

take part... be **involved**... in research



what's **inside**...

Patients share their experiences
of taking part in research at
North Bristol NHS Trust

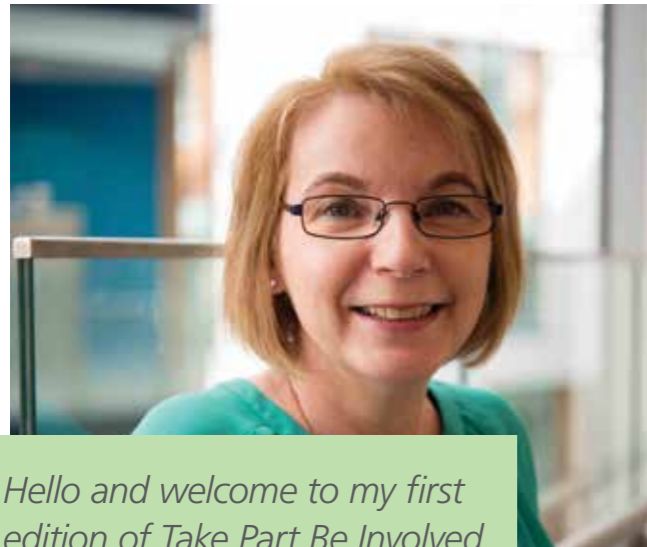
THE TEAM LOOKED AFTER
ME AS A PERSON AS WELL
AS MY PROBLEM



ISSUE 1



editor's note...



Hello and welcome to my first edition of Take Part Be Involved in Research magazine.

When I started here five years ago, I had absolutely no idea that over 500 research studies take place every year at Southmead hospital. Patients take part in a vast array of research studies which can simply be a patient completing a one-off lifestyle questionnaire to being part of a long-term research trial. During my time here, I have spoken to a large number of health professionals who are all extremely passionate about research and without exception all want to ensure that their patients receive the best possible treatment and care for their condition.

When you come into hospital, you are here because you are poorly and you may feel concerned and apprehensive about just being in a hospital environment. So, what happens when the person treating you, asks if you would like to take part in research?

I would like to share with you some experiences of the people who I have had the privilege to meet, who have all taken part in research here at Southmead hospital. Some of these people are living with an incurable disease and are still unsure if the research they are taking part in will ultimately extend their life. Each person still wanted to share their thoughts with you and to share what it was like to take part in a research study at North Bristol NHS Trust.

I would like to extend my thanks to those people who spoke to me freely about their experiences, the highs and lows of their condition and how they felt about being part of a research study. After a lot of coffee and a delicious cream tea, with their help, I am delighted to be able to share with you a sample of the exciting and groundbreaking research that takes place right here at your local hospital.

Sharon Nolan
Editor
Communications & Patient & Public Involvement
in Research Manager

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A big thank you to the Research public panel for their editing input.



Photographs of patients courtesy of Medical Photography, North Bristol NHS Trust.

Research into treating bone marrow cancer

There are approximately 4,800 people diagnosed with myeloma every year in the UK. Although it makes up about 1% of all types of cancer, it is a common type of bone marrow cancer. Myeloma is due to a growth of part of the immune system called plasma cells. The exact stage in the growth of these cells and the causes is not well understood but we do know that myeloma is characterised by changes in the DNA (the coding system to control cell growth and behaviour) found in plasma cells. What causes the DNA to change in an individual is not known but a number of risk factors – both genetic and environmental – have been identified which are associated with an increased chance of myeloma.

Improvements made to treating myeloma over the last decade mean that survival rates in myeloma are increasing among the fastest of all cancer types. The condition is not curable but can be treated repeatedly over time. In the UK an important contribution to improving survival is a sequence of national clinical trials as new drugs became available for the treatment of myeloma. A clinical trial 'Myeloma XI' was developed to test the benefits to newly diagnosed patients in the treatment of the disease.

Myeloma XI compares starting treatment with combinations of newer drugs with the current standard treatment that is provided in the UK.



"I TOOK PART BECAUSE I HAVE A CANCER THAT IS INCURABLE AND I WANT A CURE FOR MYSELF AND FOR OTHERS"

Emma's story

I asked Emma Fox a Nurse in A&E at Southmead who was diagnosed with Myeloma in August 2013 about being diagnosed with cancer and her experiences of taking part in a clinical drug trial.

