

Take Part Be Involved

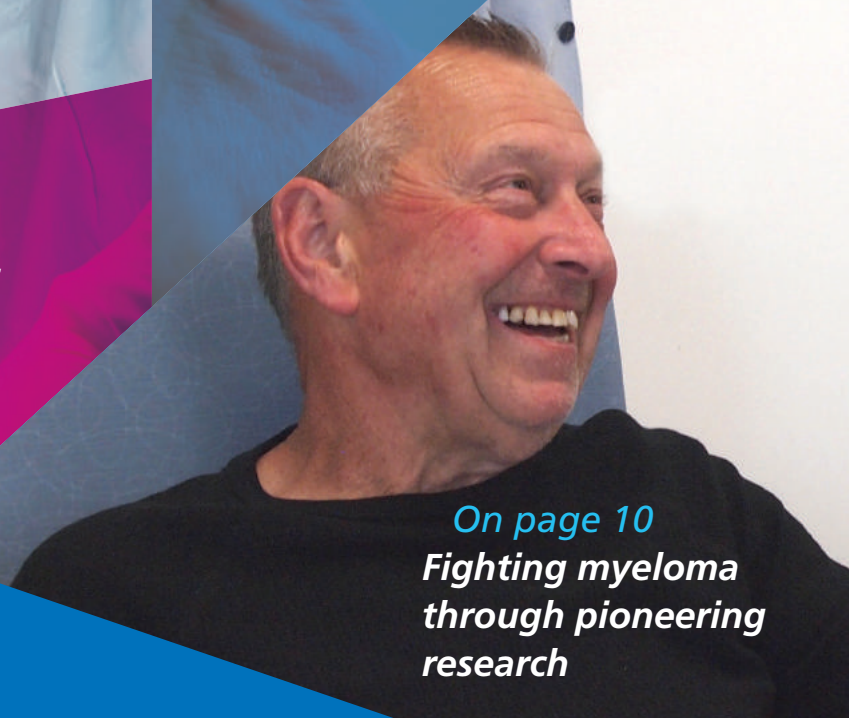
in research



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in a research study?**



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through pioneering
research**

Hello, welcome to Take Part Be Involved in Research magazine

Gone are the days when patients just sit in front of their consultant and nod, accept what is being said to them and don't question their treatment options. Patients have a stronger voice than ever before, and that extends to how we carry out clinical research. There has been a growing movement in patient and public involvement in research across the nation and here at North Bristol NHS Trust we are on that journey too.

What started as small group of interested members of the public coming together 8 years ago has expanded to where nearly all of our patients have a disease specific group they can be involved in.

How we involve patients and their families has also evolved. In the beginning, they mainly ensured that our patient information sheets and research consent forms were in plain English and easy to understand. Now, they feature in patient information videos, have spoken at conferences and educational events and work with us to ensure any new treatment ideas to improve patient care is in the best interest of the patient. They also have the option to sit on the research project groups so they get to see how the research is run, the sort of things we monitor and how we involve other hospitals across the UK and beyond.

I am always humbled by the people that I meet on a daily basis, who in some cases, have been through so much but are more than willing to be involved or share their story.

In this edition of Take Part Be Involved in Research I wanted to share with you a snapshot of both the research and patient involvement that takes place here at North Bristol NHS Trust. The projects highlighted are a perfect example of the range of topics that patients groups can be involved in. The people I met really feel they are making a difference and all talk openly about their experiences.

I would like to thank the patients who have taken the time to share their experiences with me and now you. I really hope that you enjoy the read and that you have learned that research isn't just about testing new drugs.

If you feel you would like to be involved, please get in touch with me, or if you are a patient, talk to the person treating you to see if there is a study you can be involved in. Alternatively, take a look at our website www.nbt.nhs.uk/research.



Editor **Sharon Nolan**,
Communication & Patient & Public
Involvement in Research Manager

The views expressed in this publication are those of the author(s) and not necessarily those of the NHS, NIHR or Department of Health. Photographs of patients courtesy of Medical Photography North Bristol NHS Trust.

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Thinking of taking part in a research trial?

Here are some things that you may want to have a think about.

