

# ProtecT Study

(Prostate testing for cancer and Treatment)

## Newsletter Issue 13, Winter 2015

To all ProtecT study participants from the study's organisers

Dear ProtecT study participant

We are now approaching the time when we can begin to present the long-awaited results of the study that you have contributed to, including the outcomes you have experienced following the treatment you received for prostate cancer. You have shown exceptional commitment to taking part in the study, filling in the questionnaires, and visiting the ProtecT study nurses each year. It has been a privilege being involved in this study with you, and we thought it would be helpful to take this opportunity to outline the study, explain what we will do with the findings, and let you know how the study will be organised from now on.

We also want, most importantly, to thank you very much for your participation so far. We very much hope you will wish to continue.

With very best wishes,

Freddie Hamdy, Jenny Donovan, David Neal

*Please turn to pages 3 – 5 to continue reading this message from the study's principal investigators.*

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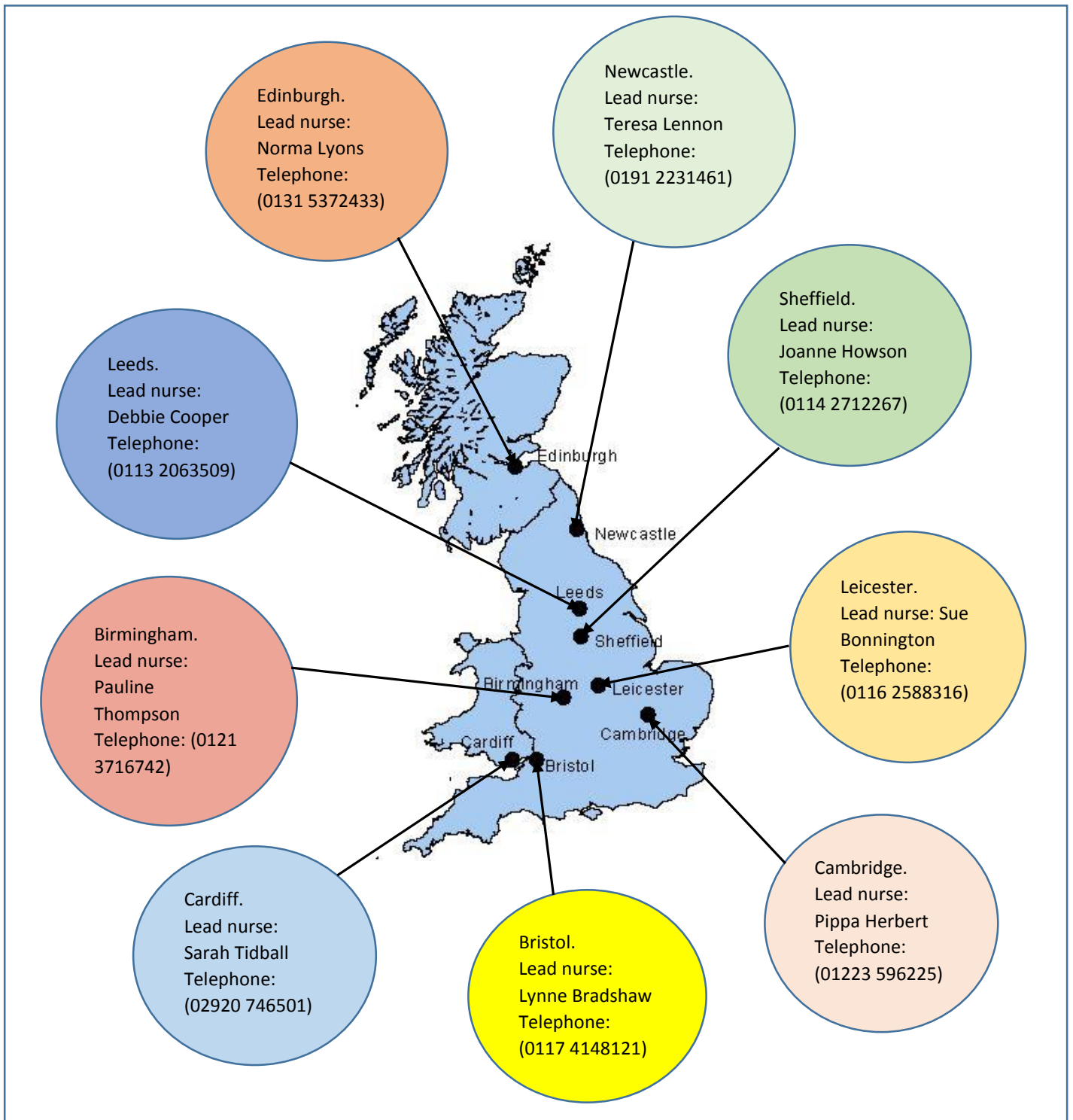


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## Useful Information

If you have moved, or need to contact us for some other reason you can by:

- Contacting your lead nurse using the number of your local centre
- Emailing us at: [info-protect@bristol.ac.uk](mailto:info-protect@bristol.ac.uk)
- Dialling Freephone 0800 7833167
- Writing to us at: The Protect Study, University of Bristol, Canynge Hall, 39 Whatley Road, Bristol, BS8 2PS.



