Protocol for development of the **St**andards for Reporting of Digital Health **Ed**ucation **I**ntervention Trials (STEDI) statement

Pawel Posadzki
Centre for Population Health Sciences (CePHaS), Lee Kong Chian School of Medicine, Nanyang Technological University, 18th floor Clinical Science Building, 11 Mandalay Road, Singapore 308232, Singapore. Email: paul.posadzki@ntu.edu.sg

Lorainne Tudor Car
Department of Primary Care, Lee Kong Chian School of Medicine, Nanyang Technological University, 18th floor Clinical Science Building, 11 Mandalay Road, Singapore 308232, Singapore. Email: lorainne.tudor.car@ntu.edu.sg

Krister Jarbrink
Centre for Population Health Sciences (CePHaS), Lee Kong Chian School of Medicine, Nanyang Technological University, 18th floor Clinical Science Building, 11 Mandalay Road, Singapore 308232, Singapore. Email: kjarbrink@ntu.edu.sg

Ram Bajpai
Centre for Population Health Sciences (CePHaS), Lee Kong Chian School of Medicine, Nanyang Technological University, 18th floor Clinical Science Building, 11 Mandalay Road, Singapore 308232, Singapore. Email: rambajpai@ntu.edu.sg

Monika Semwal
Centre for Population Health Sciences (CePHaS), Lee Kong Chian School of Medicine, Nanyang Technological University, 18th floor Clinical Science Building, 11 Mandalay Road, Singapore 308232, Singapore. Email: monika.s@ntu.edu.sg

Bhone Myint Kyaw
Centre for Population Health Sciences (CePHaS), Lee Kong Chian School of Medicine, Nanyang Technological University, 18th floor Clinical Science Building, 11 Mandalay Road, Singapore 308232, Singapore. Email: bhone.mk@ntu.edu.sg

Josip Car (Corresponding author)
Centre for Population Health Sciences (CePHaS), Lee Kong Chian School of Medicine, Nanyang Technological University, 18th floor Clinical Science Building, 11 Mandalay Road, Singapore 308232, Singapore, Telephone: +65 6904 7005; Email: josip.car@ntu.edu.sg
AND
Global eHealth Unit, Department of Primary Care and Public Health, School of Public Health, Imperial College London, 3rd floor Reynolds Building, St Dunstan's Road, London W6 8RP, UK, Email: mailto:josip.car@imperial.ac.uk

Abstract

Background: Digital health education is an umbrella term encompassing a broad spectrum of educational interventions characterised by their technological contents, learning objectives/outcomes, measurement tools, learning approaches and delivery settings used for health. These interventions, although varying greatly in content and quality, are widely evaluated in randomised controlled trials (RCTs). To the best of our knowledge, there are no guidelines outlining the key reporting items for studies on digital health educational interventions for either healthcare professionals or patients. Our objective is to develop reporting recommendations for RCTs of health professionals' and patients' digital health education that would supplement/extend the 25-item CONSORT (Consolidated Standards of Reporting Trials) guidelines. **Methods:** The development process will consist of three stages. First, we will conduct a systematic review of the literature to assess the quality of reporting in RCTs of digital health education. Secondly, a sample of 100 participants will be invited to take part in

a Delphi exercise to reach a consensus on essential items for reporting of digital health education trials. Thirdly, we will develop and pilot the Standards for Reporting of Digital Health Education Intervention Trials (STEDI) statement. **Outcome:** The final outcome will be the creation of the STEDI statement and the publication of an explanation and elaboration paper. **Discussion:** The development of digital health education research has been impeded by inadequate reporting. The standardised reporting of digital health education research will help advance the field and guide future researchers, funders and publishers.

Keywords: Randomised Controlled Trials; Reporting Guidelines; Methods; Education.

Background

Digital health education is defined as: ‘an approach to teaching and learning, representing all or part of the educational model applied, that is based on the use of electronic media and devices [information and communication technologies (ICT)] as tools to improve access to training, communication, and interaction, and that facilitates the adoption of new ways of understanding and learning [1]. It is an umbrella term which includes a multitude of interventions such as online and offline computer-based or computer assisted eLearning, Massive Open Online Courses (MOOC), mLearning/mobile learning,

Digital Game-Based Learning (DGBL), Digital Psychomotor Skills Trainers (DPST), Virtual Reality Environments (VRE), or Virtual Patient (VP) scenarios among others [2, 3]. The aim of these educational interventions is to increase learners' knowledge, skills and to develop professional attitudes or competencies.

Compared with traditional modes of learning, benefits of digital health education include unrestricted access to and constant updates of educational content, individualised, self-directed, flexible and interactive learning, novel instructional methods, automated assessment and documentation, immediate feedback; reduced resources, improved scalability as well as enhanced cognitive skills, self-reflection, and motivation of the learners; ability to simulate, rehearse and experience different clinical situations; and associative and perceptual learning experience by combining text, images, audio and video via combined visual, auditory and spatial components.

