REVIEW

SMOOTH: Self-Management of Open Online Trials in Health analysis found improvements were needed for reporting methods of internet-based trials

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Abstract

Background and Objectives: The growth of trials conducted over the internet has increased, but with little practical guidance for their conduct, and it is sometimes challenging for researchers to adapt the conventions used in face-to-face trials and maintain the validity of the work. The aim of the study is to systematically explore existing self-recruited online randomized trials of self-management interventions and analyze the trials to assess their strengths and weaknesses, the quality of reporting, and the involvement of lay persons as collaborators in the research process.

Study Design and Settings: The Online Randomized Controlled Trials of Health Information Database was used as the sampling frame to identify a subset of self-recruited online trials of self-management interventions. The authors cataloged what these online trials were assessing, appraised study quality, extracted information on how trials were run, and assessed the potential for bias. We searched out how public and patient participation was integrated into online trial design and how this was reported. We recorded patterns of use for registration, reporting, settings, informed consent, public involvement, supplementary materials, and dissemination planning.

Results: The sample included 41 online trials published from 2002 to 2015. The barriers to replicability and risk of bias in online trials included inadequate reporting of blinding in 28/41 (68%) studies; high attrition rates with incomplete or unreported data in 30/41 (73%) of trials; and 26/41 (63%) of studies were at high risk for selection bias as trial registrations were unreported. The methods for (23/41, 56%) trials contained insufficient information to replicate the trial, 19/41 did not report piloting the intervention. Only 2/41 studies were cross-platform compatible. Public involvement was most common for advisory roles (*n* = 9, 22%), and in the design, usability testing, and piloting of user materials (*n* = 9, 22%).

Conclusion: This study catalogs the state of online trials of self-management in the early 21st century and provides insights for online trials development as early as the protocol planning stage. Reporting of trials was generally poor and, in addition to recommending that authors report their trials in accordance with CONSORT guidelines, we make recommendations for researchers writing protocols, reporting on and evaluating online trials. The research highlights considerable room for improvement in trial registration, reporting of methods, data management plans, and public and patient involvement in self-recruited online trials of self-management interventions. © 2018 Elsevier Inc. All rights reserved.

Keywords: Internet trials; Reporting methods; Self-management; Online trials; Public involvement; Reporting guidelines; Self-recruited

What is new?

Key findings
- Barriers to replicability and progress in online trials were identified by unclear reporting of the trial and methods used.

What this adds to what was known?
- Little is reported about the reporting methods used in online trials and this research reviews what is reported. The technology across devices may be too recent, costly to develop, or not sufficiently stable for widespread use; early adoption of good reporting methods may provide a way for research quality and innovation to keep pace with emergent technologies.

What is the implication and what should change now?
- Challenges might be overcome by reporting on the dashboard design, software used in the intervention, and the online materials used to train, test, and assess participants. Following the sporadic use of reporting guidelines in online trials, we propose the development and implementation of an online reusable protocol where reporting requirements would be embedded in the protocol to assist authors in writing up the online trials research.

1. Introduction

Modern digital technologies can provide health interventions through the use of mobile health apps, text messaging and telehealth video consulting, and provide an opportunity to conduct research solely over the internet in the format of online randomized trials. These trials can be conducted remotely over the internet using a computer, tablet, or smartphone without the need for face to face human interactions. Online trials continue to grow in scope and accessibility, and patients are becoming empowered to use these technologies to explore their health questions. However, the methods used for these trials raise specific benefits and challenges. (Table 3).

The aim of this research is to systematically explore existing self-recruited online randomized controlled trials (RCTs) of self-management interventions and analyze the trials to assess their strengths and weaknesses and to report how participants were involved in the research process with the objective of developing guidance for the design, conduct, and reporting of online RCTs of self-management interventions.

The benefits of using digital technologies for online trials include cost-reduction through the use of online rather than physical trial sites, ease of reaching multiple sociodemographic groups, the ability to use multiple languages with minimal cost, and the inclusion of trial participants who have limited mobility but who can participate with access to an internet connection, through a computer, tablet, or smartphone [1]. These trials can also provide insights into the use of interventions outside of the lab or clinic, and online access has become affordable and accessible in low resource settings providing more equitable global access to research. Public health and epidemiology researchers in low-resource areas struggle with the challenge of accessing valid data on disease and population, where collection methods are inconsistent, culturally diverse, and subject to administrative delay [2]. Mobile device platforms might be designed for collecting valid health research data from the potential 5 billion unique mobile subscribers who account for 67—80% of the world's population as of May 2018 according to the GSMA intelligence calculator [3].

