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The experiences of patients with oesophageal cancer receiving chemoradiotherapy treatment: a qualitative study embedded in the SCOPE2 trial

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ABSTRACT

Objectives This qualitative study explored patients' experiences and perceptions of the SCOPE2 trial. SCOPE2 examined radiotherapy dose escalation in patients with inoperable oesophageal cancer treated with definitive chemoradiotherapy (dCRT).

Setting Recruitment at five clinical sites in England and Wales, UK.

Participants SCOPE2 trial participants were invited to take part in interviews from across five clinical sites. Participants self-selected to take part in up to three interviews across four different time points: baseline (before treatment) and at 2–3 months, 3–6 months or 6 months+ after baseline. There were five female and five male interview participants.

Interventions Participants were randomised to standard dose dCRT prescribed carboplatin/paclitaxel or cisplatin/capecitabine, or an escalated dose dCRT prescribed carboplatin/paclitaxel or cisplatin/capecitabine.

Methods This qualitative study used semistructured longitudinal interviews to explore the impact of treatment on patient outlook and quality of life and the impact of the COVID-19 pandemic. Interview data were thematically analysed.

Results 10 patients participated in 16 longitudinal interviews. Three participants were accompanied by companions. Participants experienced side-effects from radiotherapy and chemotherapy including nausea, throat pain, difficulties eating and regaining appetite, thrombosis and fatigue, although most of these symptoms gradually improved. Participants required more ongoing information and support regarding treatment side-effects and cancer status in order to improve their overall quality of life. Best practice examples involved key contacts providing practical advice and signposting support.

Conclusion Participants of the SCOPE2 trial reported short and longer-term side-effects from chemoradiotherapy, but these usually lessened over time. Participants attempted to be positive about their survival prospects by readjusting their expectations, priorities and lifestyles. Providing patients with ongoing opportunities to discuss detailed and timely information regarding treatment side-effects, aftercare and cancer status could improve the overall health and well-being of patients during oesophageal cancer trials and pathways.

Trial registration number NCT02741856; ISRCTN: 97125464.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study highlighted patients' ongoing trial and treatment experiences and the opportunity to inform trial conduct through longitudinal interviews.
⇒ Semistructured interviews provided rich data regarding patient experience before and during the COVID-19 pandemic, across different time points from participants across a range of age groups and genders.
⇒ Recruitment to this qualitative study was slow and the small numbers of participants recruited restricted the breadth of experiences explored across different trial arms and the additional impact of higher dose of radiotherapy on patients.
⇒ Lack of integration of qualitative study into the main trial recruitment limited opportunities for participant recruitment.
⇒ Participants were self-selecting for interview and needed to be well enough to be interviewed, thereby introducing a level of participant bias.

BACKGROUND

Oesophageal cancer (OC) has a relatively poor prognosis, as curative surgery is appropriate for only around 20% of the patient population.[1 2] Definitive chemoradiotherapy (dCRT) is offered as an alternative for patients who are unsuitable for surgery and is considered more effective than radiotherapy or chemotherapy alone.[3] However, despite improved survival outcomes, anticancer treatments may cause toxicities[4] and thus, further diminish the patient's quality of life.[5]

The SCOPE2 trial builds on the SCOPE1 phase 2/3 trial (2013) which highlighted the survival and long-term toxicity benefits of standard dCRT, as well as improved quality of life.[6] However, SCOPE1 did not capture the experiences of the trial or treatments from the patients' perspectives. Subsequently, the SCOPE2 trial embedded a qualitative component which examined real-time experiences of a subgroup of trial participants.

