

Self-Management Open Online Trials in Health (SMOOTH)

Methods and Public Involvement Survey of Corresponding Authors of Existing Online Trials

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ABSTRACT

BACKGROUND

The Self-Management Open Online Trials in Health (SMOOTH) survey reports methods as well as researcher preferences in online trials and explores to what extent public and participant involvement in online trials occurs. This survey queried researchers' experience in online trials and their perceived value of public and patient research involvement. The preparation, consideration, and publication of research involvement require the use of resources by the authors. The survey explores whether authors consider resources to be sufficient or useful to improve online trials about self-management of health.

OBJECTIVE

To identify the present state of public research involvement in online trials concerning health self-management and to explore the needs of researchers when contemplating the building and writing up an online trials protocol.

METHODS

The ORCID database of online trials was used to survey corresponding authors concerning trial methods and preferences including the frequency, format, and quality of citizen involvement in online trials about health self-management.

RESULTS

Blended trials were reported as online trials. Remote recruitment and communications were less common than local recruitment even when participants signed up online. Research volunteers helped more with recruitment and as advisors than with trial design, analysis, or outcome setting. Forty-seven percent of Corresponding authors report that an online trial was the best way of answering their research question

CONCLUSIONS

Detailed reporting of online methods and volunteer researcher involvement was hindered by role confusion between research volunteers and trial participants. Respondents were responsive to the development of protocol and reporting suggestions but were not in favor of adopting complex new frameworks that require extensive time, training, space, and funding.

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Methods and Public Involvement Survey of Corresponding Authors of Existing Online Trials

BACKGROUND

The use of participatory research for public involvement and self-management methods in online clinical trials brings unique methodological challenges and benefits(1). The authors first conducted a systematic overview of public and patient involvement in trials design and reported on the quality of methods used and the ways PPI was reported in the literature(2). This research was followed by *SMOOTH: Self-Management Open Online Trials in Health: An Analysis of Existing Online Trials*[\[1\]](#) using *The Online Randomized Controlled Trials of Health Information Database (ORCHID)*(3). The overview and the analysis offer rich insights into ways to improve online trial methods and suggested successful ways to engage members of the public and patients as research volunteers however areas that could illuminate author preferences were unreported.

It has been reported that research volunteers add value to the research and can reduce collateral expenses in the design and the running of trials(4). There are, however, many gaps in reporting on methods and public involvement in clinical trial design (5) [\[BMJ PI reporting in review\]](#). Mandatory declarations and explanations of the methods used for public involvement were commonly expected by funding bodies and dutifully supplied by researchers and yet the peer-reviewed record of this involvement is sparse(6). This motivated the authors to initiate a survey with corresponding authors of online trials in order to search out answers to these areas that were underreported and to explore ways that this situation might be remedied. Respondents were invited to comment on the usefulness of qualities to include when designing and reporting on a participatory online trial. We report researcher input and choices and discuss the implications.

METHODS

The research was reviewed by and received ethics clearance through, the University of Oxford Central University Research Ethics Committee MS-IDREC-C1-2013-174.

Sampling

The sample was a convenience sample from studies in the ORCHID Database. Respondents were authors who are principal investigators who published online trials of health self-management.

Questionnaire Administration

This was a two-part survey. Part-1 reports author's insights and preferences about online trial methods and Part-2 explored areas of public and patient participation in trials. The survey was administered online without geographical restrictions and used the validated Survey Monkey software to collect and store responses in a data secure setting.

Survey Data Entry

This study used CHERRIES(7) reporting guidelines as a check for good practice in administering surveys. Survey items were managed with JavaScript programming for consistency and completion checks before the questionnaire is submitted. For instance, a question missed will be highlighted so the person has the opportunity to complete that question. Unique identifiers stop participants from filling in the survey more than once.

Data Security

The survey platform met ethical requirements of the institutional review board and the data protection act. All survey data were treated confidentially and only the research team had access to the anonymized responses. The maintenance of confidentiality of information is subject to normal legal requirements. Responses will only be presented in aggregate form; no individuals will be named or identifiable in any reports. Any identifiable information that is obtained in connection with this study will remain confidential.