Online trials have unique methodological challenges including limited face-to-face interaction, limited to participants who are willing to respond online, reliance on self-reported outcomes, and the need for applications to work across different operating systems, be user accessible and compatible with aging technology and bandwidth variations [4]. Data protection breaches may be brought on by participants themselves through social media, or through health research data, purchased or stolen by third parties [5]. Inconsistent reporting of methods and public and patient involvement in online trials can limit opportunities for research replication, end-user experience transfer, and the development of strategies to build on previous work [6]. Therefore, research analyzing current practice for these trials might help in developing strategies to improve recruitment, intervention adherence, participant retention, research methods, and reporting practices [7].

Writing protocols to conduct online trials and to report them requires robust methods, informed by best practice. To learn from previously published research, the Online Randomized Controlled of Health Information Database (ORCHID) was constructed to collect reports of online trials and methodology research about them [8], using a search strategy available in Appendix 1. ORCHID was used to investigate reporting methods, and the extent of public involvement in online trials and preliminary analysis showed that the number of online clinical trials was growing exponentially but with limited methodology research on validity and best practice of these trials [8].

In this research study, we analyzed randomized, self-recruited, self-management trials conducted over the internet. Self-recruitment is defined as the participants themselves enrolling in a trial online, via smartphone, tablet or computer without assistance by face-to-face contact with trial personnel. For this study, self-management or self-monitoring of health is the use of a medical device, intervention, or process that, while it may be recommended by a physician or other clinician, can be used or undertaken without the assistance of a

healthcare professional. For example, self-help, wellness, diet, activity, therapy online, an anticoagulation medication that is monitored and titrated by the patient, or asthma medications with peak flow measurement recorded by patients are eligible, but interventions that are fully clinician dependent for interpretation such as radiological films or laboratory work are not. This study investigates factors affecting the conduct of online trials of self-management and identifies if, and how, these trials report the involvement of patients and public in their design [9,10].

For ease of reading and viewing a supplementary file containing the glossary and additional graphs is available in Appendix 2 Glossary Terms and Graphs.

2. Methods

2.1. Study design

A systematic review of the methods of online randomized trials of self-management interventions was used.

2.2. Inclusion and exclusion criteria

2.2.1. Inclusions

Studies were included if they were randomized trials with online self-enrollment and used internet-based technologies, such as computers, tablets, or smartphones, in the trial process. Interventions had to be related to health and well-being and could include educational or behavioral components. Trials were only included when there were self-reported outcomes.

2.2.2. Exclusions

Interventions in social care or education were excluded where outcomes were not health-related, where the population was exclusively health professionals, educators, or students, and the intervention was used for training purposes but was not a specific health intervention. Studies were excluded if clinicians or other health practitioners enrolled the population and physician intervention was needed to measure primary outcomes. Nonrandomized trials, cost-effectiveness research, and studies that were reported only as conference presentations or posters were excluded, as were aborted or withdrawn trials.

2.3. Data sources and search strategy

The ORCHID [8] (updated in July 2016) was searched for identifying eligible trials.

2.4. Screening and selection of reviews

All citations were screened in Rayyan which is an open-access tool for screening and appraising studies for systematic reviews [11]. Reviewers were not blinded to author, institution, or journal. Two researchers independently screened the title and abstract of all citations retrieved from

ORCHID for those that met the eligibility criteria. Citations were categorized as include, unsure (without checking of full paper), or exclude. Full papers were retrieved for those categorized as ''include'' or ''unsure.'' Exclusions were not documented at this stage. Full papers were stored and deduplicated in the study by Mendeley [12]. Two authors independently screened these full papers for eligibility, and agreement was reached by consensus with a third author if they could not agree on inclusion or exclusion. Reasons for exclusion were documented. A PRISMA [13] flow diagram is included.

2.5. Sampling rationale

Studies were grouped into the following strata: feasibility or pilot studies and full trials, because scoping of the literature and consultation with experts in trials methodology showed that important choices about methodology and engagement might be detailed in feasibility or pilot trials but not included in the final trial report. Half the studies were then randomly selected from each stratum using a proportionate stratified sampling technique.

3. Data extraction

Two authors independently extracted key data for the randomly selected included trials. The data extraction form was piloted in EPPI reviewer [14] and adapted for best use of resources and information quality. Results are presented using descriptive statistics and narratives. We report study characteristics and then cataloged what these online trials were assessing, assessed the methodological quality of the studies and the reporting methods used, and reported the potential for bias. We also sought information on how public and patient participation was integrated into the design of the online trial and how this was reported and noted the use of reporting guidelines, accessibility of supplementary materials, protocol registrations, and whether plans for dissemination were reported.

3.1. Study characteristics

Details for each included study containing the citation, study design, aims, objectives, study setting, health status of participants, demographics, sample size calculation, intervention details, outcomes, time points, and follow-up were prepared and included along with a table of excluded studies with reasons for exclusion.

Included trials were quality assessed for methodological strengths and weaknesses by two review authors. Discrepancies were resolved by consensus, without the need for third-party consultation. The Critical Appraisal Skills Programme (CASP) ''11 questions to help you make sense of a trial checklist'' [15] was used, and each item was scored as yes, no, or not sure/not reported. The aggregated ''yes'' count was used as a guide to quality across studies.

