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Abstract

BACKGROUND The use of online clinical trials is growing, but there remains little practical guidance on 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. Online trials of self-management may indicate how an intervention will be used in daily practice as the online environment can mirror the self-management of care increasingly expected. The Online Randomized Controlled Trials of Health Information Database (ORCHID) contains health trials undertaken using the internet which were systematically sought and cataloged. This ORCHID analysis provides insight into the current state of online clinical trials. AIM 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 participants in the research process. METHODS ORCHID was used as a sampling frame to identify a subset of self-recruited looking at self-management interventions. These were appraised to explore the qualities of self-recruited online randomized trials and to evaluate the usefulness of online trials for obtaining trustworthy answers to questions about health self-management and citizen research involvement. RESULTS The sample included (n=41) online trials published from 2002-2015. Trial quality was critically appraised as High (n=9), Medium-high (n=15), Medium (n=17), and low as (n=1). Descriptive settings in (N=23/41) trials provided insufficient information to be replicable and did not report piloting or testing platforms before the trial launch. Reporting of patient and public involvement was more common than in face-to-face trials, however reporting, replicability, and methods used in online randomized trials of self-recruited self-management interventions were sub-optimal and dissemination strategies were sparse and reported in only (n=1) trial. CONCLUSIONS The information gained in 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.

Keywords	Clinical Trials; Participatory research; health self-management; online trials methods; reporting methods
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File Name [File Type]

SMOOTHJCEcoverletter.docx [Cover Letter]

SMOOTH Highlights.docx [Highlights]

JCE_SMOOTHAmyPrice2017.docx [Manuscript File]

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Research Data Related to this Submission

Data set https://data.mendeley.com/datasets/5k2y9k32fm/draft?a=a7dae36e-e0db-4641-8c5f-4ef68bc90bdb

Data for: SMOOTH: Self-Management Open Online Trials in Health An Analysis of Existing Online Trials

Appendix-1 ORCHID search strategy Appendix-2 Glossary Appendix 3 Table of included and Excluded studies Self-Management Open Online Trials in Health (SMOOTH) What can we learn from existing trials? BACKGROUND The use of online clinical trials is growing, but there remains little practical guidance on 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. Online trials of self-management may indicate how an intervention will be used in daily practice as the online environment can mirror the self-management of care increasingly expected. The Online Randomized Controlled Trials of Health Information Database (ORCHID) contains health trials undertaken using the internet which were systematically sought and cataloged. This ORCHID analysis provides insight into the current state of online clinical trials. AIM 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 participants in the research process. METHODS ORCHID was used as a sampling frame to identify a subset of self-recruited looking at self-management interventions. These were appraised to explore the qualities of self-recruited online randomized trials and to evaluate the usefulness of online trials for obtaining trustworthy answers to questions about health self-management and citizen research involvement. RESULTS The sample included (n=41) online trials published from 2002-2015. Trial quality was critically appraised as High (n=9), Medium-high (n=15), Medium (n=17), and low as (n=1). Descriptive settings in (N=23/41) trials provided insufficient information to be replicable and did not report piloting or testing platforms before the trial launch. Reporting of patient and public involvement was more common than in face-to-face trials, however reporting, replicability, and methods used in online randomized trials of self-recruited self-management interventions were sub-optimal and dissemination strategies were sparse and reported in only (n=1) trial. CONCLUSIONS The information gained in 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.

December 21, 2017

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Dear JCE Editorial Team,

Thank you for your consideration of our research "*SMOOTH: Self-Management Open Online Trials in Health: An Analysis of Existing Online Trials*" Our research for this paper was done in collaboration with members of the public and medical students who we trained them and they worked to collect, code, analyze, contribute to the discussion, edit and write up this data.

Our vision is to grow research by finding ways to include the patients and public as citizen health scientists so they can become informed shared decision makers in their own health and research interests and so that we can learn together for best research.

We appreciate the attention to methods both old and new along with the consistent quality of JCE and we would be honored to have you consider our paper for publication.

Best Regards,

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Highlights

Barriers to replicability and progress in online trials were identified by unclear reporting of the trial and methods used. The deficit could be overcome by reporting on the dashboard design, software used in the intervention and the online materials used to train, test and assess participants.

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.

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.

SMOOTH: Self-Management Open Online Trials in Health

An Analysis of Existing Online Trials

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Conflicts of Interest

No authors have any personal, professional or financial conflict of interests to declare.

Registration and Protocol

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Self-Management Open Online Trials in Health (SMOOTH) What can we learn from existing trials?

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The use of online clinical trials is growing, but there remains little practical guidance on 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. Online trials of self-management may indicate how an intervention will be used in daily practice as the online environment can mirror the self-management of care increasingly expected. The **O**nline **R**andomized **C**ontrolled Trials of **H**ealth **I**nformation **D**atabase (ORCHID) contains health trials undertaken using the internet which were systematically sought and cataloged. This ORCHID analysis provides insight into the current state of online clinical trials.

AIM

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 participants in the research process.

METHODS

ORCHID was used as a sampling frame to identify a subset of self-recruited looking at self-management interventions. These were appraised to explore the qualities of self-recruited online randomized trials and to evaluate the usefulness of online trials for obtaining trustworthy answers to questions about health self-management and citizen research involvement.

RESULTS

The sample included (n=41) online trials published from 2002-2015. Trial quality was critically appraised as High (n=9), Medium-high (n=15), Medium (n=17), and low as (n=1). Descriptive settings in (N=23/41) trials provided insufficient information to be replicable and did not report piloting or testing platforms before the trial launch. Reporting of patient and

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The information gained in 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.

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Barriers to replicability and progress in online trials were identified by unclear reporting of the trial and methods used. The deficit could be overcome by reporting on the dashboard design, software used in the intervention and the online materials used to train, test and assess participants.

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Background

Why examine self-recruited online randomized trials?

The use of public engagement and self-management in online clinical trials and the development of best practice in this emerging field brings unique methodological challenges and benefits(1). However, there is little evidence to guide those working on these trials(2,3) and, currently, online trials may not be perceived by funders to meet the threshold standards of validation or credibility(4). This reduces their priority for funding bodies(5).

Why engage the public in health research?

The public is the end recipient of healthcare interventions, and research evidence guiding the use of healthcare interventions needs to be relevant and useful to them(6,7) They can be participants in research trials without knowing whether a trial is well run, ethical or even if it will be published(8). Trial participants report feeling confused, vulnerable and unsure of how to switch roles between patient and participant(9). The ORCHID database provides an opportunity to explore what works in terms of public involvement, engagement, and methods for online trials. This could help build a network of participatory research in methodologically sound online trials where citizens take part in every aspect of planning a trial and are not limited to being only participants within the trial.