Informed consent

Participants were emailed an information sheet outlining the reasons for the survey, how the data will be stored, used and disseminated. They were informed the survey will take less than 15 minutes of their time. Clicking on the email invitations and completing the survey online was used to indicate a participant's consent. Responses to queries were answered within two working days.

Development and pre-testing

The survey was hosted on Survey Monkey which is a validated and secure online survey site that meets the standards for the data protection legislation in the UK. The survey was developed by the researchers. The survey was piloted with 8 volunteers to increase accessibility, usability and to reduce ambiguous questions and the survey was amended according to volunteer feedback.

Adaptive questioning and Respondent Burden

Adaptive questioning where certain items, or only conditionally displayed based on responses to other items) was used to reduce the number and complexity of the questions. Questions were distributed over multiple pages with a progress bar so respondents could see their progress. Completion rates are noted to be higher when the burden on the participant is low.

Completeness check

Automated consistency or completeness checks are managed by the software before the questionnaire. All items provide a non-response option such as "not applicable" or "rather not say", "I don't know" or "I cannot remember" or "other" so participants will not have difficulty completing due to being unable to answer a survey question. No question responses were mandatory and respondents could choose to exit the survey or skip any questions they chose not to answer.

Analysis

Descriptive statistics and qualitative narratives were used to address the distribution of key outcomes. The data was used to describe author response patterns and frequencies across research manuscripts,

address the descriptive research questions, and inform the statistical analysis. The weighting of items or propensity scores was not needed to adjust for a non-representative sample as the purpose of the study was descriptive and exploratory and not to validate a measurement.

Public Research Involvement

Members of the public, patients, students, researchers, editors and peer reviewers were invited to contribute to survey question formation and edit questions for readability and usefulness. They were invited to comment on the protocol as it was posted on PeerJ (8) and on social media (Facebook and Twitter). They were invited to comment on the analysis and the readability of the final document. Patients, advocates, and students peer-reviewed the research manuscripts of those who participated in the survey to give feedback to authors on their PPI upon request.

RESULTS

Sample

Among 337 corresponding authors surveyed, we received 32 (9.5%) responses.

Part One: Your experiences of running an online trial

Corresponding authors were asked to share their previous trials experience. Table-1 shows that only (n=3/31) had only worked on online trials prior to the survey, the rest had experience with other forms of trials.

Table 1 History of corresponding authors work on trials

<i>Have you ever worked on clinical trials that were not conducted online? (n=31/32)</i>	
Yes, before the online trial	20
Yes, after the online trial	13
Yes, in parallel with the online trial	9
No, I have only worked on an online trial(s)	3
I have worked on multiple trials online and person to person and there can be overlap but the trials are not always connected	3
Not applicable	3
Other (please specify)	2
No, but I worked on a direct person to person clinical trial with others	1

When corresponding authors were asked, “Are you working on or have you applied for funding for a trial that includes public involvement?” (n=10/32) replied yes, (n=8/32) no. Only (n=4/32) had done PPI in the trial they were asked about but (n=14/32) engaged 1-3 person in PPI and (n=12/32) reported more than 4 individuals per project were added for PPI. When asked if an online trial was the best way to answer the research question (n=14/32 or 47%) agreed it was with (n=4/32) adding that their trial was blended rather than solely online.

Corresponding authors were asked if patients or members of the public were involved in the online trial as members of the research team other than as research participants and 11/32 said yes but 16/32

replied no. The open responses indicated some struggled with this question and other Corresponding authors felt PPI in the design was not needed other than through feedback from participants or as expert consultants on the patient condition. There were sentiments expressed that formal priority and outcome setting and workshops for research redesign added to cost and resources needed in unmanageable ways without increasing value for the study.

“Prior experiences of users have played a large part in intervention design, but not with any formal input. In my view, this is a far more effective means. It also includes pilot testing and modifications based on feedback”.

“Engagement is critical to proving useful feedback, in my view, much of the participant engagement stuff is pseudo engagement”.

