

Participation in a randomised controlled feasibility study of a complex intervention for the management of the Respiratory Symptom Distress Cluster in lung cancer: patient, carer and research staff views

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This paper reports findings from a nested qualitative study designed to elicit the views and perceptions of those who participated in a randomised controlled feasibility trial testing a non-pharmacological intervention, Respiratory Distress Symptom Intervention (RDSI), for the management of the breathlessness–cough–fatigue symptom cluster in lung cancer. Semi-structured interviews were conducted with 11 lung cancer patients, three caregivers and seven researchers involved in recruitment, consent, RDSI training and delivery and participant follow-up. Thematic analysis identified key considerations including: the importance of informed consent emphasising commitment to completion of paperwork and raising awareness of potential sensitivities relating to content of questionnaires; ensuring screening for the presence of symptoms reflects the language used by patients; appreciation of the commitment required from participants to learn intervention techniques and embed them as part of everyday life; conduct of interviews with patients who decline to participate; and conduct of serial interviews with those receiving RDSI to further inform its routine implementation into clinical practice. This study will inform the development of a fully powered follow-on trial testing the hypothesis that RDSI plus usual care is superior to usual care alone in the effective management of this symptom cluster in lung cancer.

KEYWORDS

carers, lung cancer, patients, qualitative, semi-structured interviews, symptoms

1 | INTRODUCTION

Lung cancer symptoms, both physical and psychological, are often chronic, resulting in significant burden, impaired physical and social function and poor quality of life (Yates, Schofield, Zhao, & Currow, 2013). In

addition, lung cancer patients may undergo a range of treatment modalities, including surgery, chemotherapy and radiotherapy, with accompanying side effects adding to patient burden (Molassiotis et al., 2015).

Compared to other types of cancer, the distress associated with symptoms arising from lung cancer has been reported as the most

intense (Schofield et al., 2008). Several studies have identified the presence of a respiratory symptom cluster in patients with lung cancer showing close associations among breathlessness–cough–fatigue (Cheville et al., 2011; Molassiotis et al., 2011). This interacting symptom cluster, called Respiratory Symptom Distress Cluster was found to play a central role in patients' symptom experiences within the lung cancer population.

The randomised controlled trial (RCT) is a central tenant of evidence based healthcare (Treweek et al., 2015). Significant challenges have been experienced in previous trials with lung cancer patients. These have been the result of patients' poor performance status and high symptom burden with complex symptomatology, which can lead to difficulties in study recruitment, retention and implementation of non-pharmacological interventions (Jordhøy, Kaasa, Fayers, Underland, & Ahlner-Elmqvist, 1999; Zhao & Yates, 2008).

BOX 1 Components of respiratory distress symptom intervention (further details regarding RDSI are provided in Yorke et al., 2015).

i) Diaphragmatic breathing

Controlled diaphragmatic breathing techniques

ii) Acupressure

Patients were taught a number of acupressure points: L7, L9, LI4; ST 36; CV 21 and 20.

Patients were taught to select any of these points in any combination and to apply pressure at least twice a day, applying steady firm pressure for 1 min to each point with the thumb or middle finger, releasing the pressure slowly after the minute. They can use these points more frequently if they so wish.

iii) Cough easing techniques

i. Increase awareness

ii. Apply controlling techniques

Once they are aware of how it felt just before they cough or clear their throat they were asked to apply one of the three following techniques: Take a sip of water; Sniff then swallow; swallow.

Patients were told that it may take a number of consecutive attempts of the controlling techniques for a few seconds of relief before the urge to cough returns. The key is to persevere—if the urges to cough returns just repeat again.

Alongside Supplementary Written Information giving practical advice about:

i) symptom experiences and communication strategies

ii) Vocal hygiene

iii) Sleep hygiene

iv) Activity management/energy conservation strategies

v) Anxiety management techniques (such as the 'calming hand')

vi) Carer support

Methodological literature is almost exclusively statistical and epidemiological, and very little of it is concerned with conduct or the particular demands that trials put on researchers and participants (Donovan et al., 2002). When feasibility testing an intervention it is crucial to explore the views and experiences of all stakeholders. Consideration should be given to issues that might make a non-pharmacological intervention more appropriate, viable, and achievably integrated into standard practice while responding to policy drives for service users to be more involved in research and health service development (Department of Health, 2006). Nested qualitative studies, using semi-structured interviews within trials are essential as they provide insight into such issues.

This paper reports the findings from a nested qualitative study, part of a RCT which aimed to evaluate the feasibility and acceptability of a non-pharmacological intervention, the Respiratory Distress Symptom Intervention (RDSI), plus usual care versus usual care alone for the self-management of breathlessness–cough–fatigue symptom cluster in lung cancer. The main results of the RCT feasibility trial are reported elsewhere (Yorke et al., 2015). RDSI had three core components focusing on, (1) breathing techniques, (2) cough easing techniques and (3) acupressure. Furthermore, patients were given a supplementary symptom experience information pack collated from existing resources (see Box 1). Patients randomised to the control group received usual care alone (see Box 2).

BOX 2 Components of best supportive usual care (Standardised according to Wagland et al., 2012).

Symptom management followed a detailed assessment of each patient's needs to rule out other possible causes for the symptoms and to assess the impact of comorbidities. Social circumstances were also considered and appropriate referrals made (e.g. occupational therapy, physiotherapy, social services, psychological services).

i. Breathlessness—according to degree of breathlessness

- Morphine
- Oxygen
- Benzodiazepines
- Ventolin or saline

All patients were given the Macmillan Cancer Support booklet 'Managing Breathlessness'

ii. Cough—according to severity

- Morphine (severe cough only)
- Codeine linctus
- Simple linctus

iii. Fatigue

- Steroids (if appropriate)

All patients were given the Macmillan Cancer Support booklet 'Coping with fatigue'.

