

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

what's inside...

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

"BY TAKING PART IN THE RESEARCH
TRIAL, I FELT AS THOUGH I WAS ABLE
TO TAKE BACK SOME CONTROL"



ISSUE 2



editor's note...



Hello, welcome to my 2nd issue of Take Part Be Involved in Research magazine.

Would you be surprised if I said that research affects us all? You might say that you have never personally been involved in research, but, you will definitely have benefitted from it. Have you ever had an operation? Have you ever broken a bone or had an x-ray or a blood test? All of these things will have involved choices and decisions by the healthcare staff looking after you and those decisions were guided by the results of previous clinical research. Research is not something that affects other people. It affects us all. Even if we have never been involved in a research study, even if we have never even heard of research, the treatments that we receive right now are based on research.

You might also be surprised to know that research isn't just about scientists sitting in a laboratory wearing a white coat with lots of tubes testing new drugs. It involves a whole mixture of medical professionals, including doctors, nurses, scientists, physiotherapists, psychologists, dieticians to name but a few.

We consider ourselves to be very lucky at Southmead hospital, research is what we do every day across all areas of the Trust, and if you are a patient here, then you will more than likely be asked if you would like to take part in a research study as part of your care.

I have had the opportunity to speak to a wide range of health professionals for this edition, including our midwives who have been helping to manage a large maternity research study. Also in this edition I wanted to highlight the projects that have been funded purely through public donations, and how members of the public work alongside us to help us to decide which projects to fund. The fund recently celebrated its 10th anniversary, which all began from a legacy from a member of the public who wanted to make a difference to healthcare.

I would also 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.

Sharon Nolan

Editor, Communications & Patient & Public Involvement
in Research Manager

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

Devote Study

The diabetes research team at North Bristol NHS Trust currently have over 600 patients taking part in a number of diabetes research studies. It is not an easy disease to manage and over time different medications are needed to maintain good blood sugar control and to avoid serious complications. Heart disease is a concern for people who also have Type II diabetes.

Georgina who has type II diabetes had a heart attack in April 2013 and took part in the international research trial for patients with diabetes and who are at high risk of a cardiovascular event. Georgina shared with me her experience of taking part in a clinical trial.

"When I had my heart attack my sugar levels were really high it and it was really worrying me. My kidneys were also damaged due to the heart attack. It was while I was waiting to see the kidney specialist that I saw a notice in the waiting room asking for people like myself to contact the Diabetes Research team at Southmead Hospital about a research trial they were carrying out for people like me.

After speaking to Sharon the diabetes Research Nurse, she said that they would be able to help me to control my sugar levels and gave me more information about the trial.

It is comparing the effects on the heart and blood vessels when taking Degludec insulin compared to that of Glargine insulin. Your details are put into a computer and it decides which treatment you are going to take."

Diabetes is a common life-long health condition. There are currently 3.2 million people diagnosed with diabetes in the UK alone.

So what did taking part in the research trial mean for you?

"Because my diabetes is progressive, there isn't a cure at this point in time, I knew I needed to keep my insulin levels down; because there are more parts of my body becoming damaged.

I took part in the research trial for five years. Over that time I had 29 scheduled visits to the hospital, to monitor my condition. If I was at all concerned though, all I had to do is pick up the phone between visits.

It involved using a small amount of blood to see what my glucose levels were in the morning, and again in the evenings. I took the research trial medication before going to bed. I was still able to take my existing medication, which is the one I take after my tea at night. The downside of taking insulin is that it increases your appetite, so it can make you plump, so you do need to watch what you are eating.

What was your knowledge of clinical research before?

I have to admit that I was a little apprehensive at first and concerned that it might damage my heart further. But, I have to say, I have nothing but praise for the Diabetes team.



"THE ONGOING SUPPORT I HAVE RECEIVED BY BEING PART OF THIS RESEARCH TRIAL HAS REALLY IMPRESSED ME"

Nothing is too much trouble, they are at the end of the telephone if I need anything or I am concerned about anything. I only see my diabetic nurse at my GP surgery once per year, so I am basically, being looked after by the diabetes research team at Southmead.

The psychological impact of having diabetes and having a heart attack is a big concern for me. While you are in hospital you have a team of medical professionals on hand to keep an eye on you, so leaving hospital was quite scary for me.

