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Original Article

Investigating patient recruitment to radiotherapy clinical trials

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Abstract

Background: Radiotherapy randomised controlled trials provide evidence to support the development of new techniques and dose/fractionation regimens. Some radiotherapy trials have previously had to close early or revise targets due to low recruitment rates. Many authors have recommended research into recruitment strategies for many areas of medicine, however little work has been carried out in the specific field of radiotherapy.

Method: Using a survey of research radiographers followed by radiotherapy patient interviews, this project provides perspectives on motives for patient participation in radiotherapy clinical trials, and how to best support people through this decision-making process.

Findings: The main factors influencing participation identified by the radiographers were altruism, treatment fatigue and concerns about the trial arms, lack of resources and lack of commitment from some medical colleagues. For patients the main factors were mainly emotional; altruism, and fears for efficacy of different trial arms featured, with requests for timely communication of trial information.

Conclusion: We recommend that strategies should be offered proactively to support patients through the decision-making process when considering trial participation. Research radiographers are ideally qualified to offer support and expert knowledge to these patients.

Keywords: clinical trial recruitment; radiotherapy; randomised controlled trial; research radiographer

INTRODUCTION

Radiotherapy trials are essential in gathering evidence for the development of new techniques. This research can be time consuming, and costly to set up, often involving implementing new treatment techniques in radiotherapy departments.[1] Low recruitment rates lead to additional costs if the recruitment period is extended or possible early closure of the trial.[2]

This research project aimed to gather information from patients about their understanding of radiotherapy trials. Although the patient's right

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to decline trial participation is appreciated, we wished to investigate if patients are fully supported and informed during the trial recruitment process at a difficult time in their lives. As radiotherapy is often an unfamiliar concept to patients, would extra support be required when considering the different radiotherapy regimens?

Research has been carried out into patient recruitment into cancer trials, often focussed on the experiences of the investigators rather than the users.[3] Overall knowledge of the patient perspective on this topic is limited, especially in literature relating specifically to radiotherapy trials. This study aimed to gain an insight from patients who either accepted or declined participation in radiotherapy trials. To inform these interviews, the experiences of the research radiographers working in radiotherapy clinical trials was sought to identify any common themes experienced.

Published literature on recruitment to trials

Systematic reviews published on clinical trial recruitment have previously acknowledged problems recruiting patients and recommended further research into recruitment strategies.[3,4] Techniques which could be implemented to boost recruitment are suggested, including telephone reminders and personalised letters contacting potential trial participants. Trial design was also identified as an important consideration factor; open designs were more successful in recruiting participants, as were 'opt out' studies.[3,4]

The ProtecT (prostate testing for cancer and treatment) study utilised an interventional technique involving in depth interviews with staff and review of taped consultations with potential patients.[5] By discussing the presentation of trials and tailoring the way information was given, the researchers managed to increase recruitment into the trial from 40 to 70%.

In a patient-centred approach Jenkins and Fallowfield[6] gained an insight to patients reasoning on declining or accepting trials. Altruism and trust in the doctor were reported to being the most reported factors in deciding to participate, concerns about randomisation the highest report factor for non-participation. Patients were more likely to choose trial participation if all randomisation arms included active treatment.

Ferguson et al.[7] suggested their high rate of recruitment to radiotherapy trials was due to a co-ordinated approach by the multi-disciplinary team (MDT), and a designed research clinic. This is in agreement with an editorial by Coles and Faivre Finn,[1] these authors conclude that the research question and design are paramount to success. The results from the successful FAST-Forward trial substantiate this. This trial offered patients the convenience of hypofractionated treatment.[8] In providing what many people perceived as an advantage to trial participation, recruitment was optimised, with the trial recruiting well ahead of target.

DESIGN OF THE PROJECT

Survey of UK research radiographers

An online survey was devised and tested on work colleagues before being sent to radiotherapy research radiographers with the help of the Society of Radiographers distribution list. Many research radiographers run radiotherapy trials and issues with recruitment that were identified by this group were later compared with those identified by patients.

PATIENT INTERVIEWS

Patients who had either accepted or declined radiotherapy trials were selected at random by the treatment radiographers and asked to take part in a semi structured interview. Interviews were recorded and then transcribed.

A grounded theory methodology was selected for data analysis of the interviews.[9] Data collection and analysis was carried out concurrently, with codes and categories identified. Data saturation was considered to have been achieved when there were no new instances of a theme are required to confirm a category. Participants were consulted to check out the authenticity of the interpretation of their interviews[10] and a co-worker independently reviewed and coded data.[11]

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RESULTS FROM RESEARCH RADIOGRAPHERS

All Radiographers involved in clinical trials reported that the first approach regarding clinical trials was made by a clinician, usually followed by a follow-up phone call. Over half of the respondents thought radiotherapy trials were more complex to explain than those involving new chemotherapy drugs. The comments provided by the respondents were insightful and broadly in agreement. For discussion here the results fitted well into three sections as described by Mills et al.[12] in their 2006 investigation of patient recruitment to clinical trials.