Why is this research important?

This will be the first research of its kind using the ORCHID database(2) and we are not aware of any other database that has exclusively collated online trials for this purpose. This analysis provides an overall view of what works for online trials and how methodology, public involvement, and engagement might be best utilized and integrated into the development of online trials as early as the drafting of the trial's protocol.

The ORCHID Database

The **O**nline **R**andomized **C**ontrolled Trials of **H**ealth **I**nterventions **D**atabase (ORCHID)(2) provides a comprehensive population of online trials. The database, developed by (ABr) with (ABu and AP) providing support, contains 3636 relevant studies that were retrieved by using systematic search strategies(2). Other researchers have validated the database content using data mining techniques and it is sufficiently complete to permit meaningful and efficient methodological research. A full description of methods used to develop the database has been published(2) and Appendix-1 contains the ORCHID search strategy.

Research Question

What can be learned from systematically exploring existing self-recruited online randomized trials of self-management interventions and how they are reported?

Objectives

Our objectives were to critically appraise and extract a subset of self-recruited online trials of self-management interventions to identify their strengths and weaknesses and assess the quality of their reporting. Trials were searched to record how patients or other members of the public were involved in the research process in order to inform the development of guidance for the design, conduct, and reporting of online randomized trials of self-management interventions.

Inclusion and Exclusion Criteria

Inclusions

Studies were included if they were randomized trials that were self-enrolled online 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 accepted if they included self-reported outcomes.

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 where the population was enrolled as patients for trial purposes and the outcomes required physician intervention for measuring primary outcomes. Non-

randomized trials; cost-effectiveness research; trials that were not online or self-enrolled; and studies that were reported only as conference presentation or posters were excluded, as were aborted or withdrawn trials.

Methods

Study Design

A secondary analysis of the Online Randomized Controlled Trials of Health Information Database (ORCHID) (2).

Data Sources and Search Strategy

The **O**nline **R**andomized **C**ontrolled Trials of **H**ealth **I**nformation **D**atabase (ORCHID) (2) was updated in July 2016 and used to identify a subset of randomized trials of self-management self-recruited interventions. The evaluation was conducted through systematic review of a subset of the qualifying trials, critical appraisal and by survey.

Screening and Selection of Reviews

All citations were screened in RAYYAN(10). Reviewers were not blinded to author, institution, or journal. Two researchers independently screened the title and abstract of all citations in ORCHID(2) that matched health, self-management, self-help, intervention, self-recruit, self-enroll, and community for citations that match eligibility criteria. The citations were categorized as include, unsure (without checking of full paper), or exclude. Full papers were retrieved for “include” and “unsure”. Exclusions were not documented at this stage.

Full Paper Retrieval

Full papers were stored and de-duplicated in Mendeley(11). Two authors screened the retrieved full papers independently against the eligibility criteria. Papers were categorized as include, exclude or unsure. Agreement on papers classified as unsure was reached by consensus of three authors, and reasons for exclusion were documented. A PRISMA(12) diagram outlining the process is available below (Figure-1).

Obtaining a Representative Sample

A proportionate stratified sampling technique to include a percentage of subgroups from eligible citations was used. This made it possible to include all subgroups or strata equally and to investigate relationships between subgroups. A pure random selection of all the trials was not used because it could result in groups not having equal representation. The studies were grouped into the following strata: feasibility or pilot studies and full trials, before randomly selecting half the studies from each stratum.

Sampling Rationale

There may be fewer feasibility and pilot trials than full trials, but a scoping of the literature and consultation with content experts of trials methodology revealed that important choices about methodology and engagement may be detailed in feasibility or pilot trials but not included in the final trials report. The sampling method increases possibilities for representative inclusion.

Data Extraction and Synthesis

Two authors independently extracted key data for included trials. The data extraction form was piloted in EPPI reviewer(13) and adapted for best use of resources and information quality. Results are presented using descriptive statistics and narratives. Characteristics of included and excluded studies are shown in an appendix-3.

Quality Appraisal and Reporting

The included trials were quality assessed for methodological strengths and weaknesses by two review authors. Discrepancies were resolved by consensus, without need for third-party consultation. The Critical Appraisal Skills Programme (CASP) "*11 questions to help you*

make sense of a trial checklist"(14) was used, and items scored as yes, no, not sure/not reported per question. The aggregated "yes" count was graphed to show quality across studies. Also recorded were the number of trials that reported a systematic review to justify the trial of the intervention, a link to the registered protocol and whether the trial followed reporting guidelines such as including the CONSORT flow diagram(15), or using CONSORT EHEALTH (16), GRIPP-1(17), GRIPP-2(18), CONSORT PRO(19) for reporting patient-reported outcomes. For studies using an online questionnaire, it was reported if the CHERRIES(20) reporting guideline was used. A summary of how, and at what stages public and patient involvement occurred and whether the value of public involvement within the study was recorded. The Cochrane Risk of Bias Assessment was used, as described in the Cochrane Handbook for Systematic Reviews of Interventions(21).

Analysis

The analysis explores interactions and correlates for areas of interest across or within the studies. The reports were descriptive and narrative, with quantitative analysis using charts and tables for ease of understanding and visual comparisons. There was insufficient data or homogeneity to support meta-analysis.

Results

We cataloged what these online trials were assessing, appraised study quality, reported on how trials were run and reported the potential for bias. We searched out and reported on how public and patient participation in online trials was integrated into the design of the trial and how this was reported. In addition, we note the use of reporting guidelines, supplementary materials and whether plans for dissemination were reported.

Search Report

Figure-1 outlines the process of study selection(22).