What do you think of research now?

I think it is all down to trust. I am being well looked after by both the cardiac and diabetes team. I also attend the cardiac rehabilitation support group and do Tai Chi each week. I really enjoy it as you meet lots of people who are in the same situation as yourself.

As well as my scheduled trial appointments, the team give you advice on exercise and diet and run regular educational evenings where you can meet people who are also taking part in diabetes research too."

Sponsored by Novo Nordisk, 7637 patients took part in the five year study across the country. The results of this trial are due to be published later this year.

Giving a gift to future mums



Helen Specialist Registrar in Obstetrics and Gynaecology with her son Arthur

Our Maternity units have recently been upgraded following a grant from the Department of Health, which now means that expectant mothers have more choice where they can give birth. They can choose either the midwifery led unit at the Cossham Hospital Birth Centre, the Mendip Birth Centre and Central Delivery Suite at Southmead Hospital, or they can even choose to have a home birth.

Featured on the popular programme One Born Every Minute, footage was captured from the reception desk to the neonatal ward; from the operating theatre to the birthing pool. Featuring dramatic, emotional and often funny moments that go hand in hand with bringing a new life into the world.

Giving birth has changed dramatically over the years, but there are a few areas that still need to be improved. According to the World Health Organisation, while maternal

mortality rates dropped 50 percent between 1990 and 2014, 800 women globally, still die every day from preventable causes related to pregnancy and childbirth.

Leaders in Maternity Research

We consider ourselves extremely lucky that Southmead's maternity services are leaders in their field ensuring that expectant mothers are cared for every step of the way during the birth of their baby.

Midwives that deliver research

Just recently, our midwives were shortlisted for a prestigious Nursing Times Award for helping to deliver research.

The midwives stood out to the judges because not only have they enabled over 1000 new mothers to take part in a research study over the past 12 months, the project has also helped to put research into the minds of everyone working in Maternity Services.

THE IMOX STUDY

Around a quarter of all global pregnancy and child-birth related deaths are due to excessive bleeding after the birth of the baby and placenta, in the UK, this affects approximately 10% of new mothers. This can cause them to need additional treatments including a blood transfusion and extra medicines, as well as prolonging their hospital stay.

The IMOX study is taking place in 6 different maternity units across the country, to compare the effectiveness, side effects and cost of Syntocinon, Syntometrine and Carbetocin, for women having a vaginal birth. All of these medicines are already used for this purpose within maternity care.

It involves a one-off injection in the mother's leg just after their baby is born and the umbilical cord has been clamped, and before the placenta being gently delivered by the midwife or doctor. Medicine is given to reduce the risk of experiencing heavy bleeding (haemorrhage). Reduce the need for extra medicines to make their womb contract well, and to reduce the need for a blood transfusion after the baby has been born. Having this injection also makes the "third stage of labour" shorter.

The IMOX study will find out which medicine is best at reducing blood loss and which allows women to feel as well as possible in the first hours after birth. The team will also be comparing the overall cost of these three medicines, to help the NHS spend its money most effectively. Knowing all of this information will help midwives and doctors to provide the best possible care for mothers giving birth.



Expectant mum signing up for the IMOX study

Helen, can you tell me why you took part in the study?

"It's so important that research happens within the NHS, so that we continue to advance medicine, and provide patients with the best possible care. Each individual patient who takes part in research makes such a big difference. I was excited to be able to contribute to the study from the "other side" as a patient myself, and contribute to our overall numbers. We actually live an hour away from Southmead, and drove here especially because I feel that this is such a fantastic and safe maternity unit, full of wonderfully kind and supportive staff.

And why as a mum?

I knew that taking part in this study is perfectly safe for my baby, and that it will help to optimise the safety and birth experience of women giving birth in future. Taking part now is almost like passing on a gift to future mums.

Is this the first time you have taken part in a study yourself?

Yes it was! I was really excited about taking part. Apparently I talked about the study a lot when I was in labour – I was just making sure that everyone remembered that I was taking part! It was also really nice completing my follow up questionnaires on day one when was in the hospital, and at week two on the phone. I think lots of patients feel this – it's great to chat to the research midwives again, and for them to meet your new little person.

