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ARTICLE

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 in terms 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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Introduction

The use of participatory research for public involvement and self-management methods in online clinical trials brings unique methodological challenges and benefits [1]. We first conducted a systematic overview of public and patient involvement (PPI) 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* 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 claimed that research volunteers add value to research projects 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]. Mandatory declarations and explanations of the methods used for public involvement are commonly expected by funding bodies and dutifully supplied by researchers and yet the peer-reviewed record of this involvement is sparse [6]. This observation motivated us to initiate a survey with corresponding authors of online trials in order to search for answers to these areas of PPI that were under-reported and to explore the ways in which 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. In the present paper we report researcher input and choices and discuss the implications of the results.

Methods

Ethical approval

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 2-part survey. Part-1 reports the 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 employed 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 prevent participants from filling in the survey more than once.

Data Security

The survey platform met the 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 are only presented in aggregate form and no individuals are named or identifiable in any reports. Any identifiable information that is obtained in connection with this study remains 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 that 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 2 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 visualize their progress. Completion rates are noted to be higher when the burden on the participant is low.

Completeness check

Automated consistency or completeness checks were 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 did 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 were 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 provide feedback to authors on their PPI upon request.

Results

Sample

Among 337 corresponding authors invited to participate, 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 3 participants (n=3/31) had worked on online trials prior to being a principal investigator for an online trial, the rest had experience with other forms of trials.

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

Table 1 History of corresponding authors work on trials

Have you ever worked on clinical trials that were not conducted online? (n=31/32)	
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

Two respondents stressed the value of recognizing and capturing successful patterns, methods, frameworks and approaches for running trials, but they stated a one size fits all approach leads to failure in research. They reported expecting what worked in one population to work in another was not wise and urged researchers to look at trials on human relationships where strategies and methods are more successful when they are tailored to fit the purpose.

## Part-2: Who Included PPI in the Trial?

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

Method of recruitment

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.

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

Figure 1 Methods by which patient research volunteers were recruited
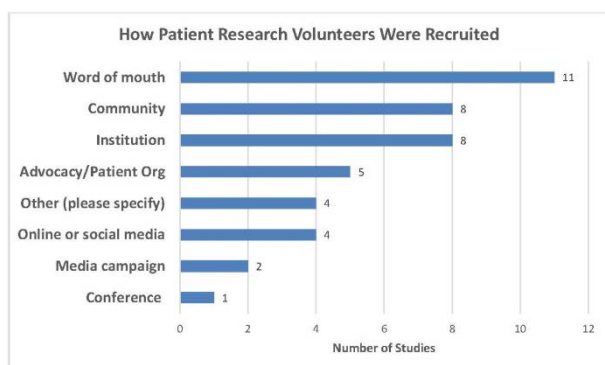
campaigns or social media (n=8). For ways patients were recruited see Figure 1.

Where PPI Occurs in the Research Process

PPI was more likely to occur in designing recruitment strategies (n=8/16) inviting partners 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
Answer Choices	
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 researchers and

volunteers. 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
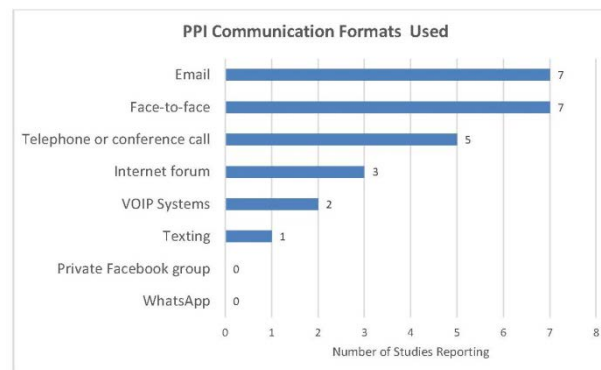
Reimbursement of PPI volunteers

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

PPI in writing up research and sharing the results

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

Part-3 Future Plans for PPI

Additional guidance for building an online trials protocol was invited in guidance formulated 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.
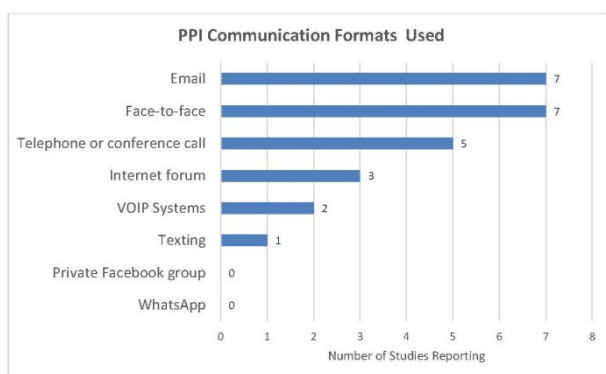
Priorities

Corresponding authors commented that any trial needed these areas to be 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*".

