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

Amy Price
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Patient Editor |Research and Evaluation, The BMJ, London UK

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?

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

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124 replicability, and methods used in online randomized trials of self-recruited self-management
125 interventions were sub-optimal and dissemination strategies were sparse and reported in only
126 (n=1) trial.
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130 **CONCLUSIONS**

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133 The information gained in this study catalogs the state of online trials of self-management in
134 the early 21st century and provides insights for online trials development as early as the
135 protocol planning stage.
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141 **Highlights**

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149 used to train, test and assess participants.
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153 sufficiently stable for widespread use, early adoption of good reporting methods
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155 technologies.
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161 online trials research.
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184 **Background**
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186 **Why examine self-recruited online randomized trials?**
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188 The use of public engagement and self-management in online clinical trials and the
189 development of best practice in this emerging field brings unique methodological challenges
190 and benefits(1). However, there is little evidence to guide those working on these trials(2,3)
191 and, currently, online trials may not be perceived by funders to meet the threshold standards
192 of validation or credibility(4). This reduces their priority for funding bodies(5).
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200 **Why engage the public in health research?**
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202 The public is the end recipient of healthcare interventions, and research evidence guiding the
203 use of healthcare interventions needs to be relevant and useful to them(6,7) They can be
204 participants in research trials without knowing whether a trial is well run, ethical or even if it
205 will be published(8). Trial participants report feeling confused, vulnerable and unsure of how
206 to switch roles between patient and participant(9). The ORCHID database provides an
207 opportunity to explore what works in terms of public involvement, engagement, and methods
208 for online trials. This could help build a network of participatory research in
209 methodologically sound online trials where citizens take part in every aspect of planning a
210 trial and are not limited to being only participants within the trial.
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222 **Why is this research important?**
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224 This will be the first research of its kind using the ORCHID database(2) and we are not aware
225 of any other database that has exclusively collated online trials for this purpose. This analysis
226 provides an overall view of what works for online trials and how methodology, public
227 involvement, and engagement might be best utilized and integrated into the development of
228 online trials as early as the drafting of the trial's protocol.
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243 **The ORCHID Database**
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247 The **Online Randomized Controlled Trials of Health Interventions Database (ORCHID)**(2)
248 provides a comprehensive population of online trials. The database, developed by (ABr)
249 with (ABu and AP) providing support, contains 3636 relevant studies that were retrieved by
250 using systematic search strategies(2). Other researchers have validated the database content
251 using data mining techniques and it is sufficiently complete to permit meaningful and
252 efficient methodological research. A full description of methods used to develop the database
253 has been published(2) and Appendix-1 contains the ORCHID search strategy.
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303 **Research Question**
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306 What can be learned from systematically exploring existing self-recruited online randomized
307 trials of self-management interventions and how they are reported?
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312 **Objectives**
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315 Our objectives were to critically appraise and extract a subset of self-recruited online trials of
316 self-management interventions to identify their strengths and weaknesses and assess the
317 quality of their reporting. Trials were searched to record how patients or other members of
318 the public were involved in the research process in order to inform the development of
319 guidance for the design, conduct, and reporting of online randomized trials of self-
320 management interventions.
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329 **Inclusion and Exclusion Criteria**
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333 ***Inclusions***
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335 Studies were included if they were randomized trials that were self-enrolled online and used
336 internet-based technologies, such as computers, tablets or smartphones, in the trial process.
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338 Interventions had to be related to health and well-being and could include educational or
339 behavioral components. Trials were only accepted if they included self-reported outcomes.
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343 ***Exclusions***
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345 Interventions in social care or education were excluded where outcomes were not health-
346 related; where the population was exclusively health professionals, educators, or students;
347 and the intervention was used for training purposes but was not a specific health intervention.
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350 Studies were excluded where the population was enrolled as patients for trial purposes and
351 the outcomes required physician intervention for measuring primary outcomes. Non-
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363 randomized trials; cost-effectiveness research; trials that were not online or self-enrolled; and
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365 studies that were reported only as conference presentation or posters were excluded, as were
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367 aborted or withdrawn trials.
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Methods

Study Design

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

Data Sources and Search Strategy

The Online Randomized Controlled Trials of Health Information Database (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).

