



'A little bit written off'

A study to understand the clinical trial experiences and needs of people living with secondary breast cancer

March 2024

In association with



This national survey covered many aspects of people's experiences and views related to clinical trials and was open to people with a secondary (metastatic) breast cancer diagnosis. Once ethics approval had been granted, the survey was launched UK wide in May 2021 and it remained open until November 2021. In total 768 people took part.

Key Findings

- 768 people took part in the research, making it one of the largest surveys of its kind - one patient said that filling in the survey was “empowering” and gave her a voice.
- Most patients have never engaged in a conversation with their oncologist about a clinical trial.
- There is a lack of information about clinical research.
- Patients are willing to travel to access a trial, especially if their expenses are covered.
- The evidence demonstrates that patients are keen to be involved in research but face barriers to inclusion.

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Introduction



This study grew out of a conversation between a patient living with secondary breast cancer, Lesley Stephen, and a clinical oncologist, Prof Carlo Palmieri. Lesley was on a clinical trial and doing well – it had enabled her to have extra years of life that she hadn't expected. When speaking to other patients she discovered that most had never discussed a clinical trial as a treatment option with their clinician and there were many misunderstandings about what a clinical trial was and how it might benefit them.

“Most had never discussed a clinical trial as a treatment option with their clinician.”

As a result Lesley and Carlo teamed up with the Universities of Warwick, Liverpool and Southampton to develop a UK-wide survey to better understand patients' experiences. They wanted to gather data to see if the evidence backed up the anecdotal stories and hoped that by better understanding barriers to clinical trial participation for people living with secondary breast cancer, ways to overcome these could be found. Lesley went on to work closely with research colleagues as a patient advocate to deliver the study, analyse the results and present the key findings.

“One of the largest surveys of its kind.”

This national survey covered many aspects of people's experiences and views related to clinical trials and was open to people with a metastatic breast cancer diagnosis. Once ethics approval had been granted, the survey was launched UK-wide in May 2021 and it remained open until November 2021. In total **768** people took part.

The team used a variety of channels to distribute the survey – posters and leaflets were displayed at NHS sites and Maggie's Centres; announcements were placed on the websites of Make 2nds Count, Breast Cancer Now, Cancer Research UK and Macmillan UK. The aim was to recruit patients from different geographical centres in the UK, striving for a mix according to age, employment status and ethnicity.

After the survey, **21** people took part in telephone interviews to explore the issues further, making this one of the largest surveys of its kind.

Breast cancer is the most common cancer in the UK with over **55,000** cases diagnosed in the UK each year.¹

It is estimated that there are **61,000** people living with secondary breast cancer in the UK. In around **5%** of women, breast cancer has already spread by the time it is diagnosed.²

Secondary breast cancer (SBC), also known as metastatic, advanced or stage IV breast cancer, is breast cancer that has spread beyond the breast to other parts of the body. It has a devastating impact on people affected and their families, yet most members of the general public have never heard of it.

Secondary breast cancer can be treated but it cannot be cured. Treatments aim to control and slow down the growth and spread of the disease to enable patients to have the best possible quality of life for as long as possible. For people living with secondary breast cancer, timely access to new therapies and other treatment lines is critical. For many, clinical trials may offer more treatment options but there are barriers to participation.

Clinical trials can improve outcomes for people living with secondary breast cancer, yet evidence shows that there are barriers to participation. Despite innovations in clinical trial research, little progress has been made to improve the diversity of clinical trial participants over the past two decades.⁵

30%

of patients diagnosed with early stage breast cancer go on to experience recurrent or metastatic disease ⁴

“Without that research and without those clinical trials nothing will change. We will never live long. So I do feel quite passionate about it.”