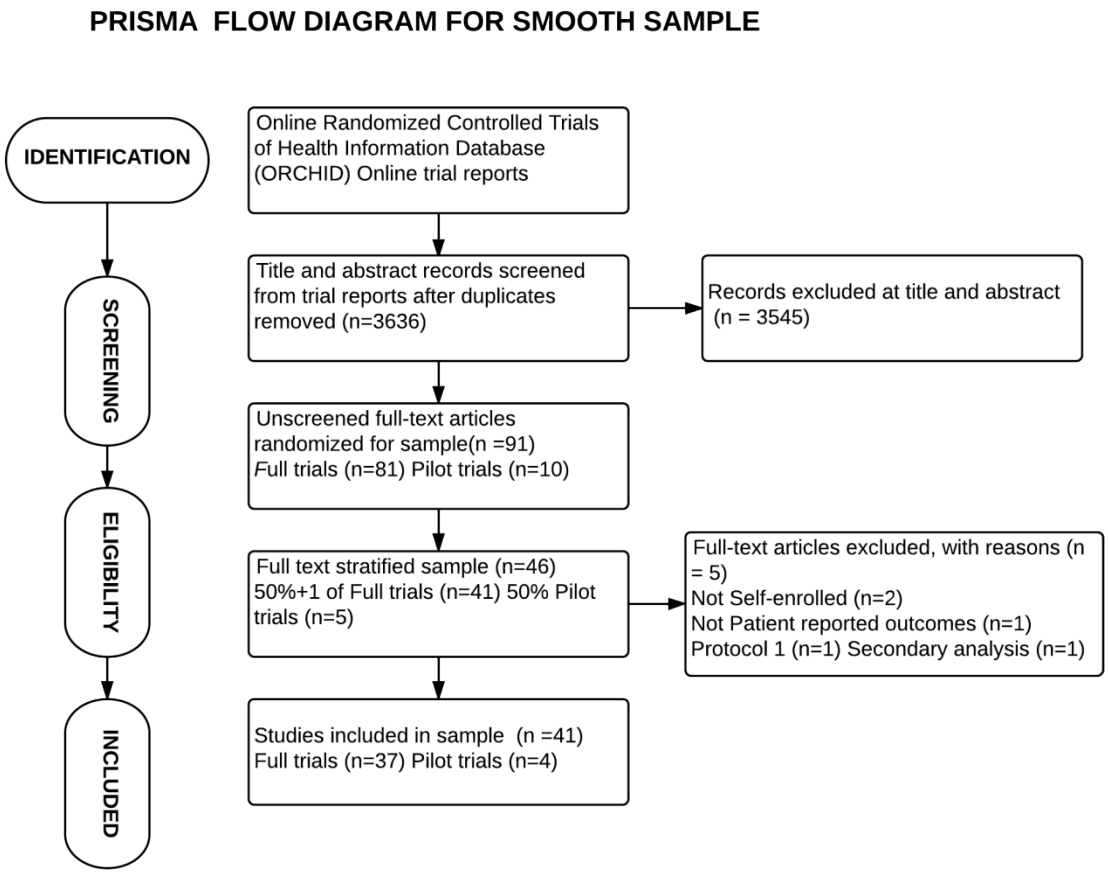

Figure-1 PRISMA Flow diagram

After resolving duplicates, the search of the ORCHID database yielded 3636 records for title and abstract screening.

Title and Abstract Screening

Full papers were retrieved for citations that appeared eligible on the basis of title and abstract, or for which a definitive decision could not be made. We excluded 3543 records at this stage, leaving 91 articles eligible for full-text screening.

Sample Stratification

These reports were full trials (n=81) or feasibility/pilot trials (n=10) and 50% random samples were led to 41 full trials and 5 feasibility/pilot trials published between 2002-2015.

Full-Text Screening

The full-text checking of these 46 articles for eligibility, led to the exclusion of 5: not self-enrolled in trial (n=2)(23,24), protocol (n=1)(25) secondary analysis (n=1)(26)and not self-reported outcomes plus quasi-experimental design (n=1)(27). This left 41 eligible trials for data extraction and analysis.

Characteristics of Trials

There were 29,348 total randomized participants from the 41 trials and of these 19,357 were included in the analysis. Intention to treat analysis was specifically reported in (n=2/41) trials. Trials ranged from (n=48 to n=9919) participants. The length of interventions was from 1 to 104 weeks. All trial reports were available in English. Trials were hosted from nine countries over the internet with (n=8) studies featuring multi-national collaborators. Of the 41 trials (n=30/41) were published between 2015-2011, (n=8/41) from 2010-2006 and the remaining trials (n=3/41) were published between 2005-2002.

Table-1Trial host countries

Country of origin for Trials	Number of Trials
USA	18
Multi-national	***8***
Sweden	5
Netherlands	5
Australia	4
UK	3
Canada	2
Japan	2
Ireland	1
Switzerland	1

Intervention and Outcome Types

Trials were broadly classified self-management interventions into the categories and outcomes in figure 2. Trials could belong to multiple categories and contain more than 1 general outcome.

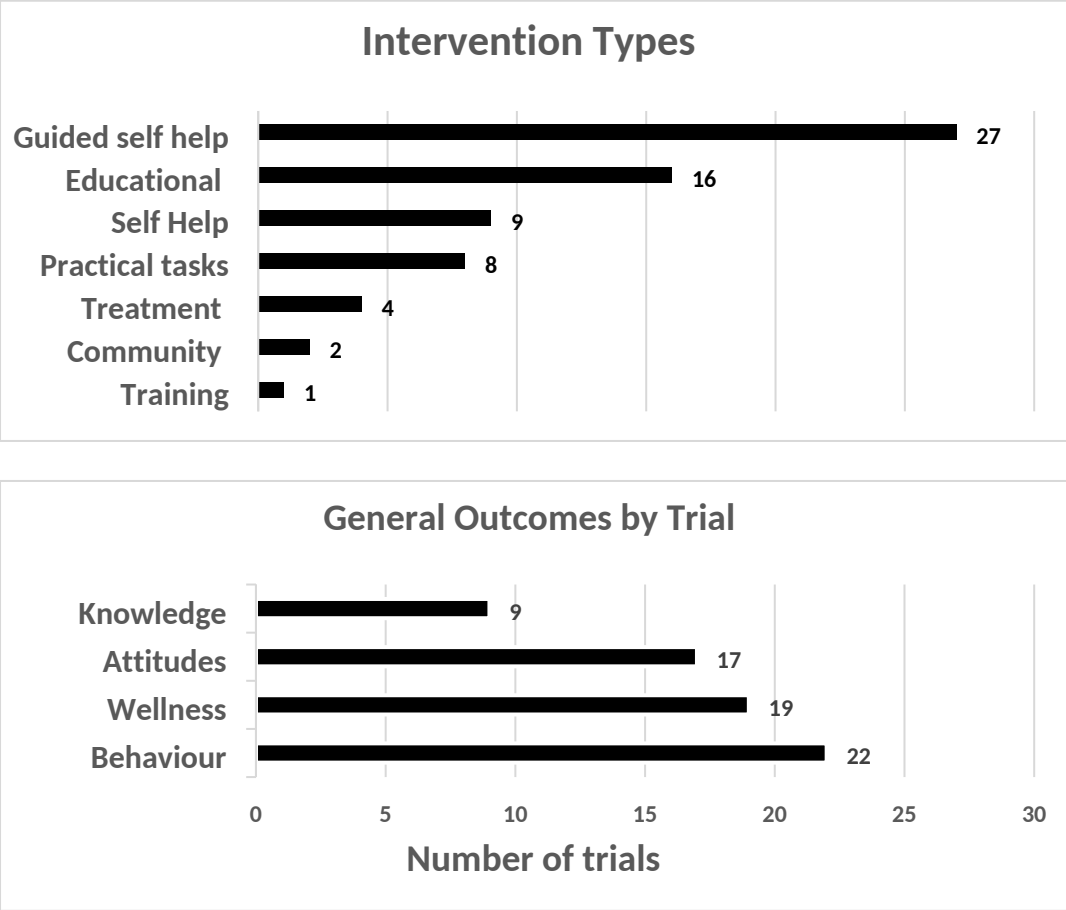

Figure- 2 Interventional and general outcomes types

Tables of included and excluded studies

A table of characteristics for included (28–57) trials and a table for excluded studies with citations and reasons for exclusions (23–27) can be accessed in Appendix-3.