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483 **Obtaining a Representative Sample**
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486 A proportionate stratified sampling technique to include a percentage of subgroups from
487 eligible citations was used. This made it possible to include all subgroups or strata equally
488 and to investigate relationships between subgroups. A pure random selection of all the trials
489 was not used because it could result in groups not having equal representation. The studies
490 were grouped into the following strata: feasibility or pilot studies and full trials, before
491 randomly selecting half the studies from each stratum.
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500 **Sampling Rationale**
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503 There may be fewer feasibility and pilot trials than full trials, but a scoping of the literature
504 and consultation with content experts of trials methodology revealed that important choices
505 about methodology and engagement may be detailed in feasibility or pilot trials but not
506 included in the final trials report. The sampling method increases possibilities for
507 representative inclusion.
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514 **Data Extraction and Synthesis**
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517 Two authors independently extracted key data for included trials. The data extraction form
518 was piloted in EPPI reviewer(13) and adapted for best use of resources and information
519 quality. Results are presented using descriptive statistics and narratives. Characteristics of
520 included and excluded studies are shown in an appendix-3.
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527 **Quality Appraisal and Reporting**
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530 The included trials were quality assessed for methodological strengths and weaknesses by
531 two review authors. Discrepancies were resolved by consensus, without need for third-party
532 consultation. The Critical Appraisal Skills Programme (CASP) “*11 questions to help you*
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543 *make sense of a trial checklist*”(14) was used, and items scored as yes, no, not sure/not
544 reported per question. The aggregated “yes” count was graphed to show quality across
545 studies. Also recorded were the number of trials that reported a systematic review to justify
546 the trial of the intervention, a link to the registered protocol and whether the trial followed
547 reporting guidelines such as including the CONSORT flow diagram(15), or using CONSORT
548 EHEALTH (16), GRIPP-1(17), GRIPP-2(18), CONSORT PRO(19) for reporting patient-
549 reported outcomes. For studies using an online questionnaire, it was reported if the
550 CHERRIES(20) reporting guideline was used. A summary of how, and at what stages public
551 and patient involvement occurred and whether the value of public involvement within the
552 study was recorded. The Cochrane Risk of Bias Assessment was used, as described in the
553 Cochrane Handbook for Systematic Reviews of Interventions(21).
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568 **Analysis**

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

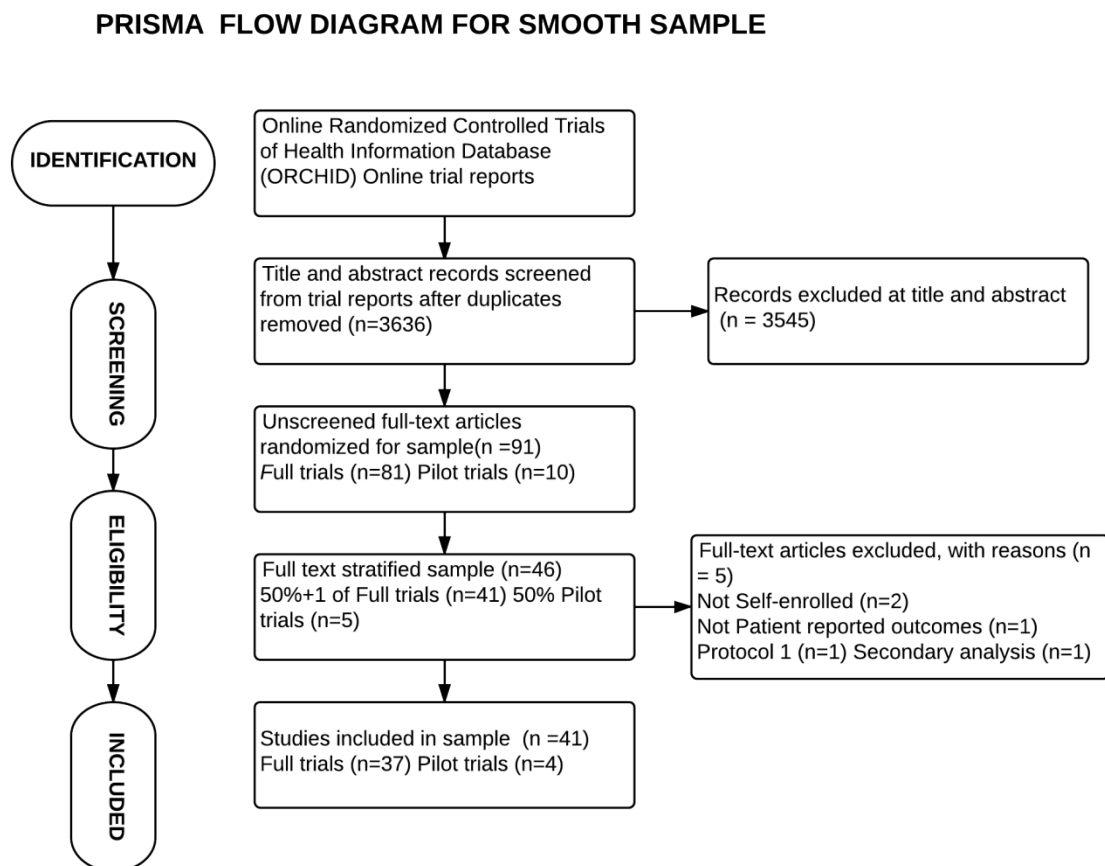


Figure-1 PRISMA Flow diagram

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663 After resolving duplicates, the search of the ORCHID database yielded 3636 records for title
664 and abstract screening.
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667 668 **Title and Abstract Screening**

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

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

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

700 There were 29,348 total randomized participants from the 41 trials and of these 19,357 were
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702 included in the analysis. Intention to treat analysis was specifically reported in (n=2/41) trials.
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704 Trials ranged from (n=48 to n=9919) participants. The length of interventions was from 1 to
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706 104 weeks. All trial reports were available in English. Trials were hosted from nine countries
707
708 over the internet with (n=8) studies featuring multi-national collaborators. Of the 41 trials
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710 (n=30/41) were published between 2015-2011, (n=8/41) from 2010-2006 and the remaining
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712 trials (n=3/41) were published between 2005-2002.
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Table-1 Trial host countries

Country of origin for Trials	Number of Trials
USA	18
<i>Multi-national</i>	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.