Taking part as a research participant

Taking part doesn't always mean being prescribed a new medicine or tablet. It can involve you providing a urine/blood sample, asking you to complete a questionnaire, or simply a researcher asking you a few questions about your treatment and experiences.

Clinical trials and studies often recruit many people as participants. But researchers need to take into account a patient's health history, age etc to ensure that patients are not exposed to avoidable risks. So even though you may be interested in taking part in research here, the clinician in charge of your care may decide that you may not be suitable for a particular research study at that moment in time.

Is it safe?

Large numbers of people take part in thousands of clinical research studies and trials in the UK every year.

All clinical research undertaken here at North Bristol NHS Trust is reviewed by an NHS Research Ethics Committee and approved by the Health Research Authority before it can start to ensure the rights, dignity, safety and wellbeing of our patients.

Each study is designed to keep risk to a minimum. The people who take part in every study are monitored carefully throughout and their safety and wellbeing comes first.

NHS
North Bristol
NHS Trust

Take Part

in research

How do I take part?

Speak to the person treating you to see if there is a research trial or study suitable for you.

Telephone: **0117 41 48136** and ask to speak to the research nurse for your specific condition.

A copy of our Take Part be Involved in research flyer can be found on our website www.nbt.nhs.uk/research.

The TARVA trial

Ankle replacement surgery vs ankle fusion

More than 29000 patients in the UK see specialists each year with Ankle Osteoarthritis symptoms which can greatly impact their quality of life.

In the early stages of this disease patients are asked to manage their disease through non-operative measures such as a change in activity levels, weight loss, physiotherapy, pain killers and ankle braces may be used, surgery is considered only once all these measures are no longer effective.

There are two types of surgery options, ankle fusion and ankle total replacement.

Both ankle fusion and total ankle replacement are good treatments to relieve pain, and each has its own advantages, but we do not know which option patients prefer. The purpose of the TARVA study is to scientifically demonstrate which treatment, fusion or total ankle replacement, provides better results for patients.

Patricia Perks

Patricia heard about the TARVA Trial following her knee surgery check-up appointment. She was asked if she had any questions and although her knee was healing really well, she asked if anything could be done to help her with the pain in her ankle. The clinician said she would write to her GP so she could be referred to Southmead to investigate whether she would be suitable for ankle replacement surgery or ankle fusion.

“When I came in to see Mr Winson, he invited me to take part in the TARVA Trial.

I thought it was absolutely brilliant. I had never heard of either so I was all for it as it was an operation that was going to help me, so I said yes.

What was really reassuring about taking part in the trial was that I was told, right up until the day of the operation on the operating table, if they decided that the one I had been randomised into would not be suitable, they would pull me from the trial and do the most appropriate surgery for me. In the end I had an ankle replacement.

I was introduced to Liz who is the Research Nurse for the trial. She went through the paperwork with me and my daughter. Liz also made sure that any additional paperwork involved with the trial was timed with my outpatient appointments which meant we didn't have any additional trips to make to the hospital to take part in the trial.



Mrs Patricia Perks with Research Nurse Liz Barnett

I have nothing but praise for Liz, she has been fantastic. Following my operation I had a plaster up to my knee for two weeks, then another plaster for four weeks, so I was moving around using a zimmer frame with my bed downstairs. I was itching to have a shower so needed a walking stick to get upstairs. I rang numerous people trying to find information about where to get a walking stick. In the end I rang Liz and she was able to sort one for me.

What would you say to one of your friends who is thinking about taking part in research?

“I would say go for it. To be honest I have nothing but praise for everything they do. They have been absolutely brilliant. My ankle is constantly improving day by day”.

Foot Note:

The TARVA trial is a NIHR funded study led by the University College London and is due to end May 2020.

LoDED Trial

Historically doctors have used many different tests including blood tests to rule out heart attacks in people with chest pain.

We currently use a method using two blood tests (called high-sensitivity troponin) taken a few hours apart. Research has now shown us that using one single blood test has a similar ability to rule out heart attacks, but what we still don't know is whether this method will allow us to discharge more patients home sooner, whether this method is acceptable to patients and whether it can save hospital resources.

Dr Edd Carlton, Emergency Medicine

"At the moment patients have to wait many hours to rule out a heart attack. From the patients' perspective this means that they are waiting a long time to be given the all clear to go home.