3.2. Assessment of reporting

We report the number of trials that included a systematic review to justify the trial's testing of the intervention, a link to a registered protocol, included a CONSORT flow diagram [16], used CONSORT eHealth [17] reporting guidelines, used CONSORT PRO [18] to report patient-reported outcomes, and contained an intention to treat analysis. For studies using an online questionnaire, we reported whether studies used the Checklist for Reporting Results of Internet E-Surveys (CHERRIES) [19] reporting guideline.

3.3. Assessment of public and patient involvement

We report a summary of how, and at what stages, public and patient involvement occurred and whether the studies used GRIPP-2 [20] for reporting this involvement.

3.4. Risk of bias

Two authors independently assessed the included studies using the Cochrane Risk of Bias tool categorizing risks as "low," "high," or "unclear." Individual bias items were evaluated as described in the Cochrane Handbook for Systematic Reviews with modifications [21]. Risk of reporting bias (selective reporting of results) did not use prospective trial registration as criteria as some trials were initiated before the expectation that trials be prospectively registered. Performance bias arising from self-reported outcomes was not assessed because the eligibility criteria included self-reported outcomes.

3.5. Public and patient participation

Members of the public collaborated as research partners during this study, from editing the protocol to designing, analyzing, contributing to the discussion, and write-up of the findings. A volunteer from Cochrane Task Exchange joined the research team (L.V.) and fulfilled the criteria accepted for authorship. The protocol was published in the public domain [22] and the link posted on social media (Twitter/Facebook/LinkedIn/Research Gate) for comments.

3.6. Analysis

Results are presented with descriptive statistics and narratives, using charts and tables for ease of understanding and visual comparisons. Characteristics of included studies are presented in Appendix 1 with the citation, study design, aims, objectives, study setting, health status of participants, demographics, sample size calculation, intervention details, outcomes, time points, and follow-up.

4. Results

4.1. Study identification

Figure 1 shows the flow of studies through this review. ORCHID contained 26,000 citations in July 2016. From these, 3,636 deduplicated citations were identified as randomized trials, and their titles and abstracts were screened for potential eligibility. Of these, 3,543 citations were excluded, leaving 91 articles for full-text screening. These
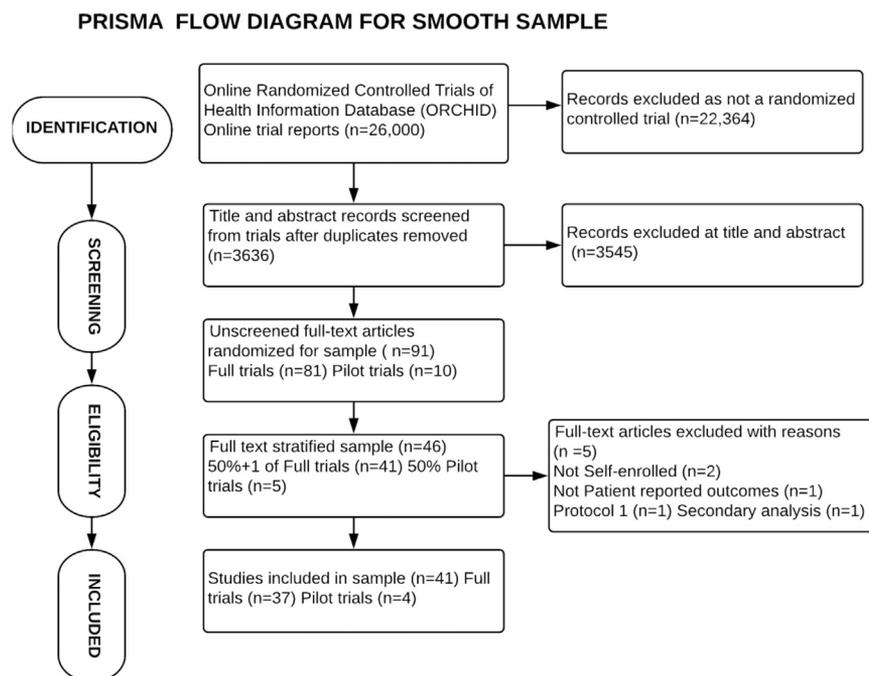

Fig. 1. PRISMA flow diagram.

reports were stratified into full trials (*n* = 81) and pilot trials (*n* = 10), and the subsequent 50% randomly selected samples included 41 full trials and five feasibility/pilot trials (total *n* = 46). ORCHID, Online Randomized Controlled Trials of Health Information Database; SMOOTH, Self-Management of Open Online Trials in Health.

4.2. Studies included for full-text screening

The full-text screening of the 46 articles for eligibility led to the exclusion of five: not self-enrolled in trial (*n* = 2) [23,24], protocol (*n* = 1) [25], secondary analysis (*n* = 1) [26] and not self-reported outcomes plus quasiexperimental design (*n* = 1) [27]. All 41 eligible trials were included for data extraction and analysis.