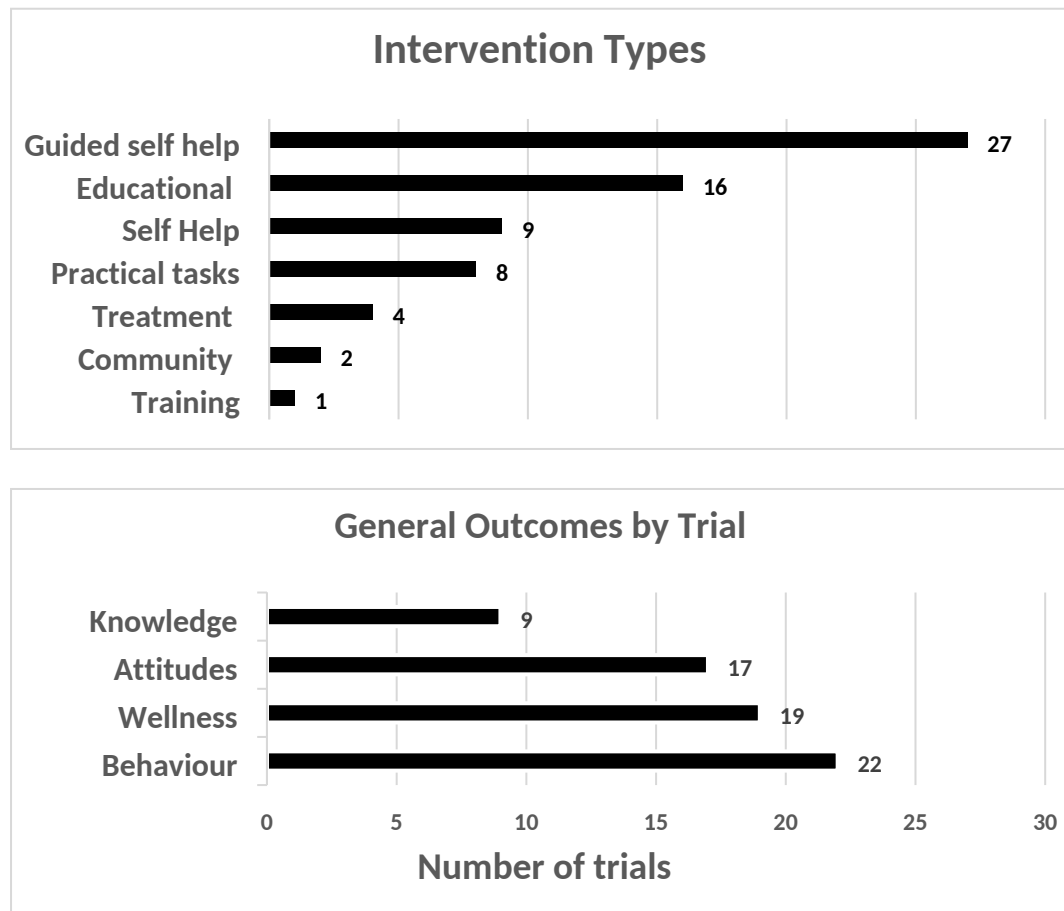


Figure- 2 Interventional and general outcomes types

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

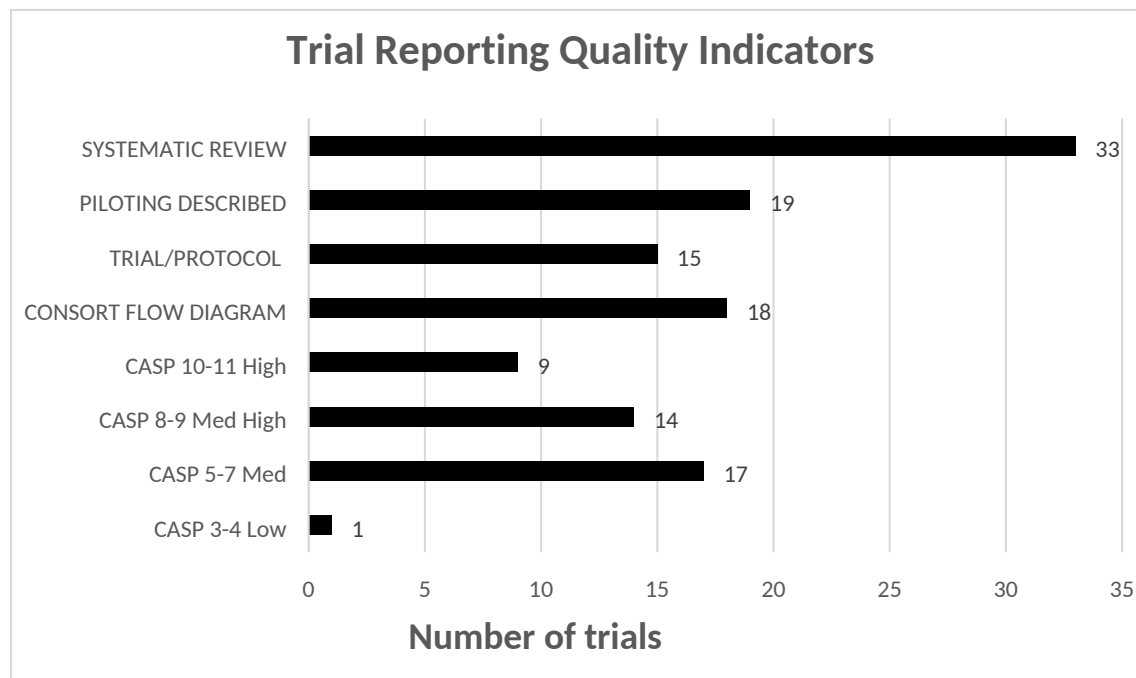
The (CASP) 11 questions to help you make sense of a trial(14) were scored per question (table-1) and graphed in Figure 2, and information was also extracted on whether the trial cited a relevant systematic review or meta-analysis to justify the trial, a link to a registered protocol and a CONSORT flow 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		
	Yes	No	*?
Questions 1-11			
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