Disadvantages of digital health education include limited access to and high costs of technologies, poor infrastructure and network connectivity in certain countries; lack of face to face interactions and feelings of isolation, loneliness, depression and anxiety [4].

Digital health educational interventions for healthcare professionals and patients represent broad spectra of technologies, contents, delivery settings or platforms, all representing a unique set of features to be considered when designing and reporting in studies. For a robust and critical appraisal of a study, the research components need to be clearly reported according to uniform, widely-accepted standards to promote consistency of reporting.

Rationale

A number of systematic reviews of digital health educational interventions for healthcare professionals [5-8] and patients [9-14] have raised the issue of suboptimal reporting and suggested the need for further advancing the field. Instances of poor reporting include: insufficient description of interventions, lack of clearly defined learning objectives/outcomes, educational theories underpinning interventions, shortage of information on outcome measurement instruments and their validity making independent replications difficult or unfeasible [4, 15].

There are more than 200 standardised reporting guidelines currently available for researchers in healthcare and medical research areas [16]; and their value is unquestionable. Currently the gold standard for reporting of RCTs is the Consolidated Standards of Reporting Trials (CONSORT) guidelines. We propose development of reporting guidelines for digital health educational interventions that will be used as an extension of the CONSORT.

To the best of our knowledge a. there is only one set of guidelines aimed at educational interventions; b. no reporting guidelines exist pertaining to the key items to be considered when reporting digital health educational interventions for healthcare professionals' and patients' education [16]. Although professionals' and patients' educational needs and requirements might differ, the ultimate purpose of the education is the same and should be achieved through active involvement in the decision making about healthcare, collaborative relationship/partnership, interactive discussions, and shared responsibilities leading to better health outcomes and reduced costs of care [17-19], hence we decided to combine those together.

This reporting guideline has the potential to fill an important gap in the literature by providing a uniform set of recommendations for reporting randomised controlled trials (RCTs) of digital health education interventions. By doing so, the guideline will benefit researchers in the field of healthcare professional and patient education, educational providers when designing curricula, health professionals themselves, and healthcare consumers by improving access to healthcare services.

The aim of this research project is to develop **St**andards for Reporting of Digital Health **Ed**ucation **I**ntervention Trials of Healthcare Professionals and Patients (STEDI) checklist based on the need to extend the CONSORT (Consolidated Standards of Reporting Trials) guideline [20-22].

Methods

The protocol will be registered with Equator at: http://www.equator-network.org/ .We will adhere to the Guidance for Developers of Health Research Reporting Guidelines as outlined by Moher *et al*. 2010 [23].

The development of the STEDI statement will include the following stages:

1. Systematically reviewing the literature;
2. Conducting a Delphi survey to gather opinions and set priorities, and holding a face-to-face consensus meetings;
3. Development and pilot testing of the draft STEDI statement and accompanying explanation and elaboration (E&E) paper.

A panel of experts will be assembled to review, monitor, facilitate and guide each of the stages of the program.

Stage 1: systematic review

This systematic review will aim to answer the following research questions:

1. What is the quality of reporting in existing RCTs on digital health education for health professionals and patients?
2. What specific type of information is reported in RCTs on digital health education for health professionals' and patients' education?
3. Is there any existing guidance on reporting digital health education trials?

Databases and search terms

We will conduct a Cochrane methodology systematic review to assess the quality of reporting of digital health education trials [24]. The following databases will be searched (from 1st January, 2017 to 30th June, 2017): MEDLINE (Ovid), Embase (Elsevier), the Cochrane Central Register of Controlled Trials (CENTRAL) (Wiley), PsychINFO (Ovid), Educational Resource Information Centre (Ovid), Cumulative Index to Nursing and Allied Health Literature (Ebsco) and Web of Science Core Collection for the most up-to-date digital health education trials.

Modifications to the search strategy have already been made by librarians from Karolinska Institutet (Sweden). Detailed search strategy for MEDLINE is presented in the **Appendix 1**.

Searching other resources

We will screen reference lists of all included studies and relevant reviews. We will also search the two trials registers: The ISRCTN and Clinicaltrials.gov for further information.

Selection procedure

Two reviewers will independently screen titles and abstracts to identify studies potentially meeting the inclusion criteria (first stage screening). The full-texts versions of these articles will be read in full, and assessed independently against the eligibility criteria (second stage screening). Any disagreements whether or not a study meets eligibility criteria will be resolved through discussion between the two authors. If no agreement can be reached, a third review author's opinion will be sought. Finally, a random sample of 100 RCTs with individual participant randomisation and 100 cluster RCTs published in the first and the second quarter of 2016 will be selected and reviewed by the Expert Panel to confirm eligibility.