The aims of the nested qualitative study reported here were:

1. To elicit the views and perceptions of patients and their carers who participated in the RCT regarding their reasons for consenting to participate, their experiences being a research participant, the RDSI package and the outcome measures used.
2. To elicit the views and perceptions of the researchers involved regarding the process of recruitment, consenting and randomisation, RDSI training and delivery, participant follow-up and their general experiences of being involved in the trial.

2 | METHODS

The study sites included two specialist cancer hospitals and nine other NHS hospitals in the northwest of England. Approval for the conduct of the main RCT and nested qualitative study was provided by the National Health Service ethics and participating hospital governance committees (reference: 12/NW/0090). All participants (patients, carers and researchers) provided written informed consent to take part in interviews discussed here.

2.1 | Sampling

2.1.1 | Patient and carer participants

A purposive sample consisting of participants, who at trial entry had indicated an interest in taking part in interviews, was approached. Criteria for selection included being a trial participant; randomised to either the intervention or control group and representative of the three cancer treatment groups as per stratified randomisation: (1) No further active cancer therapy; (2) Post-curative treatment or (3) On palliative cancer therapy follow-up. We aimed to recruit five patients in each treatment group and their carers (although interview participants were not required to be dyads).

2.1.2 | Research staff

A focus group discussion was arranged with the trial specialist practitioners who participated in recruitment and intervention delivery, complementary therapists who taught the intervention to the specialist practitioners and the research associates whose main role was to recruit and follow-up trial participants.

2.2 | Data collection

Semi-structured interviews with patients and carers were undertaken by two research associates (JE, JW) working on the main feasibility trial and both experienced qualitative researchers. Patients and participating carers were requested to be interviewed separately. The interviews were guided by an interview schedule which focused on the following key issues: reasons for taking part in the trial; general experiences of taking part in the trial; patients' experiences of

receiving the intervention; patient experiences of being in the control group; and carers' experiences of taking part in the trial. Interviewers were also free to explore other issues as they arose. Demographic and clinical data were collected either from the patient (age, gender, marital status) or from the medical records (i.e. WHO performance status, type of lung cancer and cancer treatment group). Participants were provided with the option to have interviews conducted face-to-face at a mutually convenient venue or a telephone interview. Interviews were recorded and transcribed verbatim.

The focus group with project staff was directed by a topic guide organised around the following key topics: general experience of taking part in the trial; process of recruitment, consenting procedure and randomisation; experience and views regarding the training for intervention delivery; experiences and views regarding delivery of the intervention; overall conduct of the trial and their participation in the trial and final recommendations for the main trial. All focus group participants provided informed written consent for the focus group discussion to be audio-recorded and subsequently transcribed verbatim, anonymity being assured.

All patient and carer participant interviews and the project staff focus group were conducted following completion of their study involvement.

2.3 | Data analysis

A modified version of thematic analysis, a method for identifying, analysing and reporting patterns within data (Braun & Clarke, 2006), was undertaken using interview and focus group schedules as a guide for categorising data interviews and the focus group. The researchers familiarised themselves with the data through listening to the audio-recordings and checking and re-reading the transcripts. Data analysis was conducted by the two researchers who had undertaken the interviews and in collaboration with the Chief Investigator. Throughout the analysis the researchers met regularly to discuss the analysis.

3. | RESULTS

3.1 | Patient and carer participant interviews

A total of 11 patients (six women; five men) and three carers (two women; one man) participated in interviews. Six patients had been randomised to receive the intervention and five to the control group. Six patients had received treatment for their lung cancer with post-curative intent and the remaining five were receiving palliative cancer therapy follow-up. No patients who consented to be interviewed were in the no active cancer therapy group. Two of the three carers who participated were female and all were either a spouse or partner of the patient. Detailed socio-demographic and clinical data are presented in Table 1.

All but two of the interviews took place in the patient's home, the remaining two by telephone. Ten patients and two carers provided consent for the interviews to be audio-recorded. One patient and their carer did not consent to the interview being recorded but did consent to field notes being taken. Unfortunately, due to a malfunction of the

TABLE 1 Socio-demographic and clinical data of the sample

ID	Gender	Age	Treatment Group	WHO PS	Trial Arm	Carer interview	Gender
216	Female	61	Post-curative intent treatment	2	Control	No	
217	Male	63	Post-curative intent treatment	1	Intervention	Yes	Female
303	Female	65	Post-curative intent treatment	2	Intervention	Yes	Male
312	Female	70	Palliative cancer therapy follow-up	1	Control	No	
315	Female	64	Palliative cancer therapy follow-up	1	Intervention	No	
317	Male	78	Post-curative intent treatment	1	Intervention	No	
318	Female	63	Palliative cancer therapy follow-up	2	Control	No	
408	Male	64	Post-curative intent treatment	0	Control	Yes	Female
409	Female	63	Palliative cancer therapy follow-up	1	Intervention	No	
505	Male	77	Palliative cancer therapy follow-up	1	Control	No	
604	Male	78	Post-curative intent treatment	2	Control	No	

WHO PS, WHO Performance Status: 0 = fully active; can't carry out heavy physical work; 2 = up and about more than half the day; 3 = in bed or a chair for more than half the day; 4 = in bed or a chair all the time and need complete care (Trial inclusion criteria WHO PS 0–2).

audio-recorder, the two telephone interviews were inaudible; therefore, in-depth field notes were used for analyses.

The analysis focused on patients' and carers' views and experiences regarding their involvement in the trial. Five themes were extracted from the data and centred on the study aims. These are presented below supported by indicative quotes shown in Table 2.

3.1.1 | Reasons for taking part in the trial

Participants had varied reasons for taking part in the trial. Two patients and one carer had the expectation that being in the trial might help ease troublesome symptoms, such as cough and fatigue, which were perceived as receiving little attention from healthcare professionals. Seven patients expressed no expectations whatsoever and one patient and one carer described being sceptical about how effective taking part would be. Two patients felt taking part would allow them to gain further knowledge of their symptoms and lung cancer. There was also the perception that patients felt somewhat neglected by their clinical teams and left to "get on with it" and participating in the trial may, therefore, offer an avenue for additional support.