841	6. Groups treated equally other than intervention?	37	2	2
842	7. Treatment of effect size measured?	27	8	6
843	8. **Estimate of treatment effect/confidence intervals?	20	12	9
844	9. Do results apply to local population?	22	1	18
845	10. Were all clinically important outcomes considered?	20	6	15
846	11. Are the benefits worth the harms and costs?	35	2	4

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



875 **Figure-3 Reporting Quality Indicators and CASP scores**

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

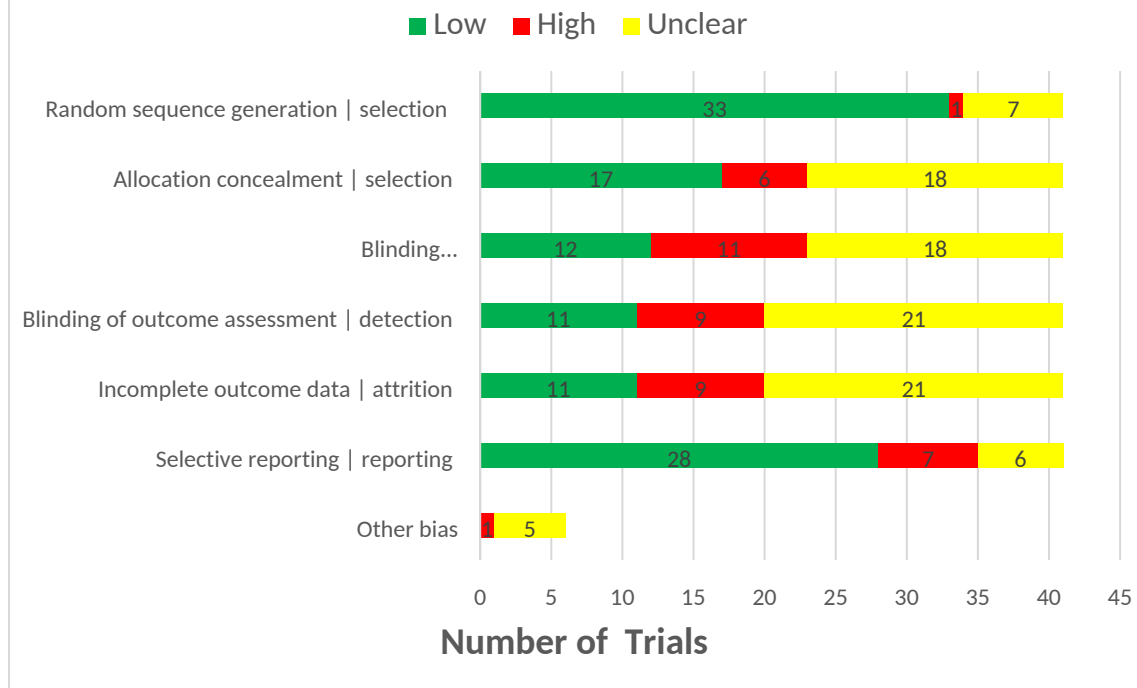


Figure-4 Cochrane Risk of Bias across trials

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.

