



RESEARCH

INFORMATION

## Participation in clinical trials by teenagers and young adults with cancer: Barriers and facilitators



### AIMS

Clinical trials are key to improving care, but currently around only 10% of teenagers and young adults (TYA) with cancer take part in one. Our study explored why this is the case and how levels of trial participation by TYA with cancer might be improved.



### KEY FINDINGS

- Few TYA with cancer take part in trials as few have the opportunity to do so. The types of cancer TYA typically develop are rare, so not many relevant trials are established. Those that are established tend only to be opened at very large cancer centres.
- Health professionals are committed to recruiting TYA to relevant trials when these are open at the centres where they work. However, they have reservations about referring newly-diagnosed TYA to trials at other centres, and few do this routinely.
- Diagnosis is an immensely challenging time for TYA (and their families) and TYA are often unwell and deeply distressed when treatment – and trials – are discussed. TYA describe ‘going into a zone’, where they focus on getting on with treatment in order to get better.
- This mind-set seems to help TYA cope, but can discourage them from engaging with information about the details of treatment and trials. Instead TYA trust health professionals to guide them towards the right decisions.
- Caregivers have concerns about TYA's capacity to engage with information and make good decisions at diagnosis. They want to help, but their priorities and information needs are not always the same as TYA's.
- If levels of trial participation are to increase, access must be improved, by opening trials at more designated specialist TYA cancer centres, and/or referring TYA patients more frequently to those centres with open trials. Different ways of organising and resourcing research/care could encourage these changes, but might bring new challenges.





## WHAT DID THE STUDY INVOLVE?

This exploratory study involved interviews with: 35 health professionals involved in cancer care and/or clinical trials in Scotland; 18 TYA diagnosed with cancer whilst aged 16-24 years; and 15 caregivers (mostly parents). We asked interviewees about their views on TYA with cancer's: experiences of cancer; decision-making about treatment; and involvement in trials. We explored what might prevent or discourage TYA from enrolling in trials and what might enable and encourage their participation. We recorded the interviews, then studied transcripts for common issues and themes. We asked relevant professionals and TYA diagnosed with cancer for advice at key points in the study. For example, at the start of the study we met members of the Managed Service Network (MSN) for Children & Young People's Youth Advisory Forum (YAF) and discussed who we should interview and the questions we should ask. We met the YAF again later in the study, to discuss the research findings and next steps.



## WHAT WERE THE RESULTS AND WHAT DO THEY MEAN?

Health professionals emphasised their commitment to trials, and to recruiting TYA diagnosed with cancer, but reported that few trials were established in the rare cancers with which TYA typically presented. They also noted that there were significant disincentives to opening these trials widely and described finding the time costs of opening trials difficult to reconcile with other service demands. They felt obliged to make 'prudent' choices about which trials to support; this led them to prioritise trials in common diseases. Support for TYA-relevant trials was more limited as they concerned the treatment of rarer diseases.

Health professionals suggested that, in principle, TYA presenting at one cancer centre might be referred to a trial open at another centre (within or outwith Scotland). However, many said they were unlikely to take this course at diagnosis. They expressed a variety of concerns about referral, including: the (in)adequacy of their knowledge of trials open at other centres; the costs/burdens TYA and their families might incur; what they perceived as patients' preferences; a desire to initiate treatment promptly; and, reluctance to take on the administrative work involved in arranging referral, and financial support, for TYA and their families.

Where relevant trials were on offer, health professionals portrayed recruiting TYA as achievable but demanding, due to the upsetting and busy context in which relevant discussions took place. Similar concerns were reported by TYA and caregivers, who often noted how TYA were extremely unwell and deeply distressed by the time of diagnosis. These issues made it hard for TYA to engage meaningfully with complex information about treatment and/or trials. In addition, TYA suggested that a key coping strategy was the adoption of a positive, recovery-focussed outlook, and they described 'going into a zone' in which their priority was starting treatment promptly. They did not want to engage with troubling information that could threaten this positive mind-set. Hence TYA largely welcomed a directive approach and, even where trial enrolment decisions had to be made, looked to health professionals for a clear steer.