Going back to the beginning, what were your symptoms?

"I had a bit of weight loss, but I'd put that down to going to the gym. I started to get swollen ankles quite regularly, but I put that down to being on my feet all the time at work. I also felt quite tired. I'd had some palpitations as well at night time. I remember my heart going into a running rhythm for a couple of seconds and wondered what that was and then it would settle down. I would wake up in the morning having totally forgotten about it.

I eventually decided to have a blood test just to be on the safe side and discovered I was running on half the amount of red blood cells I needed, so it was no wonder I was tired. The reason why my ankles were swollen was because my kidneys were just conking out on me.

I was really worried that it was going to be something that I would need long term medication for but I had no idea it was going to be something life threatening.

How did you find out about the research trial?

After being diagnosed it was pretty much one of the first appointments I had with the Haematology team. They told me they were running a randomised drug trial comparing the standard combination of three drugs, with the newer chemotherapy combination. I was randomised by computer onto the existing NHS standard combination of drugs which consisted of Cyclophosphamide, Thalidomide and Dexamethasone.

What did taking part involve?

I underwent some pre-study medical tests which included, blood, urine and bone marrow sampling. I had to sign to say I would not get pregnant and had to go onto the contraceptive pill because I was taking Thalidomide. I also needed to have regular check-ups. At one stage whilst I was undertaking my chemotherapy my appointments were 2 or 3 times a week.

What is your diagnosis at the moment?

I had a stem cell transplant in June last year and after a bone marrow biopsy and blood tests I am now in complete remission. I know it is going to come back at some point, until then I am just sitting tight and getting things back to normal again. I have just bought a house and ran the Bristol 10K in May for Myeloma UK. Taking part in fundraising events gave me a focus while feeling so helpless and really pleased that I have raised over £20K so far and still counting.

Why do you think research is important?

Without research you are not going to move forward with treatments and move forward with cures and I think research is absolutely vital."

If you have been affected by cancer, you can find further information at one of the websites below:

www.myeloma.org.uk

leukaemialymphomaresearch.org.uk

www.macmillan.org.uk

www.cancerresearchuk.org

Dementia Research...

There are more than 520,000 people in the UK with Alzheimer's disease which is the most common cause of dementia. Symptoms can include memory loss and difficulties with thinking, problem-solving or language. Despite being relatively common, the cause of this disease and the availability of effective treatments are still very limited.

Researchers at Southmead are leading a national four year study which is investigating whether a commonly used drug (Losartan) that is normally used to treat people with high blood pressure, can help slow down damage to brain tissue and as a result slow the progression of Alzheimers disease.