4.3. Characteristics of studies

Appendix 3 shows the characteristics of included trials [28–57] and excluded studies with reasons for exclusions [23–27]. There were 29,348 randomized participants in the 41 include trials, and we included data for 19,357 in the analysis. Trials ranged in size from 48 to 9,919 participants, with the length of intervention varying from 1 to 104 weeks. All trial reports were available in English. Trials were hosted from nine countries with eight studies featuring multinational collaborators (Table 1). Of the 41 trials, 30 were published between 2011 and 2015, eight from 2006 to 2010, and three between 2002 and 2005 (Table 2).

4.3.1. Trial design

All 41 trials were coded as pragmatic rather than explanatory because each contained self-reported data with self-management interventions. Pragmatic trials are used to measure the benefit that treatment produces in everyday life and reflect variations between patients that occur in everyday life, whereas explanatory trials recruit homogeneous, carefully defined participants and conduct the research in a controlled setting. Trial designs were parallel

Table 1. Trial host countries

Country of origin for trials	Number of trials
The United States	18
Multinational	8
Sweden	5
Netherlands	5
Australia	4
United Kingdom	3
Canada	2
Japan	2
Ireland	1
Switzerland	1

Table 2. CASP RCT quality appraisal across trials [15]

CASP (how to make sense of a trial) [15]	Total of 41 trial reports		
Questions 1-11	Yes	No	[a]
1. Clearly focused question?	41	0	0
2. Randomized?	41	0	0
3. Patients accounted for?	35	4	2
4. Was blinding reported?	13	11	18
5. Do groups have similar demographics?	37	0	4
6. Groups treated equally other than intervention?	37	2	2
7. Treatment of effect size measured?	27	8	6
8. [b]Estimate of treatment effect/confidence intervals?	20	12	9
9. Do results apply to the local population?	22	1	18
10. Were all clinically important outcomes considered?	20	6	15
11. Are the benefits worth the harms and costs?	35	2	4

[a] It was not reported or the reporting was unclear or incomplete.
[b] Yes = with confidence intervals. No = reported narratively or without confidence intervals.

(*n* = 32), factorial (*n* = 1), waitlist controls (*n* = 17), and pilot or feasibility studies (*n* = 4). The participatory design was mentioned in two studies, but this public and patient involvement (PPI) was restricted to consultation before trial preparation. Comparisons were assessed by waitlist controls (*n* = 17), alternative interventions (*n* = 19), current practice or standard of care (*n* = 7), and dose response (*n* = 1).

4.3.2. Trial origins and funding sources

Funding sources were reported in (34/41, 83%) trials. Multiple funding sources were reported in 15 studies. Trials were funded by government (national funders and academic institutions) (*n* = 25/41, 59%), industry (*n* = 3), NGOs (nongovernmental organizations, trusts, or charities) (*n* = 13, 32%). One trial was partially sponsored by advocacy groups who collaborated with the researchers on designing and running the trial. Information on funding was reported for two of the four feasibility/pilot trials. No trial sought crowd funding or was fully participant led and funded. All trials were initiated in high-resource regions (Table 1).

4.3.3. Recruitment

The included studies reported a variety of methods and sources for recruitment including various online and offline methods: use of websites, (*n* = 5), healthcare centers (*n* = 5), online forums (*n* = 4), bulletin boards (*n* = 4), Craigslist (*n* = 4), other universities (*n* = 4), advocacy organizations (*n* = 4), communities (*n* = 3), schools (*n* = 3),

social media ($n = 3$), newsletters ($n = 3$), internet advertising ($n = 3$), worksites ($n = 2$), newspapers ($n = 2$), and conferences ($n = 1/41$). Smartphone advertisements, texting, use of professional recruiters, canvassing at large advocacy organizations, recruiting through massive open online classrooms, online clinical sites, or referral arrangements from other trials were not reported as sources of recruitment.

4.3.4. Intervention settings

In online trials, ''setting'' includes the platform and materials used to conduct the intervention. Computers were the primary devices ($n = 38/41$, 93%), followed by smartphones ($n = 4$) and tablets ($n = 2$). The studies using smartphones and tablets did not report usability across operating systems or devices. Only one study reported using wearable devices to passively collect health data, which participants reported on and used to adapt their lifestyles. In 23 (56%) of studies, the description of the settings is insufficient to facilitate replication of the intervention and in 19/41, 46% studies piloting, or testing of platforms went unreported. Online or offline data entry was available in seven trials, but most 24 (56%) specified that data could not be entered unless participants connected to the internet. The option to share or download personal data was reported in

four (10%) of trials. Automated password recovery was supplied for nine trials. Only 10 trials reported the inclusion of methods for explaining data entry to participants.