3.1.2 | Patients' general experiences of taking part in the trial

Patients in both study arms reported gaining a greater understanding and knowledge of their illness and symptoms, especially in relation to the presence of symptoms post-cancer treatment. The support from the research team was valued, particularly by those living alone. There was a feeling that they were continuing to be monitored through participation in the study, which provided them with a sense of reassurance.

Patients expressed varying degrees of difficulty in completing the questionnaires with three out of the 11 patients describing them as repetitive and overwhelming. In contrast, two patients appeared to have benefited from completing them as it tended to legitimise their

symptoms or help them accept the realities of their disease. All patients appeared to be reassured with the knowledge that the symptoms were relatively common among lung cancer sufferers and were not unique to them. Patients stated that some of the questionnaires were not relevant as they referred to their lung cancer—yet they believed their lung cancer to have been cured and they were no longer suffering from the disease. There was a general perception that the questions asked in the study questionnaires could be upsetting to patients and their carers, however, no patients expressed feeling upset at being asked these questions themselves. One carer felt some questions were intrusive but understood why they were being asked. For this reason, additional support may be required when considering future trials.

One participant explicitly stated they found the Macmillan booklets and Supplementary Information very useful commenting on the CD in particular. However the general consensus was that far, too much information was supplied with patients finding it difficult to navigate around the various materials. Four patients appreciated the support in completing the questionnaire and felt they would have been less likely to complete them without it. Unfortunately, one patient did not recall receiving any information. Despite this, all patients in both groups were glad to have taken part in the trial and would recommend it to others.

3.1.3 | Patients' experiences of receiving the intervention

While initially two participants expressed scepticism that the interventions would work, they soon perceived a greater sense of control in their ability to manage their symptoms. Two interviewees reported immediate benefits from the intervention; the remainder discussed how benefits actualised over some time. Patients reported being able to undertake activities they had not been able to achieve since their diagnosis. Patients did not find the techniques restrictive, rather they used them as and when they felt the need. The only barrier to practising the techniques appeared to be when patients were feeling

TABLE 2 Supporting quotes from patients and carers

<i>Reasons for taking part in the trial</i>	
Expectations	<p>"Just I thought I would...it would help me with my breathing, and stuff like that. Which it did, because I read the book there, and it did help me a lot." (216, Patient)</p> <p>"No expectations at all and was happy to play it by ear." (317, Patient)</p> <p>'just to basically try and improve the lot that she's got, that she's been left with, if you like. If you can improve her breathing, which to me it did just a little, you know...but, no, it did meet them and more (303, Carer)</p> <p>"Getting more knowledge about fatigue and breathlessness." (408, Carer)</p>
<i>General experiences on taking part in the trial</i>	
Understanding	<p>"Yes, because you explained it to me... in layman's terms." (315, Patient)</p> <p>"The reason I joined the trial is because of the way things were explained – it was a better explanation than anyone has given me before..." (408, Patient)</p> <p>"Yeah, because it was treatment as normal and then this was extra that you wouldn't necessarily have had." (303, Patient)</p>
Completing questionnaires	<p>"Couldn't have completed the questionnaires without the help of the support team." (315, Patient; 318, Patient)</p> <p>"Found some off the questions very repetitive and didn't see the point of them. "Found some questionnaires difficult to fill in- had to have help." (318, Patient)</p> <p>"I find it difficult to self-assess and that wouldn't apply to every person but if it says how to...on a scale of one to ten, however, I found it difficult to assess..." (303, Patient)</p> <p>"There was one point, it wasn't upsetting, but it was a reality check. It was a question where I thought, oh gosh, yes." (303, Carer)</p> <p>"Because of the type of illness B [patient's name]'s got, I found some of the questions a little bit hard to answer, because they weren't really relevant to somebody who was more severe with the illness..." (217, Carer)</p> <p>"My first reaction was to get through it. The questionnaires made you think.....some of the questions were quite searching.... some were intrusive." (408, Carer)</p> <p>"In my opinion the one thing that probably was the paperwork, from my point of view I like the hands on, more so than sitting there filling in forms. That's probably why I enjoyed doing the work is love hands on, and I think as far as filling forms in, it's not my thing" (303, Carer)</p>
Support from the research team	<p>"Yes, there was nothing wrong with the support at all, and we were helped whenever we needed to be helped." (604, Patient)</p> <p>"Yes, in a way, because you've got somebody to fall back on. If there's something playing on your mind, or you've got a problem with something, you know there's somebody there at the end of the phone that you can phone up." (315, Patient)</p> <p>"Absolutely fantastic – wonderful people." (317, Patient)</p>
Benefits of participating	<p>"... you learn to understand things a lot better." (315, Patient)</p> <p>"I found out a lot more about the cancer, also after the cancer, the way I'd been feeling, and it helped me a lot I found out a lot, really, about things I didn't understand before. Yes, because I'm tired all the time, and that explained it. The coughing, which it explained it..." (216, Patient)</p> <p>"Keeping an eye on you...checking how you were..." (318, Patient)</p> <p>"Checking up on you ...seeing how you are." (505, Patient)</p> <p>"Of course there are benefits - it made me realise what people are going through and that people do understand." (408, Patient)</p> <p>"Yes, if it's going to help, and it's going to help other people." (217, Carer)</p> <p>"Yes, because it has been a benefit to..., so I think people should try it, whether they find it doesn't help them...but unless you try it you don't know, do you?" (217, Carer)</p> <p>"Should have this course when people need it." (408, Carer)</p>
<i>Experiences of receiving the intervention</i>	
Thoughts on being randomised to the NI	<p>"I think we were pleased really weren't we? Extremely pleased, yeah. Because we thought oh yeah we can actually do something rather than being in the controlled group, because I've been in the controlled group before and it's just...they send you surveys and what have you but you feel as though you're actually in control of your illness." (303, Patient)</p> <p>"I was quite pleased actually. It's not as though...no, how am I going to put this without sounding awful...before these exercises, I felt as though I'd just been left to get on with it, kind of thing. But when I was told I was going to be taught how to help myself with the breathing, I was really pleased." (217, Patient)</p> <p>"Shocked, because I honestly thought when we were approached it might be the other group, the smaller group, which would be just paperwork. But, when we were actually put on this one I thought that it could only be good, and I think it was." (303, Carer)</p> <p>"Yes – pleased....like I said before, because the more people are paying attention to him, the more I'm comfortable with that." (217, Carer)</p>
Breathing techniques	<p>"Well, the actual breathing exercises have been brilliant. They've really helped control it. And I got it under control a lot quicker than I was doing before." (217, Patient)</p> <p>"But I think for me it was more about the breathing that helped me overcome the sense of panic sometimes really and just level myself down. loved stretchy man...I think that was the favourite one." (303, Patient)</p> <p>"Yes, it was just the main part was getting to breathe in, but your stomach, and your bottom was supposed to go out... that is what I found difficult to begin with." (315, Patient)</p> <p>"I think it's been a good benefit to me and I'm still doing it...I do feel better when I've done the breathing exercises. It calms me down and my breathing does seem easier." (303, Patient)</p>