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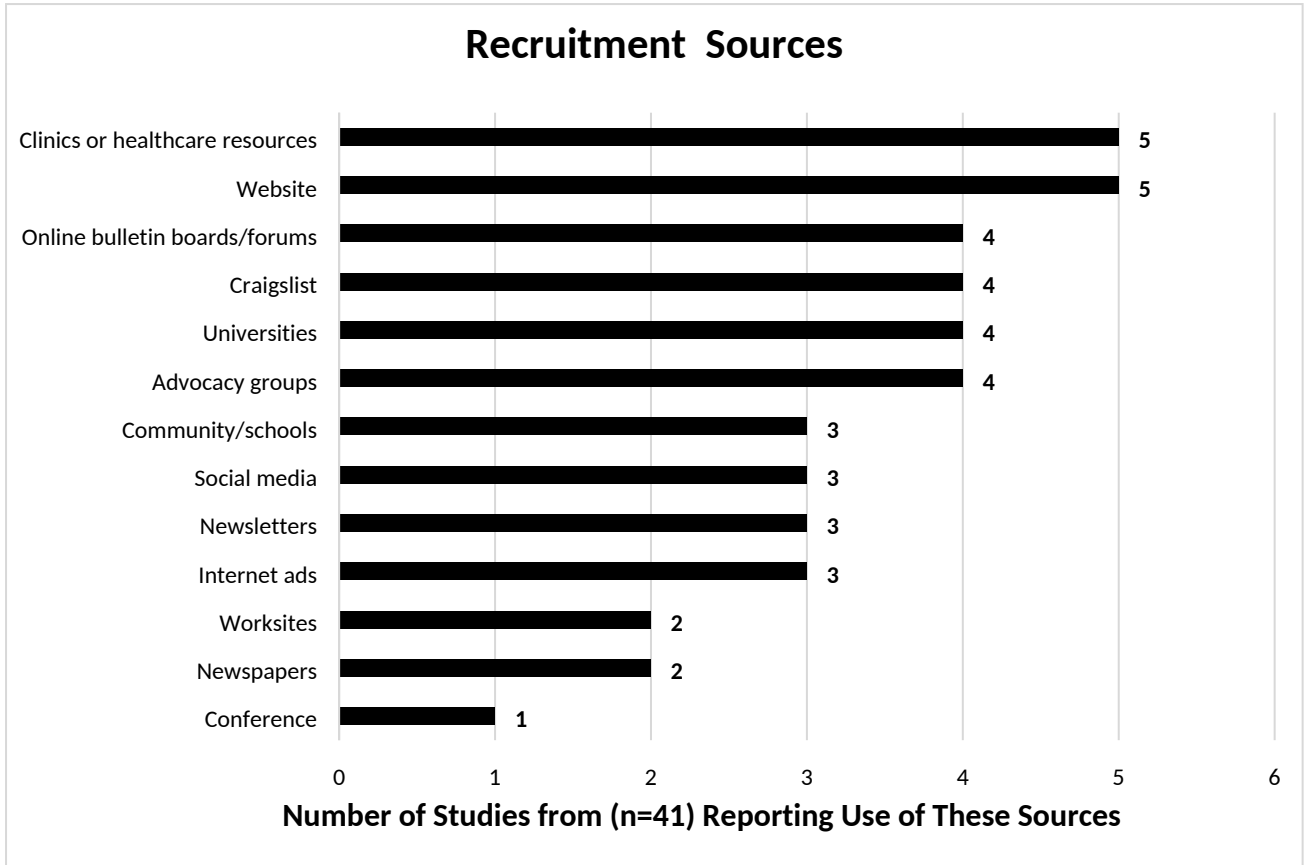


Figure-5 Reported recruitment strategies used in trials

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.

