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ctru Leeds Institute of Clinical Trials Research

What information should we give to potential research participants about stopping or reducing their participation if they decide to take part in a clinical trial?

Who are we? We are a group of clinical trials researchers and patients who are looking for additional contributors to work with us on this topic. The lead researcher is Will Cragg at University of Leeds (w.cragg@leeds.ac.uk).

What is this project about? We want to improve the information potential research participants get about what would happen if they stop or reduce their level of participation after joining a clinical trial, if they do decide to take part.

Some previous research and our experience suggest that patients do not always get clear and complete information. This can be difficult to do because information sheets about research are often very long.

This project is part of a wider piece of work called 'Persevere' (https://ukcrc-ctu.org.uk/page-persevere/), which is about researchers making sure they are properly prepared for the fact that some participants in their research may stop taking part.

What are we trying to do? Create template wording for clinical trial information sheets about stopping or reducing clinical trial/research participation.

This would deliberately be 'layered', so that all potential participants would receive a few short, key points, with more detailed information available to those who want it.

What sort of contributors are we looking for? Anyone who is interested in this topic, no matter your background or experience. We would be particularly interested to hear from:

- People with experience of being asked to read patient information sheets when considering taking part in research,
- People who have experience reviewing and providing feedback or helping to write patient information sheets,
- People who have taken part in research studies (such as clinical trials) but stopped taking part before the study finished (also known as 'withdrawing' from a study).

People without these experiences but who may be interested in health research generally should also consider volunteering. We would also be interested to hear your perspective.

What would contributing involve? We will ask volunteers to join discussion meetings (we are planning for 3 meetings over 5 hours in total, over the next few months). There would also be a a bit of work to do between the 3 meetings. The meetings might be online or might be in person (in Leeds), depending on the preferences of the volunteers. See more information below on what volunteering would involve.

How can you express an interest in volunteering? If you might like to contribute to this project, please go to https://leeds.onlinesurveys.ac.uk/information-about-stopping-participation to fill in an expression of interest form. You can fill this in on a computer or a smartphone.

This should only take a few minutes to complete. It will ask for some personal details about you so that we can get in touch with you, and to help us choose the right group of people to help with this work.

If you are happy to tell us in the expression of interest form, it would be useful to know about your age, and your gender and ethnicity (as you would describe them). We will not share this information with anyone else, and we will only use it to help ensure we get a variety of different contributions to this project.

If completing the online expression of interest form does not suit you for any reason, or you would like any of this information in a different format, please get in touch with the lead researcher, Will Cragg at University of Leeds, to discuss other options: by email w.cragg@leeds.ac.uk or by phone 0113 343 8398.

Please note that we may get more applicants for this work than we have spaces for. If this is the case, we will select contributors who we feel can bring a diverse range of experiences, between them.

We will let everyone who expresses an interest know what happens, including those people who are not selected (as long as we have valid contact details for them).

Is there payment for contributing to this work? We are able to reimburse you for your time spent at project discussion meetings, and for time spent reviewing documents between meetings. We can also cover travel and related expenses if the meetings take part in person, in Leeds. Please contact Will Cragg (w.cragg@leeds.ac.uk) if you would like more information about this.

Who is funding this work? This work is supported by the National Institute for Health and Care Research.

Can you share this opportunity with others? Yes, please do feel free to share details of this opportunity with others who may be interested to help.

More background to this project

Patients who are considering taking part in a research project must be informed of their right to withdraw their informed consent at any time and without having to give a reason.

However, there are other important things to say, for example about the practicalities of stopping participation, or what would happen in different sorts of situation. What if they lose contact with the research team during the research? What if their doctor recommends that the treatment they are receiving through a clinical trial should stop?

Potential research participants need this clear information so that they can take it into account when deciding whether to take part. Clear information can also help participants decide how they might want their participation to stop or change during their time taking part.

Some published evidence shows that potential research participants might not always get clear and complete information about this topic.

What are we trying to do?

In this project, **we want to develop template wording for clinical trial information sheets about stopping or changing participation**. We would like it to be clear and comprehensive, but not overwhelming or alarming. We would like the wording to be 'layered', with a few key points to present to everyone, and more detailed information available to those who want it.

This template wording could be helpful to participants and researchers across the UK. It could also reassure ethics committees that the information has been developed with patients, carers and/or members of the public.

How could you help?

The issue we are trying to address is about patients' experiences in research, so we cannot do the work without involving patients or carers who look after patients.

The main way you could help with this is to take part in the discussions and other work to help develop the new template wording.

You will be thinking about the information potential research participants get when they are considering taking part, and how best to communicate this information. You would be helping make sure that any template wording we produce is clear and appropriate.

There will also be opportunities to help out with other aspects of the project, including writing the final report, if you are interested to do this.

What would you need to do?

We will develop the template wording through group work. The group will have up to 8 patients on it. We do not plan to record the meetings.

We are planning for this to involve 3 meetings over 5 hours in total. It may be slightly more or less than this, depending on how our discussions go. Meetings would involve some open discussions and some structured exercises.

We will be thinking about what needs communicating to potential research participants and how we can communicate it clearly and sensitively. This might include work to explore how *not* to communicate sensitively, if it helps us understand what we are trying to achieve.

The group meetings might be online or might be in person (in Leeds), depending on the preferences of the volunteers. The meetings would be at a time to suit you. There would also be a small amount of activity to do between the meetings. Before any meetings, we will discuss with you to find out how best to support you in taking part in the meetings.

We want to carry out this work in the next few months, for example between around April and July/August 2023.

What sort of person are we looking for?

We are looking for anyone who is interested to help with this project. We are keen to get input from a variety of people, diverse in terms of their experience with research, the health problems that have affected them, and who they are as people.

You can be based in any part of the UK. If the group members preferred to meet in person, we would cover your travel costs and other expenses.