

Reporting Guideline for the Participatory Development and Evaluation of Digital Health Interventions (ParDE-DHI)

Explanation for usage

- This reporting guideline provides a set of recommendations on information that should be included for a comprehensive reporting of participatory development and evaluation of Digital Health Interventions (DHIs). This also includes guidance on how some information might best be presented and lists of possible frameworks for reference. The selection of appropriate formats and frameworks is up to the researcher and can be something that is not listed as an example.
- ParDE-DHI focuses on the development and evaluation of DHIs. Despite the comprehensive and holistic nature of the development process, it may be necessary to consider additional reporting guidelines in conjunction with it (e.g. TIDieR checklist for intervention description). This decision is up to the researchers.
- Each journal has different requirements, so some items may be required in other sections. This should not be irritating. Authors can change the order of the items if they want to keep the items under the subheadings.
- Not all items can be fully addressed in the main body of a publication, so some items include a note to add information to the appendix. Alternatively, reference may be made to other existing or planned publications that address the issue.

No.	Section and Topic	Item/Guidance for Reporting	Location where item is reported/ Reported on page
ABSTRACT			
1	Background	Briefly state the background and context of the study, including the state of the art and the research gap.	
2	Aim	State the aim of the participatory development and evaluation.	
3	Method	Describe the key methods for evaluation and participation, such as evaluated criteria & indicators, target group, geographic place of data collection, and degree of participation.	
4	Results	Report the key findings and their relevance, as well as the sample size and sociodemographic characteristics of participants.	
5	Conclusion	Summarize the main conclusions of the study and potential implications.	
6	Keyword	List relevant keywords that represent the core topics of the study.	
BACKGROUND & FOUNDATION			
7	Scientific Background	Describe the scientific background of the study and indicate which research was carried out in advance and which databases and terms were used to find information.	
8	Study Context	Describe the context of the study and the addressed problem. Describe whether the study is part of a larger research, development, or implementation project. Mention from which perspective (if any) the study is performed.	
9	Rationale	Describe the motivation and specific reasons for the study (scientific interest, justification for expenditure, insight into problems like potential unintended side effects, addressing open research questions).	
10	Ethical Vote & Considerations	Please mention the ethical vote for the study and where it was obtained. Add information about the consideration of the possibility of harm, as well as the assessment of the likelihood of risks, as well as adverse outcomes.	
11	Theory of Participation Concept*	Report the definition of participation used in the study and the belonging concept (e.g., PPI, PHR). Describe why this definition fits your study.	
12	Digital Health Intervention (DHI) Setting*	Describe the setting of the DHI and the real-world context where it will be implemented later on. Add information on the health domain it addresses, the specific healthcare issue it targets, and the intended use setting.	
13	DHI Development*	Describe how the DHI was developed and whether a specific framework or theory (such as behavioral change frameworks or GUIDED recommendations) was followed in the development process. If applicable, add a description of the history/development process of the DHI and	