4.3.5. Informed consent

Digital signatures for informed consent were accepted in 24 (56%) studies, five required only computer text (typing in yes/no or accept/decline), multimedia packages were used in three trials, and two trials used interactive formats for consent or participation information sheets. Trials did not report testing for participant comprehension or having end-users as collaborators to develop patient information sheets and consents. In seven trials, the method for obtaining consent was unspecified. There were no reports of biometric, multitrial consents (such as those used in adaptable trials), or the use of participant downloadable formats.

4.3.6. Intervention and outcome types

We classified self-management interventions into the categories and outcomes in Figure 2. All included trials measured behaviors. Trials could belong to multiple categories and contain more than one general outcome. Nine trials assessed knowledge in the general outcomes, whereas 29 trials (71%) assessed attitudes or behaviors.
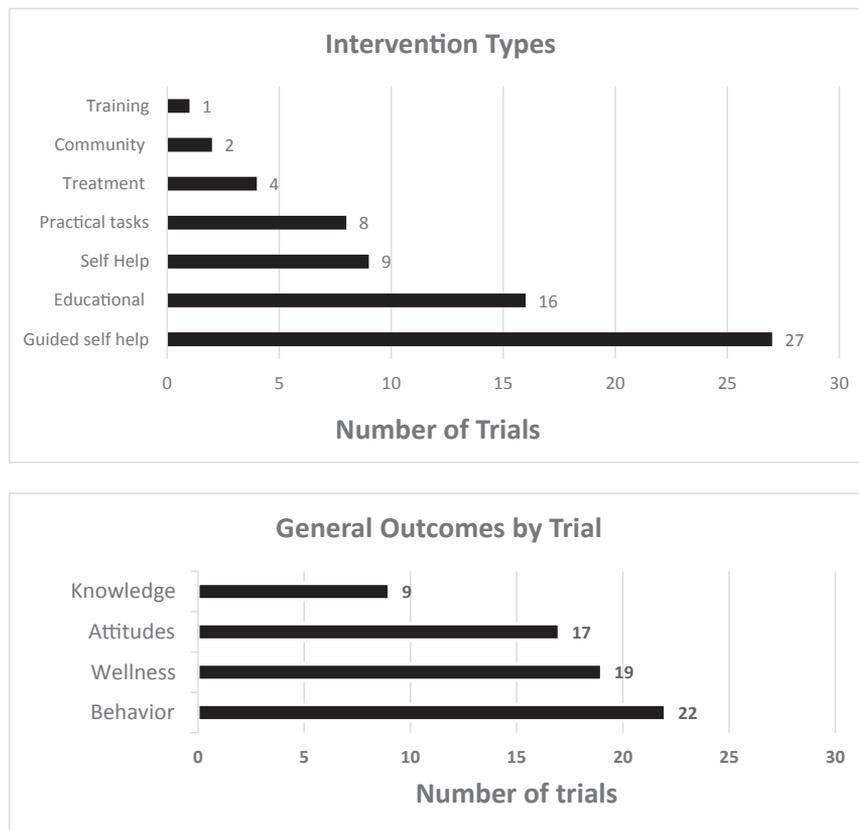

Fig. 2. Interventional and general outcome types.

4.3.7. Reminders and incentives

Most trials used email for reminders ($n = 28$). Platforms enabled participants to set reminders in two trials, and text reminders were implemented in one trial. Personalized, specific feedback was introduced as an incentive and later recommended by authors in six trials. Financial incentives ranging from US $25 to more than US $100 were offered over the course of the study in 17 trials (41%). Monetary incentives were available per task rather than as a lump sum in 10 trials. Using embedded methodology research, Bowen et al. [40], staggered the incentives per task and randomized half of the participants to higher payment for the last questionnaire. They found that increasing the incentive did not alter completion rates that were similar for both groups.

4.4. Assessment of methodological quality

We used the CASP 11 questions to help you make sense of a trial [15] to appraise quality across the trials. No trials received less than two yes responses because having a focused question and randomization (items 1 and 2, respectively) were required by our inclusion criteria. The appraisal was based on the reporting within the trial's publication without supplementation from personal correspondence with the original authors (Table 2).

We also searched whether a relevant systematic review, meta-analysis, or primary research was cited or the absence of the same mentioned to justify conducting the trial, and this information was reported in 33/41 trials.

4.5. Assessment of quality of reporting

Protocol registrations were reported in 15 trials. The CONSORT flow diagram was used in 18 trials with two including an intention to treat analysis. Piloting of the trial or platform was reported by 19 trials. Although the 41 trials included studies containing patient-reported outcomes and 40 trials containing an online questionnaire, none used the CHERRIES [19] reporting guideline for online surveys or CONSORT Pro [18] for reporting patient-reported outcomes. Four papers used the CONSORT E-HEALTH [17] reporting guidelines. However, several of the trial reports preceded the publication of reporting guidelines, including the 2010 update of the main CONSORT statement [58].