(Continues)

TABLE 2 (continued)

Acupressure	<p>“But I think I get a bit boring where I tried to do the same pressure points and I didn’t try the knees. What worked for me were the ones on the wrists and the ones on the thorax and once you get into it and once you get the hang of it...they’re not hard to do...and it’s quite hidden from other people...you can sit with your hand under your sleeve on the pressure point on your wrist and nobody knows what you’re doing but I felt the benefit that way as well.” (303, Patient)</p> <p>“The actual pressure points, the ones on my hand and on my wrist, it was a nice feeling afterwards, yes.... It’s just, it’s funny, it’s difficult to describe, you just feel relaxed. It’s as though it takes all the tension out of your arms. But the ones on the leg, and the sternum, no, they didn’t do anything for me.” (217, Patient)</p> <p>“You know, even when I’m sitting here, or whatever, and I’ll be like this so (referring to the wrist and hand points)...but didn’t like the one on the leg.” (315, Patient)</p>
Cough easing	<p>“I did the swallowing again with the water and, yeah, they helped. But I think for me it was more about the breathing that helped me (303, Patient)</p> <p>“Sometimes it worked, other times I would take a sweet or something.” (315, Patient)</p>
Additional positive effects	<p>“No, because...I’ve started going fishing again, and that was the ideal place to do it, just sat at the side of the pool, because you’re in an upright chair anyway, and it’s the perfect place to do it.” (217, Patient)</p> <p>“You can do it while you’re sitting in the bus shelter on your way to bingo.” (315, Patient)</p> <p>“I think you feel as though you’re actually doing something to help yourself. And that must have well it does have a positive effect on your treatment.” (303, Patient)</p>
<i>Experiences of being in the control group</i>	
Written information/CD	<p>“Found information very useful, especially the CD—it helped with breathing found it very calming - found the voice very soothing.” (318, Patient)</p> <p>“Well, sometimes I find these sort of things, these little booklets, overdone, if that’s the word. It’s what is told in 27 pages could probably be told in just as easily seven pages So, at the end of the day one has to ask the question, has it done me any good. Because, by the time I’d got to the 27th page I’d forgotten what the first page said, and I’m no longer 25 years old.” (604, Patient)</p>

too unwell. All six participants described benefiting from practising breathlessness techniques, which in turn helped with associated anxiety. Two patients made a specific reference to the stretchy man technique expressing how they enjoyed or favoured this one in particular.

While difficult to grasp at first, the four patients who used the acupressure technique reported they found it beneficial and unobtrusive. Not all points taught suited all patients. It was felt that an additional reminder session would have been helpful as one patient admitted stopping due to feeling unsure they were doing it correctly. For patients who suffered from cough, the easing techniques appeared to be beneficial at times. In addition, there were unexpected benefits. The breathing techniques allowed one patient to forego her “sprays,” which she claimed she no longer needed. One patient, who had previously experienced great pain and anxiety when opening her bowels, was able to apply the breathing exercises to alleviate constipation and reported immediate benefit.

3.1.4 | Patients’ experiences of being in the control group

Of the six patients randomised to the control group only one specifically expressed disappointment at this. Patients understood the process of randomisation and the necessity of having two groups were happy to have taken part and did find it beneficial. All control group participants stated they learnt a lot about their condition through the processes of informed consent. Reading the questionnaires also helped to legitimise their symptom experience and provided a sense of reassurance that other patients were likely to be experiencing similar symptoms.

3.1.5 | Carers’ experiences of taking part in the trial

All three carers interviewed were pleased to have taken part in the trial. Like patients, they appeared to gain a greater understanding of the symptoms experienced by their relative/friend by reading the study information provided and completing the questionnaires. They appeared to be reassured by the contact with the research team, which they felt was a form of monitoring their relative/friend’s illness. One carer took on an active role in encouraging and helping his spouse undertake the intervention techniques. Carers found the questionnaires repetitive, somewhat intrusive and at times not relevant since their partner did not have as severe an illness as the questionnaires implied. Like patients, carers felt the intervention should be offered to patients regardless as to where people were in their cancer treatment and post-treatment journey. This would enable people to draw on the knowledge and skills learnt as required. All three carers interviewed stated that they would recommend others participating in any future study, since it was felt that it helped their relative/friend.