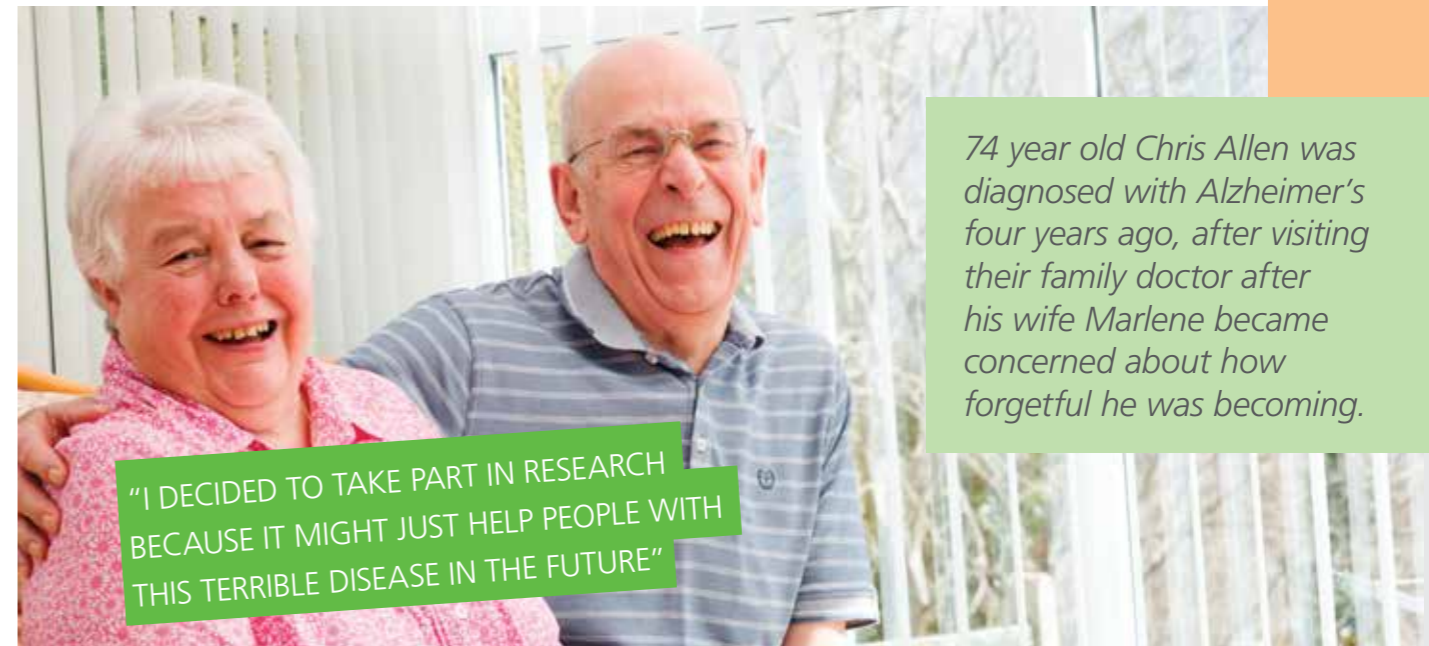
"Because we do not know whether the drug will help reduce damage to brain tissue we will randomly allocate people into two groups, giving one group the drug Losartan and the other group a placebo. (A 'dummy' treatment that will look like the genuine medicine but contains no active ingredient) Both groups of people will receive the same medical assessments irrespective of what group they have been allocated to".

Professor Patrick Kehoe, Gestetner Professor of Translational Dementia Research

Alzheimer's can affect anyone of us. Chris has led an active life, he started his working career as a telegram boy and together with his wife Marlene managed and owned a number of Post Offices in the Bristol area. Although now retired he still likes to play skittles with his local club.



Chris and Marlene's story...



74 year old Chris Allen was diagnosed with Alzheimer's four years ago, after visiting their family doctor after his wife Marlene became concerned about how forgetful he was becoming.

"I DECIDED TO TAKE PART IN RESEARCH BECAUSE IT MIGHT JUST HELP PEOPLE WITH THIS TERRIBLE DISEASE IN THE FUTURE"

What made you take part in the study?

Mr Allen: "Well, I thought, I've got it, so whatever happens to me now, I know my Alzheimer's is not going to get better. I decided to take part in research because it might just help people with this terrible disease in the future."

Marlene explained what the study involves

Chris enrolled on the study in February 2015 and it will involve seven appointments to the hospital or home visits over 12 months.

Natalie the Research Nurse came to visit us at home for the first appointment. This involved her carrying out some basic memory and thinking assessments. She asked some questions about Chris's general health, measured his blood pressure and took some blood samples. She also left him with some Losartan tablets. Natalie told us that this was the first part of the study so they can establish whether Chris is able to tolerate Losartan without any side-effects before officially starting the study.

I also helped Chris to take his blood pressure every day with a small blood pressure machine she left with us.

The second visit involved a more detailed assessment and having an MRI scan so that the researchers can have a detailed image of Chris' brain at the beginning and end of the study to see whether Losartan has made a difference to his brain tissue.

It is at this second visit that the official study starts and you are given either the Losartan or a dummy drug (Placebo) to take. We don't know which one he is taking.

What sort of support do you get from your research nurse Natalie?

Natalie is lovely. We've got a phone number for her if we need her, or if I need to ask any questions.

What's it like filling out all the forms? What's the paperwork like?

Completing the paperwork has been nice and easy. The researchers go through all the questions with us and they make a note of the answers. There are some forms that just need our initials. If we don't understand anything they will go through it with us.

Now you're in a clinical research trial, would you recommend it to someone else?

Mr Allen: Yes, definitely.