Funding sources

Funding sources were reported in 34 trials and not reported in the other 7. Multiple funding sources were reported in 15 studies. Trials were funded by government (national funders and academic institutions) (n=25), industry (n=3), NGOs (non-governmental organizations, trusts or charities (n=13). In one study, the trial was partially sponsored by advocacy groups who collaborated with researchers on designing and running the trial. Information on funding was reported for 2 of the 4 feasibility/ pilot trials. No study sought to crowdfund or was a fully participant led and funded trial.

Quality Appraisal of Included Trials

The (CASP) 11 questions to help you make sense of a trial(14) were scored per question (table-1) and graphed in Figure 2, and information was also extracted on whether the trial cited a relevant systematic review or meta-analysis to justify the trial, a link to a registered protocol and a CONSORT flow diagram(15). There were no CASP scores of 0-2 as having a focused question and randomization were implicit in the inclusion criteria. The quality appraisal was based on the published report of each trial without supplementation from personal correspondence with the original authors.

Table- 2CASP RCT Quality Appraisal Across Trials(14)

CASP (How to Make Sense of a Trial) (14)	**Total of N=41 Trial Reports**		
Questions 1-11	**Yes**	**No**	***?**
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. Have groups 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.	**Estimate of treatment effect/confidence intervals?	20	12	9
9.	Do results apply to 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

** ? It was not reported or the reporting was unclear or incomplete. **Yes = with confidence intervals. No = reported narratively or without confidence intervals*

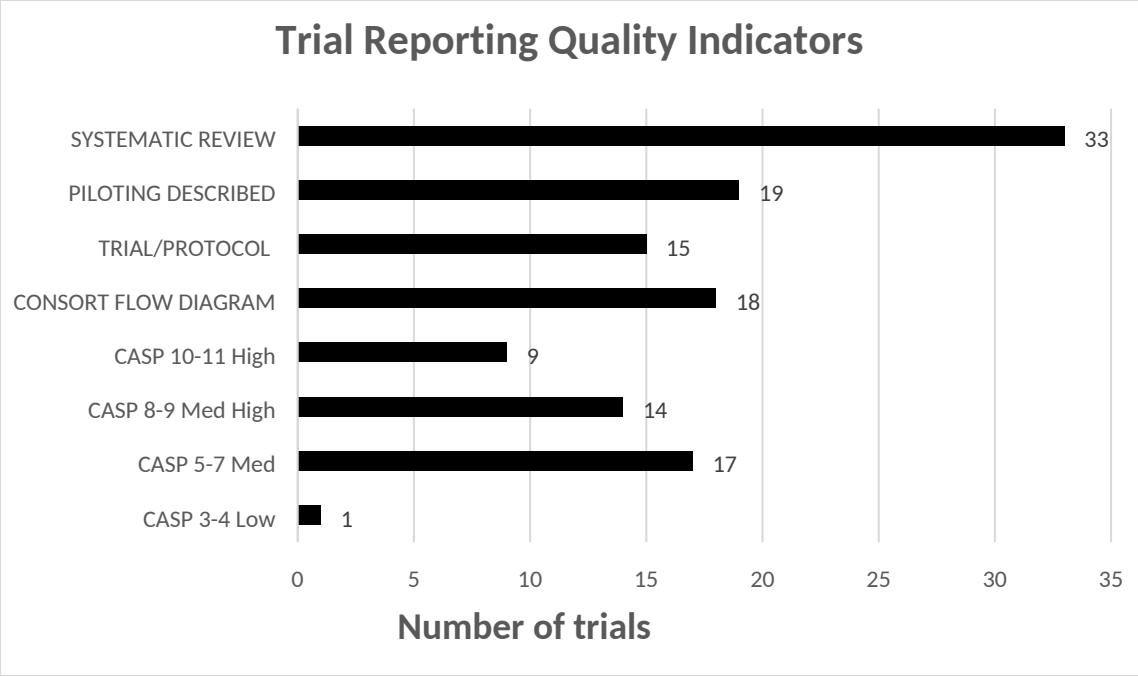

Figure-3 Reporting Quality Indicators and CASP scores

Although the 41 included studies contained patient-reported outcomes and 40/41 trials contained a questionnaire, none used the CHERRIES(20) reporting guideline for online surveys or CONSORT Pro (19) for reporting patient-reported outcomes. Four papers used the CONSORT E-HEALTH(16) reporting guidelines. Of the 10 studies that reported public and patient involvement, none referenced the GRIPP-1(17), GRIPP-2(18) guidelines for reporting. Flow diagrams (n=18) were included but consort was not always referenced hence the descriptor was adapted from CONSORT to CONSORT | FLOW DIAGRAM. Trial reports published from 2002-2015 may precede reporting guidelines, for example, CONSORT, one of the earlier guidelines was published with explanations in 2010 (58).