TYA who had enrolled in trials often acknowledged their understanding of the trial(s) as incomplete, though they did not present this as a problem. Caregivers, in contrast, were concerned about TYA's ability to process information and make good decisions at diagnosis. They described attempts to compensate, and alluded to obstacles they encountered. Caregivers had a strong desire to support informed decision-making and wanted transparent and comprehensive information. However, their priorities and information needs were not the same as those of TYA. They sometimes appeared to conflict, and needed sensitive handling.

Health professionals told us that there was potential to improve TYA's access to trials. They suggested that this could be achieved by: organising research and care in different ways; streamlining bureaucratic requirements; investing in the research workforce; and designing more pragmatic trials. Specific strategies included: centralising research (or care) further and/or developing new models of collaboration to co-deliver trials across centres; reducing duplication in regulatory/administrative activity, to minimise disincentives to opening trials at multiple centres; and allocating resources to support work on (rare disease) trials in different ways. Interviewees acknowledged that re-organising care, research, and resource frameworks would present challenges. However, they emphasised that doing nothing would also have costs. They also suggested that, as medicines became more targeted (tailored to smaller patient groups), these changes might benefit a wider range of patient groups.



## HOW DO OUR RESULTS ADD TO WHAT'S ALREADY KNOWN?

Our exploratory approach has produced new and important insights. While lack of opportunity has been suggested previously as an important explanation for low levels of participation, our work illuminates why opportunities are particularly limited for TYA with cancer in Scotland. Moreover, having elicited concrete proposals for improving access, it offers a tangible way forward. This is important, as identifying practical strategies for improving access was recently agreed to be priority for TYA cancer research across the UK and beyond. Our study also reveals how 'improving' participation can mean (at least) two quite different things: increasing levels of participation, but also ensuring that participation is properly informed. Our findings raise important questions about the possibility of, and conditions for, achieving informed consent, which should be reflected on alongside debates about enhancing levels of trial participation amongst TYA.



## WHAT IMPACT COULD THE FINDINGS HAVE?

The findings extend understanding of barriers to, and facilitators of, trial participation by TYA with cancer. They highlight the challenges of providing a small and dispersed population with access to trials and suggest how different approaches to organising and resourcing care and research might increase opportunity. However, the organisational and resource implications of those approaches are variable, and in some instances substantial. They would require the support of a wide group of stakeholders to take forward. Some may have relevance to, and benefits for, other patients with rare (forms of) disease, whose access to trials is similarly constrained.



## HOW WILL THE OUTCOMES BE DISSEMINATED?

We have prepared several more detailed reports on our findings which we aim to publish in peer-reviewed journals (details are available on request). Looking ahead, we hope to bring together a small group of experts to debate and take forward the issues arising from the research, focussing in particular on proposals for improving TYA's access to trials. Other issues our study highlights and which invite further research include: alternative approaches to involving TYA in decision-making at diagnosis; and how caregivers can be enabled to support informed decision-making by TYA.



## CONCLUSION

TYA with cancer have low levels of trial participation due to: a shortage of trials relevant to their rare diagnoses; trials not always being opened at the places where they receive care; and a widespread reluctance to refer these patients, at diagnosis, to trials open at other centres. Access might be improved by differently organising and resourcing research (and care). Such changes are likely to require the support of a wide range of stakeholders, and agreement on the best way forward. Further work, such as priority setting exercises, may be necessary to reach such a consensus. The perspectives of TYA themselves are not a major barrier to recruitment. However, where relevant trials are on offer, the challenges of achieving *informed* decision-making and consent are significant, and a re-thinking of approaches to recruitment may be warranted.



## RESEARCH TEAM & CONTACT

The project was conceived and led by **Dr Angela Jesudason**, Consultant Paediatric Oncologist at the Royal Hospital for Sick Children (Edinburgh), with the support of colleagues at NHS Lothian, NHS Greater Glasgow & Clyde, and the University of Edinburgh. Interviews were conducted, and reports drafted by, Ruth Hart, Research Fellow at the University of Edinburgh.



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