Inclusion / exclusion criteria

Studies will be eligible for inclusion if they are RCTs or cluster RCTs of any type of digital health education interventions, limited to candidates for, and holders of (including CPD, CME), the qualifications listed in the Health Field of Education and Training (091) of the International Standard Classification of Education (ISCED-F) [25], except students of traditional, alternative and complementary medicine. Participants will not be excluded on the basis of socio-demographic characteristics such as age, gender, ethnicity or any other related characteristics. No language restrictions are planned. Studies will be excluded if they are uncontrolled, cross-over, factorial, quasi-randomised, interrupted-time series, before and after; evaluate digital health educational interventions for medically compromised patients (for example, migraine sufferers, and diabetic patients) or healthy individuals; evaluate other than digital health education interventions.

Data extraction

A data extraction sheet will be developed prospectively based upon the data items used by [26-29] and the checklist of items as suggested by the Cochrane Handbook [24] (Table 1). Two reviewers will independently extract the following data for each of the included studies: study background/description, characteristics of learners, participants/personnel, infrastructure, technology platform, intervention(s) mode and delivery, content, context, fidelity, security arrangements,

outcomes and economics. Data will be compared between extractors for consistency, and any discrepant opinions will be resolved by discussion. A third review author will act as an arbiter if disagreements cannot be resolved.

Assessment of methodological quality/risk of bias of included studies

No formal risks of bias assessments are planned for the systematic review. However, as our primary aim is to describe the quality of reporting of digital health education trials, we will verify and compare that quality against the CONSORT checklist.

Data synthesis

A qualitative data synthesis is anticipated. A descriptive statistics (means, standard deviations, range) is planned along with a narrative synthesis of the results from included studies.

Outcomes

We will calculate overall prevalence of reporting of the following domains/items: study background/description, characteristics of learners, participants/personnel, infrastructure, technology platform, intervention(s) mode and delivery, content, context, fidelity, security arrangements, outcomes and economics analysis. The information gathered during stage 1, will be then used in Delphi study (stage 2) to determine their importance and relevance for reporting.

Stage 2: Delphi survey

A Delphi survey will be conducted according to the steps described by [30]. The full description of the Delphi survey is presented in the **Appendix 2**.

We will use the Delphi technique to gain consensus among a panel of experts preceded by the systematic review [31]. A four steps process will be implemented. For the round one, a set of open-ended questions is planned. The three subsequent rounds will be undertaken to provide feedback from the previous rounds and inviting further responses from experts [32]. After completing the second round, any additional items identified in the systematic review but not earlier included will be added to the Delphi list. Consensus will be defined 'a priori' as percent agreement for each item of >80% with same rating indicating substantial to excellent agreement [32]. We are planning to invite at least 100 (and no more than 200) participants in the Delphi survey. These will include corresponding authors of eligible RCTs, the journals' editors in which these RCTs were initially published as well as psychologists, methodologists, educational researchers. An invitation for the survey will be sent electronically via email outlining the aim of the study, anticipated time commitment and standard operating procedures. First and final reminders will be sent to non-responders 14 days after the initial invitation (no further reminders

are planned). An Excel spread sheet containing questions will be attached to the email to collect responses. To ensure anonymity, we will allocate a random identification number (using randomizer.org) to every responder. This information will be securely stored and password protected by the first author (PP). Using Research Electronic Data Capture (REDCAP) software, participants will be asked to provide their written consent to be acknowledged as a member of the panel in any publications or presentations arising from this research; and will be able to withdraw from the study at any time.

Stage 3: Pilot testing of reporting guideline and E&E document

The development of the STEDI reporting guidelines and E&E paper will be the final step of this research. We aim to distribute the STEDI reporting guidelines and E&E paper to all interested participants identified in round four of the Delphi. For participants who expressed willingness to pilot test the draft guideline will be asked to provide feedback on the utility of the document to be subsequently incorporated in revisions of the statement. The guiding principle for the development of the STEDI statement is to identify essential information needed to define the content (what), context (where) and technical features (how) to allow independent replication of digital health educational intervention. We aim to advance the science in the field and aid researchers, academics, journal editors and reviewers by providing a uniform set of recommendations for reporting RCTs of digital health educational interventions.

Publication plan

- Publication 1: Study protocol.
- Publication 2: A systematic review of the literature.
- Publication 3: Delphi study.
- Publication 4 & 5: STEDI statement and E&E paper.

Discussion

There are a growing number of digital health education research studies evaluating knowledge, skills, attitudes or competencies of healthcare professionals and patients. However, digital health education encompasses a wide range of platforms, technologies, contents, or delivery settings; and is underpinned by a wide variety of philosophies, educational theories or pedagogical approaches. Given this large amount of information, researchers need a unique set of guidelines in place when designing and reporting digital health educational interventions.