		previous formative evaluations (e.g., focus groups, usability testing) to the appendix. Describe formative research and/or content and/or usability testing with target group(s) clearly identified, as appropriate. If possible, it should be mentioned what influence the findings of the study have.	
14	DHI Description	Describe the type of DHI that is the object of the study by ... (If there is/are one or more comparators, all the following points also must be addressed.) a) referring to established frameworks or classification systems (e.g., TiDieR-Checklist or those provided by the WHO or NICE) to classify the DHI. The selection of an appropriate framework for the project is up to the researcher. b) listing the characteristics and key components of the DHI. Outline its primary functions as well as its user interface. Describe how the components interact with each other, and which components impact which predicted outcomes. c) describing which target group the DHI addresses and why it is likely to reach this population, as well as why the population will be likely to use it. d) outlining to what extent the DHI takes diversity of potential end-users and affected people into account (e.g., adjustment of text size, text to voice, colorblind color scheme adjuster, specificity to use by minors, offline features, left and right-handed options) and make explicit any equity concerns that may have arisen in their attempt to take the end-user into account. Outline how the equitable usage of potential end-users is considered. e) mentioning the iterations of the DHI or describing whether the intervention underwent major changes during the evaluation process, or whether the development and/or content was "frozen" during the trial. f) describing dynamic components (e.g., news feeds, changing content, usage of ongoing feedback based on the end-user's state and activities, personalization) which may have an impact on the replicability of the intervention. Describe whether there are any strategies to support tailoring the DHI to participants over time.	
METHOD			
15	Study Design	Present key study design (participatory development & evaluation), including the mention of a possible pre-registration.	
16	Study Flow	Visualize the research process (e.g., CONSORT flowchart or others appropriate to iterative participatory approaches).	
17	Informed Consent	Describe the informed consent process by which the participants were told the length of time of the study, which data were stored and where, and for how long, who the investigator was, the possibilities of drop-out, and what the purpose of the study was.	
18	Methodological Orientation	Describe what methodological orientation was stated to underpin the study, e.g., grounded theory, discourse analysis, ethnography, phenomenology, content analysis.	
19	Participatory Evaluation Method	Explain the level or nature of participation and participatory development and evaluation methods used at various stages of the study by ... a) defining the used evaluation criteria, including their underlying indicators by referring to existing frameworks (e.g., WHO, NICE, EXPH, the Swiss Evaluation framework by Kowatsch et al., the approach of Murray et al., or others). b) describing and referencing the participatory methods used (e.g., co-design workshops, user testing, or participatory data analysis). c) describing the level or nature of participation used at various stages of the study. Refer to established theories or (stage) models of participation (e.g., Wright et al.'s Stage Model of Participation, Arnstein's Ladder of Citizen Participation, Treseder's Degrees of Involvement, Shier's Pathways to Participation, Community-Based Participatory Research, or others). d) describing the reasons behind the chosen development and evaluation methods and the level of evidence of the method. e) (optional) describing if established methods, frameworks, or approaches are deemed inappropriate or inapplicable for the specific context of the DHI being evaluated, explaining the reasons for the exclusion briefly. f) describing any approaches to participate or engage potential end-users and other affected people (e.g., patients, public, communities, clinicians, or others) in the design of the study. If applicable, describe how the equitable participation of all relevant people, including people in vulnerable situations, is considered. g) outlining how it was ensured that vulnerable diversity in potential end-users and other affected people was adequately considered and represented in the participatory evaluation.	
20	Impacts/Effects of Participation	If applicable, report the methods used to explore the impact of participation as well as barriers and facilitators of participation in the study.	
21	Usage of AI	Report if AI was used to analyze the data reported in the results section.	

22	Data Collection & Measurements	Provide details on the data collection methods used for each variable of interest by ... a) describing all relevant aspects of applied data collection methods (e.g., questionnaire, interview, focus groups, observation, task-/scenario-completion, log file analysis). b) explaining which roles established measurements play in the study. If established measurements can't be used, explain why. c) If applicable, adding a detailed description of instrument development and testing (e.g., validity, reliability, feasibility, acceptability, responsiveness, interpretability, appropriateness, precision) of newly designed measurements to the appendix. d) describing the setting of the data collection as well as the dynamics (e.g., laboratory or real setting, participants were grouped into teams, worked collaboratively or individually, predefined tasks to be completed). e) describing the role of the researchers in the evaluation (e.g., supporting role, silent observer).	
23	Sampling	Describe who participated by ... a) describing any eligibility criteria for participation. b) describing the role and expertise of the participants (e.g., academics, developers, potential end-users, other affected people). c) explaining how it is ensured that the people who were involved were the people who fit the research question (e.g., stakeholder analysis, different digital health literacy levels).	
24	Recruitment & Engagement Strategies	Describe in detail how participants were recruited, and which strategies were used to engage them by ... a) explaining how participants were selected, e.g., purposive, convenience, consecutive, snowball. b) outlining how participants were approached, e.g., face-to-face, telephone, e-mail. c) describing how, how often, and where the study was announced or advertised. * d) reporting relevant dates, periods of recruitment, and follow-ups. * e) reporting if there were any incentives offered (e.g., monetary or non-monetary incentives such as an offer to provide the study results). f) describing any approaches of engaging participants (e.g., strong and balanced advisory board with clinicians, patients, technical team members able to lead the product design and development, co-creation workshops). Describe formative research and/or content and/or usability testing with target group(s) clearly identified, as appropriate. g) adding to the appendix a description of any material used to support the engagement in the evaluation (e.g., slides to explain concepts, templates to be filled out by participants). h) providing a statement on the science communication strategy. <i>*Note: Fundamentals should be included in the main part. If there is insufficient space, information should be allocated to the appendix.</i>	
RESULTS			
25	Main Evaluation Results	Report the most relevant results for the selected and previously described variables of interest and summarize them in the most appropriate total for each methodological step. If applicable, report any conceptual or theoretical developments that have emerged regarding the participation. If applicable, include a relevance or significance analysis of the findings.	
26	Participants	a) Describe detailed number and expertise of participants involved at each stage of the study (e.g., numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyzed). b) Describe the number of drop-outs and their associated context (e.g., how they were responded to, if applicable).	
27	Participant Checking	Report if participants provided feedback on the findings.	
28	Selective Reporting	If applicable, to avoid selective reporting and the risk of bias, report if any findings (e.g., negative findings) or unexpected results are not described in detail. Explain why.	
29	Impacts/Effects of Participation	If applicable, report shortly the measured impact as well as barriers and facilitators of participation at different stages of the study (e.g., development, piloting)	
DISCUSSION			
30	Key Findings	Report the key findings of the study and refer to the initial aim of the study. State, what is the (overall) assessment of the intervention.	
31	Results in Relation to Other Studies	Place your results within the current state of research. State if it supports existing work, expands or challenges other findings, and discuss possible reasons.	