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

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

PPI Communication Formats Used

Format	Number of Studies Reporting
Email	7
Face-to-face	7
Telephone or conference call	5
Internet forum	3
VOIP Systems	2
Texting	1
Private Facebook group	0
WhatsApp	0

Planning

In planning for their next trial 13 (n=13/32) corresponding authors would like to introduce more PPI and 13 (n=13/32) wanted PPI to stay about the same, with none (n=0/32) favoring no or less PPI. The comments indicated that those not responding had felt that the term and definition employed 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, 5 (n=5/32) did not think this would help and 11 (n=11/32) did not know. The question *"What would better help you to report research involvement of patients and the public?"* generated several responses such as *"I am not sure"* along with other selective quotes from corresponding authors.

Suggestions for Improvement

In terms of suggestions for improvement, the following results were obtained:

"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 patents 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

In terms of prominent concerns, the following results were obtained:

"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

In terms of comments for journals and funders, the following results were obtained:

"A protocol template and journal partnership for PPI materials."

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

Comments on Reporting

In terms of comments on reporting, the following results were obtained:

"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

The objective of the present paper was to identify the current state of PPI in online trials concerning health self-management and to explore the needs of researchers when contemplating the building and writing up of an online trials protocol. This was complicated in that corresponding authors may not include volunteers or lay research partners by name. This raises wider questions about how personal unintentional conflicts of interest in PPI volunteers or intentional influence by industry funded advocacy and how this may influence reporting [9]. Lay researchers may belong to multiple advocacy organisations and if the lay volunteers are not named, there will be no conflict of interest statements required from them. Some authors report writing dissemination plans and PPI activity into funding protocols, but state there were no requirements for reporting them. There was confusion about how roles of the participant and the patient research partner differ. This was indeed a common finding in systematic reviews about PPI and undoubtedly has hindered reporting efforts [2,10,11]. Authors state their concerns and need for support and welcomed reporting guidelines in terms of protocol design and ways to concisely report their work in terms of PPI. They suggested adequate funding, help with author processing costs and standardized methods could improve quality and free up resources for PPI inclusion in their research.

One purpose of the SMOOTH survey was to capture knowledge the SMOOTH Analysis may have missed as it assessed only the trial reports and to increase knowledge by including the full sample of these trials. The quantitative information remained constant, however open comments reveal corresponding authors struggle with public involvement methods and the writing of protocols for these trials. The resistance and power struggles cited by other publications [12] was not evident in this sample. Respondents readily shared their willingness to engage but report their uncertainty about how to start. Some share the survey questions and got them thinking about how they could add patient involvement for future work. All respondents reported PPI as relevant to online trials of self-management interventions.

The survey presents previously unreported information from a small sample of corresponding authors of online trials for self-management interventions and enabled sampling of experiences, values and preferences from the corresponding authors. More than half the sample was unopened (n=190/51.6%) and only (n=53/14.4%) clicked on any link. It may be that the survey was blocked by institutional spam filters. Of the 53 authors who did click

on a link 32 of these submitted responses and an additional 2 authors preferred to be interviewed for a total of 64%. Given that authors ran full trials online, internet survey technology was unlikely to present a personal barrier. The absence of incentives, lack of familiarity with the topic of survey and no other connection points with the research team could contribute to lower response rates [13]. The survey may have benefitted from providing more detail on how PPI is defined and by providing for blended (partially online trials) although spontaneous comments about blended trials were elicited by open-ended questions.

Mandatory PPI 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 [6]. More work will need to be done to address the wider questions of how personal unintentional conflicts of interest in PPI volunteers may influence reporting and how this can be mitigated. Methods are not transparent if they remain unreported and this, in turn, limits the construction and adaptation of successful strategies as they are not accessible from trial reports. It also reduces the scope for external validation or reporting of impact [5].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. Studies within a trial or survey (SWATs) could be used to test what works in to improve the methods used in future research.

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.

Acknowledgements and Conflicts of Interest

conflicts of interest to report. Dr. Amy Price is the patient editor for research and evaluation at the *British Medical Journal*.

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