The issue of insufficient reporting in digital health education studies has repeatedly been raised including the often inadequately described interventions, unclear learning objectives or educational theories underpinning the interventions as well as a dearth of information on measurement instruments and their validity. Those need to transparently be reported in digital health education RCTs allowing independent replications and further advancing the field.

Current standards or reporting frameworks are insufficient in ensuring consistency of reporting of digital health education research. Therefore, it is difficult to critically appraise or replicate a study. One of the intentions of the STEDI guidelines is to create a common reporting framework thereby allowing clarity and uniform comparisons between studies.

Based on the need to extend the 25-item CONSORT (Consolidated Standards of Reporting Trials) checklist, we aim to develop a reporting guideline (STEDI statement) and an E&E paper to allow the uniform and consistent reporting of digital health educational interventions.

The rationale for the study is that guidelines for reporting digital health educational interventions are inconsistent or missing. Hence, STEDI reporting guideline intends to a. benefit many important stakeholders in the field including researchers,

educators, health professionals, editors, reviewers or students, b. facilitate transparency in describing RCTs of digital health educational interventions, c. strengthen manuscripts methodologically, d. streamline grant applications [33].

During the process, we will adhere to the Guidelines described by Moher et al.[23] Several phases of the process are planned including establishing the need for the guideline, systematically reviewing the literature, identifying experts and participants, conducting a Delphi exercise, developing and pilot testing of the STEDI guidelines and accompanying E&E paper. We will incorporate feedback from other researchers to further develop and update the guidelines.
We aim to incorporate ICT solutions such as Skype™, emails, Microsoft Excel™ spreadsheets, REDCAP to discuss the results of the Delphi study, the content of the STEDI statement and E&E paper.

The number of Delphi participants varies considerably and the optimal sample size is still a matter of debate, ranging from 10 to almost 2,000 [34]. We aim to invite at least 100 participants (trialists, editors, reviewers) in the Delphi survey which is reasonably representative of researchers in the field.

Four steps of the Delphi process are planned. These include a set of open-ended questions in the round one. Round two involves a feedback from the previous round to maximise survey responses [30]. In round three, we will include any

additional items to be identified in the systematic review. In the round four, the participants will be invited to review and comment on the items, layout, wording and structure of the documents.

Throughout the process, we will ensure that the researchers opinions are not transferred on the survey participants, by using open-ended questions; and stopping the survey when a consensus is reached. Although there is no commonly accepted definition of the necessary level of consensus for the Delphi survey, we will use the '*a priori*' defined cut-off point of 80% indicating substantial to excellent agreement [32]. The development of the STEDI statement and E&E paper, which provides the background and justification of the process, will be the final step of the process. Upon project completion, we will set-up a robust dissemination strategy targeting digital health education researchers and inviting them to use the STEDI statement and to provide feedback on its usability.

Additional files

Additional file 1: Appendix 1: MEDLINE (Ovid) search strategy

Additional file 2: Appendix 2: Detailed description of the Delphi study

Declarations

Ethics approval and consent to participate
Not applicable.

Consent for publication
Not applicable.

Availability of data and material

Data will be available with the corresponding author on request.

Competing interests
The authors declare no competing interests.

Funding

This research is supported by the Lee Kong Chian School of Medicine, Nanyang Technological University eLearning grant.

Authors' contribution

PP initiated the protocol, conceptualised the research plan for the proposed systematic review, wrote the manuscript and reviewed it for important intellectual content. LC, KJ, RB, MS, BK and JC critically reviewed the methodology, wrote the manuscript and reviewed it for important intellectual content. All authors read and approved the final manuscript.

Acknowledgements

This review is conducted in collaboration with the World Health Organization (WHO) Department of eHealth, Knowledge Management and Sharing. We would also like to thank Mr Carl Gornitzki, Ms GunBrit Knutssön and Mr Klas Moberg from the University Library, Karolinska Institutet, Sweden, for developing the search strategy. We gratefully acknowledge funding

from the Lee Kong Chian School of Medicine, Singapore, Nanyang Technological University, Singapore, eLearning for health professionals education grant.