Interview respondent, 2021

2 Years

is the average life expectancy of a secondary breast cancer patient once diagnosed ³

1. Cancer Research UK www.cancerresearchuk.org/health-professional/cancer-statistics-by-cancer-type/breast-cancer (Accessed: June 2023)

2. Breast Cancer Now breastcancernow.org/about-us/media/facts-statistics (Accessed: June 2023)

3. Macmillan Cancer Support www.macmillan.org.uk/documents/abouts/health_professionals/primarycare/primarycare10toptips-metastaticbreastcancer.pdf (Date accessed: July 2023)

4. Breast Cancer Research Foundation www.bcrf.org/blog/metastatic-breast-cancer-symptoms-treatment (Date accessed: July 2023)

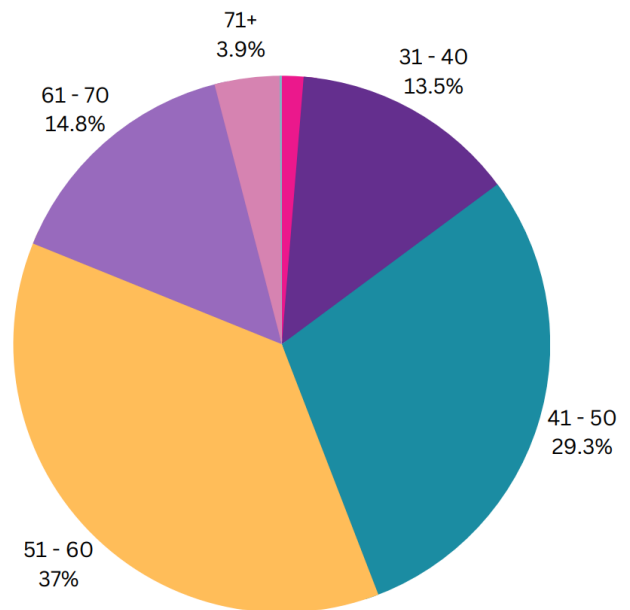
5. Eligibility of real-world patients with metastatic breast cancer for clinical trials by Atul Batra, Shiyong Kong, Winson Y. Cheung. *The Breast* (2020) Vol 54, p171-178, doi.org/10.1016/j.breast.2020.10.005

Participants

In total **768** people took part in the national survey:

- The majority found the survey through social media and charity websites
- **765** participants were female, **2** were male and **1** didn't report their gender
- **52%** of participants were in work, and **28%** reported being retired or off sick
- The median age was **55**, and **96.8%** of participants were from a white ethnic group
- **31%** were diagnosed with 'de novo' disease
- There was a broad geographical spread across UK
- **14%** had taken part in a clinical trial

Age Distribution of Participants



“I suppose it feels like metastatic breast cancer is like a little bit written off because we can't survive this so we should try our best to live as long as possible, you know.”

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Key Learnings

This research gives a fascinating insight into the conversations taking place between patients and their clinical team about trials and the experiences of patients navigating their care and searching for further information. A recurring point was that patients felt 'a little bit written off', and their presumed limited survival meant that they were given fewer opportunities in a healthcare environment.

Shockingly, the survey found that only **23%** of oncologists had raised the subject of clinical trials with patients, and only **32%** of patients had raised the subject with their clinician themselves.

86%
of patients feel they understand clinical trials

14%
of patients in this survey had been recruited into a clinical trial

There is a clear interest in the secondary breast cancer community about clinical trials, but many have not had the opportunity to access one. Three key themes contributing to this lack of involvement emerged in this study:



Lack of information

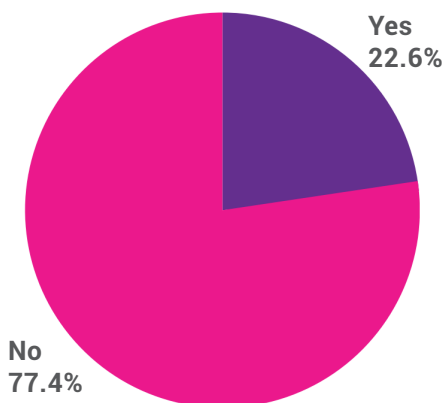


The perception of clinical trials

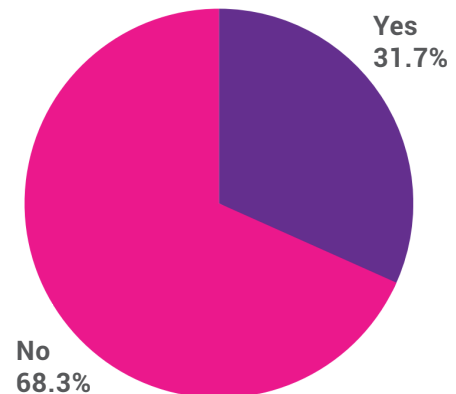


Perceived barriers to accessing trials

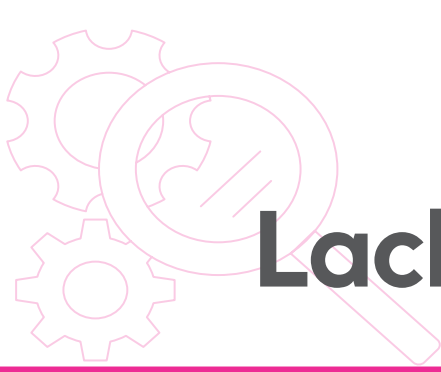
Has your oncologist ever raised the subject of taking part in a clinical trial with you?



Has your ever asked your oncologist about the possibility of taking part in a clinical trial?



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Barrier 1: Lack of Information

The information surrounding clinical trials is complex and ever-changing. Most healthcare professionals do not have time to maintain in-depth knowledge of clinical research taking place at other hospitals.

Many people taking part in this research were unhappy with the information they had been given or accessed. They wanted much more information about the availability of clinical trials and research for secondary breast cancer, even if they were not personally considering joining a trial.

They felt that there was a poor awareness in society generally, as well as little information offered specifically at diagnosis.

Some felt that they were even given less support within the healthcare environment compared to people with primary breast cancer. Few had access to dedicated SBC

"He told me to look into trials myself and if I found anything, let him know."

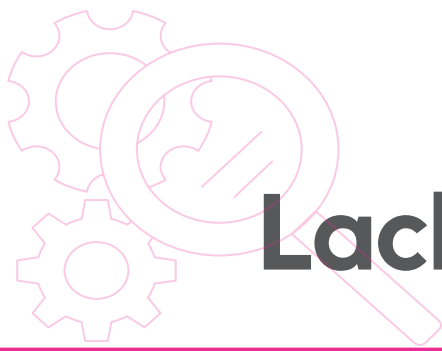
nurse specialists or research nurses and often cited this to describe their inability to access information.

This disparity was blamed on the assumption that people with secondary breast cancer would have limited survival.



Illustration by Tass Haines, a patient living with metastatic breast cancer.

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Barrier 1: Lack of Information

When asked how they wanted to receive information about clinical trials, the vast majority of patients wanted to receive that information from a trusted healthcare professional.

80%	61%	12%	29%	18%
Consultant	Specialist Nurse	Friend	Database	No Preference

Many also called for a website, database or telephone helpline where all relevant and up-to-date information about studies could be held and accessed. Some patients had tried to search a trial database, but didn't find the information they were looking for. **87%** said they would search trials databases themselves, if they were patient friendly.

"I find trawling through the internet trying to find stuff is hard. Yeah, it would be much more helpful to have one place because I'm very interested but sometimes it takes ages... even if patients could be given a web page, or somewhere just to go and have someone to speak to down the line that is up to date with all these trials. Because even the medics don't know all the trials that are going on, do they? Certainly, if their centre isn't involved in it."

75

Secondary breast cancer trials are currently recruiting in the UK

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Barrier 2:

The perception of clinical trials

Clinical research into secondary breast cancer is critical to improving treatments, quality of life and outcomes for those living with the disease. As secondary breast cancer remains incurable, research offers hope for a better future.

"My oncologist was very unsupportive. She said most trials fail and should only ever be a last resort."

What might encourage you to take part in a trial?	What things might stop you taking part in a trial?
96% - Access to new therapies	63% - Possible side effects
93% - Help future patients	43% - Unsure of benefits
81% - Play an active role in my health	37% - Cost
72% - Frequent check-ups	34% - More visits to hospital

Patients understood the perceived benefits of taking part in a clinical trial and described what would stop them taking part:

63% were discouraged by the possible side effects of being on a trial. Many reported that they thought they would be treated as 'a guinea pig', that a trial was a last resort, or that they would be given a placebo.