Did you have any side-effects?

No, I didn't. Taking part in the study actually makes you overall less likely to experience side effects. It's a win-win situation!"

Did you know that more than 6000 babies are born with us every year?

The Imox study began in 2015 and is due to end in 2018.

How effective is physiotherapy for patients after knee replacement surgery?

About 70,000 people have a knee replacement in the NHS every year. It is a major operation with a long recovery period. Physiotherapy is an important part of the recovery process because it can help improve strength and movement in the replaced knee and allow people to gain the maximum benefit from the operation. However, not all hospitals offer additional physiotherapy to patients once they have been discharged after their knee replacement operation.

Researchers at the University of Bristol and Southmead Hospital are leading the ARENA research study involving 250 patients to find out whether it is helpful for patients to be offered exercise classes following their knee replacement. Patients from two hospitals in Bristol have been invited to take part. Half of the people will be chosen at random to receive 'usual care' where they will be provided with a booklet about exercise and referred to outpatient physiotherapy on a needs basis e.g. if they have poor mobility. The other half of people will be invited to attend physiotherapy exercise classes, in addition to receiving 'usual care'.

ABOUT THE CLASSES

The exercise classes take place every week for six weeks, starting at six weeks after the patient's knee replacement surgery. In the classes, patients practice task-related exercises such as walking, stair climbing, and kneeling. Each patient also receives two individualised exercises, designed by the physiotherapist, to help them with specific goals important to them. Patients are also given written information and advice for continuing the exercises at home after they have completed the classes.

There are also health questionnaires to complete by the patients, before the patient has their operation, and then three, six and 12 months following their operation. Patients who attend the classes are also asked some questions over the telephone about their experiences of the classes and what they found helpful or unhelpful.

After the study is finished, all patients who took part will be sent a summary of the study findings. A plain English summary of the findings will be added to the Musculoskeletal Research Unit website. (<http://www.bristol.ac.uk/clinical-sciences/research/musculoskeletal/>) The findings will also be published in academic journals and presented at national and international conferences.



Lynda Riley

Lynda is no stranger to research after having taking part in a research study 15 years ago and felt that she was looked after so well, she had no hesitation in agreeing to take part in the ARENA study.

"I have suffered with my knee for years and the last couple of years before my knee replacement; it stopped me from being able to live a normal life. I would go out to the shops with my husband and my knee would just give way and it was extremely painful. The pain was so severe; it was beginning to ruin my life and stopped me from doing normal day to day activities. On one occasion, my husband had to fetch the car to take me back home."

"I heard about the study during my knee operation consultation. A researcher came in to see me to ask if I would like to take part. She took a few notes about my knee and general health and explained what the research study would involve. She also explained that being allocated to the physiotherapy part of the study was not guaranteed as patients are chosen at random, a bit like tossing a coin. So I would either have the usual standard care, or standard care as well as the physiotherapy exercise classes.

Six weeks after my knee replacement, I was told that I had been allocated to the physiotherapy part of the study. This involved going to a group exercise class at Cossham Hospital every week for six weeks. I found the gym exercises really helpful, and amazed at how quickly I could walk on the treadmill. I feel as though my mobility has really improved because of it.

PAPERWORK

There is a lot of paperwork, but it is all very easy to understand. You have to log all your exercises and the level of pain that you experience. I would complete it immediately and send it straight back.

WOULD YOU RECOMMEND RESEARCH TO ANYONE ELSE?

Yes, definitely, taking part in this research, I was able to have additional physiotherapy classes which are not normally available on the NHS.

OUR PATIENT GROUP HELPED US TO DESIGN THE RESEARCH

Dr Vikki Wylde
Principle Investigator leading the research

"We work closely with our Patient Experience Partnership in Research (PEP-R) group. This is a group of nine public members, who all have experience of musculoskeletal conditions. They meet regularly with us and are able to use their experience as patients to help us when we are designing and delivering our research studies."

The PEP-R group helped us to write our study documents, such as the patient information leaflet and study questionnaires. They also helped us to make some really important decisions about the physiotherapy classes. For example, we realised that some people did not want to take part in the study because they didn't want to come to Southmead Hospital for the classes,

After my operation I was in a lot of pain. You feel at the time that you are the only one in pain. But actually, when I met other people in the physiotherapy group, I was actually doing very well. I was moving around so much better than some of the people in the group, which gave me more confidence, because it made me realise just how well I was doing.