References

1. Sangrà A, Vlachopoulos D, Cabrera N. Building an inclusive definition of e-learning: An approach to the conceptual framework. IRRODL. 2012;13:15.
2. Cazellet L. E-learning, distance education and continuing professional education. Soins 2014;63-4.
3. Guri-Rosenblit S. 'Distance education' and 'e-learning': Not the same thing. High Educ. 2005;49:467-93.
4. Rasmussen K, Belisario JM, Wark PA, Molina JK, Loong SL, Cotic Z et al. Offline eLearning for undergraduates in health professions: A systematic review of the impact on knowledge, skills, attitudes and satisfaction. J Glob Health. 2014;4:010405. doi: 10.7189/jogh.04.010405.
5. Feng JY, Chang YT, Chang HY, Erdley WS, Lin CH, Chang YJ. Systematic review of effectiveness of situated e-learning on medical and nursing education. Worldviews Evid Based Nurs. 2013;10:174-83.
6. Maertens H, Madani A, Landry T, Vermassen F, Van Herzeele I, Aggarwal R. Systematic review of e-learning for surgical training. Br J Surg. 2016;103:1428-37.
7. Sinclair P, Kable A, Levett-Jones T. The effectiveness of internet-based e-learning on clinician behavior and patient outcomes: a systematic review protocol. JBI Database System Rev Implement Rep. 2015;13:52-64.
8. Voutilainen A, Saaranen T, Sormunen M. Conventional vs. e-learning in nursing education: A systematic review and meta-analysis. Nurse Educ Today. 2016;50:97-103.
9. Corpman DW. Mobile Health in China: A Review of Research and Programs in Medical Care, Health Education, and Public Health. J Health Commun. 2013;18:1345-67.
10. de Jongh T, Gurol-Urganci I, Vodopivec-Jamsek V, Car J, Atun R. Mobile phone messaging for facilitating self-management of long-term illnesses. Cochrane Database Syst Rev. 2012;12:Cd007459.

11. Omaki E, Rizzutti N, Shields W, Zhu J, McDonald E, Stevens MW et al. A systematic review of technology-based interventions for unintentional injury prevention education and behaviour change. Inj Prev. 2017;23:138-46.
12. Saffari M, Ghanizadeh G, Koenig HG. Health education via mobile text messaging for glycemic control in adults with type 2 diabetes: a systematic review and meta-analysis. Prim Care Diabetes. 2014;8:275-85.
13. Vodopivec-Jamsek V, de Jongh T, Gurol-Urganci I, Atun R, Car J. Mobile phone messaging for preventive health care. Cochrane Database Syst Rev. 2012;12:Cd007457.
14. Whitehead L, Seaton P. The Effectiveness of Self-Management Mobile Phone and Tablet Apps in Long-term Condition Management: A Systematic Review. J Med Internet Res. 2016;18:e97.
15. George PP, Papachristou N, Belisario JM, Wang W, Wark PA, Cotic Z et al. Online eLearning for undergraduates in health professions: A systematic review of the impact on knowledge, skills, attitudes and satisfaction. J Glob Health. 2014;4:010406.
16. Network TE. Available from: http://www.equator-network.org/. Accessed 28 May 2017.
17. Siegel CA. Shared decision making in inflammatory bowel disease: helping patients understand the tradeoffs between treatment options. Gut. 2012;61:459-65.
18. Oshima Lee E, Emanuel EJ. Shared decision making to improve care and reduce costs. N Engl J Med. 2013;368:6-8.
19. Spatz ES, Krumholz HM, Moulton BW. Prime Time for Shared Decision Making. JAMA 2017;317:1309-10.
20. Schulz KF, Altman DG, Moher D, CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. BMJ. 2010;340:c332.
21. Schulz KF, Altman DG, Moher D, CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. PLoS Med 2010;7:e1000251.
22. Schulz KF, Altman DG, Moher D, CONSORT Group. CONSORT 2010 Statement: Updated guidelines for reporting parallel group randomised trials. J Clin Epidemiol. 2010;63:834-40.
23. Moher D, Schulz KF, Simera I, Altman DG. Guidance for developers of health research reporting guidelines. PLoS Med 2010;7:e1000217.
24. Higgins J, Green S. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration. 2011;2011(Available from: www.cochrane-handbook.org). Accessed 28 Mar 2017.
25. United Nations Educational SaCOIfS. ISCED Fields of Education and Training 2013 (ISCED-F 2013). Montreal, Canada, 2014.
26. Agarwal S, LeFevre AE, Lee J, L'Engle K, Mehl G, Sinha C et al. Guidelines for reporting of health interventions using mobile phones: mobile health (mHealth) evidence reporting and assessment (mERA) checklist. BMJ. 2016;352:i1174.
27. Cheng A, Kessler D, Mackinnon R, Chang TP, Nadkarni VM, Hunt EA et al. Reporting Guidelines for Health Care Simulation Research: Extensions to the CONSORT and STROBE Statements. Simul Healthc. 2016;11:238-48.
28. Eysenbach G, Group C-E. CONSORT-EHEALTH: improving and standardizing evaluation reports of Web-based and mobile health interventions. J Med Internet Res. 2011;13:e126.
29. Salas E. Reporting Guidelines for Health Care Simulation Research: Where Is the learning? Simul Healthc. 2016;11:249.