I have been trying to rule-out heart attacks faster for the past 8 years and one of the ways of doing that for patients who arrive in the Emergency department are new blood tests which can rule out a heart attack much sooner. The new blood test we are using has been in use since 2012, but we are using it in a slightly different way.

We are able to measure very low levels of heart muscle damage which hasn't been done before. So what we are doing is establishing whether a single blood test when patients first come in to A&E is clinically effective. This means that we may be able to discharge patients home sooner and in a safe way, without patients needing to wait in A&E for longer than is necessary or be admitted to a ward unnecessarily.

Whilst designing this study, we were mindful that patients may worry about being discharged too quickly and we wanted to reassure them that they are safe to go home. There is always going to be a possibility that they have had the wrong diagnosis, whether they are part of this study or not. In this instance it is about a 1 in a 1000 chance of a wrong diagnosis.

To ensure the information that we give to patients would put their mind at rest at being discharged, we worked closely with members of our own patient group, the British Heart Foundation and a member of the public Gareth Williams who is our lead patient representative and part of our trial steering committee who agreed that reassuring patients in this study is key.



Mr Gareth Williams

Gareth Williams

I have had a heart attack and been through the process of attending A&E and having to wait around for my 2nd blood test to confirm that I had indeed had a heart attack. So I am very interested in this research and pleased to be asked to input from a patient perspective.

Did you have any initial concerns about this study?

No, not in the way it is being done. Patients are given a full explanation about the study and are able to ask any questions, the important thing is that they feel confident to make an informed decision as to whether to take part or not, which I felt was a good thing. All emergency departments are crowded and we are hoping that this will help reduce the amount of time that patients will spend in hospital, which is a lot better for them and reduces the number of people that are waiting to be seen.

How have you been involved?

I was invited to be part of their Patient Experience Group and attend the trial committee meetings. I am given a slot on those meetings to give my view on the patient facing material to ensure they are easy to read. Hopefully, a clearer dialogue between patients and clinicians will take place as a result of my input. Patients feel very apprehensive and nervous attending A&E in the first place and I hope that my input has made a difference to ensuring the study is very patient focussed and it seems to be the case.

Edd "Gareth has been involved right from the start of this process. He helped us to write the funding application and made lots of corrections to the initial plain english summary. Gareth's input was essential in ensuring all of our written materials could be understood by members of the public. The outcome is we now have patient friendly information which ultimately means that everybody will get more out of the research."

Foot Note:

LoDED (Limit of Detection of Troponin and ECG Diagnostic Strategy) Emergency Department Assessment of Chest Pain Randomised Controlled Trial)

This project is funded by the National Institute for Health Research (NIHR) under its Research for Patient Benefit (RfPB) Programme.

Once available the results will be published on our website www.nbt.nhs.uk/research

Please contact ed.carlton@nbt.nhs.uk if you would like to be part of our patient experience team.

Support and treatment after joint replacement (STAR)



“My consultant mentioned that they were setting up a patient group. I said yes straight away as I wanted to help the researchers help people like me. I wanted to give my experience of pain, which I still have and to help other people with my experience.”

Many people with severe knee pain because of osteoarthritis have a total knee replacement, which involves replacing the painful knee joint with an artificial joint. Over 75,000 total knee replacements are performed annually by the NHS and as the population continues to age numbers are expected to rise. People often find that they have pain in the first three months after surgery although most people get better. About 1 in 5 patients have ongoing pain after 3 months, we call this long-term pain.

John, Enid and Colin came together as a patient group in September 2015 to support the STAR research programme which is researching long term pain after knee replacement.

“One of the projects we have been involved in was a health questionnaire posted to patients after their knee surgery. A researcher came along to our meeting and said that the responses had been poor and wanted our thoughts and whether their approach of sending another questionnaire to the patients who had not responded was acceptable.

After looking at it we thought it was really long and that it may put people off completing it. We suggested rather than just sending out another questionnaire, why didn't they call the patient to ask if they needed any help to complete it. As a group we felt that personal contact was far more patient friendly, and also meant that the patient could ask any questions at the same time.

