The research nurse’s role in managing patient expectation in clinical trials

Registered nurses will be aware of the Nursing and Midwifery Council (NMC)’s code and its requirement to always practise in line with the best available evidence (NMC, 2018). Evidence-based practice has become the cornerstone of safe and effective nursing care. The process of generating new knowledge and transforming this into evidence-based practice is underpinned by clinical research, as has been recognised by the role of research in responding to the coronavirus pandemic. Research-active organisations are known to have better patient outcomes. For example, trusts that report high engagement in research have reduced post-operative mortality rates (van’t Hoff and Selva-ratnam, 2018). Research nurses are essential for delivering clinical trials. This article explores factors which influence patient expectation within research.

Managing expectations
Managing expectations can begin early, during the first discussions about the types of studies that the patient may be eligible for. When patients are enrolled into a study, they must provide written consent and do so voluntarily, feeling well informed, aware of the benefits and risks, and after being assessed as having capacity to decide (Health Research Authority, 2021). Other tasks required in the role include the reporting of adverse events, maintaining accurate data collection, and specific tasks, such as blood sampling, specimen collection and administration of investigational medicinal products. Research nurses act as the vital interface between patients and study sponsors, often starting at the initial discussion with patients to assess their eligibility for a clinical trial (Flocke et al, 2017).

Patients’ expectations can be assessed at key milestones: during recruitment and consent visits, at follow-up, before unblinding, and during the final study visit. For randomised controlled trials, the process should be clearly explained to participants at recruitment.

In this article...
● Why research nurses have a vital role in managing patient expectation
● How patients’ expectations can be linked to their understanding of the trial
● Why trials offer an opportunity to revisit patient understanding and experience

Key points
Research nurses are key for ensuring trial participants have a safe and positive experience.
Nurses should check trial participants’ understanding to manage their expectations.
It is important to understand patients’ motivations for participating in a clinical trial.
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Keywords Research nurse/Clinical trial/Patient experience

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have to provide a reason. Anyone considering taking part in a study should be given information in an accessible format and in a way that they understand (HRA, 2021).

The research nurse should allow enough time to clarify complex information and explain the purpose of the study to patients and their families (Flocke et al, 2017). This article focuses mainly on research done in randomised controlled trials. Identifying patients’ reasons for taking part in trials can provide insight into what their expectations may be. Kwakye et al (2016) suggested three broad reasons for why patients may volunteer for research: curiosity about their own condition; a sense of altruism and contributing to future treatments; and seeking personal benefit in improving their own symptoms.

It is crucial for the research nurse to explain what phase of clinical trial the participant is enrolled on, as understanding the different phases of research can also be useful in managing patient expectation (Table 1). For example, Phase 1 trials in oncology are mostly about establishing therapeutic dosage and scheduling for novel drugs, and do not guarantee therapeutic benefit to individual trial participants (Dolly et al, 2016).

In randomised controlled trials, it is also essential to explain that the patient will be randomly assigned to either the treatment arm of the trial, where they may receive experimental treatment, or the control arm, which may consist of usual standard of care or placebo (Flocke et al, 2017). The options will depend on the type of study and the trial setup. It must be made clear to potential participants that there may be no direct benefit to themselves, but that the data collected from their participation may benefit others or inform further research.

### Treatment expectation and randomisation

In randomised controlled trials with a treatment arm, participants may be motivated by and expect to receive a treatment that may directly benefit their condition (Kwakye et al, 2016). However, it is important to remind them that sometimes differences in success rates may be small or the differences between the standard of care and treatment arm may be non-significant. The challenge is to strike a balance in communicating that trials contain a degree of uncertainty, but are closely monitored and regulated to ensure safety (Tarrant et al, 2015).

The concept of random allocation is an element that has been poorly understood by some trial participants (Behrendt et al, 2011). Where applicable, the research nurse should ensure that patients understand fully what randomisation means. For example, some patients have mistakenly believed that allocation to trial arms was decided by the consultant, dependent on age or health status (Behrendt et al, 2011).

Nurses can clarify terminology and ask the patient to explain randomisation back to them, to check their understanding. Participants will be blinded, meaning they are not informed of which arm they were randomised to. Trials which blind only the study participants are known as single-blinded. Double-blinded trials are when both the researchers and study participants are blinded. There may be a stage in the trial where the participant is unblinded and informed of whether they were receiving treatment or placebo/usual standard of treatment.