Mrs Allen: Even though living with someone with Alzheimer's can be really draining because you have to keep repeating yourself, I would still recommend it to someone else, because so far it hasn't been hard. Chris is hopefully helping people in the future and everybody is so nice. Nothing is too much trouble. Natalie even bought us some sandwiches when we had to go for the MRI appointment as she knew we were going to be there for a couple of hours and was concerned we might be hungry.

If you have been diagnosed with Alzheimers disease and you are interested in taking part or finding out more about this study please contact:

Natalie Rosewell, Research Nurse:
Tel: 0117 414 8239 Email : natalie.rosewell@nbt.nhs.uk

There is a memory café held every Wednesday 2-4pm Level 5 Gate 28 Brunel Building where you can come and have a cup of tea and chat with people who understand Dementia.

Alzheimer's Society national helpline: 0300 222 1122 or webpage: www.alzheimers.org.uk/ where you can find out more information on dementia as well as local dementia services.

This project is funded by the Efficacy and Mechanism Evaluation (EME) Programme, an MRC and National Institute of Health Research (NIHR) partnership.

Protecting the kidney during a transplant



Researchers were investigating whether a simple technique such as inflating a blood pressure cuff over the arm of the kidney donor and recipient for short-periods before and after their operation can reduce damage to the kidney during transplantation.

How does this work?

Previous small studies have indicated that reducing the blood flow to the arm for a short period of time can protect the heart, lungs and kidney from injury caused by an interruption of the blood supply. The temporary stoppage of blood to the arm activates a reflex that makes internal organs more resistant to the harmful effects of low blood flow.

Researchers at Southmead hospital were part of a three year large scale study involving 406 pairs of living donor renal transplant patients in over 13 centres across the UK, France, Belgium and Holland.

The study results

The results of the REPAIR study do show that applying a blood pressure cuff to the planned inflation pressure is safe. However, it also showed that there was some improvement in the function of the transplanted kidney if you had the cuff inflated just before you had your surgery. There is no evidence to suggest that applying the blood pressure cuff 24 hours prior to the operation has any effect. The improvement in kidney function could potentially mean that the transplant lasts for up to two to three years longer than it might otherwise do.



Carole had a kidney transplant in 2013 donated by her husband Barrie.

Carole took part in this study in 2013 after being told she would need a kidney transplant.

"I was diagnosed with high blood pressure in 2000 and it was during this time that I noticed that I was also becoming increasingly tired. My GP referred me to a consultant at the Bristol Royal Infirmary where I went through a period of trying to control my blood creatinine levels through medication. Eventually, I was transferred to the specialist Renal Unit at Southmead hospital to investigate kidney dialysis options.

Whilst being prepared for dialysis I had to have a fistula inserted into my wrist. It is made by connecting an artery to a vein under the skin. When the artery and vein are connected the pressure inside the vein increases which makes the vein stronger and bigger. Once the vein has become strong two needles can be put into it. One needle is used to take blood out to the machine whilst the other needle returns blood back to the body.

It was quite a show stopper as it makes your hand swell slightly. I told my family that I really wasn't keen on the idea of having dialysis, but I knew that would be my only option if I couldn't have a kidney transplant.

My son offered to be a donor, but I was reluctant to let him as I was concerned that he may have inherited high blood pressure from me. It was also discovered that I have multiple cysts on both kidneys so that did it for me; I did not want to put him at any possible risk in the future.

"UNLESS PEOPLE DO RESEARCH, THEY ARE NOT GOING TO COME UP WITH ANY ANSWERS TO HELP PEOPLE IN THE FUTURE"

It was at a routine appointment that my husband Barrie enquired whether he could be a donor. Unlike many other types of organ donation, it is possible to donate a kidney while you are alive, because you only need one kidney to survive. After the initial tests to see if he was a match, it was all systems go and in February 2013 we had our transplants.

Everything appears to be ok for both of us and we are really looking forward to going away on holiday for the first time since the operation.



I didn't feel as though I was part of a research trial, as it was incorporated into my normal treatment. We both had two cuff inflations in the first 24 hours of surgery and the second immediately before surgery. I would definitely urge people to take part in a clinical trial if they have the opportunity; I think it is really important. Unless people do

research, they are not going to come up with any answers to help people in the future."



Prostate cancer is the most common cancer in men in the UK, with over 40,000 new cases diagnosed every year. It usually develops slowly which means that there may be no signs you have it for many years.

