

## **Developing and piloting a template communication to improve information and help elicit preferences in people who stop trial participation early**

### **Abstract**

Good quality information for participants about a study and their involvement in it can benefit all participants as they progress through a study. Participants who stop taking part before their participation was originally due to end may have specific information needs, particularly as stopping participation early can be a difficult experience for some. There is limited existing guidance about how to provide information to this group, and it is possible that sensitivities around participants' right to withdraw consent may make researchers reluctant to provide it. Providing good quality information may improve participants' experiences taking part in research and therefore increase their willingness to take part in future. It may also ensure participants are informed about, and fully involved in, any decisions that affect their level of involvement in the study. This may lead to more participants agreeing to remain involved but with reduced commitment (where possible within a study's design), continuing to contribute study outcome data in the process.

We conducted a comprehensive literature review to identify relevant existing evidence, and used the results to collate a list of information topics that might be relevant to communicate to participants who stop taking part early. We then convened two groups of patient contributors. A 'development group' took part (with representatives from other relevant stakeholder groups) in a series of structured discussion group meetings to produce a template for researchers to use to provide information to research participants who stop taking part early. A separate, larger 'review group' of patients provided feedback on the draft resource.

The literature review identified 413 relevant reports. From these we assembled a list of 94 items that could be communicated to participants who stop taking part early. The patient group members were diverse in their characteristics and experiences, and many had personal experiences of stopping research participation early. Following our discussions, the final resource is not a template but comprehensive guidance for researchers about how to provide useful information to this participant group in a sensitive way, with example text where this could be helpful.

The final guidance is publicly available online. We plan to undertake further piloting of the guidance in practice. We have also carried out statistical planning for a proposed Study Within A Trial that would evaluate the effect of providing information to participants on the availability of trial outcome data.

## Introduction

Good quality information - useful, interesting and relevant information about a study and participants' involvement in it, delivered in a timely manner and in an accessible and digestible way – can benefit research participants as they progress through a study. It can help them understand what is happening during their time taking part, keep them engaged, clarify what their choices are about their ongoing involvement and help ensure the choices they make are well informed. Inadequate information, on the other hand, may affect participants' trust and confidence in a study, or willingness to take part in future studies.

The benefits of good quality information apply equally to research participants who stop taking part in some or all aspects of a study earlier than originally planned. Participants who stop taking part early also have information needs specific to their situation. Good quality information could remind them what stopping participation means for them. It could provide support, as some evidence suggests that ending participation can be a stressful experience,<sup>1</sup> with participants can feeling unsupported or even 'abandoned'.<sup>2</sup>

While there is existing guidance about providing information to participants at the end of a study (for example from the Health Research Authority<sup>3</sup>) there is limited guidance specifically about providing information to participants when they stop their participation early. Participants who stop taking part early may be less likely than other participants to receive information they want or need because of sensitivities around whether or not it is appropriate for researchers to contact participants who have withdrawn their consent.

As well as being beneficial for research participants, ensuring participants get good quality information might also be helpful for research. On a general level, it may improve patients' experiences of taking part in research, and may increase their willingness to take part in research in future.

Providing good information might also benefit individual studies. The currently prevalent view of 'withdrawal' as a binary phenomenon (i.e. participants have either given consent to participate, or they have withdrawn it and all participation has stopped), as well as demonstrated inadequacies in information given to potential participants about study retention and consent withdrawal,<sup>4,5</sup> suggest that participants may not often be well-informed about reducing or changing their participation.

Substantial anecdotal evidence from collaborators on the PerSEVERE project<sup>6</sup> within the UK CRC Registered Clinical Trials Unit Network suggests that participants are also not always as involved as they should be in decisions about how their participation should change. Instead, a participant may make a broad statement about wanting to stop study participation or study-specific clinic visits, and their wishes are inferred by research staff without further discussion.

Evidence about why some participants stop participating early suggests it is often to do with difficulties meeting the commitment required by study participation, rather than because they no longer support the study and its aims.<sup>7-9</sup> This might indicate that many participants, if they were given the chance to make an informed decision about exactly how their participation should change (assisted by good quality information), would still be willing to

continue making some sort of contribution to the study but with reduced commitment. This might mean study outcome data could still be collected, for example through routine healthcare data sources.

The aim of this project was to develop and pilot a template for a written communication (e.g. a letter, leaflet or similar), with accompanying implementation guidance, for researchers to give to research participants when they stop taking part early. This information would be given both for its own sake and also to inform participants' choices and help them to be fully involved in any decisions that are made about their study participation.

## **Methods**

We developed our main output in collaboration with two groups of patient contributors, using results of a comprehensive literature review as source material for discussions. There was additional patient input into the earlier stages of the project from patient contributors already working with the Clinical Trials Research Unit, University of Leeds.