SCOPE2 is a randomised phase 2/3 trial for locally advanced non-metastatic oesophageal cancer patients. It examines radiotherapy dose escalation (standard dose of 50 GY vs high dose of 60 GY) and the effects of standard chemotherapy drugs (cisplatin and capecitabine, or carboplatin and paclitaxel). All patients were randomised into one of four arms. Additionally, it embedded a phase 2 trial whereby patients who had not responded to the first 2 weeks of chemotherapy (as assessed by a second a positron emission tomography (PET) scan) could be randomised to either continue this chemotherapy regimen or switch to alternative one.[7]

Previous qualitative studies embedded into cancer trials have provided in-depth insights into the experiences of patients with cancer relating to trial processes, their treatments and their recovery.[8 9] In an OC trial (ROCS), real-time reporting of patients' perspectives prompted trial amendments to increase recruitment and highlighted existential concerns around the issues of physical and social eating, along with the burden of side-effects of radiotherapy and hospital appointments.[9] In ROCS, patients were randomised to receive a stent or a stent plus radiotherapy. Those who received chemoradiotherapy treatment experienced longer-term toxicity and a high symptom burden including dysphagia, lack of appetite, fatigue, dyspnoea (difficulty breathing) and pain, having a significant impact on physical functioning and quality of life.

This qualitative study was integrated within the SCOPE2 trial to provide an in-depth understanding of a subset of patients' and their companions' first-hand experiences of the demands of the trial and treatments, which are not captured through other trial data. The ongoing needs of participants were reported to the trial team with the aim of informing practice.

Aims

The aim of the qualitative component of the SCOPE2 trial was to explore patients' experiences of chemoradiotherapy and perceptions of participating in the trial. SCOPE2 escalated definitive chemoradiotherapy dCRT compared with standard dose, and of the two drug regimens based on the outcomes of PET scans.

Objectives:

1. To assess patients' experiences and perceptions of each dCRT arm of the trial.
2. To consider how participants' views change over time spent on treatment.
3. To examine the personal impact of treatment on participants' health and well-being.

Qualitative findings discussing the trial conduct, recruitment and reasons for declining the trial are available in a full qualitative report, available on request.

METHODOLOGY

Study design

This was a multicentre, longitudinal qualitative study of a sample of clinical trial self-selecting participants with potentially curable OC. Qualitative methods were chosen to explore the nuanced and individual experiences of participants.

Public and Patient involvement

The trial was overseen by a Trial Management Group which included two patient representatives known as Research Partners recruited through the Involving People Network.[10] The research partners provided review and input into assessments of trial documentation, in particular, patient facing documents, assisted with Scientific Milestone Reports, and contributed to Trial Management Group meetings. A patient and public involvement representative also reviewed final qualitative summary findings.

Ethics approval statement

SCOPE2 has full ethical approval from Wales Research Ethics Committee 3 (dated 22 January 2016, with subsequent approval of each amendment; REC reference 15/WA/0395) and is conducted in accordance with The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI2004/1031) and subsequent amendments, and the Declaration of Helsinki 1996. Written informed consent has been obtained from all study participants, with separate consent obtained for participants in the qualitative interview study.

Recruitment

The qualitative study took place between July 2017 and December 2021. Due to the COVID-19 pandemic, the trial was closed to recruitment between March and August 2020 and the qualitative study between March and October 2020. The main trial began in 2016 completed recruitment December 2023 and closed in February 2024.

SCOPE2 trial participants were invited to take part in interviews from across five clinical sites (hospitals) in England and Wales. Potential participants were informed of the optional qualitative interview study at the point of consent into the main trial or at any point during the following 24 months after recruitment to the main trial. Initially, patients were invited for interviews up to 6 months after baseline, but due to slow recruitment, ethical approval was obtained to expand the timescale for recruitment to interviews up to 24 months after baseline. This coincides with trial follow-up periods. Patients were provided with a qualitative study patient information sheet (PIS) and consent was obtained once the patient had sufficient time to review the PIS. The qualitative study team were informed of the patient's contact details via secure

email if patients provided written consent. Otherwise, patients provided their contact details to the qualitative team using a reply slip and a stamped addressed envelope. The qualitative researchers contacted trial participants directly to arrange an interview and requested signed consent at the time of interview (face to face or via post). Participants were offered the opportunity to ask any questions before consenting. Companions who accompanied patients during interviews provided written consent which allowed for the capture of additional information that they discussed. All consent forms were held securely by the qualitative research team. Each participant was invited to participate in a maximum of three interviews and was not offered payment.