3.2 | Project staff focus group

The focus group was held in a private meeting room and was attended by the chief investigator (Chair), the lead complementary therapist (conducted intervention training and delivery), two complementary therapists (conducted intervention delivery); two specialist practitioners (one physiotherapist and one clinical nurse specialist who conducted recruitment and intervention delivery) and two research associates (conducted recruitment and study follow-up). The focus group lasted

Table 3 Supportive quotes from focus group with research staff

Process of recruitment, consenting and randomisation	<i>Screening questions for symptoms</i>
	<p>“... the different doctors gate keeping their patients...some doctors would let you screen the notes, other doctors wouldn't even let you put a sheet on the front of the notes to remind them of the eligibility criteria; so a lot of variability in being able to recruit from different consultants.” (P1)</p> <p>“I think in terms of identifying some of the patients, when you've met them before we've found there's some people that actually deny the symptoms that they've got and you know that they're breathless and you can hear them, but they say, no, no, I'm fine.” (P2)</p> <p>“They've [symptoms] become normalised, because we had quite a few where it wasn't bothersome to them-they've adjusted their life around their symptoms.” (P1)</p>
	<p><i>Inclusion criteria too restrictive</i></p> <p>“Especially in the palliative and the no further treatment groups because even with treatment you would expect those patients to continue to have these symptoms. The treatment doesn't relieve them of the symptoms so making them wait until they've been eight weeks on the TKI or four weeks post other treatments it felt like, why? We want to demonstrate the benefit of this intervention; these patients are going to continue. We're not expecting these treatments to cure them. They are going to continue to have symptoms and symptoms relating to the treatment as well, never mind the illness that they're having the treatment for.” (P1)</p>
	<p><i>Participant support throughout trial participation</i></p> <p>“I think the ones that said, no, I'm fine, I tended to think that they were wanting to go on to talk about other things in their lives and trying to get...and were more needy in that way, psychologically. Then almost thinking, well, I might be completely wrong, but it was like, they agreed to the study because they're going to get this extra intervention and it's not always...” (P2)</p> <p>“So it's about attention and support.” (P3)</p> <p>“I think it did reveal a lot of unmet needs. I can remember one of the consultants who we were recruiting from said, oh, how lovely we've got this study. Now we've got something to offer our patients. That really upset me. Well, actually you've got a lot of services in your area that you could be referring to now and you're not using them. It upset me the number of patients that did have significant unmet needs that this study was attending to some of them.” (P1)</p> <p>“We had a couple of patients who refused because they were actually blind or partially sighted and...one in particular, felt that because her son had said he would help her to fill them in, but because the diary was a daily diary et cetera, she felt it was too much to ask him to do. So we excluded patients, not intentionally, but we are excluding some patients, aren't we?” (P4)</p> <p>“We also had somebody who wanted to be a carer but was dyslexic and just said, “no, any blood you want, fine, but paper, no”. So that's perhaps something to think about.” (P5)</p>
	<p><i>Carer involvement</i></p> <p>“There is a sense of protectionism because I had one patient I phoned the other day regarding the follow-up and she said, “I think he's too ill now to participate. He's very poorly, he's very confused now.” So the sense of protection is in that part and sometimes we went to do the follow-up, a telephone follow-up, then it would be the carer or it could be not necessarily in the trial, but a daughter or a son or somebody who answered the phone. They would say how they were rather than you talk one to one with the patient.” (P4)</p>
	<p><i>Completing the Paperwork</i></p> <p>“It's quite challenging and time-consuming isn't it, for them. I find a few of my participants have found it difficult to actually understand the questions because their literary levels vary so much. So you have to ask them how easy, well, ‘it was easy because you've helped me, but if I had to do it, I couldn't do this, because I don't understand the questions’.” (P4)</p> <p>“I had a husband and wife team who seemed quite keen but they dropped in and out and then finally dropped out because they thought the paperwork was too much. Having to attend to it every day kept drawing their attention back to it [illness]. One of them was okay with it, but the other one said, no.” (P7)</p> <p>“I had a relative who got really emotional and got so emotional that I was, like, if it's going to distress you, feel free if you want to come back to it. I just thought it was hard then to teach all the techniques while she'd got upset initially.” (P1)</p> <p>“... it [completing the paperwork] forces them to think about things that they have not thought about and although personally I would try and prepare them ‘there may be some things that you may not expect, but please tell us if it's too distressing’.” (P4)</p> <p>“I've had actually patients refuse on that grounds to do it, because it does not apply to me. ‘No, this isn't applicable to me. I haven't got lung cancer anymore.’”(P4)</p> <p>“I think one of the main difficulties is quite a few of these patients have had surgery, chemotherapy and/or radiotherapy and they believe themselves to be cured. So a lot of the questions it says, the treatment for my lung cancer, and they turn round and they say, I have not got lung cancer anymore.” (P6)</p>

(Continues)

TABLE 3 (continued)

Experience and views regarding the training for intervention delivery	<p>"I know there's a range of different practitioners" skills around the table, we're not all from the same health profession, so we've all got different levels of expertise. Some of us would focus more on some aspects of their presentation than others. It was difficult to know if I was going to go into parts of the information booklet that would be relevant for my particular skill set" (P1)</p> <p>"I think maybe for training the trainers if we could have had a better baseline of how we were using the supplementary information that would have assisted treatment fidelity for the intervention." (P1)</p> <p>"I was fairly new to it. I'd done hand massage in the past things like that. I'd never actually done the acupuncture points. I did have to try it on myself and my husband before so I could gain confidence, but no, they all accepted that and it was quite good really." (P2)</p>
Experiences and views regarding delivery of the intervention	<p>"I talked about the practicality of how it works because I learnt very quickly that people appreciated them when they actually understood there was a purpose behind it." (P6)</p> <p>"So like the woman who thought her lungs were this big, when we sort of went, oh, you know, you're stretching and lifting and filling up those bags in your lungs, she really got that idea." (P6)</p> <p>"I had some patients who asked a lot more questions about the information booklets and went a lot more off topic than others. One of my last ladies in the study ... said, I've learnt more in the two hours of your visits than I have in the whole of my illness about taking care of myself." (P1)</p> <p>Again, because that needs to be there earlier on to give people the skills, that's what these interventions are about." (P1)</p>

Key: P1 (Physiotherapist) and P2 (lung cancer nurse specialist): Specialist Practitioners responsible for intervention delivery. P3 (clinical lead), P4 (trained therapist) and P7 (trained therapist and registered nurse) Complementary Therapists, responsible for training of Specialist Practitioners and intervention delivery. P5 and P6: Research Associates responsible for day-to-day trial running, recruitment, consent and follow-up.