“Our methodological trials did not include patients or members of the public”

Two Corresponding authors stressed the need for recognizing and capturing successful patterns for each trial and stated a template approach concerned them as they felt it might take away from the importance of treating each trial as an individual. They learned through failures that expecting what worked in one trial to work in another even if it was a different population but the same intervention was not wise and urged researchers to look at trials like human relationships where there are some common rules for engagement but individual attention and adaptation is required.

Part-2: Who Included PPI in the Trial

Corresponding authors whose trials included PPI were (n=16/32)

Recruiting

Recruiting methods included an online screening questionnaire (n=4/16), telephone (n=4/16) or face to face meeting with the trial team and then signing up online (n=5/16) and (n=3/16) responded other.

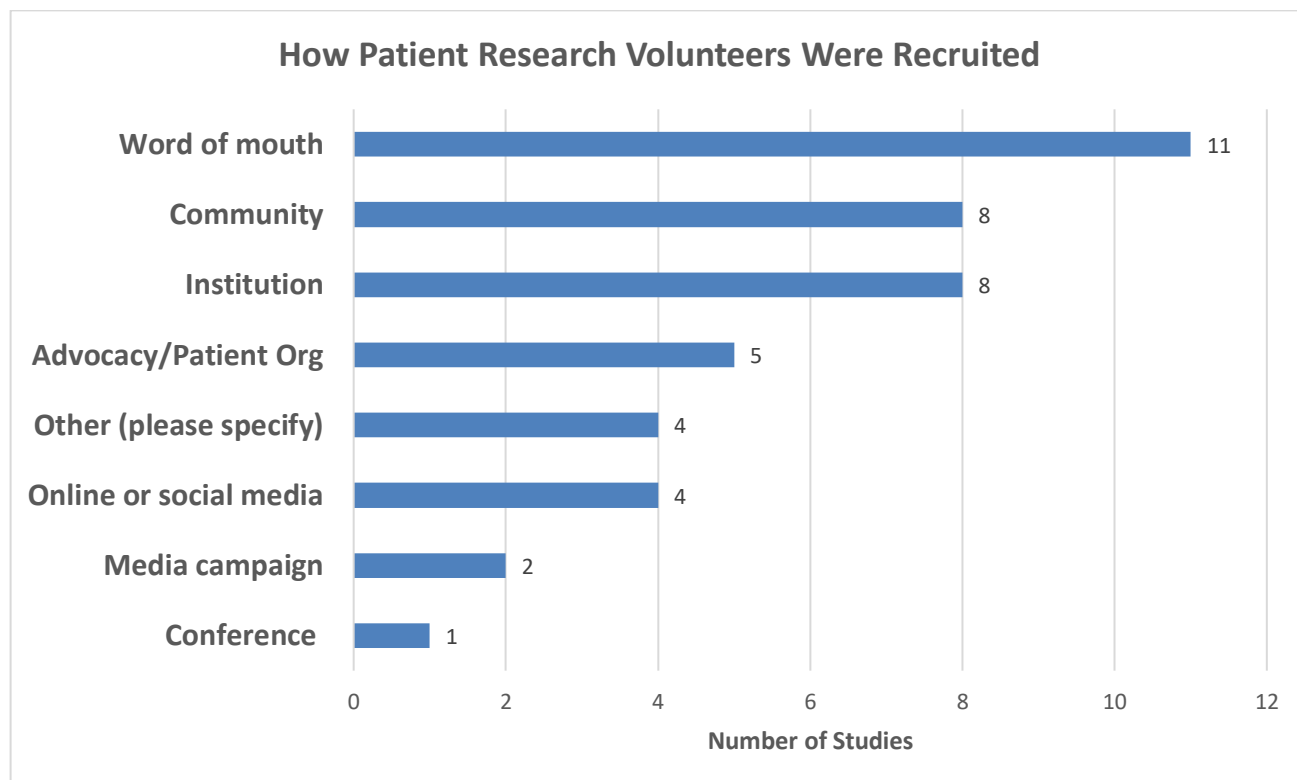


Figure 1 Methods by which patient research volunteers were recruited

Participants were less likely to be recruited by remotely even though they would be enrolled in an online or blended trial (n=31) versus remote recruitment via media campaigns or social media (n=8).