Another problem with the questionnaire was that patients did not respond to some of the questions, so we helped the researchers to re-word them. The research team now also send out a pre-notification card to give patients the heads-up that the questionnaire is coming and they also enclose a teabag to encourage patients to take a break and have a cuppa whilst completing it.

At one of our regular meetings Amanda our co-ordinator confirmed that all of our recommendations had been put into place which means that our input has made a real difference.

“It's Important that we still do the research so we can stop this pain in the future”

About the study

Our study is investigating a new best care pathway to see if it is of benefit to patients with long-term pain after knee replacement.

The findings from this study will help us to know if providing the STAR care pathway can improve patient's outcomes after knee replacement and is good value for the NHS.

Foot Note:

This project is funded by the National Institute for Health Research (NIHR) under its Programme Grants for Applied Research programme (RP-PG-0613-20001). Due to be completed in 2020

New Drugs 4 Bad Bugs

New Drugs 4 Bad Bugs is a European wide study named COMBACTE-MAGNET which is fighting the war against antibiotic resistant bacteria by uniting experts across Europe.

Resistance to available antibiotics is a significant and a growing global threat to human health. Antibiotic resistant bacteria kills 25,000 people in the EU every year; so there is an urgent need for the development of new antibiotics.

The Patient and Public Involvement (PPI) part of the programme is being co-ordinated by Sally Grier who works here at Southmead Hospital. PPI is going from strength to strength in the UK; but it is virtually unheard of in Europe, especially when it comes to laboratory research. For this reason, together with partners from the University West of England, members of the public have been contributing to the development of a Toolkit to help our European partners who would like to implement PPI in their own research.



Sally Grier, PPI Co-ordinator, Quality and Programme Manager

Sally "Patients are at the centre of what we do here, so setting up the group was essential to the success of the programme. Microbiologists seem to find it more difficult to involve patients and members of the public than perhaps clinical teams who see patients on a daily basis."

Why David & Lesley became involved

David & Lesley both had serious infections. Lesley has now recovered from Septicaemia after a two month stay in hospital plus a further 3 months taking a combination of antibiotics, and David needed antibiotics after acquiring an infection following surgery.

"...we didn't really know what to expect, but it has opened a whole new world to us."

Lesley: "It is well known now that antibiotics are becoming ineffective, so I was keen to be involved to see if we could find a new medication from a purely selfish view, but also for the future for our grandchildren. We didn't really know what to expect, but it has opened a whole new world to us."

"At the beginning, we had a few meetings where the whole process was explained to us, some of the technical terms and generally bringing us up to speed on the research process and how we could help.

We have spent a fair amount of time working closely with the team to create a patient involvement tool kit focused on the antimicrobial medicine development cycle which we hope the scientific researchers will find useful across Europe."

David: "Being part of this process has opened up a whole new experience for me. I had no understanding at all about the research process, and the project is much larger than I originally thought. In the beginning when I first became involved, I thought

Lesley: "Hopefully, our involvement so far will be of assistance to others"

it was a small project just within Bristol. But, we are part of a huge European study with many partners across Europe. We are sent links to listen in on Webinars which has been very enlightening about the future of treating infections.

We were also given the opportunity to learn more about research through a free online clinical research course which explains the research process and the terms that researchers use."

Have there been any Challenges?

David: "Sometimes understanding some of the technical details and abbreviations. I have to say though that when we have asked questions the team have never been dismissive. There has always been complete honesty, where they have said, I'm not the right person to answer that, but we can do a session with the right person on that next time."



Lesley & David

The OPTIMISE study

Can pelvic floor exercises help multiple sclerosis (MS) patients with Incontinence?

Multiple sclerosis (MS) is a condition which can affect the brain and/or spinal cord, causing a wide range of potential symptoms, including problems with vision, arm or leg movement, sensation or balance.

It's a lifelong condition that can sometimes cause serious disability, although it can occasionally be mild. In many cases, it's possible to treat symptoms. It's estimated that there are more than 100,000 people diagnosed with MS in the UK. It's most commonly diagnosed in people in their 20s and 30s, although it can develop at any age. It's about two to three times more common in women than men.

What causes MS?