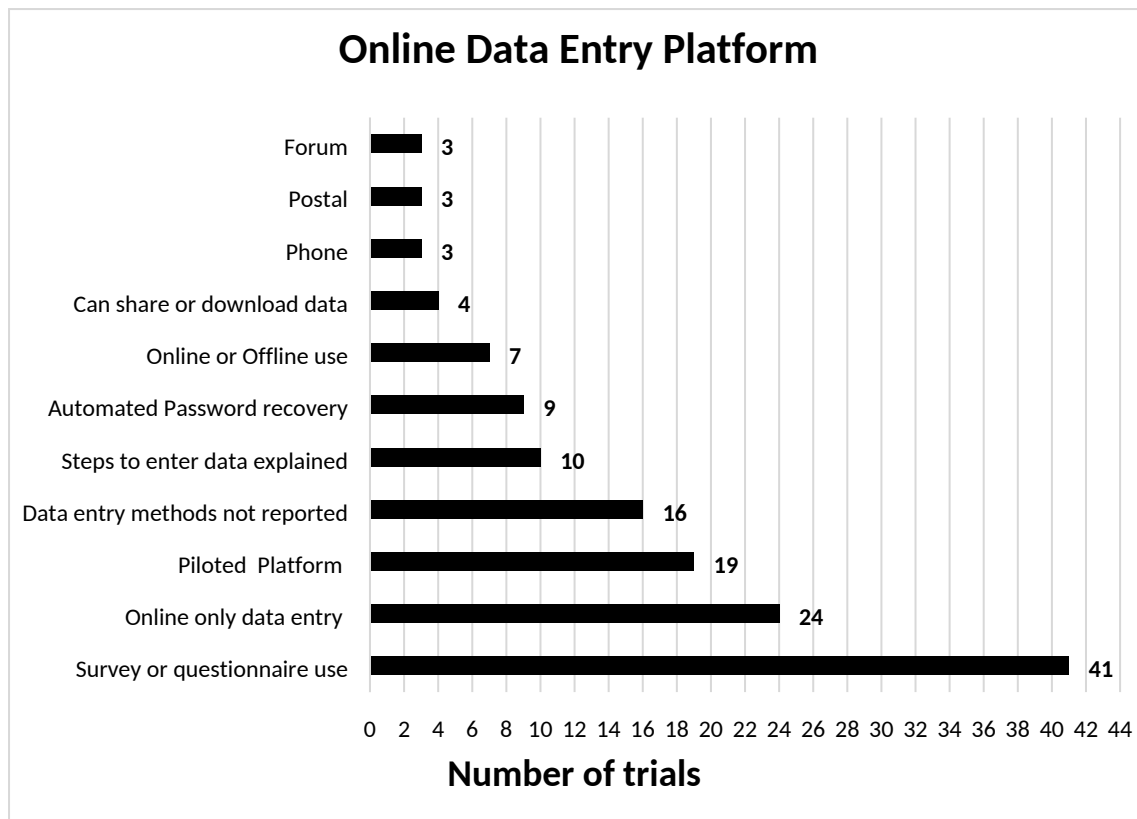


Figure-6 Platform use and available data entry options

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).