PROtecT study

Symptoms often only become apparent when your prostate is large enough to affect the urethra (the tube that carries urine from the bladder to the penis). When this happens, you may notice things like an increased need to urinate, straining while urinating and a feeling that your bladder has not fully emptied. These symptoms shouldn't be ignored, but they do not mean you definitely have prostate cancer.

Researchers need to find out about the best way of treating prostate cancer before it causes any problems. At present, nobody knows which of the current standard three treatments provided by the NHS is best either:

1. an operation to remove the prostate
2. radiotherapy to the prostate
3. careful monitoring with regular check-ups

The PROtecT study is a research project that took place in nine parts of the UK from 2001 to 2009. Over 1600 men aged between 50 – 69 have taken part. These men were asked if they would agree to be randomly selected to have one of the standard treatments.

Researchers are using this information:

1. To assess survival of patients with localised prostate cancer at 10 years and 15 years after treatment
2. To investigate their disease progression, any treatment complications and lower urinary tract symptoms in these patients
3. To investigate the psychosocial impact of cancer detection and treatment on these patients, including generic health status, quality of life, and sexual function
4. To estimate the resource use and costs of detection, treatment, and follow-up
5. To compare costs and outcomes of treatment in terms of survival and health-related quality of life

Patients who have taken part in the study will be followed up for ten years following their treatment to monitor their progress and will be asked to complete a health questionnaire.

Mr Bennett shares his story...

"THE TEAM LOOKED AFTER ME AS A PERSON AS WELL AS MY PROBLEM"

Mr Bennett was diagnosed with Prostate cancer in 2008. He was diagnosed by chance after responding to a letter from his GP to take part in a research study called PROtecT to test men between a certain age band for signs of prostate cancer.

Unfortunately, he discovered that he did have early stage prostate cancer. His treatment was an operation to completely remove the prostate.

How did you feel when you were first diagnosed?

"I was stunned. I was fit and healthy and the last person in the world I had expected to have some type of cancer. I don't smoke, I don't drink that much and I maintain a healthy diet and keep fit. I immediately thought that is was going to be a bad outcome.

I had been to see my GP a few months before with urine flow problems, so when this trial came along, I thought it would be a good opportunity to have a closer look.

When you were asked to take part in a clinical trial what were your first thoughts?

Hopefully I might be cured. The researchers told me that they can cure prostate cancer now, but of course there were no

guarantees. It helped me to know the odds of survival but there is still the possibility that you are going to have a terminal disease. It is a very worrying time.

What about the level of care that you received?

The PROtecT trial broadened my view of research, it made me realise that there is a much bigger picture such as the support you receive whilst undergoing these trials.

Has it stopped you in your tracks?

The fact that I've had the treatment hasn't really affected me – of course there are a few side effects due to having my prostate removed, but it hasn't stopped me in my tracks.

Physically things are good, I still go jogging. I really enjoy climbing and have climbed all of the central peaks in the Lake District."

Prostate cancer facts

- Prostate cancer is the most common cancer in men in the UK.
- Prostate cancer accounts for a quarter of all new cancer cases in men in the UK.
- There are 35,000 new cases every year in the UK.

- Over the last 35 years prostate cancer rates in Great Britain have more than tripled, although much of the increase is due to increased detection through widespread use of the PSA test.
- More than a third of prostate cancer cases are diagnosed in men aged over 75 years.

For more information please visit: www.cancerresearchuk.org

Recruitment for the study ceased in 2009. Further funding has now been granted for the follow-up phase of the study. It is intended that all men are followed up for 10-15 years.

Watch & Wait



Cancer research trial

Lymphomas are cancers of the lymphatic system. They occur when some of the lymphocytes (cells) become cancerous. Our lymphocytes are always dividing to make new lymphocytes. When fighting an infection, lots of new lymphocytes are made very quickly. Only those that target the infection we have at the time are useful to the immune system. Any lymphocytes that do not target that infection will die, meaning it is only the useful lymphocytes that survive.

Lymphomas can occur when there is a breakdown in the control of the system. Instead of dying in the normal way, untargeted 'rogue' lymphocytes start to divide in an uncontrolled way. The rogue lymphocytes collect together to form a lump, most commonly in a lymph node. This is a lymphoma.