Patients eligible for the trial who chose not to consent were also invited to participate as non-consenters in the qualitative study to explore their experiences of being invited to take to the SCOPE2 trial. The results of these interviews are not discussed in this paper, as they focus on trial conduct but are available in the qualitative report.

An initial sample size of 24–40 participants (6–10 per arm) was based on researcher judgement and theoretical saturation.[11] However, due to time and financial limitations, the qualitative study finalised data collection in 2021. Barriers to recruitment are discussed in the limitations section and are more fully discussed in the qualitative report.

Data collection

The qualitative researchers conducted semistructured interviews. These researchers have experience in thematic analysis, as well as interviewing participants concerning sensitive subjects including cancer. They collected and analysed the data through a critical lens of researchers working outside the main trial team and focused on understanding the lived experience of participants.

Interviews were conducted face to face at participant's homes or at the hospital before social restrictions were imposed in March 2020 due to the COVID-19 pandemic, and by telephone thereafter. Participants were invited to be interviewed up to three times across four different time points: baseline (consented to the trial before treatment), 2–3 months, 3–6 months or 6 months+ after baseline. This reflected the key time points in the trial before, during and after treatment. Demographic information was collected and is reported descriptively but was not used as sampling criteria.

Before contacting participants for initial or follow-up interviews, the qualitative researcher consulted the recruiting site's nurse to confirm that the patients remained in the trial and were well enough to be interviewed. Due to the short timeframe between recruitment and treatment, or consent processes, it was not always possible to interview all participants at baseline, in these instances, participants were asked to recall their experiences of trial recruitment in later interviews.

A semistructured interview schedule was used to ensure a degree of consistency across the interviews, while still allowing for information to be elicited iteratively as interviews progressed (online supplement 2). A revised version of the interview schedule (v.30, Protocol 7.0) was used after February 2021, which included questions regarding the impact of COVID-19 on the participants' experiences (online supplement 3). These schedules include questions for participants at baseline and another set for those after treatment. Guide questions were tailored appropriately to each time point. Questions relating to this article are highlighted in the interview schedule supplements. Topics covered in the interviews, in line with the aims above included:

- Impact of treatment on physical function, health and well-being.
- Personal needs and expectations.
- Patients' and their companions' perceptions of the trial and their future aspirations.

Interviews were audio recorded and transcribed verbatim by members of the team or an external transcription company.

Data analysis

Longitudinal interviews were used to provide opportunities to gain an understanding of the patient's experience over time and draw attention to the processes and factors that influence change for the patient at different time points.[12] This qualitative study does not aim to be fully generalisable but to provide in-depth insights into patient experiences of chemoradiotherapy. Data were analysed thematically.[13 13] This analysis was an iterative process, involving inductive coding and interpretating data separately, then jointly identifying concepts and developing codes. The main researcher coded all data using the NVivo 12 software programme, with 20% double-coded transcripts by the other researcher to ensure rigour. The researchers jointly developed a framework for analysis, through a process of cross-checking and deliberation of themes. Themes were generated, reviewed and categorised into key themes and subthemes.

Additional details about how this study was conducted are available in the COREQ checklist online supplement 1.

RESULTS

Participants characteristics

10 participants took part in a total of 16 longitudinal interviews (table 1). There were five female and five male interview participants, and three participants were accompanied by companions. The age range was 57–82 years and mean age was 70 years old. Five participants received the second PET scan (as part of the PET substudy) while five did not receive this second scan (table 2).

Participants were interviewed from across all four treatment arms of the trial: standard dose dCRT prescribed carboplatin/paclitaxel (Arm 1); standard dose dCRT prescribed cisplatin/capecitabine (Arm 2); escalated dose dCRT prescribed carboplatin/paclitaxel (Arm 3);

Table 1 Number of participants interviewed pre-pandemic and post-pandemic

Data collection period	Number of participants interviewed	Number of interviews
Pre-March 2020 (in-person interviews prior to COVID-19 pandemic)	4	7
Post-October 2020 (telephone interviews after qualitative study suspension from March 2020 to October 2020 due to COVID-19 pandemic)	6	9
Total	10	16

and escalated dose dCRT prescribed cisplatin/capecitabine (Arm 4) (table 2). All interviews were conducted within 7 months after baseline. Chemoradiotherapy was completed within 12 weeks.