1 h and 10 min and was transcribed verbatim. Data are presented in four themes representing the study aims and evidenced by indicative quotes shown in Table 3.

3.2.1 | Process of recruitment, consenting and randomisation

Several key points were identified regarding the process of recruitment. At a number of research sites recruitment was dependent on the doctors identifying potential participants. It was suggested that some doctors were acting as gatekeepers and that the screening and recruitment process varied across the sites. Those involved in the recruitment process reported that the inclusion/exclusion criterion was too restrictive. As a result, it was felt that many patients who may have benefited from participation in the trial were excluded. This was found to be particularly relevant for patients who were within 4 weeks of chemotherapy or 8 weeks of commencing tyrosine kinase inhibitors. The general perception was that patients should be able to receive the intervention regardless of where in the illness trajectory they were.

There was a sense that many patients who were identified as being suitable to participate tended to deny their symptoms, having become normalised and adjusted their lives accordingly. These patients when asked about their symptom experience responded that they were "not bothered" by their symptoms and therefore were ineligible. There was also a general sense that some patients participated because they would be receiving increased attention and support that may have been lacking from the clinical team. This view was also expressed by clinicians—the study was viewed as a way of helping to meet perceived unmet patient needs. The time frame between providing consent and receiving the first intervention (suggested 1 week) was found to be problematic, as some patients became ill during that period whilst others had problems fitting in the intervention visits around other appointments.

3.2.2 | Experiences and views regarding the training for intervention delivery

The specialist practitioners received two training sessions delivered by the lead complementary therapist. A training manual was also provided and ongoing telephone support was available, if required. The training and review sessions were generally well received and staff found the Good Clinical Practice (research conduct and ethics training in the UK) training beneficial and increased their knowledge and skills particularly regarding consenting and the research process. The specialist practitioners found the training manual was important with regards to supporting the different techniques, although it was felt that some key information was missing. In particular, it was felt that the role of physiotherapy, physical activity and exercise was underplayed in the fatigue information section.

Given that those delivering the intervention were from different disciplines with different levels of expertise presented an issue, particularly at the beginning of the trial, was how to use the information provided (Supplementary Information Booklet, Macmillan Managing Breathlessness and Coping with Fatigue). It was highlighted that they would have benefited from a better understanding of when and how to use the information booklets, although it was noted that the Supplementary Information Booklet provided the opportunity to talk about other issues (other than their normal clinical practice) and patients may benefit from this.

3.2.3 | Experience and views regarding the delivery of the intervention

The delivery of the intervention varied across sites for example at one site all patients attended the hospital for the intervention whilst at a second site, patients received the intervention at home. The study protocol did not stipulate where the intervention was to be delivered and sites had the choice of delivering it at the hospital or in the

community; specialist practitioners found the latter more convenient for patients. Participants also stated that it was challenging to fit the intervention training session around other commitments such as hospital and personal appointments. One specialist practitioner suggested that a video element may have been useful. Generally, those delivering the intervention reported that the experience had been quite educational for patients and carers as they benefited from being able to see how to do the techniques and understood the dynamics of how they worked.

Focus group participants suggested that the level of involvement of carers varied, but where they were involved it was perceived that they played a key role in encouraging patients to practice the different intervention techniques. However, there was also a sense of protectionism identified from the carer. This was especially evident in some circumstances when the researcher would conduct a follow-up call yet the carer would speak to the researcher on the patient's behalf.

Specialist practitioners expressed some difficulty taking on the research role as the requirements of the trial differed slightly to what they would do in normal clinical practice. It was noted that some health professionals may be tackling the sessions from a physiological perspective whereas others may tackle it from a psychological level, but the key focus was on optimising participant self-management of symptoms. In addition, it was felt that different health professionals may have focussed differently on different components of the intervention.

It was agreed that several questionnaires included in the participant study packs asked directly about lung cancer symptoms—yet for those patients who believed they were cured following treatment made questionnaires difficult to complete as they could not relate to the questions and in some instances prevented people for taking part in the trial. Completing the paperwork also brought patients/carers focus back to the disease, which was viewed as evoking distress as it forced them to think about issues they may not have previously thought about or chose not to.

4 | DISCUSSION

Feasibility studies of complex interventions are important to test not only potential effectiveness but also to assess acceptability and practicality of the intervention, and to refine and improve it prior to conducting a fully powered trial. This nested qualitative study provides support for the intervention and development of a subsequent trial while highlighting aspects that require further development. In this qualitative study, we elicited both general and specific feedback from trial participants (patient and carers) and study staff involved in all aspects of the trial including recruitment, intervention training and intervention delivery. This approach provided a broad range of experiences, views and expectations with recommendations from key stakeholders.

It has been previously suggested that eligibility criteria for trials of supportive care intervention for people with lung cancer should

be broad in an attempt to counteract relatively low recruitment rates and high attrition rates (Schofield et al., 2008). In the current trial, patients were excluded if they had a chest infection or had received chemotherapy/radiotherapy within the previous 4 weeks. However, all interviewed patients and carers felt that the intervention should be available for patients when they most needed it and regardless of current or recent cancer treatment. This view was also shared by the research staff who found the eligibility criteria to be “restrictive.” This perhaps reflects the positive views held by participants about the intervention. It is known that patients' experiences of symptoms such as breathlessness, cough and fatigue are influenced by recent infections and cancer treatments and therefore may impact on the results of studies designed to ameliorate such symptoms. As such, eligibility criteria will remain the same for the subsequent trial, where RDSI effectiveness will be tested. Following successful completion of the trial, RDSI will be recommended for people with symptoms regardless of previous infection or stage of cancer treatment.