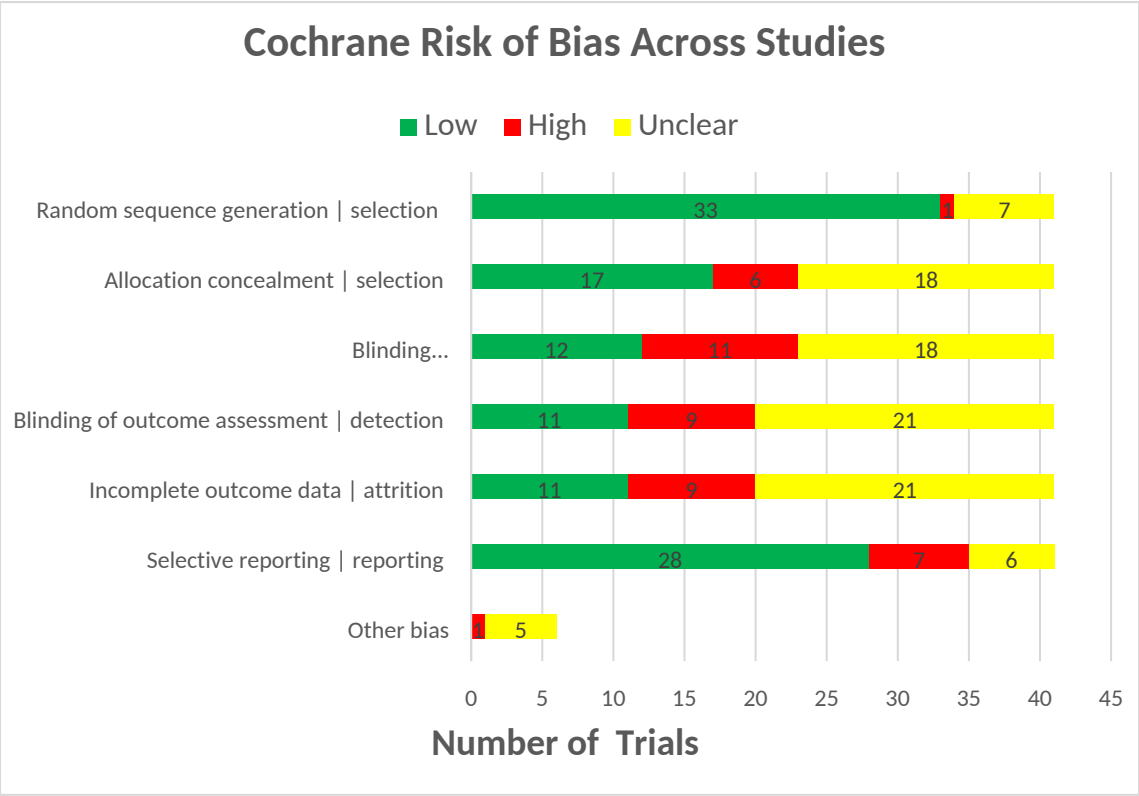

Figure-4 Cochrane Risk of Bias across trials

Trial Study Design

The 41 studies were coded as pragmatic rather than explanatory, as the trials contained self-reported data with self-management interventions. Trial designs were parallel (n=32), factorial (n=1), waitlist controls (n=17), and pilot or feasibility studies (n=4). Participatory design was mentioned in (n=2) studies, but these authors appeared to limit the volunteer researcher's role to 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).

Recruitment

Included studies used a variety of methods of recruitment (Figure 3), in addition to snowball methods, working with their own departments or manual distribution of recruitment materials through posters or handouts.

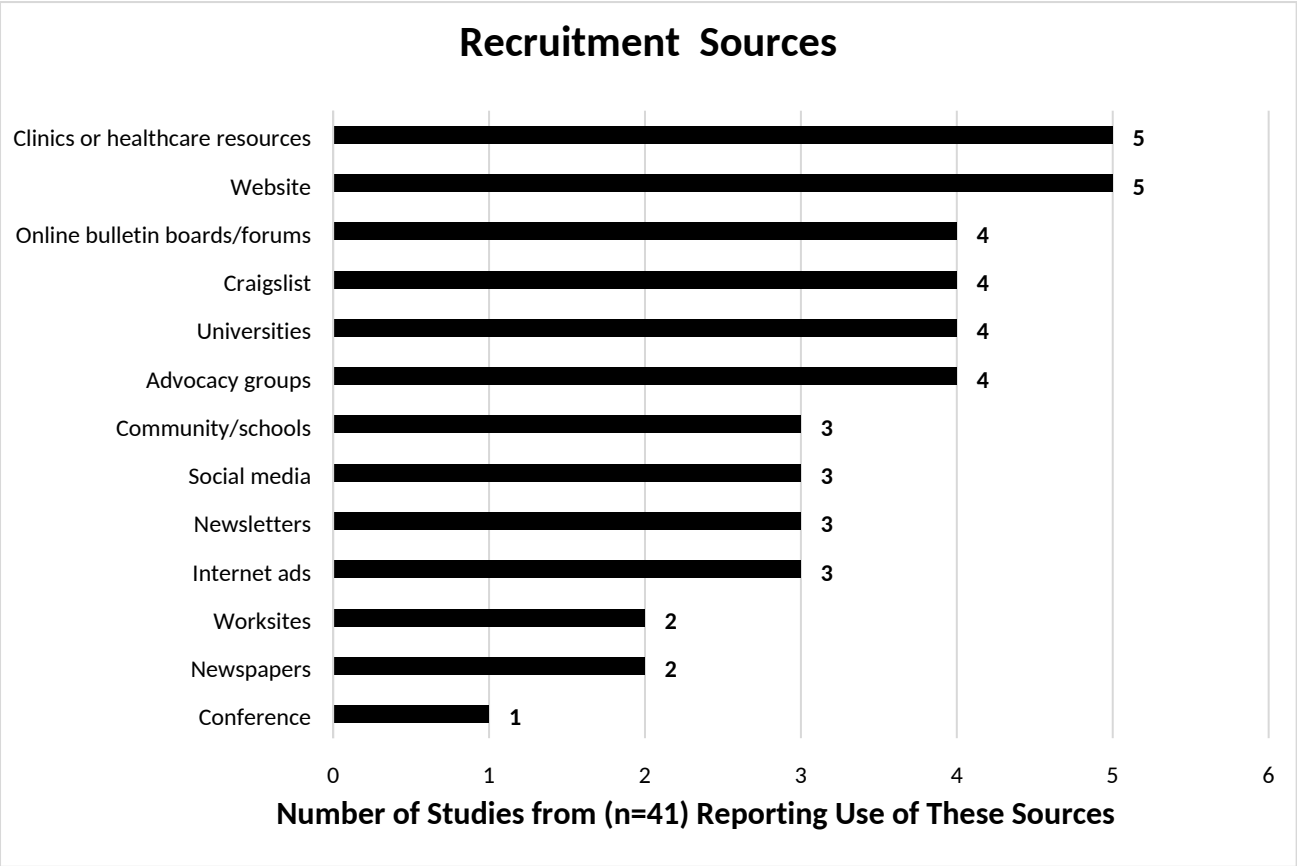

Figure-5 Reported recruitment strategies used in trials

Smartphone advertisements, use of professional recruiters, canvassing at large advocacy organizations, recruiting through MOOCs, online clinical sites, or referral arrangements from other trials were not reported as sources of recruitment in the 41 trials.