Qualitative findings

The experiences of participants were captured throughout the trial, which highlighted changes at different time points in participants' perspectives, and the impact of treatment regimens on quality of life, including daily, family and social life.[14 15] The following results highlight the findings from the interviews, relating to the following key themes: experiences of treatments, treatment impact over time, patient outlook and quality of life after treatments, and impact of COVID-19. A hierarchy of themes and subthemes is presented in table 3. A discussion of these findings is outlined below, with illustrative quotations. A comprehensive outline of all relevant quotations is available in online supplement 4.

Experiences of treatment

Participants described the impact of receiving the treatment (radiotherapy and chemotherapy) including side-effects, and improvements to health. They emphasised how information provision and support from clinical trial and NHS staff before, during and after their treatments impacted on their overall psychological, as well as physical well-being.

Impact of treatment

Initial chemoradiotherapy treatment and support provided by clinical teams earlier in the trial were described as having resulted in small improvements for some participants' cancer symptoms. These cancer symptoms mainly related to difficulties eating.

> When I started, I had difficulty swallowing obviously with the oesophagus tumour and it was sort of every meal, every few mouthfuls were getting difficult and I found in about 2 weeks into the first cycle, I was pretty much able to swallow normally. So, something positive is happening. **Participant 4 (2–3 months)**

> I had a tube fitted in my arm yesterday, ready for the chemo on Friday, and I've got a feeding tube, so I don't have to worry about not getting enough nutrition in, so I think a lot of worries I had at the beginning have faded. **Participant 6 (Baseline)**

Side-effects from treatments

Participants experienced short and longer-term side-effects from the trial treatments including pain, dysphagia, tiredness and thrombosis. Several participants experienced multiple side-effects including pain and fatigue, or general degradation in their health, although most participants felt that these subsided over time.

Table 2 Participants' information and interviews

Participant	Arm	Companion accompanied	Second PET scan at day 14	Baseline interview	Between 2 and 3 months after baseline	3–6 months after baseline	6 months+ after baseline
P 1	2	X			✓	✓	
P 2	2		X			✓	
P 3	1	X	X		✓		
P 4	1				✓	✓	✓
P 5	1					✓	
P 6	4			✓		✓	✓
P 7	2		X			✓	✓
P 8	3		X			✓	
P 9	2		X				✓
P 10	4	X		✓			

PET, positron emission tomography.

Table 3 Themes

Themes	Subthemes	Secondary subtheme
Experiences of treatment	Impact of treatment	
	Side-effects from treatments	Side-effects from chemotherapy Side-effects from radiotherapy
	Recovery after chemoradiotherapy	
Treatment impact over time	Information and support needs after treatment	
Patient outlook and quality of life after treatments	Psychosocial impact Gradual improvements to quality of life Adaptation and normality Positive outlook after treatment	
Impact of COVID-19	Vulnerability and isolation	

> During the first cycle … the pain in my feet and little bit sort of pins and needles like that, I think that's the worst side effect that I have experienced … Tiredness, you know, I just feel worn out … the other thing that I get is almost like fatigue in my thighs… I think 1 day where I felt sick which is (from) just cleaning my teeth. **Participant 4 (Baseline)**

Side-effects from chemotherapy

Participants described common side-effects they experienced after receiving chemotherapy including muscular fatigue, pain and neuropathy in their feet. While most of these were expected, they were at times unprepared for certain side-effects.