During the focus group research staff indicated that potential participants were missed because the patient had “adjusted their life” and therefore symptoms were not viewed as “bothersome.” As we did not interview patients who declined to take part in the trial, these results cannot be confirmed. However, during post-trial discussions with our cancer patient reference group, it was suggested that the use of the term “bothersome” may have been perceived by some patients as “complaining” (Yorke et al., 2015). Therefore, the screening question was changed to focus on daily activities that symptoms may interfere with: “Are you affected in your day-to-day life by breathlessness?” and repeated for each symptom. Research staff also suggested that the time frame between participant consent and delivery of the intervention was too restrictive and difficult to adhere to. The reasons for this were valid: patients became ill during that time or were busy with other commitments. This presents challenges when designing controlled trials as every effort is made to ensure that all participants are managed in a similar way. In the light of this, the timeframe between consent and delivery of the first RDSI session has been expanded to 2 weeks.

There was a perception that some patients agreed to participate in the trial, because it acknowledged and legitimised their symptoms to themselves, family/friends and healthcare providers. It was felt that participants who were post-curative intent treatment were often left to “get on with it”: taking part in the trial in contrast provided the opportunity to legitimise symptoms and take some control. In particular, patients and carers indicated that taking part in the trial increased their knowledge about lung cancer and their symptoms. The search for symptom legitimisation is a familiar phenomenon in patients' post-cancer treatment which can continue for several years (Rosman, 2009). In this study, the informed consent process appeared to provide an educational session about lung cancer and its associated symptoms. This suggests the need for targeted patient education by clinicians during and after cancer treatment and reinforced with patients in long-term follow-up when patients are likely to be experiencing a range of symptoms (Hofman, Ryan, Figueroa-Moseley, Jean-Pierre, & Morrow, 2007).

The specialist practitioners felt that available services for palliative and supportive care were not being fully utilised by clinical staff.

One focus group participant in particular, expressed disappointment that some clinicians regarded the trial intervention as only now having “something to offer our patients,” implying a lack of knowledge about available supportive services. It has been estimated that only approximately 15% of newly diagnosed lung cancer patients receive a referral to a breathlessness clinic at specialist centres, where such clinics exist (personal communication with Prof Miriam Johnson, based on pilot data for a breathlessness intervention study across five tertiary centres in the UK). This may, in part, relate to clinicians’ lack of awareness of the availability of palliative and support services for symptom management (Wagland et al., 2012). However, this provides some evidence of the clinical need for an intervention like RDSI that can be delivered by a range of healthcare professionals who receive appropriate training.

Patients and carers expressed some discontent with the questionnaires and this was seen as a potential barrier to recruitment and retention. However, since the main RCT was a feasibility study the number of questionnaires was justified to enable the identification of the most useful measures for the planned follow-on trial. The research team also identified the amount of paper work as a barrier to recruitment, but the importance of informed consent was noted as being essential for participant retention. Ensuring that potential research participants are fully informed about research expectations, including paper work completion, forms part of the Good Clinical Practice training programme, and was adhered to in this study. For the follow-on trial, key outcome measures have been identified and participant response burden should reduce due to the decrease in the number of patient and carer-reported outcomes (Yorke et al., 2015).

Sensitivity is also required when informing patients and carers about the content of study questionnaires. It was apparent in the interviews that some participants found some items confronting and distressing. For some participants, the questionnaire items probed areas that they had not thought about or had chosen not to think about. Despite the decrease in the number of questionnaires to be used in the subsequent trial, there are likely to be some items in the retained questionnaires that may evoke a range of emotions and responses from participants. Although it is important to meet recruitment and questionnaire response rates, this needs to be balanced against the need to recruit fully informed participants and thereby meet acceptable ethical principles (Hunt, Shlomo, & Addington-Hall, 2013).

Patients in this nested qualitative study who were randomised to the intervention arm appeared to find it acceptable and valuable, in some cases with unexpected benefits. In addition, some patients felt they were able to return to activities they had not undertaken for some time. Not all techniques suited all patients, however, they appeared to find the flexibility of choosing to utilise techniques relevant to what symptoms they were experiencing within the intervention beneficial. Flexibility, particularly with complex interventions that target a cluster of symptoms has been previously identified as an important factor for patients with lung cancer (Ellis et al., 2012). The opportunity to implement intervention techniques as part of everyday routines was particularly welcomed—such as applying different RDSI techniques whilst “sitting in the bus shelter.” However, it was also acknowledged by patients and carers that learning the different techniques requires

patience and persistence. It is important to inform patients that it takes time to learn the different techniques and for them to have an effect. Reinforcement was viewed as important but could be timely and costly to the Health Service. A potential alternative might be the addition of an instructional video.

Patients and carers did not generally appear to find the supplementary written information useful with some having forgotten they had received it. Likewise, specialist practitioners were not sure when and how to introduce the supplementary information with many participants feeling somewhat overwhelmed by the volume of information. For the subsequent trial, only the Macmillan booklets for breathlessness and fatigue will be provided. Participating specialist practitioners who were physiotherapists also suggested that the role of physical activity, especially in the management of fatigue and breathlessness, should be incorporated as a key component of RDSI rather than only appearing in the written information. Given the strong evidence base for structured activity in the management of cancer-related symptoms (Schwartz, Mori, Gao, Nail, & King, 2001; Speck, Courneya, Mâsse, Duval, & Schmitz, 2010) this has been added as a key component to RDSI.