The sessions had an additional benefit for us the patients as it became a support group. We used to have a cup of tea afterwards and share our experiences. I still keep in touch with one of the ladies who was part of my group.

"MY QUALITY OF LIFE HAS DEFINITELY IMPROVED"

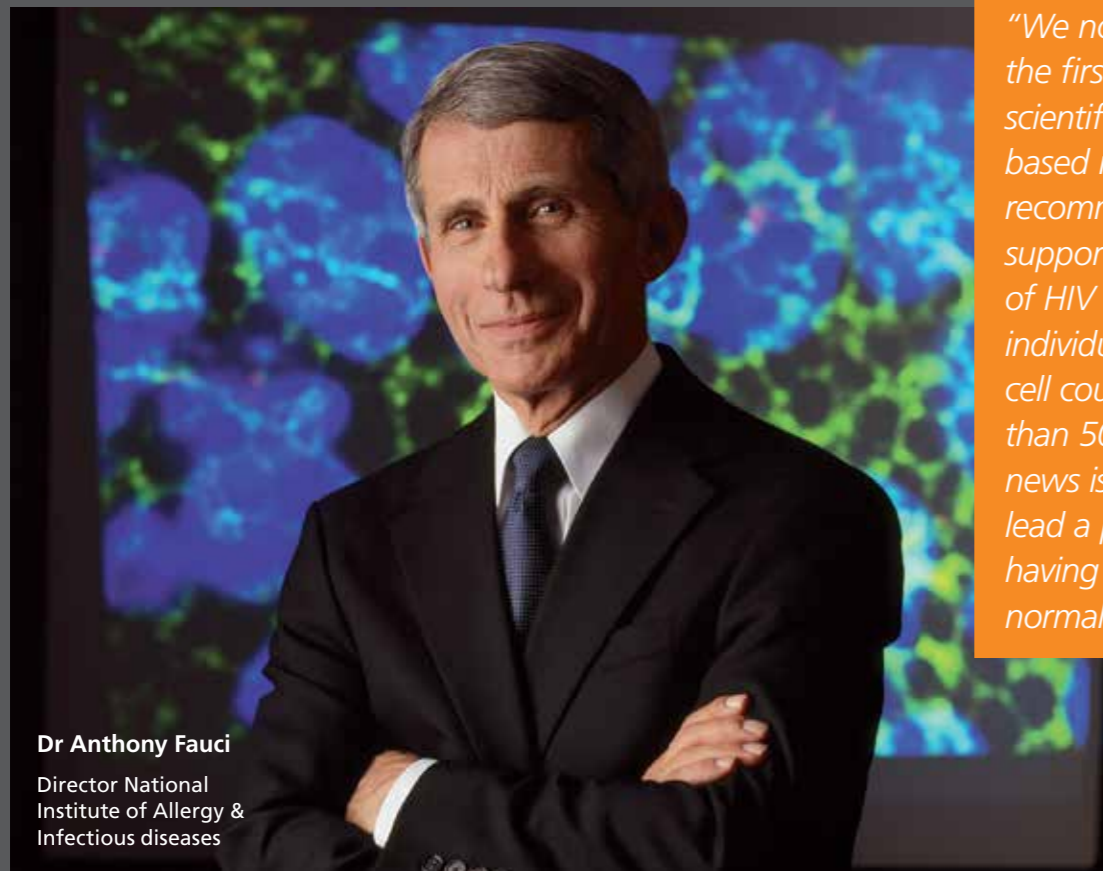
Following a knee replacement, you have to be prepared for pain at the beginning. I can get around really well now and feel that having the opportunity to have physiotherapy really helped with my recovery. I recently went to Denmark to see my grandchildren and was able to walk around for two hours which I haven't been able to do for years!"



PER-R patient group

due to the new hospital building works and parking restrictions at that time. When we discussed this with the PEP-R group they suggested that Cossham Hospital would be a better location for the classes. Based on their advice, we moved the classes there."