Patient-related issues

When discussing recruitment, nearly all respondents mentioned patients' altruism as a motivation for participation:

> Patients wish to help patients in the future is something I hear a lot.

For many patients it was felt that 'treatment fatigue' created difficulties in decision making as were concerns about treatment options offered:

> Risk/Uncertainty of some trial protocols sometimes deter patients or they respect their relatives wishes not to take risk with uncertainties.

Staff-related issues

The respondents expressed a real enthusiasm for their role in many comments, for instance

> research radiographers should be more involved in the recruitment process for radiotherapy trials, offering specialist knowledge to patients in a difficult to understand subject area.

However this enthusiasm was mixed with feelings of frustration about lack of resources, such as availability of clinic rooms, and the difficulties of working in peripheral clinics. There were many comments citing a lack of support for trials from the medical staff:

> patients don't seem keen if the consultant hasn't mentioned it first.

The issue of MDT members discussing standard treatment pathways which then biased patients against the trial treatment was also identified:

> (Participation) is often influenced by what the surgeons have said to the patients.

The relationship between the research radiographer and patient was seen as a positive factor:

> Some patients feel security from knowing that 'somebody else' will be looking out for them and enjoy the relationship that develops.

Trial design issues

Respondents reported that trials involving more complex design were less attractive to patients as it is difficult to understand and compare with standard treatment. Other issues raised are below:

> Some patients do not like the idea of receiving experimental treatment, especially if this is perceived as being 'less' treatment. Often patients are put off by additional hospital visits BUT sometimes this is a reason for accepting a trial because they feel they will be monitored in trial follow up.

DISCUSSION FROM RESEARCH RADIOGRAPHER SURVEY

The discussion from this group of respondents featured communication as a barrier to recruitment, but more in respect to time commitment and reluctance of clinicians to approach patients, rather than the quality of the communication. This correlates with the reports from authors on the importance of allocating sufficient resources as well as educating and enthusing co-investigators.[1,13,14] The positive motivation of the radiographers who responded to the survey was illustrated in their comments, but they agreed with the published research in that their assertion that the whole MDT needs to be involved in the trial process.[7]

The issue of patient altruism was expressed by many respondents, however it was noted that concerns over efficacy or treatment fatigue could affect patients motivation for discussing and

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considering trials, especially those with a more complex design or requiring more hospital visits.

PATIENT INTERVIEW FINDINGS

In total, 12 patients were interviewed; six who were participating in trials and six who had declined to enter. The themes identified after the interviews are described below.

Altruism

The opinions expressed by these patients about participating in research and helping others in the future were overwhelming:

> I made the decision (to take part in trial) because I was so shocked that I was told I had cancer, and had to go through the process of treatment. I would like to help others go through it.
> If I can help at this stage then maybe someone further down the line can benefit because they will know better how to treat it.

For some, the uncertainty of participating in research was too demanding when dealing with a life threatening illness, other respondents discussed the impact it would have on their own health. For example

> My first thoughts were, is it beneficial to me?

These emotions and feelings are similar to those reported by McCann et al.[15] They describe a 'conditional altruism' suggesting that although patients may like the idea of helping others, it should be beneficial to them. McCann's work was done in a non-cancer background and this 'conditional altruism' seems to be a rational response, however for some of these radiotherapy patients the cancer diagnosis had such an impact on their lives they wanted to support others and be part of research to improve cancer treatment.

Fear and uncertainty

Patients discussed the concerns about the efficacy of research treatment compared with the 'tried and tested' method. Many had concerns about the impact that participating in research on others and expressed feelings about having to choose what they perceived as the 'safest option' for the sake of their families and children:

> It came down to the children and the age of my children that I thought for them it was probably the safest option that I had. I had to go with what was proven.

The contrary view to this was also expressed with some thinking that the research arms actually might be to their advantage:

> I thought I might have the opportunity of getting a treatment which would be more effective in terms of survival.

Fears about treatment were mitigated by trial design for some respondents. One of the trials offered a chance of hypofractionation of treatment. This trial design offered convenience for participants, and in many cases participation was accepted without negative thoughts.

Education, knowledge and understanding

When asked to define the term clinical trial all patients showed a good understanding, with common terms being 'the future' and 'helping others'. The process of randomisation, which is widely identified in the literature as a barrier to recruitment,[16] was not offered as a problem by any of the participants and when participants were encouraged to explore this issue, it seemed to be well understood. The satisfaction with trial literature was good and many respondents mentioned that it was clear and helpful.