For ways patients were recruited see figure-1

Where PPI Occurs in the Research Process

PPI was more likely to occur in designing recruitment strategies (n=8/16), and as advisory board members (n=7/16) or in assessing the burden of the intervention on participants (n=6/16). It was least likely to be a part of the analysis (n=3/16), ethics, or grant proposals (n=3/16).

Table 2 Types of PPI used throughout a trial

At Which Stages of the Research Did PPI Occur	Number of Responses
<i>Answer Choices</i>	
The design of recruitment strategy	8
Advisory boards or steering committees	7
Assessing the burden of the intervention (where applicable)	6
Development of the research question	5
Interviewing or collecting feedback from trial participants	5
Selection and or development of outcome measures	4
Decisions for data acquisition	4
The review of patient information documents	4
Dissemination or presenting research	4
Grant writing and/or ethics applications	3
Analysis and/or interpretation of study results	3
Other (please specify)	3

Communication between researchers and volunteers

Email and in person were the most popular ways of communication (n=7/16) for both. This was followed by telephone(n=6/16). Facebook and WhatsApp were not used (figure-2).

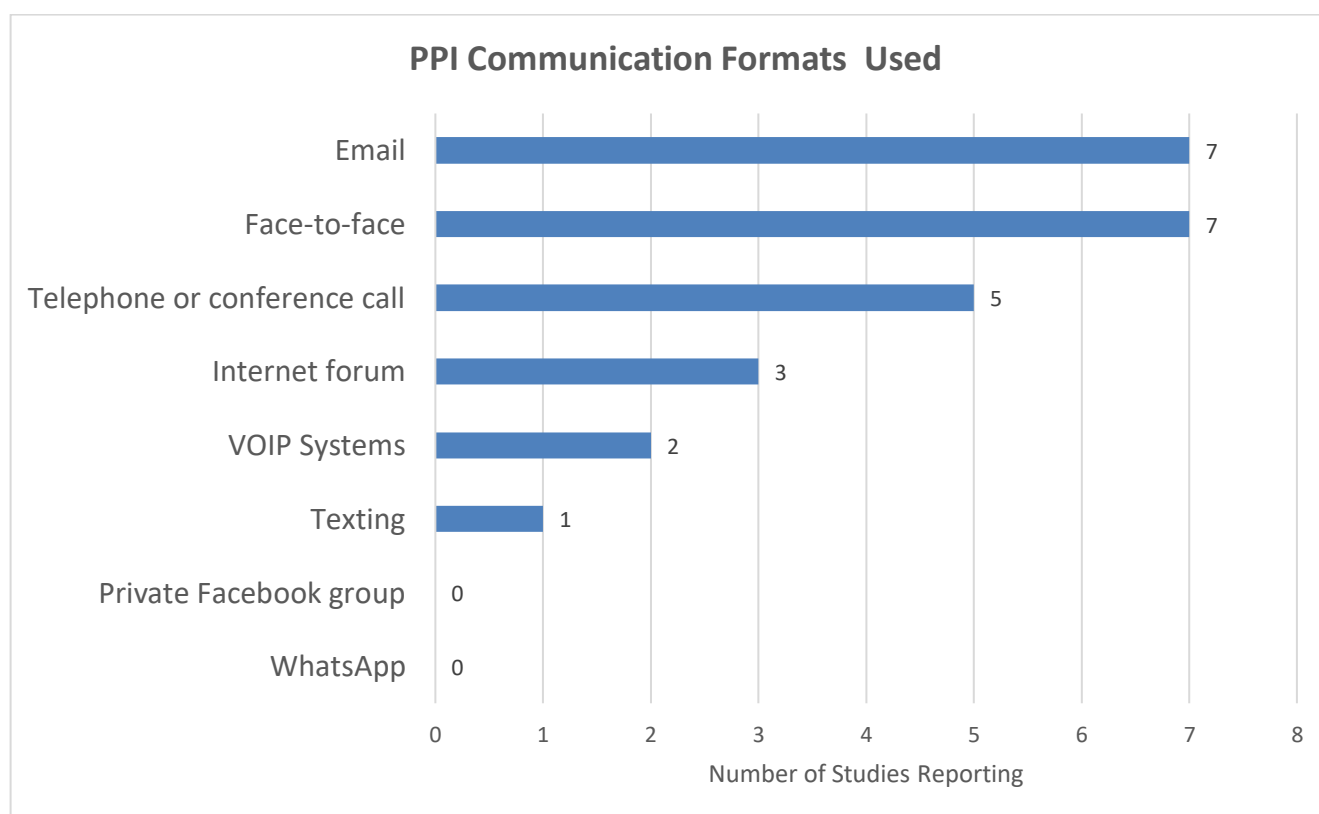


Figure 2 The ways researchers chose to communicate with PPI volunteers

How were PPI volunteers reimbursed?

In (n=4/16) trials PPI volunteers were paid in addition to expenses, in (n=5/16) the expenses were met and in (n=2/16) trials no reimbursement was offered.

PPI in writing up research and sharing the results