> The side effects I've I had are quite sore feet at one stage when I was on the chemotherapy, which was difficulty walking. **Participant 7 (3 months)**

> Cos everybody expected when I stopped the chemo, especially me, I thought that was it (laughs), you know stop the chemo and that's fine. And, then I stopped the chemo, and I got ill (laughs). **Patient 6 (6 months)**

Four patients reported that during the trial, their chemotherapy treatment had been changed or stopped due to pre-existing conditions, side-effects that they had experienced or that the treatment was not positively affecting their cancer outcomes. Two patients' experiences of these chemotherapy switches are described below. This demonstrates the complexities patients and clinicians may face when weighing up the side-effects of different chemotherapy regimens.

> I found the capecitabine taking those every day I think they were the hardest of the drugs that I was taking… I did notice with them the nausea and the sickness, and the fatigue was massive. When, they put me on (another chemotherapy drug) … I felt it was much gentler … unfortunate(ly) for me … having a blood clot … I think that was the worst thing … the blood clot was harder to recover from than the cancer (laughs). **Participant 4 (3 months)**

> The first chemo I was on, they had to change … I've got … Neuropathy … So, they changed it. And another one was because of my kidneys. They changed that to a different one right at the very beginning. **Participant 5 (3 months)**

Side-effects from radiotherapy

The experience of receiving radiotherapy was reported by most participants as being physically and psychologically arduous. Difficulty and pain swallowing experienced after radiotherapy were the main side-effects described by several participants.

> Because of what the radiotherapy does, it sort of burns all the inside and it's very difficult to swallow… but that was the worst thing to be perfectly honest with you, the thing is I would like to able to eat like I used to, but at the moment I can't but I am getting there … definitely tons better now. **Participant 2 (2–3 months)**

> With the radiotherapy… I was completely and utterly flat out, nothing mattered at all … You can't win it at any point … you can't concentrate or want anything, you feel bad if there is no pain, nevertheless you feel dreadful. **Participant 1 (6 months)**

Recovery after Chemoradiotherapy

After the completion of chemoradiotherapy, during the recovery period, participants experienced symptoms which ranged from mild to severe, with physical and psychological outcomes. Nausea, as well as fluctuations in appetite, weight and energy levels were reported by participants, often relating to pain and issues swallowing.

> I lost my appetite a bit, but … that's come back now, and … I am starting to regain weight… I still have problems digesting food … some foods just get stuck in my oesophagus, and that is still a little bit painful. **Participant 7 (3 months)**

Some participants recalled having to adapt to the fatigue caused by difficulty sleeping and pneumonia.

Participants' symptoms tended to lessen over time, and when they had received support to reduce these symptoms from clinical services, they usually recalled noticeable improvements. Post-chemotherapy issues relating to bowel function included constipation and diarrhoea. Other symptoms were also reported including low immunity and hair loss.

> I had pneumonia… I started with the infection as soon as I finished the chemo… I was in hospital for a week. And, I had about four different courses of antibiotics and they just weren't working on the pneumonia. And I felt worse with that than I had been through all the treatment. And I was just starting to get better before we went away… within days I suddenly was much, much, much better. **Participant 6 (6 months**)

> I had trouble sleeping for quite some time and that has sorted itself out now and can sleep perfectly well now without any paracetamol at all, so night-time is good. **Participant 1 (2–3 months**)

It was not always possible to differentiate between the impact of chemotherapy or radiotherapy treatments, as participants described their symptoms more generally and did not necessarily attribute them to individual treatments.

Treatment impact over time

Participants reflected on their cancer treatment journey and how their symptoms had changed over time, including facing adversity throughout treatment regimens and gradual improvements.

> At the time during the treatment … I've felt really, really, really ill, worse than before I started the treatment… The treatment was tough… I have (had) a lot of symptoms, side-effects from it. But those have finished now, so obviously things are improving… when it finished, I was having problems … but each day I'm getting better. **Participant 5 (3 months**)

> I'm just feeling better every day and my eating is improving all the time. **Participant 6 (6 months**)

Information and support needs after treatment

Concerns were raised by several participants and their companions regarding what would happen post-treatment, as they felt that there was less information and support available than before and during their treatment. Participants expressed a need for further and more timely information and updates from healthcare professionals regarding potential side-effects, and recovery timescales post-treatment.