32	Implications	Explain whether now or in the future, the findings of this study are used to develop or improve a DHI. Highlight the potential influence on digital health design and policy.	
33	Generalizability	Discuss to what extent the study results could be generalized for other DHIs, populations, or organizations.	
34	Lessons Learned	Describe any lessons learned from the participatory evaluation of the DHI that could be used to improve future evaluations and outcomes. Reflect on the things that went well and those that did not (e.g., success factors, challenges, or budget considerations).	
35	Limitations	Acknowledge the limitations of the study, including methodological, ethical, and equity considerations. Address potential impacts on patients and healthcare professionals, policy or practice, and highlight challenges or biases in the participatory approach.	
36	Future Work	Describe your plans or give recommendations for future research. Refer to the limitations you mentioned, give concrete ideas on how further areas could be examined, or how your results could be integrated in practical implementations.	
37	Reflecting Participation	Discuss the process and the results of the participation by ... a) commenting if it was possible to carry out the participation as planned. Reflect on the facilitators and barriers for participants to participate in the research and design process. b) describing how participation influenced the study overall. Report (intended or unintended) positive and negative impacts that participation has had on the research, the participants involved (including patients, healthcare professionals, technical team members, and researchers), and wider impacts. Report on any differences the involvement made to the approach or findings of the study. c) reporting the influence of any process or contextual factors that enabled or hindered the impact of participation. d) mentioning barriers or facilitators to the adoption of the intervention among study participants. Relates to individual-level structural, economic, and social barriers or facilitators to access, such as affordability and other factors that may limit a user's ability to adopt the intervention.	
OTHERS			
38	Funding	Describe sources of funding and other support.	
39	Conflict of Interest	In addition to the usual declaration of interests (financial or otherwise), also state the "relation of the study team towards the system being evaluated", i.e., state if the authors/evaluators are distinct from or identical with the developers/sponsors of the intervention.	
40	Contributions	Share a detailed description of the contributions of the authors to the published work (e.g., using CRediT). Report if participating citizens or patients or healthcare professionals, or technical team members did co-author and report contributions of team members that are not authors.	

** Note: Fundamentals should be included in the main part. If there is insufficient space, information should be allocated to the appendix, or a document describing these matters should be cited.*

Corresponding article can be found here:

Weirauch, V., Mainz, A., Nitsche, J. et al. Consensus-based reporting guideline for participatory development and evaluation of digital health interventions. npj Digit. Med. (2026). <https://doi.org/10.1038/s41746-026-02355-5>