Kwakye et al (2016) noted that for some participants, there can be a sense of disappointment, frustration or anger on learning they had been randomised to the control arm. Before and during unblinding, it can be useful for the research nurse to review the patient’s expectations and manage any potential anxieties. Patients could experience a sense of disappointment that they have not been receiving the experimental treatment during their participation and may perceive this as an opportunity lost (Kwakye et al, 2016). This has been found to be of particular concern in oncology trials or those involving life-limiting illnesses (Weinfurt et al, 2012). Oncology nurses have reported concerns that some patients believed that participating in a clinical trial provided a certain cure (Flocke et al, 2017). Disappointment could also stem from a sense of doubt about whether their contribution to the study was important. Reminding patients that their participation is valued could alleviate these feelings.

Explaining the limitations, risks and potential benefits of clinical trials can ensure that patients do not develop unrealistic expectations. Do not promise outcomes of a curative nature, as trials are experimental and their purpose can include finding out about drug side-effects, comparison between standard and new treatment, and whether benefits are long-term.

Patient expectations have been shown to have important effects on the placebo effect (Stone et al, 2005). Those enrolled onto interventional trials may self-monitor at home and selectively report events or symptomatic improvements consistent with their own expectations (Stone et al, 2005). If participants believe they were assigned to the treatment arm, they may observe side-effects that they expect to experience or minor improvements in their own symptoms.

Unblinding needs to be handled professionally and sensitively, addressing any

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**Table 1. Understanding clinical trial phases**

<table>
<thead>
<tr>
<th>Clinical trial phase</th>
<th>Overview</th>
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<tbody>
<tr>
<td>Phase 0</td>
<td>Usually only 10-20 participants enrolled</td>
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<tr>
<td></td>
<td>Usually examines whether a low dose of trial drug behaves as investigators would expect, based on previous laboratory (non-human) tests</td>
</tr>
<tr>
<td>Phase 1</td>
<td>Small trials involving 20-50 participants to examine dosages and side-effects of trial drug</td>
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<tr>
<td>Phase 2</td>
<td>Randomisation and control/treatment arms may be introduced in this phase</td>
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<tr>
<td></td>
<td>Control arm may use placebo</td>
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<tr>
<td></td>
<td>Participants are monitored for side-effects and comparisons made between control and treatment groups</td>
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<tr>
<td>Phase 3</td>
<td>Most involve randomisation</td>
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<tr>
<td></td>
<td>Larger numbers of participants recruited</td>
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<td></td>
<td>May compare new treatment to current standard treatment</td>
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<tr>
<td>Phase 4</td>
<td>Treatment or product has been licensed at this stage and proven to work</td>
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<tr>
<td></td>
<td>This phase examines how effectively the drug works when used more widely</td>
</tr>
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Source: Adapted from Cancer Research UK (2019)
Clinical Practice
Discussion

Discussion

Potential concerns, and allowing the participants to make sense of their trial experience (Kwakye et al, 2016). Some clinical trials allow for crossover from the control to the treatment arm, depending on the study design. Research nurses should familiarise themselves with their respective protocols and crossover should only be discussed if the participant is eligible and the study permits.

Providing a patient information sheet can help patients understand what participating in research will involve. The research nurse should allow the patient enough time to read it through and weigh up whether taking part in research is right for them. It is usually study-specific and supplied by the institution sponsoring the study. Patient information sheets should be written in lay terms – in a way the patient can understand – but they can be lengthy. Patients should be given time to read through them and have the opportunity to discuss the trial with their family or GP. By explaining the terminology in this patient information, the research nurse is complying with the NMC code requirement to “act in partnership with those receiving care” and help them “access information and support when they need it” (NMC, 2018).

Discussions before and during consent are the ideal opportunity to provide information and address any queries. Brown et al (2004) describes seven components in the informed consent process, including encouraging the patient to ask questions and letting them express their existing knowledge of trials (Brown et al, 2004). By encouraging questions throughout the research process, open dialogue is more likely and patient-held expectations will be revealed.

In cases where recruitment and consent were completed by the consultant overseeing the study, it is worth summarising the study and checking the patient’s understanding during follow-up. Kunhuny and Salmon (2017) found that occasionally, principal investigators (doctors responsible for overseeing a study) recruited patients by withholding some aspects of trial information. This sometimes resulted in participants withdrawing from the trial on learning more. Addressing gaps in patients’ knowledge also meets the NMC code requirement of being “open and candid with all service users about all aspects of care and treatment” (NMC, 2018), and if patients are well-informed they are more likely to have reasonable expectations. Contact details for the designated nurse assigned to the study should be provided to those recruited into the trial. Good clinical practice is an ethical and scientific set of standards by which all clinical research is done and which requires valid and informed consent (Medicines and Healthcare products Regulatory Agency, 2012).