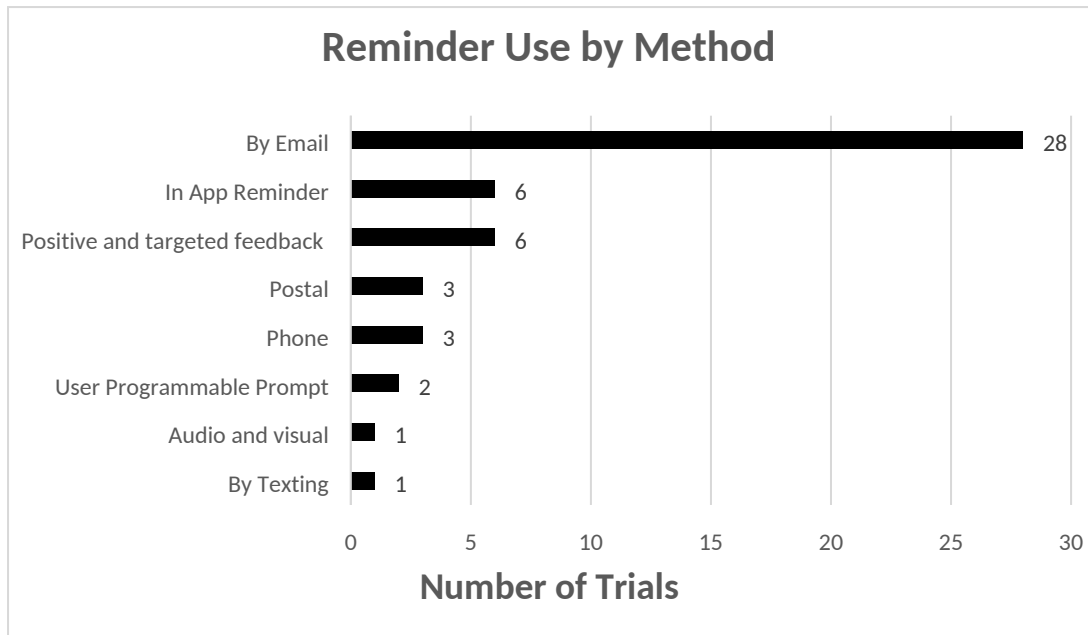


Figure-7 Reminder vehicles used for participants

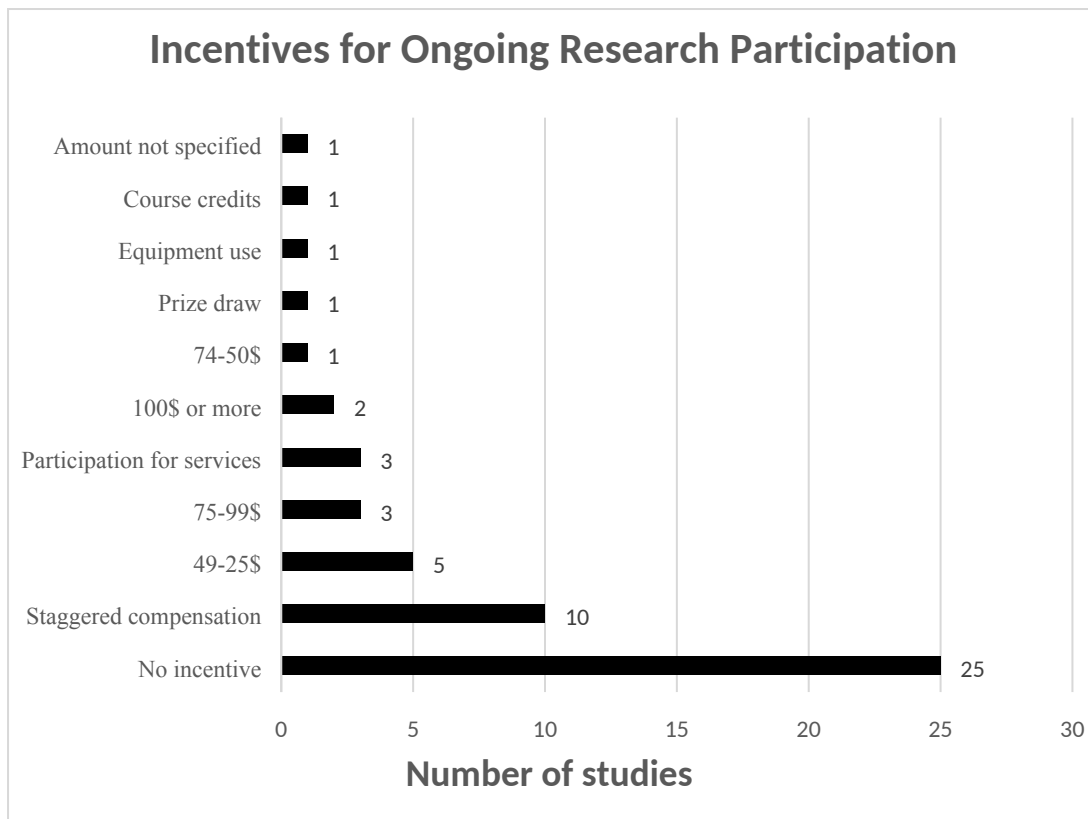


Figure-8 Incentive use by trial

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.

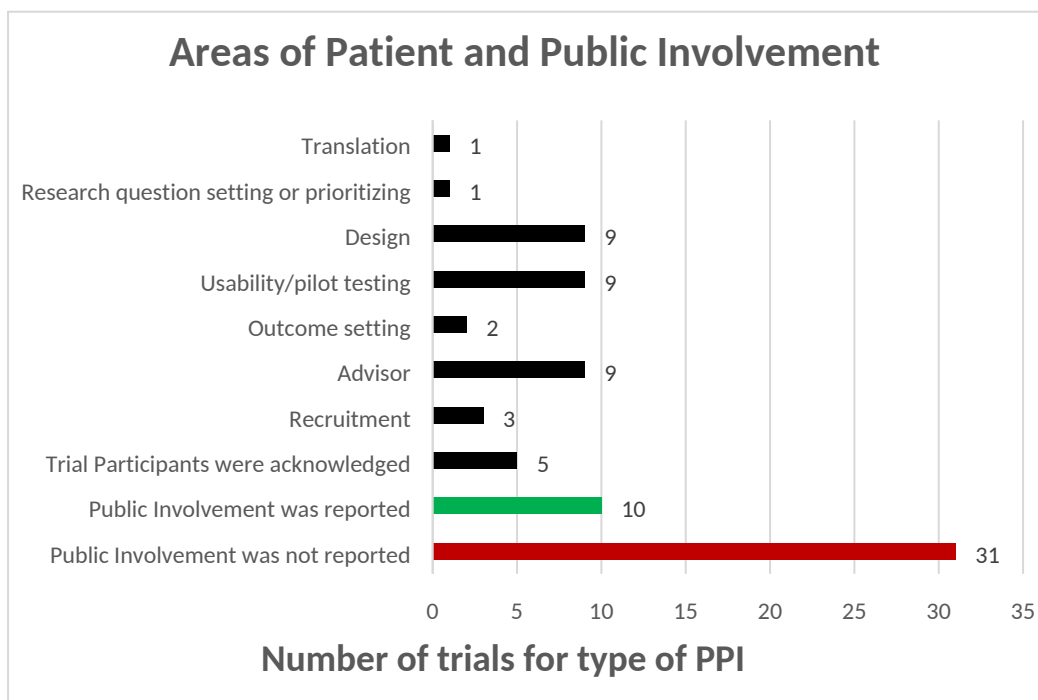


Figure-9 Public and Patient involvement

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

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1262
1263 interested in usability rather than only study quality and wanted to test durability of the
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1265 resources offered and advocated for public access to trialed products. They were clear about
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1267 removing jargon and adding a glossary which they assisted in building. They expressed
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1269 interest in enabling cross-device and operating system platforms where data could be entered
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1271 online or offline. Volunteers are now working with us on a dissemination plan to share the
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1273 findings of this study with patients, clinicians, the public, and researchers. Software
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1275 developers from RAYYAN(10) and Mendeley(11) contributed to the research by
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1277 customizing their products for use with citizen researchers.
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1281 **Discussion**