Although (n=7/16) Corresponding authors did not include PPI in writing the manuscripts, there was substantive involvement in other trials PPI was used in the dissemination strategy especially for the design aspect (n=6/16). Patient collaborators were acknowledged in (n=6/16) studies but this was most frequently in the acknowledgment section and not by name (Table-3).

Table 3 PPI activities and acknowledgment of PPI in writing up and dissemination plans

PPI in Manuscript Authoring, Dissemination and Acknowledgement	
PPI within the research writing process	N=# of Trials
No contributions	7
Reading drafts of the manuscript	4
Revising drafts of the manuscript	3
Writing sections of the manuscript	2
Final approval of the manuscript	4
PPI in the Dissemination Plan	N=# of Trials
Designed dissemination strategy or materials	6
PPI in Dissemination to patient groups or communities outside of the trial	4
Disseminating results to participants (peer to peer)	1
How was PPI acknowledged in the Manuscript	N=# of Trials
Acknowledged but not individually named	6
Named advocacy groups	2
Named individuals	5
It was not acknowledged	2
Where was the PPI acknowledged	N=# of Trials
Authorship	4
Contributorship Statement	4
Acknowledgement section	7
An additional paper was written to report the Public Involvement in the trial	1
Public Involvement was not acknowledged	1

Part-3 Future Plans for PPI

Additional guidance for building an online trials protocol was invited in: guidance to build the full protocol plus financial and personal conflict of interest statements. Survey reporting help was the area fewest Corresponding authors reported guidance as needed although every online trial reported a survey or questionnaire. The areas of interest can be seen in (Figure-3).