4.6. Assessment of reporting public and patient involvement

Public and patient involvement (defined as involvement in the research other than as a trial participant) was reported in 10 trials and forms the participatory element in online trials. Face-to-face PPI and email were the most common forms of interaction with PPI. There was participation in steering groups, community sessions, board meetings, focus groups, pilot testing sessions, computer iteration laboratories, dashboard design, surveys, or interview design. In some trials, advocacy groups were used as a proxy for individual patients or the public. Four reports included PPI activity in the acknowledgments section. Trials implemented PPI for advisor roles ($n = 9$), design of a trial interface and user materials ($n = 9$), usability testing and piloting ($n = 9$), recruitment ($n = 3$), selection of outcomes ($n = 2$), setting the research question ($n = 1$), and translation ($n = 1$). The 10 trials reporting PPI did not cite the GRIPP-1 [59] or GRIPP-2 [20] guidelines for reporting, but, again, some of the trials predated the publication of those guidelines.

4.7. Risk of bias

The risk of bias from the generation of the random sequence was generally low because most studies used computer-generated algorithms for randomization. Attrition (incomplete outcome data) and blinding of outcome assessment might be problematic for online trials as only 11 trials for each of these two domains showed a low risk of bias. For the blinding of participants or personnel, 12 trials were assessed as low risk of bias. Selective reporting is an important issue that is reduced when trial protocols are registered in advance. Trials that were not prospectively registered were assessed as unclear, and trials were assessed as high when there was a discrepancy between the results of the paper and what was highlighted in conclusion and abstract or multiple areas of risk of bias including the absence of a trials registration or protocol. As already noted, analysis by intention to treat was reported in only two trials. One trial reported the number of participants in control and experimental groups but only reported the experimental condition. This trial had other areas that were high risk and so it was classified as high risk of bias not otherwise classified (other bias)*. The prevalence of reporting bias in online trials was at least as high as in conventional trials [60] (Figure 3).

5. Discussion

5.1. Summary of results

Quality was consistent or comparable to that of traditional trials. However, gaps central to the success of online trials were identified, and recommendations to bridge these gaps are suggested in Table 3. The barriers to replicability and risk of bias in participatory online trials included inadequate reporting of blinding in 28/41 (68%) studies, high attrition rates with incomplete or unreported data in 30/41 (73%) of trials, and 26/41 (63%) of studies were at high risk for selection bias as trial registrations were unreported. Compliance and intervention engagement per session and over time were not systematically reported in the 41 trials in our sample but could be seen in part by viewing the CONSORT flow diagrams, where higher adherence was common in waitlist control groups. This suggests the engagement with interventions over time were not optimal. In 38/41 (93%) of studies computers were the only resource

Fig. 3. Risk of bias across trials.

available for entering study data, and this is in contrast to the growing number of individuals, particularly in low-resource settings who have smartphones or tablets as their primary vehicle for online usage. Public and patient involvement was not referenced or reported in 31/41 (76%) of trials. In general, the methods were not reported with sufficient detail for replicating the work. A multiuse protocol template might help authors focus on trial methods, design, and implementation.

5.1.1. Comparison with other studies

To the best of our knowledge, this is the first review of the quality of a sample of online self-management trials, but similar reviews exist for more conventional trials. This study and those earlier studies show that these online trials face some of the challenges of face-to-face trials regarding validity, data security, viable methods, and the challenge of providing valid self-reported outcomes [63]. These may be greater challenges for online trials because of the lack of face-to-face interaction to troubleshoot participant interaction or assess validity. About PPI, our findings are similar to those reported by others [64,65]. However, given the speed of the development of the internet and of devices that interface with it, the 41 trials in our sample might not reflect the current situation for online trials because of advances in methods and technology since the cutoff date for articles in ORCHID.

5.2. Implications

5.2.1. Challenges for online participatory trials

Our application of the CASP appraisal criteria identified only one of the 41 trials as low quality. The higher risk of

bias scores may be due to features that online trial researchers are powerless to change, such as the use of self-reported outcomes. However, as with conventional trials, we found substantial barriers to replicability and progress due to the lack of clear reporting, for example, about the setting where participants engaged with the intervention. Within online trials, settings can be particularly influential when one considers attrition in online trials that might arise due to unresolved technical difficulties. Designing, piloting, and monitoring all interfaces with end-users could increase the durability, stability, and usability of the resources needed to complete the intervention and the trial, from enrollment of participants to follow-up. Public and patient involvement collaborators in this study highlighted the importance of automated password recovery, plus online and offline data entry across devices. They identified a preference to access, manage, and share their research-related data but also raised concerns about how research data might be shared for a fee with third parties without their specific consent. It would be useful for researchers doing online trials to consider these concerns. Behavioral interventions and waitlist controls featured in 17 trials. The use of a comparative intervention in a parallel design may produce more reliable results because the use of a waitlist control design might artificially inflate intervention effect estimates [66]. The mechanism for this inflation may be the participant's determination to comply, so they will not miss out on the "real" intervention [67].