Online Consent and Participant Information Sheets

Digital rather than manual signatures were used in (n=24/41) studies, (N=5/41) required only computer text (typing in yes/no or accept/decline), multimedia packages were used in (n=3/41 trials and (n=2/41 used interactive formats for consent or participation information sheets. No trials reported testing for participant comprehension or mobilizing end users as collaborators to develop patient information sheets and consents. In (n=7/41) trials the methods for obtaining consent were not specified. The use of biometric, multi-trial consents such as those used in adaptable trials, and participant downloadable formats were not reported.

Dashboard

The setting for an online trial ideally includes a description of the platform and dashboard, since collection of online self-management data requires an online vehicle to collect data. In (n=23/ 41) trials descriptions of the settings were insufficient to facilitate replication or did not report piloting or testing platforms prior to trial launch. Automated password recovery was supplied for (n=9/41) trials, however, only (n=10/41) trials included methods for explaining data entry to participants.

The devices used to run trials were computers (n=38/42) used singularly rather than combining the benefits of portability by using smartphones(n=4/41) or tablets (n=2/41). Only one study reported using wearable devices to passively collect health data which participants reported on and used to adapt their lifestyles. The (n=4/41) studies using smartphones and (n=2/41) using tablets did not report usability across operating systems. Online or offline data entry was an option in (n=7/41) trials, with (n=24/41) specifying data entry was only possible while connected to the internet. Only (n=4/41) trials allowed sharing or downloading of participant data at any point during or after the trial.

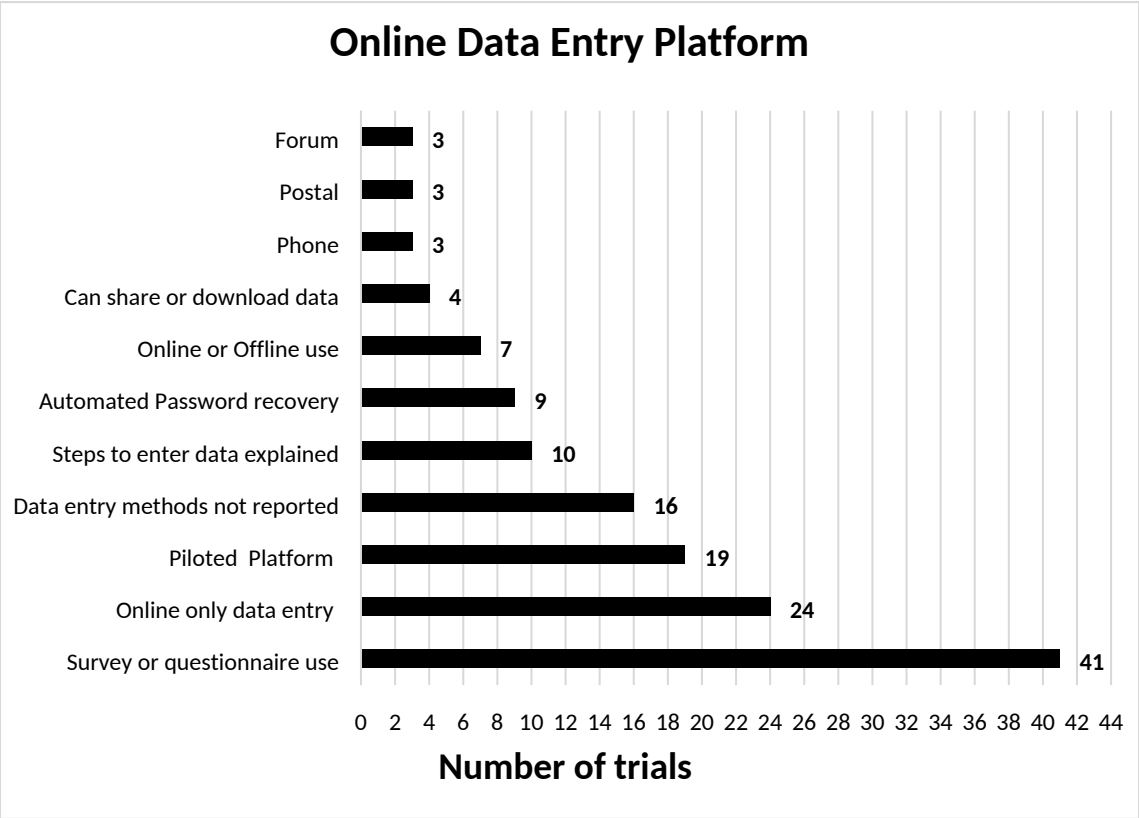

Figure-6 Platform use and available data entry options

Reminders and Incentives

Email was used most frequently as a reminder method (n=28/41). One trial used texting for reminders. Trial platforms were programmed to enable participants to set reminders in (n=2/41) trials (figure-7).

Financial incentives were used in (n=17/41) studies to maintain compliance and reduce attrition (Figure 6). In (n=10/41) trials, monetary incentives were staggered across the tasks rather than provided in a lump sum. Using embedded methodology research, Bowen et al(30) staggered the incentives per task and randomized half of the participants to a higher payment for the last questionnaire. They found that increasing the incentive did not alter completion rates which were similar for both groups (figure-8).