> We actually felt that we have huge information on side-effects during treatment but virtually nothing on after (treatment). **Companion of Participant 1 (2–3 months**)

> Patient: No interest at all in checking my general condition which could have changed because of the treatment …
>
> Companion: And you just hope that all the drugs are compatible … They all interact with each other and that is another hurdle. Who knows?…
>
> Patient: It's thousands of, it's thousands of trials. How can you do it, interaction of drugs is a massive problem being tackled all the time. **Participant 1 (2–3 months**)

Participants described difficulties with eating and dietary needs and expressed the importance of being provided with relevant information from clinicians regarding how the disease or treatments impacted on these fundamental needs.

> One thing that I asked all along was really about how much I could eat, we have been asking, haven't we? You sort of (know) it is going to get more difficult, is my throat going to be smaller, will it get bigger again, how much will I be able to eat? Will I be able to eat properly at the end and I think that all our questions have been like that. **Participant 3 (2–3 months**)

Several participants described the high level of personal support from clinical and third sector services, including key workers, which made a significant impact on their trial and treatment experience. They described the support and information they received relating to their quality of life and practical needs.

> I have phone calls from the clinical nurse (key worker) … sometimes just to ask how I am, he's helped to make appointments for me when I've had problems making them myself. And he's managed to make everything seamless from one thing to another, which I greatly appreciated, because I was a bit all over the place, especially at the beginning of diagnosis… if (clinical nurse) thought that maybe I wasn't getting something, that the Oncologist was saying to me … maybe sometimes I was lacking a bit of understanding and he always made sure that I left that room understanding everything. **Patient 6 (3 months**)

> The medical staff have really been great, and … I've got all the information … all I need to do is pick the phone up and I know I can speak to somebody with any questions … I have been in contact and … am on various forums with Macmillan, … which … my wife and I have accessed quite frequently … just to view other peoples' experiences, which has been good, because obviously whatever side effects you're having, there's always somebody else who's had them as well … it reinforces and puts you at ease really to see other people have gone … through the same thing. **Patient 7 (3 months**)

Patient outlook and quality of life after treatments

Psycho-social impact of treatments

In the first few months during and post-chemoradiotherapy, patients described the psycho-social impact of treatment. This included disinterest or lack of energy to participate in previously enjoyed hobbies and social activities.

> Things that I would have done, I am a cellist, I play cello and other things and no way, [I am] completely uninterested, stopped, books and all I read, stopped. **Participant 1 (2–3 months)**

Gradual improvements to quality of life

Participants explained how the treatment had impacted on their quality of life. Most participants experienced gradual improvements to their health and well-being. This related to regaining their capacity to participate in previous routines and social activities. However, they also felt that their physical health post-treatment had placed restrictions and strains on their everyday routines. Some felt they had relied heavily on their family for support with daily activities.

> My wife has done everything for me and is very, very protective… I do think it would have been lot tougher if I had been on my own. My daughter stepped in and did all the work … she moved heaven and earth to make sure that for the last 3 months she was available … There were days when I (said) 'it's okay, let me drive' and getting back into that was a biggish step but now I am back into driving. **Participant 4 (6 months)**

Adaptation and normality

Regaining a sense of normality was important but complicated for some participants when re-adapting to life after treatment, as their daily lives had been significantly impacted by their experiences of cancer and treatment. Several participants explained that they had struggled to readjust to life after treatment due to the change in outlook that they needed to make, or the extra support that they had received on the trial, which was no longer available.

> I think there was a feeling of … as if you were left on your own. You get that initial feeling because the 12 weeks of treatment were so intense… we were in the hospital everyday, sometimes twice a day and then you know it's 'off you go then'. It been couple of months now - rest, recuperate relax, get back to normal life and I found that quite a strange statement and I got to admit that's perhaps the hardest thing to do now was getting back to normal life. **Participant 4 (6 months)**

Positive outlook after treatment

Several participants described how they attempted to sustain a positive outlook about their survival prospects and their circumstances overall. Thus, being provided with adequate support and updated information aided their positive outlook.