This project is funded by the National Institute of Health Research (NIHR) partnership under its Research for Patient Benefit (RfPB) Programme (Grant Reference Number PB-PG-1013-32010).



"We now have for the first time, solid scientific evidence based reasons to recommend and support the treatment of HIV infected individuals whose CD4 cell count is greater than 500. The good news is that it can lead a person to now having a close to normal life span."

Dr Anthony Fauci
Director National Institute of Allergy & Infectious Diseases

Global HIV drug study has shown that **earlier treatment** benefits all HIV infected individuals

There are 36.7 million people in the world living with HIV

The START study, which stands for Strategic Timing of Anti-Retroviral Treatment was designed to investigate the optimal time to begin anti-retroviral therapy (ART) in patients who have been diagnosed with HIV. It opened widely in 2011 and was due to end in 2016, but results were released early due to overwhelming evidence that starting treatment early is beneficial for patients.

The World Health Organisation (WHO) has now updated its guidelines and most patients are now able to begin treatment at any CD4 cell count rather than waiting for their cell count to drop to 350 cells per cubic millimetre or less.

There have been previous much smaller trials that have indicated that if they began their treatment at a cell count of 500, it is of great benefit to the person. But, concrete scientific evidence was needed to confirm these earlier results.

Patients who are HIV positive are at risk of developing AIDS, but it is unusual to develop symptoms of AIDS when your cell count is above 350, although it does happen in some people. Studies have shown that other serious illnesses, like heart attacks, liver disease,

or kidney failure, also happen less often in people whose cell count is higher. In these studies, the chance of having one of these serious illnesses appears to increase as your cell count drops. In some studies, people who took HIV medicines and kept their cell counts high, had fewer of these serious illnesses than people not taking HIV medicines. Scientists still do not completely understand why this happens.

Patients took part for a period of three years to establish if the chances of getting one of these serious illnesses or of getting AIDS are less if you start taking HIV medicines at a time when your CD4+ cell count is still fairly high (500 count), instead of waiting until the recommended 350 count or less.

Researchers were also aiming to learn if starting HIV medicines earlier might affect other things, such as the chances of developing other illnesses or resistance to HIV medicines (where the HIV virus changes so that some medicines no longer work against it), how often you need to see a doctor, the cost of your medical care, and your general health and satisfaction with your life.

Becky Mitchell

Becky had been feeling under the weather and was feeling extremely tired which was unusual for her. Her fitness regime would put most of us to shame, so she is very tuned into her health and well-being and could not understand why she felt as though her body was under attack. By chance she discovered that her ex-partner was carrying the HIV virus so, concerned, she immediately went to see her GP who confirmed her worst fears, that she was now living with the HIV virus through absolutely no fault of her own.

"I caught up with Becky in between her training sessions. She is currently preparing for a 20K run in Portugal. She is also the running lead in her local club and takes spinning and kettle bell classes.

How did you hear about the Study?

It was during one of my consultations at the hospital. He mentioned the START study and that I would meet the criteria for taking part. He also explained that it was randomised, so I had a 50/50 chance of taking part in the early treatment group, or the usual care group.

Within a couple of weeks I met Louise the Research Nurse who told me more about the trial and what it would involve. She also explained that it would mean some extra visits to the hospital in addition to my normal clinic appointments. I then got a call to say that I had been selected to go into the early treatment group.

How did you feel about taking part?

I was really angry by being infected with a virus that could easily have been avoided. By taking part in the research trial, I felt as though I was able to take back some control. I was a little nervous about having to take a toxic drug when I wasn't actually feeling unwell, so I was quite apprehensive. But, actually I feel fine.

I had a discussion with the Pharmacist to determine which of the drugs would be best for me. I now take a tablet once per day which fits in well with my lifestyle. I responded really well to the treatment. Within two weeks my viral load was undetectable. The team called me back in to re-do the test as they were surprised at how quickly I had responded to the treatment.

What would you say to other people about research?

I feel as though I have been receiving more specialist care being part of this study. The research team are always at the end of the phone if I have any worries. They are really supportive about my whole health and well-being."