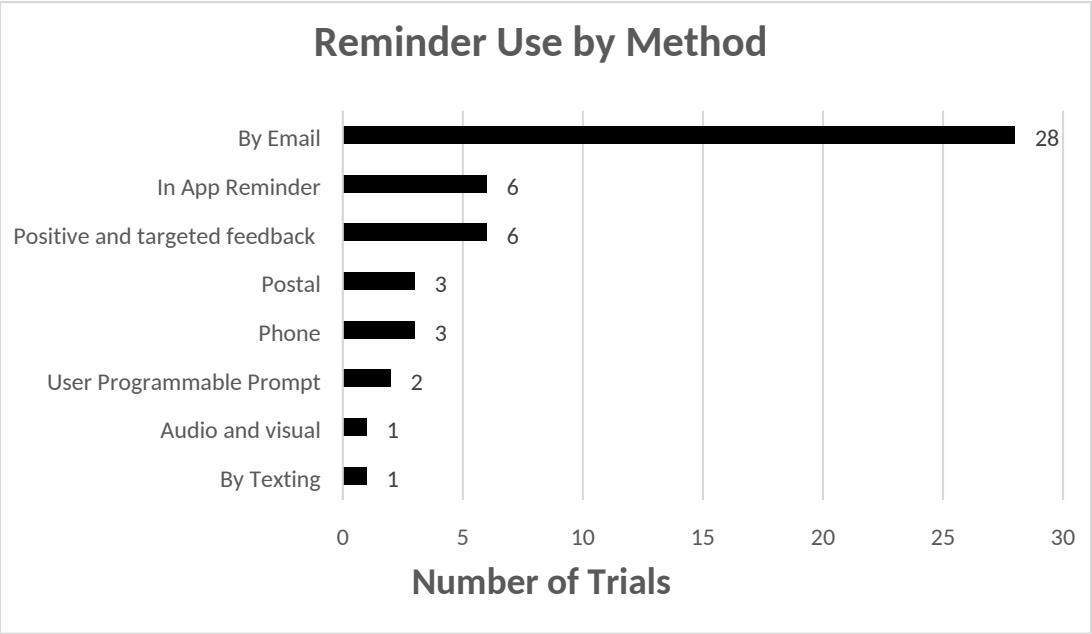

Figure-7 Reminder vehicles used for participants

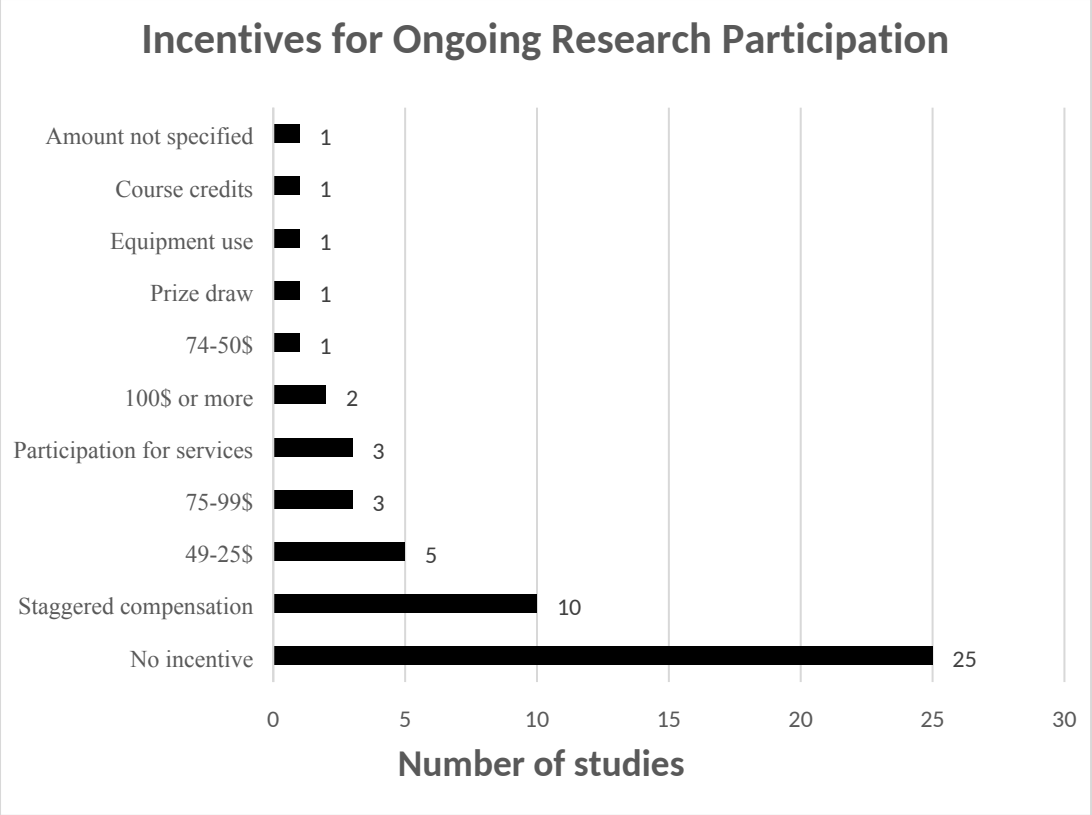

Figure-8 Incentive use by trial

Extent of Public and Patient Participation (PPI)

PPI was reported in (n=10/41) studies and was defined as involvement in the research other than as a trial participant. Face to face PPI and email were frequent forms of trialist to

researcher communication. There was participation in steering groups, community sessions, board meetings, focus groups, pilot testing sessions, computer iteration labs, dashboard design, surveys or interview design. In some trials, advocacy groups were used as a proxy for individual patients or the public. In (n=4/41) manuscripts volunteer activity was included in the acknowledgment section. Patients or members of the public were identified as authors in (n=0/41) manuscripts. Figure-8 shows where public and patient involvement occurred within included studies.

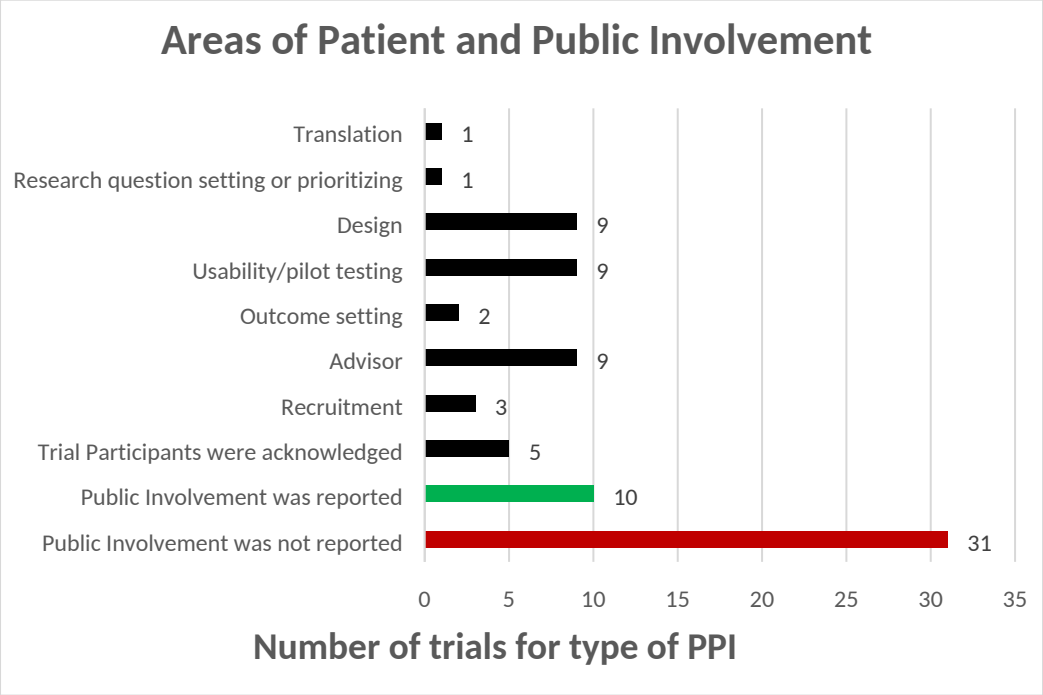

Figure-9 Public and Patient involvement

SMOOTH Internal Public and Patient Participation Methods

Members of the public collaborated as research partners on our study, from editing the protocol to designing, analyzing and writing up the findings. A volunteer from Task Exchange joined the research team (LV) and fulfilled the criteria accepted for authorship. The protocol was published in the public domain(59) and the link posted on social media (Twitter/Facebook/LinkedIn /Research Gate) for comments. The feedback from the public helped clarify our research question, methods and focus the outcomes. The respondents were