> Things improve on a daily basis and hopefully it will continue to improve. I don't like it (laughs) … a lot (laughs), yeah but that's fine you know, there will come a day when it will be fine and I will be able to go (out) again, so I will just wait for that day. **Participant 2 (3–6 months)**

> I feel a lot better. Obviously, the time I was diagnosed it was a bit of a bolt out of the blue and I was left you know in big, big shock. So, the fact that they've now said to me that the cancer's gone, it's obviously a huge relief. **Participant 7 (6 months)**

Impact of the COVID-19 pandemic

Vulnerability and isolation

Some participants reflected on how the pandemic may have intensified the sense of isolation and stress that other patients felt during their treatment process, although these participants did not feel personally affected in this way.

> When you were sat in radiotherapy and chemo, some people probably needed somebody with them in chemo, I didn't … but there were people that were a lot sicker than I was I suppose. Pre-Covid you could have a friend with you to keep you company through the day. **Participant 8 (3 months)**

> When we were filling in the clinic surveys … isolation wouldn't have been isolation if it hadn't had been for Covid … Covid had an influence on everything … From times of clinics to staff levels … it was an influence on everything. **Participant 8 (3 months)**

The pandemic caused an increased sense of vulnerability and cautiousness among these patients. However, the comprehensive social restrictions put into place for infection control, and the vaccination programme at times allayed some of their fears and eased the sense that these participants missed out on their usual social activities.

> I haven't been out since the beginning of Covid … it's been isolation all the way… if everybody else wouldn't have been in isolation as well, I suppose it would've affected me more but because everybody else was in isolation … I don't suppose it bothered me that much. **Participant 8 (3 months)**

> Having the chemotherapy treatment … that's like causing my immunity to be lowered … I've read … which could have made me more vulnerable to Covid … to counter that … I had my two vaccines … quite quickly because… of the cancer I've had, so that most

probably countered that bit … the stress of that … against catching the Covid. **Participant 7 (3 months)**

DISCUSSION

Main findings

This qualitative study captured the experiences and perceptions of SCOPE2 trial participants, using longitudinal interviews. These interviews highlighted participants' practical, physical and psychosocial needs at different time points. Participants described expected and unexpected side-effects from the radiotherapy and the chemotherapy at different time points, although most of these symptoms lessened over time. Participants attempted to be positive about their survival prospects and applied coping strategies by readjusting their expectations and priorities, and focusing on regaining a sense of 'normality'. More timely and comprehensive information regarding the longer-term side-effects of chemoradiotherapy, aftercare and cancer status was highlighted as necessary to improve overall patient experience and quality of life.[16 17]

Comparison with the existing literature

Consistent with earlier qualitative studies, participants in this study experienced varying side-effects from the chemoradiotherapy treatments across the trial arms, which ranged from mild to severe. Shorter-term side-effects included pneumonia, fatigue, difficulty sleeping and pain swallowing, reflecting symptoms have also been reported more generally among oesophageal cancer patients.[16] Gastrointestinal effects were also described by participants, including nausea, satiety and diarrhoea, poor appetite and weight loss, reflecting side-effects after surgery reported in other studies.[17 18] Due to the low number of participants in this qualitative study, it was not possible to differentiate the impact that each treatment arm or PET scan had on the participants. However, the side-effects reported do reflect those expected for this group of participants, the number of cases relating to chemoradiotherapy are reported in more detail in the SCOPE2 PET paper and will be available in the SCOPE2 trial findings.[19]

Participants' perceptions of their treatment and side-effects changed over time and they attempted to be positive about their survival prospects by readjusting their expectations and priorities, as reported in prior research.[20] Similar coping strategies and approaches to resilience and adaptation have been identified in studies that highlight the changing emotions that patients deal with when facing the uncertainties of life-threatening illnesses.[21 22] As reported in prior research findings, participants reflected on the importance of regaining a sense of 'normality', as their daily lives had been significantly disrupted by the cancer and its treatments, but for the most part were improving over a period of months.[23 24]

Participants described varying levels of uncertainty and a lack of knowledge regarding potential longer-term side-effects from treatment. This reflects previous research findings illustrating the need to provide timely and appropriate patient communication and information, particularly relating to treatment aftercare, which can reduce anxiety and increase patients' well-being and their sense of agency.[16 17 25] In contrast, best practice examples were described as key contacts organising appointments and providing signposting to appropriate information,[26] which reduced psychological and physical burdens on the participants during a time when they were acutely ill.