Becky Mitchell

STUDY SPECIFICS: The START study opened widely in March 2011. 4685 patients in 35 countries who had never taken antiretroviral therapy and with a (CD4 cell count above 500 cells per cubic millimetre) were enrolled into the study. The patients were divided at random into two groups. Group one, began their treatment immediately (early treatment), and the second group waited until their CD4 cell count had declined to 350 cells per cubic millimetre as per the current global guidelines.

HELP AND SUPPORT:

Terrence Higgins Trust
<http://www.tht.org.uk/myhiv/HIV-and-you/Relationships/Supporting-someone-with-HIV>



RESEARCH RESULTS:

News release from National Institute of Allergy and Infectious Diseases (NIAID)
<https://www.niaid.nih.gov/news-events/starting-antiretroviral-treatment-early-improves-outcomes-hiv-infected-individuals>

SPONSOR & PRIMARY FUNDER:

The University of Minnesota, Minneapolis, Minnesota, USA

In collaboration with London International Coordinating Centre for INSIGHT network

START Team, MRC Clinical Trials Unit UCL, Institute of Clinical Trials & Methodology, Aviation House, 125 Kingsway, London, WC2B 6NH

Primary Funder: National Institute of Allergy and Infectious Diseases (NIAID)

How public donations help fund research

Due to the generous nature of members of the public who donate to our research fund, we are able to launch early stage new research projects. One of the most difficult parts of the research process is getting new research ideas off the ground, exploring which research ideas will potentially bring the most benefit to patients and make NHS services more efficient and effective. The Research Fund has been invaluable in helping our staff to do just this by providing that first pot of money.

I would like to share with you an early stage project that has benefited from your donations which is investigating whether we can detect brain tumours sooner. This project touched me personally and I hope that you feel this is a really exciting and worthy project to receive funding.

Kathreena Kurian Consultant Neuropathologist in brain tumour research

"The project was to develop a test to detect brain tumour cells within the blood. When patients have a suspected brain tumour, the symptoms are very non-specific; it can be a headache for example, so it can be very difficult for a GP to diagnose.

On average 40% of brain tumour patients go to their GP up to five times before being diagnosed and sadly some are admitted to A&E when it is too late to help them.

Our idea was, if we could develop a blood test for the GP, they would have a really quick way of diagnosing a patient with a suspected brain tumour.

The fund was important to us, because it helped us to research an early stage project, which if it proves to be successful, we can then apply for larger funding from larger national funding organisations.

We are really excited about this project had hope to have some preliminary results in the next couple of months."



Members of the public are a key part in helping us to decide which projects to fund.

Fondly named the Motley Crew, David, Maureen, John B, Eddie, Ian, John R, Tony & Nick have been working alongside us for the past 6 years. We offer funds on an annual basis to researchers and as part of that process, they work with us to review the applications and help us to decide which projects are funded. A film has recently been produced to showcase some of the projects that have been funded, together with the Motley Crew sharing their experiences of being involved.

"I LIKE BEING ON THE PANEL BECAUSE I FEEL AS THOUGH I AM INVOLVED"



David

David Hanna

"I joined the panel 6 years ago, and really glad I did. Our role is to look at the research submissions that have applied for funding. The researcher writes a non-technical lay summary, so non-health professionals like myself can understand what the project is about.

We read the lay summaries at home and then we meet as a group to review and discuss how that research will potentially benefit patients and the NHS. We then give each application a score which is collated and given to the Research Fund Chair. There is only a limited amount of funding, so it is our role to help the Research & Innovation team to decide which projects that we feel should be funded."

"AS THE MONEY THAT HAS BEEN DONATED COMES FROM THE PUBLIC, IT IS GOOD TO MAKE SURE IT'S WELL SPENT ON WORTHY RESEARCH"



Maureen

"WHAT IS AMAZING IS THE WIDE RANGE OF RESEARCH THAT TAKES PLACE HERE"



John



be involved in research

You can support us in the following ways:

Donate on line by visiting:

www.southmeadhospitalcharity.org.uk/research

Donate by text:

RAIF16 £chosen amount to **70070** eg: **RAIF16 £10**

Donate by cheque and post to:

**Southmead Hospital Charity Research Fund,
Trust Headquarters, Learning & Research building,
Southmead Hospital, Bristol, BS10 5NB**



www.southmeadhospitalcharity.org.uk/research

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