Other concerns included the cost of taking part in a trial, the travel involved and the time off work or childcare needed. When asked about travel, **56%** of patients said they would be interested in taking part in a trial if travel expenses were covered.

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Barrier 2:

The perception of clinical trials

Due to a lack of readily available and trusted information, there is a persistent assumption in the secondary breast cancer community that clinical trials are only available when all other treatment options fail. It is deeply concerning that this myth is perpetuated in a healthcare setting.

When raising the subject of clinical trials, many patients report being told that **“now is not the time”** or that they can look into trials when they have **“run out of options.”** Some found that their oncologist was unsupportive, which often led to a loss of confidence in staff who they believed would be less likely to consider them.

“I think the medics and the nurses should be talking to people about trials earlier on because I think we all feel that trials are the last resort, right? And I think that is a perception that I was given that you only go on a trial when everything else fails. That's because it's been never mentioned to me.”



Illustration by Tass Haines, a patient living with metastatic breast cancer.

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Barrier 3:

Perceived barriers to accessing trials

The secondary breast cancer community is acutely aware of a greater emphasis placed on primary breast cancer in the mass media and public sphere. The lack of awareness, funding and clinical trial options contributes to a sense of loneliness and being devalued.

It is estimated that only **7%** of research funding on breast cancer in the US and the UK is dedicated to metastatic disease.¹

A feeling of being **"written off"** was described by many people in the survey. Being less of a priority compared to those with primary breast cancer was also perceived to be a barrier to research, with those interviewed being conscious that there are very few research options out there for people with metastatic disease.

"Once you get to stage four, is it almost like you're written off, right?"

Many feel that their voices are unheard and blame the media for not giving enough attention to secondary breast cancer, and therefore raising the profile of the inequalities they face on the healthcare agenda.

"I think there needs to be a lot more done for stage four. There seems to be a lot of primary but secondary doesn't have the same ...ultimately, they know you're going to die."

¹ Metastatic Breast Cancer Alliance, Changing the Landscape for People Living with Metastatic Breast Cancer October 2014, www.mbcalliance.org/projects/landscape-analysis/

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Barrier 3:

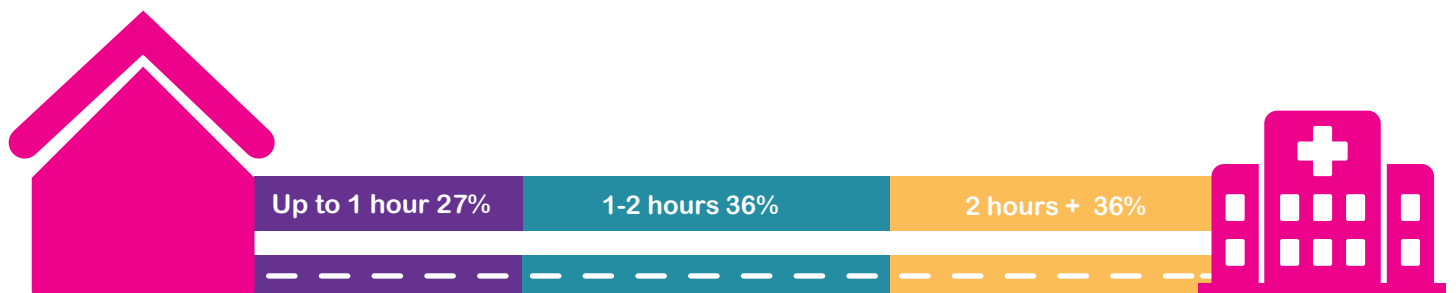
Perceived barriers to accessing trials

Secondary breast cancer patients in the UK are facing a postcode lottery in their treatment and care, with significant disparities across the country in approval of treatments, centres offering trials and availability of clinical nurse specialists.

Although many of the people surveyed said they were willing to travel to take part in a clinical trial, there was a recognised **"postcode lottery"** of trial accessibility. Some cancer centres are more research active, and people who lived in certain places in the UK felt they faced barriers because of their location.

55% reported that they could fund their own travel, however the provision of travel grants is not the only solution. Many people living with secondary breast cancer have children or caring responsibilities, and many are in employment or have other commitments that can limit their availability to travel.