### **Literature review**

We conducted a comprehensive literature review to find reports addressing broad research questions:

- What information should research participants get around the time they finish taking part in a research study?
- Of the information topics/items identified, which are specific to participants who end participation early?
- How does each information topic/item need to be changed or made more specific for participants who end participation early?
- What is the best method of getting this information to participants?

We broadly followed scoping review methodology.<sup>10</sup> Full details of the search methodology will be published in the planned peer-reviewed article describing this work.

We developed a search strategy by devising search terms across a range of relevant concepts, then combining these groups of terms in different ways. Searches were carried out in Pubmed, Ovid Medline and Embase, and CINAHL.

No limitations were built into the search strategy regarding date of publication, study type, study setting or publication language. Search results were excluded if they did not contain relevant information or did not relate to the relevant setting.

We carried out Google searches based on the same terminology lists in order to find materials not published in peer-reviewed journals. We added to the final results list reports that were already known, or that were identified ad hoc during the literature review period, or that

were found through reference and citation searching on any directly relevant reports we identified.

We collected data from all relevant reports using a pre-specified data collection form. This included to record which topics each report indicated should be provided to research participants at the end of their time taking part in a study.

### **Developing and reviewing a topic list**

We produced a draft list of topics/items using the results of the literature search and two other sources: 1) the Health Research Authority's guidance on end of study information, and 2) topics arising from the PeRSEVERE project.

The topic list was sent, with guidance about how to feed back, to interested research professionals and patient contributors involved in the PeRSEVERE project, as well as research professionals linked to the Trial Methodology Research Partnership retention and communications subgroups.

### **Identifying patients and other project contributors**

We sought patient contributors to form two separate groups: a 'development group' to work in detail on the template communication and guidance, and a 'review group' to conduct a separate review of the template and guidance once they had been drafted. We developed a Patient and Public Involvement plan, aiming to find a diverse group of contributors who, if possible, had experience of stopping research participation early. Patient contributors helped develop the plan and select the final membership of the two groups.

We were also interested to get input from research nurses to inform the project, as they represent the group that would often be involved in delivering the information to research participants. An invitation to contribute to the project was disseminated to several research nurses already known to the project lead, and via Twitter with encouragement for the message to be shared.

### **Developing the resource**

The final resource was developed principally through six structured discussion group meetings. These were led and facilitated by the project lead, and attended by the development group of patients (who formed the majority of meeting attendees), by other researchers from the lead clinical trials unit and sometimes by interested research nurses. The topic list mentioned above served as a starting point for resource development. The meetings followed a rough, pre-defined plan, but included flexibility to deal with unexpected challenges as they arose, and so that the patients in the group could help shape the final project output. Decisions were made via informal consensus following discussion and debate.

The review group was invited to answer a few specific questions about quality, suitability and appropriateness of the resource, and to feed back on any other aspects they might want to.

## **Results and Conclusion**

### **Literature review and topic list development**

The literature review ultimately identified 413 relevant results from all sources. The results of the review suggested that the needs of participants who stop taking part early have not been considered enough in previous, relevant work. For example, we found 155 reports recommending that participants receive information about how and when they can receive the results of studies they took part in. Only around 10% of these were clear (or implied) that participants who stopped early should also get this information. A few of the remainder said that these participants had been (or should be) actively excluded from this information sharing, without giving a clear justification.

The eventual topic list contained 94 items that could be communicated to research participants who stop taking part early. We will make the full topic list available with a future peer-reviewed publication as we feel it has wider value and further potential applications in participant communications.

The expert consultation review was carried out by 17 research professionals and 4 patient contributors, and led to useful refinement of the draft topic list.

### **Recruiting patient and professional volunteers**

Following 31 expressions of interest, we successfully convened a development group (seven patients) and a review group (15 patients) with diverse characteristics and experiences. Around half of the development group had personal experience of stopping research participation early.

We involved eight research nurses in the project, six of whom were identified via Twitter. All of the research nurses inputted into the project in some way, e.g. at least through a short discussion with the project lead about their experiences working with research participants during the process of stopping their participation early. Use of Twitter to get input from research professionals in the NHS may be a useful idea for other methodological projects.

### **Developing the researcher resource**

The development group meetings successfully led to the development of a resource to guide researchers in providing written information to participants who stop taking part early. Although the original plan had been to develop a template communication for researchers to

use, it was decided early on that the variation in types of research study and research participant potentially in scope of the work might make a single template difficult to achieve. Instead, it was agreed to develop guidance with examples, and encourage individual research teams to develop their own templates using these.