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1283 The findings point to opportunities for the use of a multi-faceted emergent technology with
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1285 global reach for divergent cultures and the potential to provide increased access to clinical
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1287 trials for people in remote areas or with mobility challenges(60). This could prove more
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1289 economical than running clinical trials across multiple physical sites(61). As anticipated,
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1291 online self-management trials face challenges shared with face-to-face trials in terms of
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1293 validity, data security, viable methods and the challenge of providing valid self-reported
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1295 outcomes and the influence of media reporting(62) but some of these may be greater for
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1297 online trials where there are no face-to-face opportunities to assess validity.
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1301 ***Challenges for Online trials***

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1303 The CASP appraisal identified only (n=1/41) trials as low quality. The GRADE scores were
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1305 low in areas that online trial researchers may be powerless to change, such as the use of self-
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1307 reported outcomes. In addition, as people might be randomized before they know the full
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1309 conditions of the trial, they are more prone to drop out, leading to high attrition if participants
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1311 sign up on impulse and decide later to withdraw. In a face-to-face trial, participants will meet
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1313 people working on the trial and may develop loyalties before making a commitment to the
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1323 trial. Barriers to replicability and progress were identified due to the lack of clear reporting of
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1325 the setting where participants engaged with the intervention. This could be overcome by the
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1327 inclusion of information on dashboard design, software used in the intervention and online
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1329 materials used to train, test and assess participants. The technology across devices may be too
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1331 recent, costly to develop, or not sufficiently stable for widespread adoption. The trial sample
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1333 was published from 2002-15 and many studies in the sample were designed several years
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1335 before this, in a time when computers were the primary gateway to the internet.
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1340 ***Limitations of Waitlist controls***

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1342 Behavioral interventions and waitlist controls were combined in (n=17/41 trials. The use of a
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1344 comparative intervention in a parallel design may produce more reliable results because the
1345
1346 use of a waitlist control design might artificially inflate intervention effect estimates(63). The
1347
1348 mechanism for this inflation may be the participant's determination to comply so they will not
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1350 miss out on the “real” intervention(64). Compliance and intervention engagement per session
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1352 and over time were not systematically reported. This was most obvious in the CONSORT
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1354 flow diagrams(15), where higher adherence was common in waitlist control groups.
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1359 ***Dissemination and supplementary materials***

1360
1361 Even when the main report of a trial is not published open access, free-to-view dissemination
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1363 of the findings can still take place through blogs, social media, conference presentations and
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1365 teaching sessions. Dissemination strategies are not addressed within reporting guidelines or
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1367 protocol templates leaving authors with little guidance about whether to report dissemination
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1369 other than when it is required for funding bids.
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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

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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

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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

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1443 the general population of this type of trial, as our findings are similar to those reported by
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1445 others(71,72). Our analysis was dependent on what authors reported, which may differ from
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1447 what they did and there may be additional relevant information stored in inaccessible
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1449 formats, contained in related papers, or unreported. However, the analyses reflects the
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1451 information that is readily accessible to users of these trials and, therefore, is valid as a
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1453 description of what can be easily found by potential users of online randomized trials.
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1456 1457 **Future directions and conclusions**

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1459 The SMOOTH (Self-Management of Open Online Trials in Health) analysis points to the
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1461 value of good methods in trial conduct including those involving patients and the public in
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1463 trial design be introduced as early as the protocol planning stage. As for trials generally, there
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1465 is considerable room for improvements in reporting(73). While we recognize that online trials
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1467 are still an emergent field, careful application of new findings for best research practice could
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1469 improve the quality of online trials.
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1473 Reporting ways to improve interventions or trial design is helpful in online trials, but this was
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1475 rarely discussed in the articles even though authors delivered interventions like Cognitive
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1477 Behavioral Therapy repeatedly across conditions and populations with minimal difference in
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1479 effect(74,75). Online trials could benefit from applying methods research within the context
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1481 of a functioning trial such as in the use of core outcome sets as highlighted by the
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1483 COMET(76) initiative and the use of embedded methodology research in the form of a study
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1485 within a trial (SWAT)(77). Trial investigators could improve the uptake of their interventions
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1487 by preparing and implementing dissemination plans and partnering with patients to improve
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1489 access, usability, and quality.
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1503 Following the sporadic use of reporting guideline usage in online trials, we propose the
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1505 development and implementation of an online reusable protocol. This could assist authors by
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1507 suggesting elements to include from the most appropriate reporting guidelines and by
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1509 providing a standardized structure to include data privacy wording, a data management plan,
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1511 interactive reusable consent, adding patient and public involvement content and could include
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1513 a checklist to verify what to report when building an online trial.
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Declarations

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1569 those who commented in the protocol to improve it, edited the document, or provided other
1570 help including those who helped locate relevant research but did not wish to join the team as
1571 researchers or preferred to not to be named.
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Contributions of authors

1578 All authors have fulfilled the ICJME requirements for authorship.
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Declarations of interest

1583 None of the authors have any personal, professional or financial conflict of interests to
1584 declare.
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Differences between protocol and review

1589 The preliminary protocol was amended following public feedback and the input was
1590 incorporated into the data extraction. The impact of the online research was not reported and
1591 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.