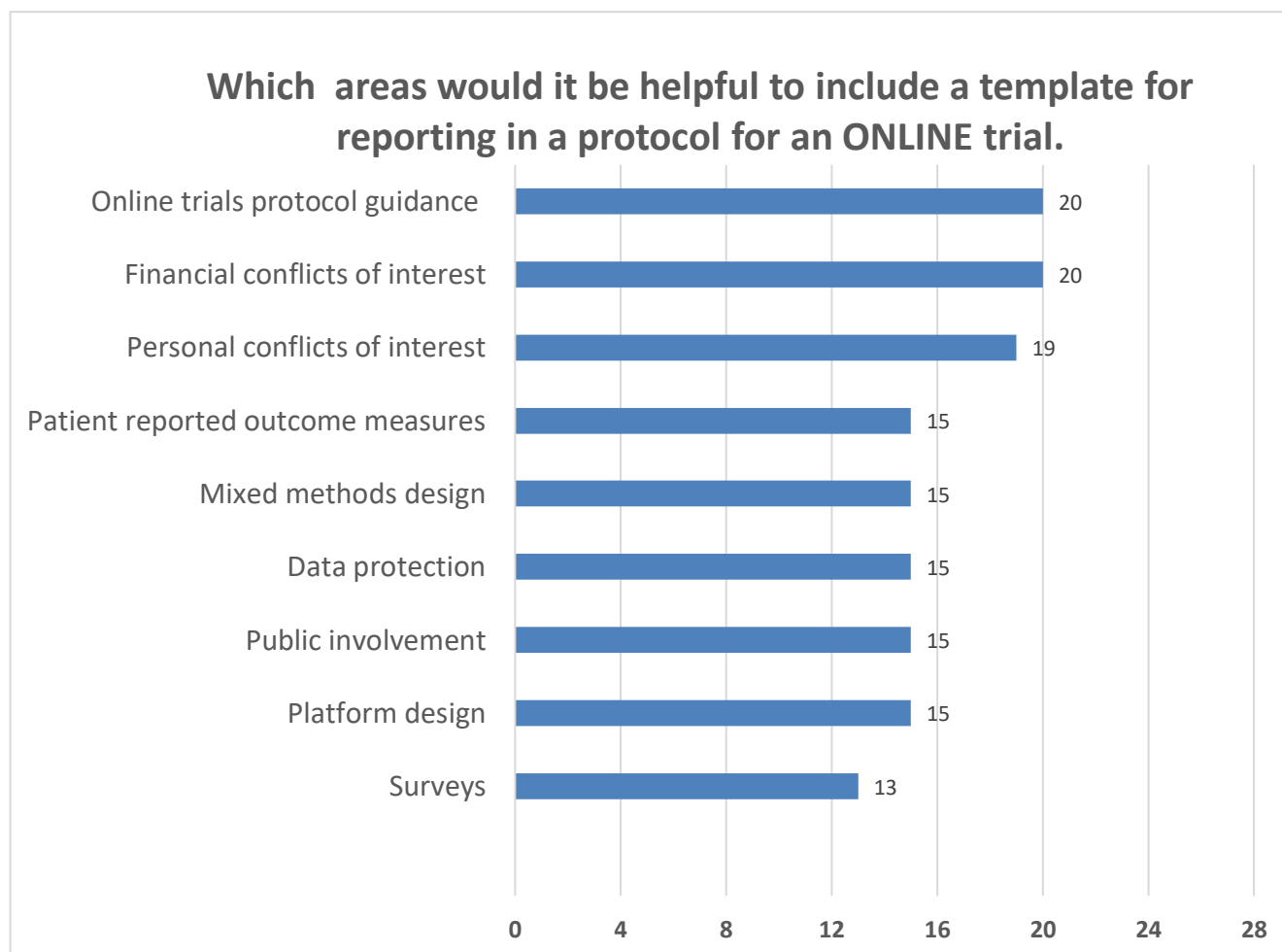


Figure 3 Results on queries for where additional reporting guidance would be helpful

Corresponding authors commented that any trial needed these areas identified and that the priority for inclusion was dependent on the research question. Only one author commented on the unique needs of an online trial and the need to adapt methods to make them viable. Others identified “*Safety considerations for a mental health trial (e.g., backup in the case of suicide ideation or intent)*”. They recommended reporting “*How the site would be sustained over time*” They also suggested “*There*

should be more standardized information on technology and exact content of protocols that are used in online trials (e.g. the flow of a participant through an online trial protocol is very different from face-to-face trials” Another point made was *“there is also great diversity between online trials - in order to be able to compare between trials we need standardized criteria/information”*.

In planning for their next trial (n=13/32) Corresponding authors would like to introduce more PPI and (n=13/32) wanted PPI to stay about the same, (n=0/32) favored no or less PPI. The comments indicated those not responding felt the term and definition used for PPI lacked clarity. When asked if a modifiable protocol template would be useful for planning a trial (n=13/32) Corresponding authors responded affirmatively, (n=5/32) did not think this would help and (n=11/32) did not know. The question *“What would better help you to report research involvement of patients and the public?”* generated several *“I am not sure”* along with other selective quotes from Corresponding authors.

Suggestions for Improvement

“Easier access to volunteers and a better response rate without having to chase people down!”