30. Phillips AC, Lewis LK, McEvoy MP, Galipeau J, Giasziou P, Hammick M et al. Protocol for development of the guideline for reporting evidence based practice educational interventions and teaching (GREET) statement. BMC Med Educ. 2013;13:9.
31. Pinnock H, Epiphaniou E, Sheikh A, Griffiths C, Eldridge S, Craig P et al. Developing standards for reporting implementation studies of complex interventions (StaRI): a systematic review and e-Delphi. Implement Sci. 2015;10:42.
32. Diamond IR, Grant RC, Feldman BM, Pencharz PB, Ling SC, Moore AM et al. Defining consensus: a systematic review recommends methodologic criteria for reporting of Delphi studies. J Clin Epidemiol. 2014;67:401-9.
33. Moher D, Weeks L, Ocampo M, Seely D, Sampson M, Altman DG et al. Describing reporting guidelines for health research: a systematic review. J Clin Epidemiol. 2011;64:718-42.
34. Sinha IP, Smyth RL, Williamson PR. Using the Delphi technique to determine which outcomes to measure in clinical trials: recommendations for the future based on a systematic review of existing studies. PLoS Med. 2011;8:e1000393.

Table 1 Proposed 12 data extraction items

	Information to be extracted
Study background/description	Author(s), credentials, affiliations, corresponding author's contact details, journal, year of publication, language, country, sponsors, and owners of technology evaluated (if any, and their role, including any potential conflicts of interests), study design.
Learners	Learners' level of education, age, profession or professional discipline, previous digital health education (technology evaluated) exposure, sample size, randomisation, allocation concealment, blinding (if, when and how), learning outcomes and objectives; financial or other incentives. Were learners informed about the programme including training/support; how they were recruited.

	Information to be extracted
Participants/personnel	Instructors'/trialists' qualification, experience in digital health education, level of their involvement instructions, technical assistance), blinding (if, when and how).
Infrastructure	The availability of infrastructure such as the Internet connectivity, electricity, or access to power to support technology operations in the study location.
Technology platform	Type of technology used and a justification for it; including a type of hardware/ software used, and any details of changes/modifications made to those.
Interventions mode and delivery	Detailed description of type of interventions, duration, frequency, intensity or mode of delivery; description of technical features/components of the interventions, co-interventions and comparator to allow replicability (e.g., source codes, algorithms, etc.); how the interventions were assessed by participants, in what context/setting, at what time, synchronously or asynchronously; were there any barriers or facilitators to adopt the interventions at either individual, social, economic, or structural levels. Was there a description of any other co-interventions, potential or actual confounders, or effect modifiers? Was there a theoretical underpinning for the design of interventions and co-interventions?
Content	Details of the content of the digital health educational intervention(s) are described in sufficient depth including any modifications of the interventions content; usability testing with target group(s). Describes whether (and how) the interventions are tailored to individual needs/preferences and allows learners to monitor their progress and get and leave feedback, e.g., satisfaction, perceptions, preferences.

	Information to be extracted
Context	Adaptability of the interventions to a different language(s), population or socio-cultural context.
Fidelity	Strategies used to assess the fidelity of the digital health educational interventions.
Safety/security arrangements	Data protection protocols, confidentiality procedures, other security arrangements.
Outcomes	Type and name of measurement/assessment method/instrument (e.g., multiple choice questionnaire, survey, observation), validity, reliability, quality of measurement, psychometric properties (if any reported). Outcome(s) at background assessed (and how). What constitutes a change (in outcome) compared with baseline?
Economics	Basic cost evaluation (in lieu of a full economic analysis) of the digital health educational interventions from diverse perspectives, e.g., costs of set-up or software, external examinations, etc.

Appendix 1 MEDLINE (Ovid) search strategy

1. exp education, professional/ not education, veterinary/
2. Education, Predental/
3. Education, Premedical/
4. exp Students, Health Occupations/
5. ((medic* or premedic* or dent* or laborator* or predent* or midwi?e* or nurs* or nutrition* or orthop* or podiat* or pharmac* or psycholog* or psychiatr* or health or healthcare or occupational therap* or physiotherap* or physical therap* or clinical or surg* or radiolog* or obstetric* or gyn?ecolog* or orthodont* or An?esthesi* or Dermatolog* or Oncolog* or Rheumatolog* or Neurolog* or Patholog* or P?ediatric* or Cardiolog* or Urolog*) adj3 (student* or graduate* or undergraduate* or staff or personnel or practitioner* or clerk* or fellow* or internship* or residen* or educat* or train* or novice* or tutor*)).tw,kf.
6. patient$.mp.
7. individual$.mp.
8. consumer$.mp.
9. exp Patients/ed
10. exp Consumer Behavior/
11. exp Adult
12. or/1-11
13. Computer-Assisted Instruction/
14. exp Internet/
15. Computer Simulation/
16. Patient Simulation/
17. software/
18. Mobile Applications/
19. User-Computer Interface/
20. Video Games/
21. Web Browser/
22. Education, Distance/
23. Computers/
24. exp Microcomputers/
25. exp Cell Phones/
26. Games, Experimental/