MS is an autoimmune condition. This is when something goes wrong with the immune system and it mistakenly attacks a healthy part of the body – in this case, the brain or spinal cord of the nervous system.

MS can be a challenging condition to live with, but new treatments over the past 20 years have considerably improved the quality of life of people with the condition.

Can Pelvic floor exercises help patients with MS?

THERE IS STRONG evidence that pelvic floor exercises can help with both bladder and bowel incontinence.

Dr Nikki Cotterill, Research Fellow at North Bristol NHS Trust ran a trial over 12 weeks to compare the success of group classes with self-taught methods for bladder and bowel incontinence.

Nikki "As well as attending the classes patients were asked to complete a questionnaire at different stages of the project. Patients were also asked to complete a training diary to highlight any improvements or problems which may or may not be as a consequence of the exercise routine.

We had no idea how successful the project would be, and wanted to know whether it would be feasible for patients with MS to attend weekly sessions with a physiotherapist for a 12 week period or to complete the sessions at home by themselves. Both groups of patients were followed up after four, eight and twelve weeks to establish if there was any improvement.

What was really beneficial for the patients attending the classes was that there seemed to be a real need

for the peer support element. Even though it was mixed groups of men and women, they all met up for coffee after, talked about their common issues and all wanted the group to continue.

The patient part of the study came to end at the end of 2017. I am now looking at the results to see what we have learned so that we can hopefully extend this trial across the country."

*...**“What was really beneficial for the patients attending the classes was that there seemed to be a real need for the peer support element.**”*



Dr Nikki Cotterill

Diane Raymond has lived with relapse remitting MS for more than 20 years.

She finished full-time work as a senior manager for a large defence company six years ago after a major relapse.

How Diane helped Nikki as a patient with experience of MS

I was keen to help a study that could make life better for people like me, having had to cope with such problems for many years. I am a huge supporter of self-help, although my own attempts at pelvic floor exercises had not been particularly successful. By contributing, I felt at last there was something positive that could come from my experiences of regular mad dashes to the toilet, and suffering from tiredness having woken several times a night to empty my bladder!

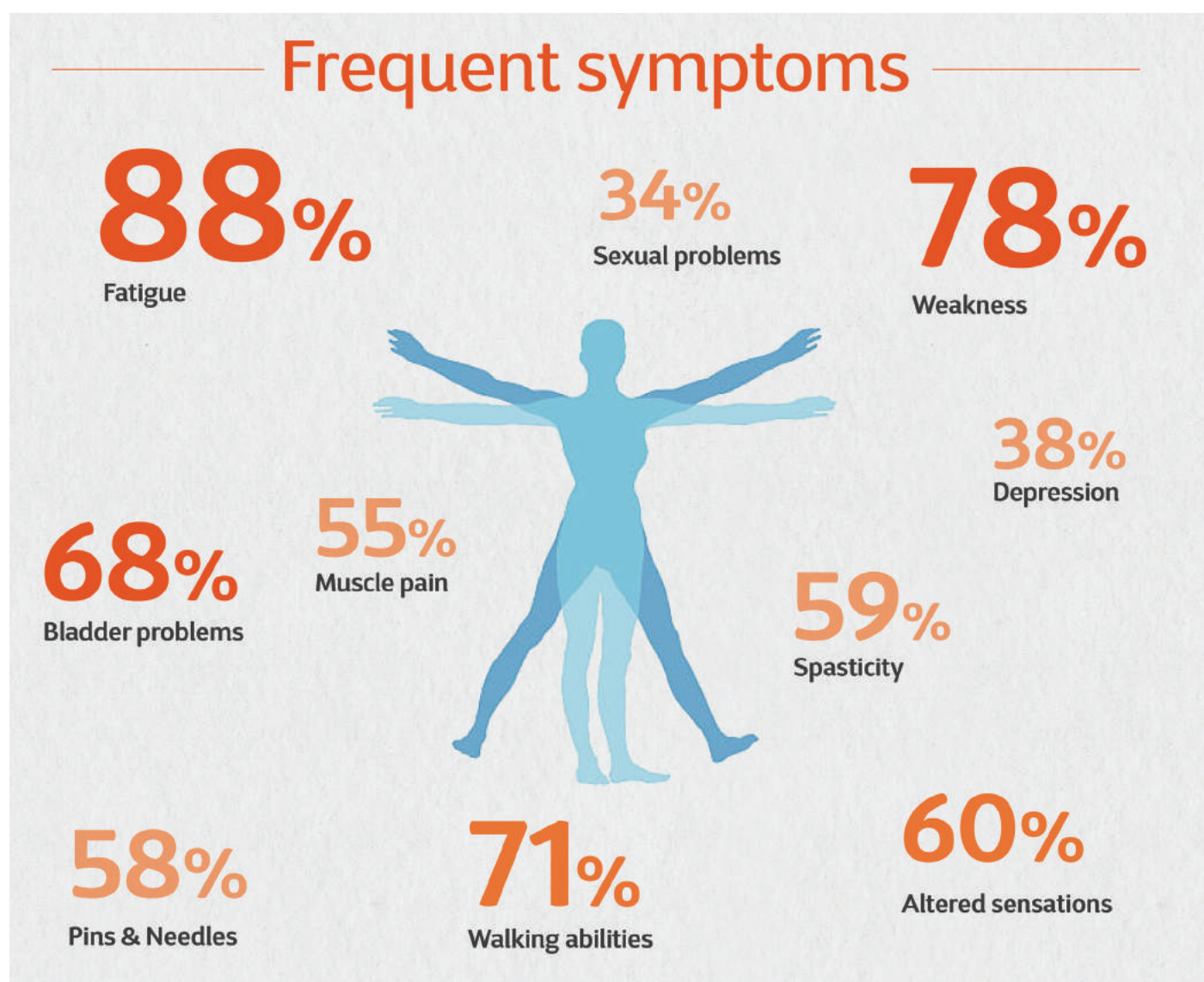
I felt my own personal experience made a real difference and was pleased to get some positive feedback from Nikki. She said it always helps to have a fresh pair of eyes, and get the perspective of