Radiotherapy doses and fractionation schedules were only identified as difficult to understand by one respondent. There appeared to be an acceptance that there were different ways of giving radiotherapy just as with any other treatment.

One respondent explained that

> It wasn't really the understanding; it was whether I should take part, it was personal reasons.

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Approach, communication and timing

Many patients had undergone chemotherapy before radiotherapy and expressed 'treatment fatigue', describing problems with concentration and decision-making ability:

> I had chemotherapy sessions and it affected me more in fatigue and concentration…. So I wasn't really bothered about making decisions, it wasn't my priority at the time.

Others agreed that the timing of trial information was important with respondents reporting that it was given too late, requesting that it be accompanied by a follow-up appointment. Many reported problems with concentration after chemotherapy and felt that they needed to be 'verbally fed' the information with 'human contact' rather than reading through it themselves:

> If I could have had the information before my chemotherapy started and a chance to meet with you to discuss things then I think I would have gone ahead with it.

Trust

Some patients required more information from their consultations and were left with questions after their consultation, often looking for reassurance that trial participating would be as effective as the standard:

> The pressures upon clinicians is about doing things but not actually telling the patient what is happening and not checking that the patient is happy with the level of information.
> You feel in an empty hole. I know that nothing is black or white but I do feel that you are kept very much in the dark.

DISCUSSION FROM PATIENT INTERVIEWS

Nearly all patients discussed feelings of altruism. Those patients who chose not to participate in the trials conveyed a feeling to the interviewer that they wanted to discuss and justify their non-participation. These tie in with research by Jenkins and Fallowfield, they describe how patients may give more 'socially desirable' results in order to be viewed in a positive light by others.[17] Although this may be the case with some respondents, the impression the interviewer was left with was that for most of these patients interviewed, the diagnosis of a life threatening disease had impacted on their lives to such an extent that they empathised and wanted to support people who would be going through the same experience in the future. This altruism was balanced with concerns about efficacy of trial treatment, which was often the deciding factor in participation.

Some patients who were struggling with their decision looked to their consultant for reassurance on trial participation, not fully appreciating that often due to the research question those reassurances could not be given. Research into decision-making processes in health care provision for cancer patients shows that many patients have a desire for greater involvement in their treatment options.[18,19] In a systematic review of the literature in 2010, Tariman et al.[19] notes a lack of innovative interventions to facilitate this decision-making process. Some patients might find it useful to have a more visual representation of treatment options especially if suffering from 'treatment fatigue'. Timing of information was obviously important to these patients, in future the trial information needs to be offered at an earlier stage when it can be considered or stored away for later discussion.

None of the patients expressed discomfort with being approached to participate in a trial, the level of understanding of the trial processes was greater than the researcher had anticipated. Trial design had a large impact with the convenience of hypofractionated treatment being attractive to many, but causing concern to others, who preferred the standard treatment regime.

The emotional aspect of decision making appeared to be the most influential factor in decision making for this group; altruism was balanced against anxiety about treatment efficacy.

CONCLUSION

This patient group did not consider the different radiotherapy regimens as difficult to understand,

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radiotherapy was simply viewed as another form of treatment. The principle concerns facing these patients about trial participation were emotional factors, but other issues discussed were similar that those noted in previous research in trials involving chemotherapy or surgery. All patients were happy to consider trial participation although the decision-making process was not easy in all cases. Patients should be offered the information before treatment fatigue affects this process. Clinicians' might be interested to note the amount of enthusiasm for research expressed by this group, although not all eventually participated in trials. Recruitment could be optimised by approaching all eligible patients and sharing the decision making, rather than only approaching patients who appear initially receptive. Previous work and the survey of radiographers show the importance of having the commitment of the whole MDT to the research process.

The issues identified in this project are similar to those experienced by other research radiographers in their practice. The research radiographer role offers a unique opportunity to provide patients with expert knowledge on radiotherapy trials. Clinicians are often limited in how much time they can allocate to consultations, the research radiographer post is ideal to following up patients, and to check they have had sufficient information and discussion to support their decision-making process. Contact details are provided on the written patient information but a more proactive approach, inviting patients for additional appointments to meet face to face has been implemented at the authors' department. This approach was not initially employed in case patients felt coerced or pressurised to participate in trials, but this project has confirmed that patients may need the additional opportunity to talk to a health care professional for information or emotional support, and at a vulnerable time may not actively seek that support.

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Conflicts of Interest

None.

Ethical Standards

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national guidelines on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008, and has been approved by the institutional committees' the Health Research Authority Hampshire A NRES, and Research and Development at South Tees Hospitals NHS Foundation Trust.

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