27. exp Models, Anatomic/
28. Audiovisual Aids/
29. Educational Technology/
30. Electronic Mail/
31. exp Telemedicine/
32. Telenursing/
33. Telecommunications/
34. Webcasts/
35. exp Videoconferencing/
36. ((computer* or digital* or hybrid or blended or mixed mode or distance or remote* or electronic or mobile or online* or interactiv* or multimedia or internet or web* or virtual* or game* or gaming or Videogame* or Videogaming) adj3 (classroom* or course* or educat* or instruct* or learn* or lecture* or simulat* or train* or teach* or tutor* or platform*)).tw,kf.
37. (Simulat* adj3 (course* or educat* or instruct* or learn* or train* or teach* or platform* or high-fidelity)).tw,kf.
38. e-learn*.tw,kf.
39. elearn*.tw,kf.
40. m-learn*.tw,kf.
41. mlearn*.tw,kf.
42. smartphone*.tw,kf.
43. smart-phone*.tw,kf.
44. ((mobile or cell) adj2 phone*).tw,kf.
45. iphone*.tw,kf.
46. android*.tw,kf.
47. ipad*.tw,kf.
48. Personal digital assistant*.tw,kf.
49. handheld computer*.tw,kf.
50. Mobile App?.tw,kf.
51. Mobile Application?.tw,kf.
52. webcast*.tw,kf.
53. webinar*.tw,kf.
54. flipped classroom*.tw,kf.
55. Serious game*.tw,kf.

56. Serious gaming.tw,kf.
57. Patient Simulat*.tw,kf.
58. Virtual patient*.tw,kf.
59. ((educat* or instruct* or learn* or simulat* or train* or teach* or interactiv*) adj2 technolog*).tw,kf.
60. Massive Open Online Course?.tw,kf.
61. Mooc?.tw,kf.
62. (Canvas network or Coursera or Coursesites or edx or Futurelearn or iversity or miriada x or moodle or novoed or openlearning or open2study or plato or spoc or udacity or pingpong).tw,kf.
63. Social Networking$.mp.
64. exp Social Networking/
65. social medi$.mp.
66. twitter messaging.mp.
67. exp Social Media/
68. or/13-67
69. 12 and 68
70. Education.fs.
71. Education/
72. Teaching/
73. Learning/
74. exp Inservice Training/
75. Curriculum/
76. educat*.tw,kf.
77. learn*.tw,kf.
78. train*.tw,kf.
79. instruct*.tw,kf.
80. teach*.tw,kf.
81. or/70-80
82. Health Personnel/
83. exp Allied Health Personnel/
84. Anatomists/
85. "Coroners and Medical Examiners"/
86. exp Dental Staff/

87. exp Dentists/
88. Health Educators/
89. Infection Control Practitioners/
90. Medical Laboratory Personnel/
91. exp Medical Staff/
92. exp Nurses/
93. exp Nursing Staff/
94. Personnel, Hospital/
95. Pharmacists/
96. exp Physicians/
97. Physician*.tw,kf.
98. Doctor*.tw,kf.
99. Nurs*.tw,kf.
100. Surg*.tw,kf.
101. Health Personnel.tw,kf.
102. healthcare professional*.tw,kf.
103. radiolog*.tw,kf.
104. dentist*.tw,kf.
105. Pharmacist*.tw,kf.
106. Hospital Administrator*.tw,kf.
107. Podiatr*.tw,kf.
108. Psycholog*.tw,kf.
109. Psychiatr*.tw,kf.
110. An?esthesi*.tw,kf.
111. Clinician*.tw,kf.
112. Dermatolog*.tw,kf.
113. General practioner*.tw,kf.
114. Cardiolog*.tw,kf.
115. Oncolog*.tw,kf.
116. Rheumatolog*.tw,kf.
117. Neurolog*.tw,kf.
118. Pathолog*.tw,kf.
119. P?ediatric*.tw,kf.

120. Physiotherap*.tw,kf.
121. Physical therap*.tw,kf.
122. Occupational therap*.tw,kf.
123. dieti?ian*.tw,kf.
124. Dietetic*.tw,kf.
125. midwi?e*.tw,kf.
126. nutrition*.tw,kf.
127. orthopti*.tw,kf.
128. obstetric*.tw,kf.
129. gyn?ecolog*.tw,kf.
130. orthodont*.tw,kf.
131. Urolog*.tw,kf.
132. or/82-131
133. Health Occupations/
134. exp Allied Health Occupations/
135. Biomedical Engineering/
136. Chiropractic/
137. exp Dentistry/
138. exp Evidence-Based Practice/
139. exp Medicine/
140. exp Nursing/
141. Dietetics/
142. Optometry/
143. Orthoptics/
144. exp Pharmacology/
145. exp Pharmacy/
146. Podiatry/
147. Psychology, Medical/
148. Serology/
149. Specialization/
150. exp Surgical Procedures, Operative/
151. exp Radiography/
152. or/133-151