someone who actually has the condition being discussed. My experience supporting Nikki has encouraged me to get more involved in other MS Research projects.

The researchers I have worked with have said that they valued my feedback, However the one thing I often find myself explaining to researchers is the lack of predictability in MS which makes the emotional issues as difficult to deal with as the physical ones. Also the less obvious things such as bladder issues which make it difficult for others to understand.

I would certainly recommend people with MS to get involved with research as they bring a perspective that others don't have. It also makes me feel that in some small way I am helping to make a difference for those people who will have MS in the future.

“I felt my own personal experience made a real difference”



Schematic provided by UK MS Register.

Fighting cancer through research



Stephen myeloma patient

At any one time there are around 17,500 people living with myeloma in the UK. It accounts for 15 per cent of blood cancers, and two per cent of all cancers.

Myeloma is a type of cancer that develops from cells in the bone marrow called plasma cells. Bone marrow is the spongy tissue found inside the inner part of some of our large bones. The bone marrow produces different types of blood cells.

Myeloma can develop wherever there are plasma cells. So it can be anywhere there is bone marrow, including the pelvis, spine and ribcage. As it can occur in several places in the body, it is often called multiple myeloma.

Although this type of cancer is treatable, there is currently no cure for myeloma.

Pioneering treatment

Pioneering work into the prevention, diagnosis and treatment of cancer has helped save millions of lives. Over the past 40 years survival has doubled, thanks to the great progress research has made. At North Bristol NHS Trust we diagnose over 3,000 new cases of cancer and treat approximately 5000 new and recurrent cancers each year, making us one of largest cancer centres in the South West.

“When I was first diagnosed I had no hesitation in taking part in the drug trials. I looked at it in two ways. 1) You would be helping me and 2) I would be helping you “so it would be hopefully a win win situation.”

Myeloma research is looking at better treatments, achieving better quality of life and whether some treatments could be a cure. New chemotherapy agents and other therapies bring the risk of new problems so understanding how someone on treatment feels is an important part of most new studies. With the growth of treatment options a particular challenge is working out which one will work best for an individual's myeloma to minimise side effects.

The two trials highlighted compared treatments for myeloma are now part of standard care in the NHS.

Stephen who has been fighting myeloma for 11 years shares with us his story about living with his condition and taking part in research.