The results of this study need to be seen in the light of its limitations. All of the interview participants who took part in the study had completed the trial. Had we been able to interview those who did not complete the trial, we may have a better understanding of the factors that had influenced this decision. Another limitation is that interviews were cross-sectional and at the end of the trial. Ideally, for a follow-on trial, patients who do not wish to take part should also be approached for interview as this may provide important information about successful implementation in practice. In addition, longitudinal interviews with both control and intervention group participants should be conducted as a way of exploring the impact of interventions beyond statistical results and to identify important implementation strategies that are based on the experiences of those receiving the intervention (Farquhar et al., 2014).

5 | CONCLUSIONS

The findings from this nested qualitative study are important as they provide crucial insight into the views and perceptions of patients, carers and researchers who participated in a RCT of the feasibility and acceptability of the RDSI for the management of breathlessness–cough–fatigue in lung cancer patients. Informed by these qualitative insights, we have been able to improve and refine the intervention and trial processes in order to conduct a fully powered trial. Considering such findings will help ensure that the trial is person-centred and reflects the diverse needs and preferences of this particular population in appropriate and sensitive ways.

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REFERENCES

- Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, 3, 77–101.
- Cheville, A. L., Novotny, P. J., Sloan, J. A., Basford, J. R., Wampfler, J. A., Garces, Y. I., ... & Yang, P. (2011). Fatigue, dyspnea, and cough comprise a persistent symptom cluster up to five years after diagnosis with lung cancer. *Journal of Pain and Symptom Management*, 42, 202–212.
- Department of Health (2006). *A stronger local voice in the development of health and social care services*. London: Author.
- Donovan, J., Mills, N., Smith, M., Brindle, L., Jacoby, A., Peters, T., ... & Hamdy, F. (2002). Quality improvement report: Improving design and conduct of randomised trials by embedding them in qualitative research: ProtecT (prostate testing for cancer and treatment) study. *British Medical Journal*, 325, 766.
- Ellis, J., Wagland, R., Tishelman, C., Williams, M. L., Bailey, C. D., Haines, J., ... & Molassiotis, A. (2012). Considerations in developing and delivering a nonpharmacological intervention for symptom management in lung cancer: The views of patients and informal caregivers. *Journal of Pain and Symptom Management*, 44, 831–842.
- Farquhar, M., Prevost, A., Mccrone, P., Brafman-Price, B., Bentley, A., Higginson, I., ... & Booth, S. (2014). Is a specialist breathlessness service more effective and cost effective for patients with advanced cancer and their carers than standard care? Findings of a mixed-method randomised controlled trial. *BMC Medicine*, 12, 194.
- Hofman, M., Ryan, J. L., Figueroa-Moseley, C. D., Jean-Pierre, P., & Morrow, G. R. (2007). Cancer-related fatigue: The scale of the problem. *The Oncologist*, 12, 4–10.
- Hunt, K. J., Shlomo, N., & Addington-Hall, J. (2013). Participant recruitment in sensitive surveys: A comparative trial of 'opt in' versus 'opt out' approaches. *BMC Medical Research Methodology*, 13, 3.
- Jordhøy, M. S., Kaasa, S., Fayers, P., Underland, G., & Ahlner-Elmqvist, M. (1999). Challenges in palliative care research; recruitment, attrition and compliance: Experience from a randomized controlled trial. *Palliative Medicine*, 13, 299–310.
- Molassiotis, A., Lowe, M., Ellis, J., Wagland, R., Bailey, C., Lloyd-Williams, M., ... & Smith, J. (2011). The experience of cough in patients diagnosed with lung cancer. *Supportive Care in Cancer*, 19, 1997–2004.
- Molassiotis, A., Uyterlinde, W., Hollen, P. J., Sarna, L., Palmer, P., & Krishnasamy, M. (2015). Supportive care in lung cancer: Milestones over the past 40 years. *Journal of Thoracic Oncology*, 10, 10–18.
- Rosman, S. (2009). 'Recovered from cancer but still ill': Strategies used to legitimise extreme persistent fatigue in disease-free cancer patients. *European Journal of Cancer Care*, 18, 28–36.
- Schofield, P., Ugalde, A., Carey, M., Mileshekin, L., Duffy, M., Ball, D., & Aranda, S. (2008). Lung cancer: Challenges and solutions for supportive care intervention research. *Palliative and Supportive Care*, 6, 281–287.
- Schwartz, A. L., Mori, M., Gao, R., Nail, L. M., & King, M. E. (2001). Exercise reduces daily fatigue in women with breast cancer receiving chemotherapy. *Medicine and Science in Sports and Exercise*, 33, 718–723.
- Speck, R. M., Courneya, K. S., Mâsse, L. C., Duval, S., & Schmitz, K. H. (2010). An update of controlled physical activity trials in cancer survivors: A systematic review and meta-analysis. *Journal of Cancer Survivorship*, 4, 87–100.
- Treweek, S., Altman, D. G., Bower, P., Campbell, M., Chalmers, I., Cotton, S., ... & Clarke, M. (2015). Making randomised trials more efficient: Report of the first meeting to discuss the trial forge platform. *Trials*, 16, 261
- Wagland, R., Ellis, J., Bailey, C. D., Haines, J., Caress, A., Williams, M. L., ... & Molassiotis, A. (2012). Considerations in developing and delivering a non-pharmacological intervention for symptom management in lung cancer: The views of health care professionals. *Supportive Care in Cancer*, 20, 2565–2574.
- Yates, P., Schofield, P., Zhao, I., & Currow, D. (2013). Supportive and palliative care for lung cancer patients. *Journal of Thoracic Disease*, 5, S623.
- Yorke, J., Lloyd-Williams, M., Smith, J., Blackhall, F., Harle, A., Warden, J., ... & Molassiotis, A. (2015). Management of the respiratory distress symptom cluster in lung cancer: A randomised controlled feasibility trial. *Supportive Care in Cancer*, 23, 3373–3384.
- Zhao, I., & Yates, P. (2008). Non-pharmacological interventions for breathlessness management in patients with lung cancer: A systematic review. *Palliative Medicine*, 22, 693–701.

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