153. 132 or 152
154. 68 and 81 and 153
155. Psychomotor Performance/
156. motor skills/
157. ((psychomotor or procedural or technical) adj3 skill*).tw,kf.
158. (psychomotor adj3 performance).tw,kf.
159. or/155-158
160. 12 and 159
161. 69 or 154 or 160
162. limit 150 to yr="1990 -Current"
163. randomized controlled trial.pt.
164. controlled clinical trial.pt.
165. randomized.ti,ab.
166. placebo.ti,ab.
167. drug therapy.fs.
168. randomly.ti,ab.
169. trial.ti,ab.
170. groups.ti,ab.
171. or/163-170
172. 162 and 171

Appendix 2 Detailed description of the Delphi study

Round one

An invitation to take part in the survey will be sent via email outlining the aim of the study, key definitions, anticipated time commitment and standard operating procedures. In the email, we will also emphasise the importance of completing all four rounds of the survey.

The first round will be initiated by the following open-ended question:

> *"If you were critically appraising an RCT study on digital health education, what type of information about the intervention(s) would need to be included? Please list everything you think should be included in such a study to sufficiently describe the interventions."*

Email reminders will be sent to non-responders 2 weeks after the original invitation and once again a week later. A timeframe of 7 days will be provided to respond. Round one of the Delphi survey will end 28 days after the initial survey has been sent.

First round: data analysis

Specific themes identified within written responses to the questions raised will be grouped into the 12 categories anticipated for the data abstraction in the systematic review: Study background/description, Learners (characteristics of), Participants/personnel, Infrastructure, Technology platform, Interventions mode and delivery, Content, Context, Fidelity, Security arrangements, Outcomes, and Economics. Themes which are not clearly assignable to a domain will be discussed within the Team until a consensus is reached. Then descriptive statistics will be calculated including the number and prevalence of categories among participants.

Round two

The list of themes/categories identified in the first round with concealed frequency of occurrence and random order will be provided to all participants. We will ask the participants to rate the importance of each theme on a 10 points Likert-like scale. A score of 0-4 will indicate low importance for inclusion and reporting; a score of 5-6 will indicate moderate importance; a score of 7-10 will indicate high or very high importance.

The following instruction will be provided for the participants:

"Please find the enclosed a list of themes which other study participants felt ought to be included when reporting digital health educational interventions. For each theme, kindly rate the importance of each one for being reported in digital health educational interventions on the scale."

Following the rating exercise, we will ask participants the following questions:

- For the themes you rated as <4 or >6, please supply a short justification to support your selection.
- Are there any other themes/topics/items that in your view should be included in studies on the use of digital health education for health professionals' and patients' education?
- Do you have any additional comments/thoughts?

Second round analysis

Again, we will calculate a descriptive statistics including percentage of agreement, means and standard deviations) for all completed Delphi surveys and the overall score for each theme and each domain. Ratings will be allocated into the three below-mentioned groups; and Cohen's kappa statistic calculated.

Using the above-mentioned definition of consensus, ≥80 % of respondents will have to rate a theme's importance within the following range for each category: not important 0–4, moderately important 5–6, highly or very highly important 7–10).

Round three

The list of all items from the previous round of the exercise will be verified against the themes derived from the systematic review. Any themes not appearing in the results of the round two of Delphi but identified during stage one (systematic review) will be incorporated as 'additional themes' to be considered in this round. This new list of themes including any additional ones derived from participants from the second round will be randomly ordered and provided to all participants for rating (Likert scale) during the third round. We will also provide them with descriptive feedback for each theme and each domain including any items which have already achieved consensus. For those, no further comments will be required from participants.

After finishing the scoring exercise, we will ask again participants the following questions:

- On the themes you rated as <4 or >6, kindly provide a short rationale for your selection.
- Are there any other themes/topics/items that in your view should be included in studies on the use of digital health education for health professionals' and patients' education?
- Do you have any additional comments/thoughts?

Third round analysis

This will be reiteration of the analyses from the round two including the number of participants and the rating scores for each theme and any themes achieving consensus.

Round four

In this round, we will repeat the steps from the two preceding rounds.

We will include feedback and results from the preceding round as part of the survey.

At the end of this round, participants will be asked the following questions:

- Would you like to review a draft version of the STEDI guideline?
- Are you running a randomised trial on digital health educational intervention(s) at the moments and planning to publish it? If so, would you be interested in piloting the draft guideline?

Fourth round analysis

This round will include iteration of the analyses from the previous rounds.

The following outcomes are anticipated from the Delphi survey (and the systematic review): 1. List of themes meeting the consensus for eligibility in the reporting guideline; 2. List of themes not meeting the consensus but potentially eligible in the reporting guideline; 3. List of themes not meeting the consensus and mean rating scores suggesting they should be excluded from the reporting guideline. The content of these two lists 1-2 will feed into the first draft of the STEDI statement.