He has taken part in two trials the Myeloma IX and the Myeloma X trials to compare new combinations of drugs with treatments already used to see which worked best.

“When I was first diagnosed I had no hesitation in taking part in the drug trials. I looked at it in two ways. 1) You would be helping me and 2) I would be helping you “so it would be hopefully a win win situation.”

"The research involved having a few additional visits to the hospital to have some blood tests and different types of scans. There was a lot of paperwork to read and my wife was very good, she read a lot of it as some days I didn't feel up to it due to my chemotherapy treatment.

The drugs they were trialling seemed to be working which made me feel a lot easier about living with my cancer. I am a very positive person and try not to think about the negative aspects of living with this disease.

Suriya my research nurse was keeping me informed all the way through my treatment. Seeing the same nurses is really important. I feel very reassured that I know all the nurses here. I did feel a little isolated when I had to go to a different hospital for one of my chemotherapy appointments. When you are on chemotherapy you visit the hospital for five to six hours at a time having weekly treatment so the nurses are like your extended family.

I am no longer on a research trial as my myeloma has progressed. My current treatment is five to six hours of treatment once every week. Soon the treatment regimen will change to once a fortnight, then to once a month depending on how the treatment is going. I'm glad to say that the treatment seems to be working so far.

The Takeda (Millennium Study)

Sponsors Takeda (Millennium Pharmaceuticals, Inc.)

This research trial will assess whether taking the drug ixazomib as a maintenance therapy after standard treatment extends the period of time that a patient's cancer stays inactive. Maintenance therapy means that a drug is taken for a relatively long period (in this study, up to 24 months) to prolong the time that the myeloma remains under control after a prior therapy.

"I feel as though I am being looked after and if I have any questions, I can call the research team."



Cher myeloma patient

"It is really easy. I have no idea whether I am taking the study drug or a placebo, but I do feel well. I will be taking part in the trial for 24 months and followed up for 36 months at the end of my treatment."

Ixazomib is being tested to slow disease progression and improve overall survival in people who have newly diagnosed multiple myeloma, who have had a major positive response to initial therapy and have not undergone stem cell transplantation.

It is not yet proven whether maintenance therapy given to people in certain situations is better than waiting until the myeloma comes back to receive additional treatment.

Cher was diagnosed with myeloma just over two years ago

"Before being diagnosed, I was extremely busy running a small catering business from home, which I started 15 years ago. My day began at 4.30am making and delivering sandwiches to local businesses around the Aztec west area and some days would not finish until 9pm. I also organised buffets for private parties.

How has the myeloma affected your daily life?

I can't cope with the long days now and I need lots of rest between doing normal day to day activity such as going to the shops. If I have had a couple of busy days I might spend the whole day on the sofa and not move except for a cup of coffee.

How has your treatment been going?

I have had six months of chemotherapy which I seem to have responded well to. I was offered a stem cell transplant but I decided that I really needed to delay this for now. It meant going into hospital for a month and then not being able to leave the house for a long period of time due to possible infection. It was also an important time for my children. One of my sons was in the middle of his GCSE's and my older son was in his last year of university, so, I have decided to delay it and felt as though the research trial would be a better option for me.

It is really easy. I have no idea whether I am taking the study drug or a placebo, but I do feel well. I will be taking part in the trial for 24 months and followed up for 36 months at the end of my treatment. I am being closely monitored by both the Haematology team and the research trial team to see how well I am feeling and how well I am tolerating the study drug. I take one tablet 3 times per month, then I get the fourth week off. They also see me once per month to take a number of blood samples.

I feel as though I am being looked after and if I have any questions, I can call the research team. I recently had a few questions about going on holiday abroad and my treatment. These queries were addressed swiftly and the trial treatment did not impact my holiday. I feel confident that I have made the right decision for me at this point in time".

Foot Note:

In 2017 North Bristol NHS Trust was designated a Myeloma UK Clinical Trials Network Accessory Site which means that our patients will have access to drugs that are not currently available on the NHS.



Donate to Southmead Hospital Charity and make a difference to the research of tomorrow

Your support means that we can fund research into new treatments and care pathways, improving healthcare for the next generation.

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