“More substantive involvement of the public with regard to the design and the research protocol and manuscript writing”.

“We make a point of in our press communications and have narrative stories with pictures of our partners”

“I think it's important to include patients in as many aspects as possible and to also think more about asking patients to create the questions of interest. I do think that we need to think about the best places to include patients, though, and let the goals of the work drive inclusion”

“PPI gives value to our research. we also learn a lot of reality about patients”.

Concerns

“Has inherent challenges, but can be meaningful”

“It can be valuable if protocol design can anticipate and exclude bias”.

“The more we can involve the public the better but it's very challenging to do so in a mutually beneficial way”

Comments for Journals and Funders

“A protocol template and journal partnership for PI materials”

“APC reimbursement from university for unfunded PPI research, better provision from funders, or a waiver from the journals”

Comments on Reporting

“There could be a reporting checklist”.

“More and more guidelines (e.g., PCORI in the US) are helping with this”

“I guess I would have to report it if it would be recommended or compulsory”

DISCUSSION

What was Found

The objective was to identify the present state of public research involvement in online trials concerning health self-management and to explore the needs of researchers when contemplating the building and writing up an online trials protocol. We found that corresponding authors did not always report person to person contact in the manuscripts as was the case with dissemination plans and PPI activity. There was confusion about roles of the participant and the patient research partner. This was a common finding in systematic reviews about PPI and undoubtedly has hindered reporting efforts(2,9,10). Authors stated their needs in terms of protocol design and what and how to report their work in terms of PPI. They suggested adequate funding, help with author processing costs and standardized methods could free up resources for PPI inclusion.

Strengths and limitations of the study

The survey presents previously unreported information and enabled the sampling from experiences, values, and preferences of Corresponding authors. The survey attracted authors from multiple countries, however, the sample was small as the number of online self-management was limited and the

authors had no pre-existing connections with the researchers. The survey may have benefitted from providing for blended (partially online trials) although spontaneous comments about blended trials were elicited by the open-ended question option.

Mandatory declarations and explanations of the methods used for public involvement were commonly expected by funding bodies and dutifully supplied by researchers, however this may not be reported in the research paper(11). The methods lack transparency when they remain unreported and this, in turn, limits the construction and adaptation of methods used as it is not accessible from trial reports. It also reduces the scope for external validation or reporting of impact(12).

Unanswered questions and future research

We could find no existing similar or larger survey that addressed the research question(s). This limits representativeness of the population, however, the field is emergent and this sample provides information that could be used in a Delphi process and to guide online trial protocol development.

CONCLUSIONS

Detailed reporting of online methods and volunteer researcher involvement was hindered by role confusion between research volunteers and trial participants. Respondents were responsive to the development of protocol and reporting suggestions but were not in favor of adopting complex new frameworks that require extensive time, training, space, and funding.

DECLARATIONS

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We would like to acknowledge the 12 volunteers who piloted this research and the additional 4 volunteers who shared valuable feedback on our preliminary methods. The volunteers, NAME THEM were community members, physicians, researchers, patients, editors, and teachers. We thank the researchers who completed the survey and the two Corresponding authors who chose to be interviewed. Their insights and perspectives were of value in increasing our understanding.

Conflict of Interest Disclosures

No authors have financial conflicts of interest to report. MC, AB, SL, and AP report involvement in online trials development and have sought or plan to seek funding for online research.

Authors' contributions

AP designed the study and drafted the questionnaires. AP extracted the samples of authors and reviewers from the ORCID database. Anne Brice built the database with support from AP and AB. AP managed the surveys on SurveyMonkey and acquired the volunteers. AP analyzed the anonymised data with feedback from other authors. AP drafted the manuscript. All authors interpreted the results and contributed to the writing of this manuscript.

Dissemination

All Corresponding authors could opt in to receive a link to the full paper. The publication will be followed by a blog and all participants will receive a link to this content. The results will be used in teaching sessions and presented at conferences. The public will be invited to comment on the results through social media.

Data sharing

De-identified Data available on reasonable request.

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