Distance Patients Are Willing to Travel



57%

of patients are willing to travel abroad to take part in a clinical trial.

"I'm only in a small district general hospital so the big kind of research centre has more available. I think there's a disparity to what people might get in London to what I get up in the North East. So, I think that's a massive thing. That's the postcode lottery of what's available for people."

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Barrier 3:

Perceived barriers to accessing trials

Patient safety is at the heart of clinical trial eligibility, but difficulties in recruiting trial participants slows research progress and rigid exclusion criteria rule out many patients in need.

This is particularly apparent for people living with secondary disease because metastases often have an adverse impact on health generally which makes it harder for them to fulfil certain criteria, such as **'performance status'**.

Patients with brain or liver metastases, common to secondary breast cancer, still can't enrol in most trials.

In a recent study

1/3

of patients with metastatic breast cancer were ineligible for clinical trials ¹

"I'm very much up for trials but I'm now at a point where I've outstayed my welcome as it were, I've lived far too long, I've had too many treatment lines and therefore trials, much as though I think it would possibly be of benefit, not necessarily to me but people who will come behind me, I now can't get on one ... the longer you live with this disease and the more treatment you have, it precludes you and there are so many other preclusions to clinical trials that part of me thinks, 'Just how fit do you have to be to get into one?' because there are more pages on exclusion criteria than there are on inclusion criteria and I just wonder who this perfect person is at times, you know?"

1. Eligibility of real-world patients with metastatic breast cancer for clinical trials by Atul Batra, Shiyong Kong, Winson Y.Cheung. The Breast (2020) Vol 54, p171-178, doi.org/10.1016/j.breast.2020.10.005

Moving Forward

“Is there any aspect of your experience with breast cancer that you feel requires, or should be the focus of, future research?”

Patients with secondary breast cancer want to be included in research planning and have much valuable experience and knowledge to input into the research process. Those who shared their experiences with us also raised research priorities within their own disease type and many echoed the call for a database of clinical trial information.

Only

39%

of patients felt very involved in making decisions about their treatment.

“I think it’s very positive to hear things about trials. I survive on the knowledge that other people are doing well, you know, success stories. I am not naïve to my diagnosis, I know it’s life limiting, but I also know that it’s treatable; and you know the more things out there for me, like someone’s been on this treatment, they’ve been doing really well. So more of an overview of hope would be something I would really like, more positive stories and people doing well on it would make a lot of difference to a lot of us.”

When asked their own priorities for research, many talked about the value of **‘good news’** in hearing about clinical trials and the importance of positivity in facing metastatic disease. The emotional impact of ongoing treatment for secondary breast cancer is clear.

Living with a sense of hope and resilience has been recognised as a significant factor in helping people adjust to living with cancer, reduce psychological distress and improve wellbeing.

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Make 2nds Count

Make 2nds Count is a UK-wide patient and family focused charity dedicated to giving hope to women and men living with secondary breast cancer.

Research into secondary breast cancer is underfunded. Make 2nds Count's mission is to fund secondary breast cancer research which contributes to advancing an increased quality of life for patients.

Our Support programme has a focus on quality of life and helping patients affected by this incurable disease by informing, sharing and offering practical advice & support.

Education is an integral part in everything that we do and we aim to raise awareness of secondary breast cancer through effective marketing and education programmes across the UK. We also empower patients through increasing their knowledge and understanding of research, treatments and options.

Over

450

patients have accessed the Patient Trials Advocate service since it was launched in 2021.

Just some of what we have achieved since 2021

With input and support from our community, we have worked hard to address the issues raised in this study by developing bespoke services and resources:

Patient Trials Advocate Service

A free and confidential service providing information and support on clinical trials for patients across the UK living with secondary breast cancer

To book an appointment:

www.make2ndscount.co.uk/support/pta

UK Clinical Trial Registry

A dedicated database of active clinical trials in the UK, specific to secondary breast cancer, and their locations

To find out more:

www.make2ndscount.co.uk/research/research-trials/uk-clinical-trial-registry



Giving **hope** to those affected by
secondary breast cancer.

Acknowledgements

We wish to thank the following people and organisations:

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