The current standard NHS treatment is a watch-and-wait approach for most patients who are at an early stage of the disease. Delaying treatment until the disease progresses further, based on the assumption that this results in an improved quality of life by not exposing patients to the toxic side effects of chemotherapy unnecessarily; reducing hospital visits and by decreasing the need for blood tests.

Rituximab has been found to be a useful treatment for follicular lymphoma with relatively few side effects. It was first approved for use in patients with lymphoma in 1997 and since then it has

become an integral part of lymphoma treatment. It works by identifying a 'target' often found on the surface of lymphoma cells called CD20 and causes the destruction of that individual cell. In 2006 Rituximab in combination with chemotherapy was approved for first line treatment of symptomatic follicular lymphoma in the UK and more recently it has been approved as a maintenance treatment for this disease.

The Watch and Wait study was designed to see whether immediate treatment with Rituximab followed by a period of watchful waiting can further delay the time until chemotherapy or radiotherapy needs to be started, compared with an initial period of watchful waiting alone. In addition, the study measured the effect the different treatment options have on a patient's quality of life and whether any of the treatments can improve a patient's chance of living longer.

Patients that took part were randomised into either a:

1) Watchful waiting group, where their specialist closely monitors their disease progression. (This is standard NHS practice)

OR

2) Given Rituximab for the treatment of their lymphoma

Craig's story...

"I HAVE CERTAINLY CHANGED MY OUTLOOK ON LIFE"

Craig was diagnosed with Grade 3 Follicular lymphoma in 2008 which is the commonest single type of low-grade non-Hodgkin lymphoma and immediately agreed to take part in the trial.



"I was diagnosed with a non-curable lymphoma in 2008 after going to see my GP when I found a huge lump in my throat.

I had no hesitation in joining the trial but admit I was really disappointed when I was randomised into Watch and Wait, as I really wanted to trial the Rituximab. I was quite surprised when I was told that the normal treatment is to wait. When you are first diagnosed with cancer, the first thing you want to do is to remove it as quickly as possible. The last thing you want to hear is that it will not be treated until it is absolutely necessary.

The trial appointments fitted around my regular hospital visits. Surya the Research Nurse went through everything with me and explained that I would need to provide quite a few blood and bone marrow samples, but she would arrange to do these at the same time as my hospital appointment. It just meant that I had to provide six samples instead of three.

The downside for me about taking part in the study was actually completing the Quality of Life questionnaires as they were a constant reminder that I had cancer. It asked some really serious questions and made me think about stuff, that

had I not been involved in the trial I would probably not thought that much about; I never really thought about the cancer unless I was going to hospital and the questionnaires were an added reminder.

Taking part in the Watch & Wait research study has only really been a small part of my overall treatment. Having cancer is like being on a rollercoaster, but I am fighting it every step of the way. My priorities have completely changed. It used to be all about money and working and now I am working to live. I have certainly changed my outlook on life."

www.cancerresearchuk.org

Results of this trial can be found on the Cancer Research UK website

www.lymphomas.ork.uk

The Lymphoma Association has developed a patient information booklet which explains more about Lymphoma



SOUTHMEAD HOSPITAL CHARITY

With your help Southmead Hospital Charity can fund ground-breaking medical research, provide specialist equipment at the cutting-edge of technology and improve treatment facilities for generations to come.

Southmead Hospital Charity raises money to support the work of Southmead Hospital, Cossham Hospital and community health services in the Bristol, South Gloucestershire and North Somerset.

Working alongside our staff and patients, we fundraise for projects that are beyond the remit of the NHS but have a huge impact on the lives of patients.

The charity provides funding to medical and health research projects through the Springboard fund.

The scheme makes annual grants to support high quality research projects with the potential for making a real impact within the NHS.

The Springboard Fund was set up in 2006 and over the last 6 years has funded 55 projects to a total of £548,371.

There are currently 32 active projects funded through the Springboard fund.

Previous research projects include:

- Researching whether a patient's own immune system can be used to fight lung cancer
- The educational and developmental outcomes for premature babies
- Whether a blood test can be devised to detect a brain tumour

Find out how you can donate or fundraise for medical research through the Springboard Fund by visiting www.southmeadhospitalcharity.org.uk

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