overall process. Further detail on how to integrate stakeholder contributions within intervention reporting are available<sup>20</sup>.

**Item 10.**

*Description:* Report how the intervention changed in content and format from the start of the intervention development process.

*Explanation:* Due to the iterative nature of intervention development, the intervention that is defined at the end of the development process can often be quite different to the one that was initially planned. Describing these changes and their rationale enhances understanding and enables other intervention developers to learn from this experience. For example, it may be that some intervention components were considered but ultimately discarded due to complexity or expense of delivery.

**Item 11.**

*Description:* Report any changes to interventions required or likely to be required for subgroups.

*Explanation:* Specifying any changes that the intervention development team perceive are required for the intervention to be delivered or tailored to specific sub groups enables readers to understand the applicability of the intervention to their target population or context. These changes could include changes to personnel delivering the intervention, to the content of the intervention, or to the mode of delivery of the intervention.

**Item 12.**

*Description:* Report important uncertainties at the end of the intervention development process.

*Explanation:* Intervention development is frequently an iterative process. The conclusion of the initial phase of intervention development does not necessarily mean that all uncertainties have been addressed. It is helpful to list remaining uncertainties such as the intervention intensity, mode of delivery, materials, procedures, or type of location that the intervention is most suitable for. This can guide other researchers to potential future areas of research and practitioners about uncertainties relevant to their healthcare context.

**Item 13**

*Description:* Follow TIDieR guidance when describing the developed intervention

*Explanation:* Interventions have been poorly reported for a number of years. In response to this internationally recognized guidance has been published to support the high quality reporting of health service interventions [REF] and public health interventions [REF]. This guidance should therefore be followed when describing a developed intervention.

**Item 14.**

*Description:* Report the intervention development process in an open access format.

*Explanation:* Unless reports of intervention development are available people considering using an intervention cannot understand the process that was undertaken and make a judgement about its appropriateness to their context. It also limits cumulative learning about intervention development methodology and observed consequences at later evaluation, translation and implementation stages. Reporting intervention development in an open access (Gold or Green) publishing format increases the accessibility and visibility of intervention development research and makes it more likely to be read and used. Potential platforms for open access publication of intervention development include open access journal publications, freely accessible funder reports or a study web-page that details the intervention development process.

## **Discussion**

Intervention development is a vital component of the MRC Developing and evaluating complex interventions guidance. This study presents a mixed method international consensus study to produce detailed reporting guidance for the intervention development phase of the MRC Complex Intervention Guidance. The GUIDED checklist provides a list of 14 intervention development items each with an accompanying explanation for why it is important to include this information in publications and outputs that describe the intervention development process. The GUIDED checklist was developed in collaboration with a range of stakeholders, each of whom contributed a range of expertise and perspectives on the intervention development process. *Despite efforts to include participation from a global audience, the majority of participants come from within the UK. Among developers, we had a good response from European countries but a poorer response from the rest of the world. Among wider stakeholders, the response was poor from all outside the UK. It seems likely that the study was more relevant to developers and that developers were also more likely to know of the study team, which may have influenced participation. To maximise response, any similar research in the future may benefit from a preliminary email endorsement from an influential person based in the same geographical region as the intended participant.*

The GUIDED reporting checklist and its associated item descriptions have been systematically developed to support readers to understand key aspects of specific intervention development studies. Adhering to the GUIDED item checklist across the variety of formats in which intervention development publications already occur should improve the quality, transparency and consistency of intervention development reporting.

### What gap does GUIDED fill?

Good quality effectiveness studies with detailed guidance on intervention description are necessary<sup>5</sup>  
<sup>14</sup>. GUIDED is offered as complementary reporting guidance to detail the intervention development process. Presenting intervention development studies in line with GUIDED recommendations reported in this paper will enable commissioners and practitioners to understand the context and methods that were used to develop the intervention to help them make judgements about the quality and relevance of the intervention. This information will be useful in guiding their decisions about whether to evaluate or implement an intervention within their specific context. Finally, high quality and transparent reporting of intervention development in line with GUIDED recommendations will enable methodological lessons to be learnt and incorporated into future intervention development studies. We therefore recommend that authors follow GUIDED when reporting intervention development studies, and journal editors and research funders endorse the use of GUIDED within any publications that report intervention development studies. The GUIDED checklist will be placed on the EQUATOR network website and we request that Journals provide links to the EQUATOR site and signpost potential authors to this guidance where appropriate.

## How does GUIDED fit with other reporting guidance?

GUIDED provides a more comprehensive description than previous guidance<sup>21</sup> of what should be reported when publishing intervention development studies. GUIDED complements and can easily be integrated or signposted to within other reporting guidance. Papers that are written to describe interventions should follow existing guidance<sup>5 14</sup> and signpost readers to where they can read about the intervention development process, reported in line with GUIDED recommendations, so they can judge the appropriateness of the intervention development process. Where randomised controlled trials are being reported using CONSORT guidance<sup>15</sup> then authors could signpost (for example in reporting CONSORT Statement 5: Intervention) to where a GUIDED description of intervention development has been reported. Where patients and the public contributed to intervention development, the GRIPP 2 guidelines can be used<sup>20</sup>.

## **Conclusion**

The GUIDED checklist and reporting guidance has been developed by following internationally recognised methods for developing reporting guidance<sup>7</sup>, with items based on extensive primary<sup>4 22</sup> and secondary<sup>3 11</sup> research to enable greater transparency and quality of reporting development of complex interventions. The GUIDED checklist and guidance provide a clear and structured basis for the reporting of intervention development studies in a range of formats. It has the potential to facilitate learning about how early intervention development decisions impact across the life history of an intervention: through feasibility and efficacy testing, cost-effectiveness evaluations and translation into health care practice change.

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