“Study participants often experience many benefits when taking part in research and value the close monitoring and follow-up that research involves”

Trial burden

Lovell et al (2020) discussed the concept of trial burden, and how participants prefer trials that are reasonable to accommodate and fit appropriately within their busy lives. Elements of a trial that can contribute to perceived trial burden may include fasting blood tests requiring early-morning appointments, or the challenge of balancing study visits with full-time employment for working-age participants (Lawton et al, 2003). The research nurse can address this early on during recruitment and consent by discussing the follow-up schedule, number of questionnaires and the tests required (for example, blood samples, imaging). A visit schedule could be included in the patient information sheet, which would address expectations about the level of trial burden and lay the foundations of what is expected.

Building a professional relationship with patients based on trust and knowledge sharing meets the NMC’s requirement to be open about all aspects of care and treatment (NMC, 2018). To reduce trial burden where feasible, research nurses can ensure any questionnaires are in the participant’s preferred format, offer remote visits and involve carers where appropriate (Lovell et al, 2020).

Additional monitoring

Some participants report a sense of reassurance from attending follow-up visits, and additional monitoring is a key factor in their continued engagement during the trial (Lawton et al, 2003). The expectation of additional monitoring can be a motivating factor for enrolling in research and this benefit can be discussed during screening and recruitment. A study by Tarrant et al (2015) found that participants were more likely to withdraw from a trial if they felt the trial team paid no concern or vigilance to their wellbeing. Studies with a considerable follow-up period may involve several regular clinic visits and participants report practical and emotional benefits of research involvement (Lawton et al, 2003). Some participants report feeling more active in the management and monitoring of their own long-term condition; for example, participants in the UK Prospective Diabetes Study valued study visits in between their usual GP-led diabetic reviews (Lawton et al, 2003).

Some participants who have been engaged in trials with a lengthy follow-up period, have described a sense of loss or anxiety when it comes to an end (Lawton et al, 2003). Preparing participants as the end of study approaches can ease some of the anxieties associated with trial completion and research nurses can inform participants of the expected completion date. Transitional care should be handled sensitively and spoken of in advance of the final study visit. Advanced warning can help participants feel informed and manage expectations as the study draws to a close (Lawton et al, 2003). A final visit should involve the research nurse and the clinician, provide the patient with the opportunity to ask questions, ensure any adverse events have been resolved, record some final observations and allow for reflection on the research experience. This should be followed up with timely communication with the participant’s GP. Clinically based nurses may see parallels in this aspect of expectation management with discharge planning processes on the ward.

Conclusion

Patients’ expectations during the research process can fall into three main categories:

- Curative expectations or expectation of a certain treatment;
- Perceived trial burden, which may impact on engagement and retention;
- Expectation of additional monitoring of health condition.

Research nurses should be mindful that expectations can be fluid, as they can alter during the trial and be influenced by the various factors described in this article. It is important to revisit participant expectations and to gauge understanding at key intervals, such as during recruitment and consent, scheduled follow-up visits, before unblinding (if applicable) and in the lead-up to the final study visit.

To manage expectations, the nurse should explain research terminology and provide appropriate written materials,
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keep communication open, reiterate and explain the randomisation process and ensure that the patient can recall what the trial involves. Study limitations should be explained to address any misplaced curative expectations and the patient should be made aware of different arms involved in the trial. Emphasising the randomisation process is critical, as this element has previously been found to be poorly understood. Providing an overview of the visit schedule, trial duration and tests involved can shape expectations and, if provided before consent, can help the patient assess whether the benefits of participating outweigh the trial burden.

Where possible, the nurse can ease trial burden by arranging visits according to the patient’s schedule, offering remote visits where appropriate and reimbursing travel expenses, if this is covered by the study sponsor. Questionnaires should also be in the participant’s preferred format and the nurse should be available to assist if needed. Finally, participants should feel prepared as the study comes to an end and be made aware in advance of final visit dates.

Study participants often experience many benefits when taking part in research and value the close monitoring and follow-up that research involves. Participants can also feel empowered and more knowledgeable about their own condition as a result of taking part in research.

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