The guidance included background to the project and its aims, a suggested process to follow when developing patient-facing communications for this group (we suggest this has lasting value in that it could be applied to other sorts of patient-facing communications) and guidance on the sorts of topics to communicate, how to communicate them, and some example text where this could be useful.

The guidance also contains novel recommendations on what to include in pre-study information (i.e. for patients considering taking part in a research study). We suggest these recommendations could start to address the deficiencies in pre-study information mentioned in the Introduction, above.

The draft guidance was reviewed by 14 out of 15 of the designated 'review group' members. They were generally supportive of the aims of the work and did not overall recommend significant alterations to the guidance, including the example wording. However, there was a strong sense that the existing guidance was lengthy and hard to navigate. In response to this, it was agreed to present the guidance primarily in an online format, giving users the chance to engage with it in whatever way suits them best. The full document will also be made available to those who might want it, along with other downloadable resources.

The final, online guidance is publicly available at <https://ctr.u.leeds.ac.uk/communication-with-research-participants-who-stop-participating-early/>. We will continue to make amendments to this in future, and make additional resources available for download as we develop them.

### **Piloting and evaluation**

We have begun to try out the guidance in an ongoing clinical trial run through the Clinical Trials Research Unit, University of Leeds. The aims of this piloting are to establish a) if researchers not involved in developing the guidance can follow it, b) whether ethics committees will approve the use of such participant communications, and c) how the proposed communications will be received by clinical trial sites and patients (if any such feedback is available).

We aim to collect further feedback from ethics committees if possible, including in a more structured way (e.g. via a survey). Results from this evaluative work will be reported in the research outputs from this project.

## **Preparation for possible future Study Within A Trial (SWAT)**

With a view to further, more formal evaluation, we developed a broad plan for a future SWAT. This would be implemented across multiple trials, and would evaluate the effect on outcome measure availability of providing participants with a written communication (output from this project) and providing relevant training and resources to trial sites (intervention to be developed separately). This multilevel intervention lends itself to a type of factorial design referred to as “split-plot” in Design of Experiments literature. Here, separate components of a complex intervention are randomised to more than one set of recipients (in this case, the written communication is randomised to participants and the second intervention to sites, both within trials).

The broad plan includes the i) eligibility criteria for the trials, ii) outcomes to be assessed, iii) method of randomisation, iv) expected sample size, and v) primary analysis model. Following development of the site-level intervention, a detailed protocol for the SWAT will be developed based on the preparation done within this project.

## **Conclusions**

We have successfully engaged patients with relevant lived experience to work with researchers to tackle this novel, complex and important subject. Our work helps to serve an ‘underserved’ group, i.e. research participants who stop taking part in studies early and who do sometimes feel unsupported, and may contribute towards better experiences for research participants.

Our publicly available guidance provides researchers in the UK and beyond with practical advice about how to provide communications to this group, while incorporating their own setting-specific knowledge and expertise. As well as the guidance, the topic list resulting from our literature review, and our two-group method for developing guidance like this is potentially useful to others, both for future research and in further, practical applications.

## **Dissemination**

Our guidance is publicly available at <https://ctr.leeds.ac.uk/communication-with-research-participants-who-stop-participating-early/>.

We will develop a full dissemination and impact plan to ensure that we notify a broad range of potentially interested people about the guidance, and that we record any assessable impacts. Dissemination will generally include, if possible:

- Dissemination within our clinical trials unit, via presentations and adding the resource to existing guidance;
- Conference abstracts and peer-reviewed journal articles;
- Webinars delivered to relevant groups (e.g. the UK Trial Managers’ Network and/or the Registered Clinical Trials Unit Network);

- Direct dissemination to individuals and organisations who have prior knowledge of the project, including organisations that shared the research involvement opportunity;
- Direct dissemination to other individuals and organisations who may otherwise be interested to hear about the project and its outputs.

Other specific groups and organisations we would like to engage with include: the Trial Methodology Research Partnership Communications group (part of the wider Trial Conduct theme) and the UK Health Research Authority to potentially link with their existing resources on informed consent and participant communication. There will also likely be opportunities to promote this resource through dissemination work linked to the PerSEVERE project.

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## Acknowledgements

Contribution of authors:

- Will Cragg (Regulatory and Governance Affairs Officer, Leeds CTRU) initiated and led this project, conducted the literature review, coordinated the process of identifying patient contributors, facilitated all discussion groups, drafted the main output (guidance for researchers) and produced the final output version using feedback received.
- Rebecca Walwyn (NIHR Advanced Fellow and Associate Professor of Clinical Trials Methodology, Leeds CTRU) led the work on statistical planning for a future Study Within A Trial, and provided overall project oversight and support.

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## **Appendices**

None

## **Conflict of interest declaration**

The authors have no conflicts of interest to declare.