5.2.2. Reporting challenges

Inadequate reporting may not reflect a poor-quality trial [68] but incomplete reporting and research without public input into the design can impede replicability and might

Table 3. Protocol and reporting recommendations to evaluate for online participatory trials

Checklist item	Research recommendation for online participatory trials
Trial title and registration	The trial registration is reported, prospective, and has IRB approval. Include in the title the fact that the trial was online
Study design	State design, describe arms, report number of participants in each arm, report if control group will have access to the intervention post-trial, and report online components if the trial is not fully online.
Public and patient research involvement(PPI)	Report at what stages and in what form members of the public were involved in the research as part of the research team. Report in what ways they contributed to the design, oversight, running, analysis, and writing up of the trial report. We suggest PPI be reported in the methods section with a link to other sources if applicable where PPI was reported. For a checklist of what to include and report in an online participatory trial, we suggest the GRIPP-2 [20] short form reporting guidelines.
Questionnaire inclusion	Forty of the 41 studies analyzed contained a questionnaire or survey. We recommend using and citing the Checklist for Reporting Results of Internet E-Surveys (CHERRIES) [19] for best research practice.
Randomization	The point at which randomization takes place, e.g., before or after collection of baseline characteristics (we recommend that it should be after collection of baseline characteristics to minimize attrition rates)
Flow diagram	Consider including a flow diagram to show the path of the participant through the intervention.
Recruitment	Report methods used for recruiting and for validating that the data have come from a participant.
Pilot or feasibility	State how the study was piloted. We recommend piloting with people not only using computer models or people familiar with the platform. Pilots need to be completed by fully online participants representative of the population in addition to any other platform testing that takes place.
Informed consent	Describe online informed consent methods, their validation, and how participants could contact study personnel, given the lack of face-to-face communication. Convey to participants the time resources and risks of contributing. Assess participant understanding and their knowledge of the purpose of the study.
Setting	Describe in detail the software and algorithms used in the trial and the launch date of the online site. Include the period for which the online site remained open for recruitment and in what timeframe the online site remained open for data input.
Patient-reported outcomes (PRO)	We suggest reporting how the outcomes were informed by patients and if patient or public volunteer assessments of the outcomes were carried out before launch. Specify parties, including patient contributors, who developed PRO content. For other areas of reporting patient outcomes, we recommend adopting the SPIRIT PRO extension [61].
Replication	Include access to all materials and settings needed to replicate the research. Include explicit statements about platform downtime or failures even if none occurred, as this may explain some loss to follow-up and the stability of the setting
Compliance and loss to follow-up	We recommend building on and reporting consistency and completeness checks at each stage of the intervention process as this contributes to best practice and replicability.
Data protection	Outline how personal information was collected and protected. Include methods for password storage and recovery if applicable.
Data sharing	Policy on retention and use of already collected data, if a participant withdraws from the intervention or control (we recommend that data collection should be used to optimize the information available to the study and that participants should be aware of this in informed consent) State who has access to the data during and post-trial including third parties and how this was consented. State whether participants will have the option to download personal data collected during the trial
Contributory statement	Online trials may be run across countries and cultures with not all team members having access to the raw data. Stating who contributed and to what extent increases transparency and accountability
Competing interests	We recommend financial and personal competing interests be declared by all parties within the research team including members of the public or advocacy groups.
Supplementary Materials	If not supplied by the publisher, we suggest authors establish ways that the supplementary materials can be linked to the primary paper and in a file format that is accessible to readers. Multifile type open access repositories can be used such as Zenodo, Dataverse, or GitHub [62].
Dissemination	Consider building and reporting on a dissemination plan for reaching nonprofessionals. This could be through social media, blogs, the trial website, through the public report to the funders, and in conferences and training venues.

Abbreviation: IRB, Institutional review board.

lead to the unnecessary repetition of research, waste of resources, and unnecessary complexity [69,70]. Reporting shortfalls may slow the redesign or implementation of existing interventions [71] and are not limited to online trials. Initiatives such as the "All Trials" campaign for registering all trials and reporting all results may help to redress some of these problems about the access to trial findings [72], and uptake of the Template for Intervention Description and Replication checklist and guidance should improve the reporting of trial interventions [73]. An additional limitation is that technology across devices may be too recent, costly to develop, or insufficiently stable for widespread adoption. The trial sample was published from 2002 to 2015, and some studies in the sample were designed several years before this, in a time when computers (rather than mobile phones or tablets) were the primary interface for the internet.