interested in usability rather than only study quality and wanted to test durability of the resources offered and advocated for public access to trialed products. They were clear about removing jargon and adding a glossary which they assisted in building. They expressed interest in enabling cross-device and operating system platforms where data could be entered online or offline. Volunteers are now working with us on a dissemination plan to share the findings of this study with patients, clinicians, the public, and researchers. Software developers from RAYYAN(10) and Mendeley(11) contributed to the research by customizing their products for use with citizen researchers.

Discussion

The findings point to opportunities for the use of a multi-faceted emergent technology with global reach for divergent cultures and the potential to provide increased access to clinical trials for people in remote areas or with mobility challenges(60). This could prove more economical than running clinical trials across multiple physical sites(61). As anticipated, online self-management trials face challenges shared with face-to-face trials in terms of validity, data security, viable methods and the challenge of providing valid self-reported outcomes and the influence of media reporting(62) but some of these may be greater for online trials where there are no face-to-face opportunities to assess validity.

Challenges for Online trials

The CASP appraisal identified only (n=1/41) trials as low quality. The GRADE scores were low in areas that online trial researchers may be powerless to change, such as the use of self-reported outcomes. In addition, as people might be randomized before they know the full conditions of the trial, they are more prone to drop out, leading to high attrition if participants sign up on impulse and decide later to withdraw. In a face-to-face trial, participants will meet people working on the trial and may develop loyalties before making a commitment to the

trial. Barriers to replicability and progress were identified due to the lack of clear reporting of the setting where participants engaged with the intervention. This could be overcome by the inclusion of information on dashboard design, software used in the intervention and online materials used to train, test and assess participants. The technology across devices may be too recent, costly to develop, or not sufficiently stable for widespread adoption. The trial sample was published from 2002-15 and many studies in the sample were designed several years before this, in a time when computers were the primary gateway to the internet.

Limitations of Waitlist controls

Behavioral interventions and waitlist controls were combined in (n=17/41 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(63). The mechanism for this inflation may be the participant's determination to comply so they will not miss out on the “real” intervention(64). Compliance and intervention engagement per session and over time were not systematically reported. This was most obvious in the CONSORT flow diagrams(15), where higher adherence was common in waitlist control groups.

Dissemination and supplementary materials

Even when the main report of a trial is not published open access, free-to-view dissemination of the findings can still take place through blogs, social media, conference presentations and teaching sessions. Dissemination strategies are not addressed within reporting guidelines or protocol templates leaving authors with little guidance about whether to report dissemination other than when it is required for funding bids.

Supplementary materials were not always accessible, especially once the article was downloaded and some were behind paywalls making it difficult for anyone without library access to replicate the research. Details of software used in online trials was reported using static screenshots leaving insufficient information on models, coding structure, or usability for replication. As the sample spanned 2002 -2015, earlier papers may have been written for print journals only. Journals may be restricted by file structures their platforms can process. FAIR standards (findable, accessible, interoperable, re-usable) could still be met by using responsive repositories such as Zenodo, Dataverse, or GitHub and providing a DOI to these files within the publication(65).

Reporting challenges

Inadequate reporting or supplementary file deficits may not reflect a poor quality trial (66) but incomplete reporting and research without public input into the design impedes replicability and might lead to unnecessary repetition of research, wasting resources and adding complexity(67,68). Reporting shortfalls may slow the redesign or implementation of existing interventions(69) 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 (70).

Study Limitations

Identifying relevant internet-based health trials presented a challenge given the lack of specific search terms that are available. To help mitigate this, the ORCHID database from which the analysis was done was underpinned by research on search strategies and filters in order to establish the optimal trade-off between exhaustiveness and precision. The 41 studies may not be representative of current online randomized trials, given the growth in methods and technology after the database was updated. However, the sample was representative of

the general population of this type of trial, as our findings are similar to those reported by others(71,72). Our analysis was dependent on what authors reported, which may differ from what they did and there may be additional relevant information stored in inaccessible formats, contained in related papers, or unreported. However, the analyses reflects 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 potential users of online randomized trials.

Future directions and conclusions

The SMOOTH (Self-Management of Open Online Trials in Health) analysis points to the value of good methods in trial conduct including those involving patients and the public in trial design be introduced as early as the protocol planning stage. As for trials generally, there is considerable room for improvements in reporting(73). While we recognize that online trials are still an emergent field, careful application of new findings for best research practice could improve the quality of online trials.

Reporting ways to improve interventions or trial design is helpful in online trials, but this was rarely discussed in the articles even though authors delivered interventions like Cognitive Behavioral Therapy repeatedly across conditions and populations with minimal difference in effect(74,75). Online trials could benefit from applying methods research within the context of a functioning trial such as in the use of core outcome sets as highlighted by the COMET(76) initiative and the use of embedded methodology research in the form of a study within a trial (SWAT)(77). Trial investigators could improve the uptake of their interventions by preparing and implementing dissemination plans and partnering with patients to improve access, usability, and quality.

Following the sporadic use of reporting guideline usage in online trials, we propose the development and implementation of an online reusable protocol. This could assist authors by suggesting elements to include from the most appropriate reporting guidelines and by providing a standardized structure to include data privacy wording, a data management plan, interactive reusable consent, adding patient and public involvement content and could include a checklist to verify what to report when building an online trial.

Declarations

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Contributions of authors

All authors have fulfilled the ICJME requirements for authorship.

Declarations of interest

None of the authors have any personal, professional or financial conflict of interests to declare.

Differences between protocol and review

The preliminary protocol was amended following public feedback and the input was incorporated into the data extraction. The impact of the online research was not reported and in 41 of the studies, the impact could not be easily measured by others.

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Highlights

Barriers to replicability and progress in online trials were identified by unclear reporting of the trial and methods used. The deficit could be overcome by reporting on the dashboard design, software used in the intervention and the online materials used to train, test and assess participants.

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.

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.