These findings illustrate how the COVID-19 pandemic had varying effects on participants when receiving cancer treatment. Some participants felt that due to social restrictions, the impact on their social activities was less than it usually would have been pre-pandemic. Conversely, others felt a heightened sense of social isolation and reduced opportunities for peer support, as previously reported in studies of patients with cancer during the pandemic.[27 28]

Strengths and limitations compared with other studies

This longitudinal qualitative research provided nuanced and in-depth insights into participants' perceptions and experiences of the trial and impact of chemoradiotherapy before and during the COVID-19 pandemic. These insights are not comprehensively captured through other types of data collection (quantitative and clinical data).[29] Using longitudinal interviews has also informed the trial team of patients' ongoing information and support needs. However, recruitment to this qualitative study was slow and the relatively small numbers of participants that were recruited restricted data saturation. This particularly impacted the breadth of experiences explored across different trial arms and the ability to understand the additional impact of higher dose of radiotherapy on patients. Recruitment to the qualitative study was delayed pre-pandemic and post-pandemic, as permissions to recruit to the qualitative element were granted separately to the main trial.

Although the qualitative study was considered embedded in the overall trial, recruitment was not fully integrated, as trial and qualitative study participants were consented at different times. This increased the time and resources required for qualitative recruitment. Additional barriers limiting recruitment included lack of available staff for recruitment, the health of participants and delays due to the COVID-19 pandemic. In contrast, some quantitative[30] or combined qualitative and quantitative studies[31] which examined patients' experiences or quality of life after oesophageal cancer treatment recruited higher numbers of participants. These were able to compare the broader range of patients' experiences of chemoradiotherapy. Nonetheless, these studies did not explore the depth and range of trial and treatment experiences through qualitative interviews.

Implications for policy makers and future research

OC clinical pathways need to provide opportunities for patients to discuss, revisit information and ask questions before, during and after their treatments, in order to enhance patient satisfaction with their trial, treatment and recovery experiences. Consistent signposting to charities and peer support could also enable patients to access relevant and timely support. Future trials and pathways should ensure ongoing access to support through the provision of a key contact for the patient. Sharing updates regarding the progress of the trial where possible would also be useful for participants. A more integrated approach to qualitative studies embedded in trials including incorporating real-time reporting in future trials could provide improved opportunities for recruitment and patient experience.

CONCLUSION

Qualitative study participants of the SCOPE2 trial were generally positive about the impact of their treatments and recovery experiences, despite experiencing a range of side-effects, some of which were unexpected. Future trials and cancer services should consider patients' needs for ongoing information and support regarding treatment, aftercare, longer-term side-effects and cancer status to improve their overall health and well-being.

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Contributors TC Chief Investigator responsible for overall trial design and oversight of study progress. AN designed and oversaw qualitative evaluation. ML oversaw the qualitative study. DHH drafted the results and manuscript. DH-H and ML collected and analysed qualitative data. SB was the study manager and contributed to trial study design, qualitative recruitment and quantitative data. LN contributed to trial study design, study management (including study documentation) and monitoring oversight. MH contributed to the trial design. TC is responsible for the overall content (as guarantor). All authors contributed to revisions of the manuscript and approved the final version.

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Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants. SCOPE2 has full ethical approval from Wales Research Ethics Committee 3 (dated 22 January 2016, with subsequent approval of each amendment; REC reference 15/WA/0395), and is conducted in accordance with The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI2004/1031) and subsequent amendments, and the Declaration of Helsinki 1996. Written informed consent has been obtained from all study participants, with separate consent obtained for participants in the Qualitative interview study. Participants gave informed consent to participate in the study before taking part.

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