5.2.3. Supplementary materials

Supplementary materials were not always accessible for the trial reports. This is a particular problem if the article is downloaded for offline use. Details of the software used in online trials were reported using static screenshots leaving insufficient information on models, coding structure, or usability for replication. We recognize that the sample of trial reports was published from 2002 to 2015 and earlier papers may have been written for print journals without an option to store supplementary files, models, or software. Furthermore, even current online journals may be restricted by the file structures their platforms can process. However, researchers might be able to comply with the FAIR standards (findable, accessible, interoperable, reusable) by using responsive multifile open access repositories such as Zenodo, Dataverse, or GitHub and putting links to the files in their publication [62].

5.2.4. Dissemination

If the main report of a trial is not published open access, free-to-view dissemination of its findings can still take place through blogs, social media, and teaching. It is also increasingly possible for researchers to provide free access to prepublication versions of their manuscripts through institutional repositories. Dissemination strategies are not adequately addressed within existing reporting guidelines or protocol templates, leaving researchers with insufficient guidance on how to report or highlight their dissemination strategies (other than, perhaps, within the relevant sections of their applications for funding).

5.3. Study limitations

Identifying relevant online trials presented a challenge, given the lack of specific search terms that are available in bibliographic databases such as MEDLINE and Embase. To help mitigate this, the design of ORCHID (from which we searched the included trials) was underpinned by research

on search strategies and filters to establish the optimal trade-off between exhaustiveness and precision; and, so, we believe that we have a representative sample of eligible trials from the early 21st century. We limited the analysis to 50% of the 81 titles and abstracts that matched inclusion criteria as the research was unfunded. We note that quality improvement assessments traditionally analyze only a 10% sample of the available data. As with other assessments of trial quality [67], our analysis was dependent on what authors reported, which may differ from what they did. We assessed the trials who did not report protocol publication or trials registration as unclear for risk of selective reporting. For trials enrolling participants before 2005, this may reflect changes in reporting requirements rather than the trial quality. Clinicaltrials.gov originally encouraged registration for trials that dealt with serious illness. This position was expanded when The International Committee of Medical Journal Editors announced in 2005 that their journals would no longer publish reports of trials unless they were prospectively registered in a trial registry that met the quality standards recommended by the World Health Organization [74]. The risk of selective reporting remains a threat in 2017 where approximately one-third of trials listed in ClinicalTrials.gov were registered 3 months following participant enrollment and of these, 50% were not registered within the first 12 months [75]. In addition, not all trials report the outcomes that are consistent with registry entries [76]. In online trials, limited guidance available to support online trial protocols or registration is cited [8] and it is hoped that bridging the reporting gap might reduce the risk of bias in online trials. We were unable to access additional potentially relevant information stored in inaccessible formats, contained in related, but unlinked papers, or that was unreported. However, our analyses reflect the information that is readily accessible to users of these trials and, therefore, is valid as a description of what can be easily found by users of online trials.

5.4. Future directions and conclusions

The Self-Management of Open Online Trials in Health (SMOOTH) analysis highlights the importance of consideration being given to good practice and reporting as early as the protocol planning stage for an online trial. Reporting of trials was generally poor. In addition to recommending that authors report their trials in accordance with CONSORT guidelines, we make the following recommendations: trialists should cover when reporting, and readers of trials should evaluate when reading, an online participatory clinical trial (some of these may also be applicable to nononline trials). There are items included in a protocol that will not be reported in the final manuscript. These might be described as aspirational, whereas the manuscript reports what took place. For example, a protocol could have a back-up plan for recruitment when the sample size is not reached or for alternative equipment if technology fails; however, this is unlikely to be reported in the published

manuscript. Also, there may be handbooks, software algorithms, and models that will not be part of a short protocol document, but they are trial documentation that is needed to replicate the work. This is why links to protocol registrations and other relevant trial documentation need to be reported in the published report.

The SMOOTH analysis reported here highlights the importance of consideration being given to good practice and reporting as early as the protocol planning stage for an online trial. Although online trials are still an emergent field, careful application of new findings for best research practice could improve the quality of online trials. The researchers' insights into ways to improve interventions or trial design were rarely discussed in publications even when authors trialed interventions repeatedly across conditions and populations with minimal difference in effect [77,78]. Online trials could benefit from the practicality and cost savings of applying methodology research within the context of a functioning trial, nesting Studies Within A Trial [79] in host trials and by making use of the Trial Forge initiative [80]. Following the sporadic use of reporting guideline in these reports of online trials, we propose the development and implementation of a reusable online protocol that follows good practice for reporting these trials. An adaptable protocol template could provide strategies for data management plans, reusable interactive consent, patient and public involvement methods, and a checklist to verify what to report from available guidelines when conducting an online trial. We also suggest that researchers might improve the uptake of their interventions by partnering with patients to improve access, usability, quality, and dissemination.

Acknowledgments

Registration and protocol

Research Registry# 1986 http://www.researchregistry.com/browse-the-registry.html#home/registrationdetails/5856b9bd759db5ec4609d880/.

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Supplementary data

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