## Outline and history of the ProtecT study

As you may remember, we started the ProtecT study in Sheffield, Newcastle and Bristol in 2000. Between 2001 and early 2009, we invited over 200,000 men living in Sheffield, Newcastle, Bristol, Edinburgh, Leeds, Leicester, Birmingham, Cardiff or Cambridge to come to an appointment with a study nurse for a PSA test. Over 82,000 men had a PSA test. After biopsies, 2,664 men were diagnosed with clinically localised prostate cancer and were suitable for all three treatments in the ProtecT study. At this point, 1,643 (62%) agreed to be allocated following randomisation to one of the treatments – active monitoring, surgery or radiotherapy – and 1,021 chose a treatment. After treatment, all men have been followed up every year with a long questionnaire about symptoms and experiences and a meeting with a ProtecT study nurse.

The organisers of the ProtecT study including principal investigators Freddie Hamdy (far left), David Neal (second from left) and Jenny Donovan (front).



## ProtecT study findings

The information you have provided will be analysed for the first time over the next few months. At this time, half of all the men who have taken part in the ProtecT study will have been followed up for at least 10 years. That means that some of you will have been followed up for six years and some for as long as 15 years – depending on when you were first recruited.

We think we will be ready to publish the findings in early Spring 2016. There are two major ways we plan to do this:

1. We will write a ProtecT study newsletter summarising the findings and send it to you as soon as we can.
2. We will prepare the findings for publication in medical journals. We are expecting at least two papers comparing the three treatments of active monitoring, radiotherapy and surgery over the average period of 10 years. One paper will show how many men who received each treatment are alive and well, and how many have died of prostate cancer or other conditions such as heart disease, and how many have cancer that has worsened, spread outside the prostate (metastases) or caused other problems. The other paper will describe the findings from the questionnaires, showing the impact of the treatments on urinary, bowel and sexual function, and everyday activities – again compared between the three treatments over the 10 year period.



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The rules of publication mean that we have to wait until the medical journal is ready to publish the papers before we can send you the details in the newsletter. We will do our very best to send your newsletter to you as close to the publication date as we can. As it is such an important study, it may be that you hear about the results on the news or in the papers shortly before you receive the newsletter. As soon as we can, we will send you the ProtecT study newsletter with the findings.

## How the study will be organised in future

The funding body (National Institute for Health Research - NIHR) has provided funds for recruitment and follow-up. These funds have been awarded every five years or so, and you may remember that we have reported in previous newsletters (or the study nurses will have told you) that we had to seek further funding to continue follow-up after we publish the findings. NIHR has now given us funds to follow up all men in detail up to 10 years, and for continued and stream-lined follow-up from 2018 onwards.



Debbie Cooper, lead nurse of our Leeds centre, visiting the nursing team in Sheffield

It is very important that we continue to follow up all the men involved in the ProtecT study. It was essential in the first 10 years to assess the impacts of the treatments in detail – through your use of NHS services and care, and the long questionnaires you filled in each year. The NHS now collects a lot of information electronically in your hospital and GP records. This means that we think we can obtain quite a lot of the information from those records. However, there are still important things that we cannot get from the records that the nurses need to ask you about. For most of you, the symptoms following treatments have now settled down, and some of you have told us that the questionnaires are too long and repetitive. We want to make things easier, and so we are going to shorten the questionnaires soon so that they will take much less time and effort to complete.

## How will changes to the study affect me?

Over the next two years – 2016 and 2017 – the organisation of the study will gradually change. ProtecT study nurses will still see you regularly. If you have not yet reached 10 years of follow-up, everything will stay the same – the annual visits and long questionnaire. If you are at 11 years of follow-up or longer, the ProtecT study nurse will discuss with you the plan for follow-up beyond 2017. This will be an individualised plan for you that will arrange follow-up that fits with the national NHS guidelines, as agreed with the ProtecT lead urologist in your clinical centre. At one of the appointments in 2016 or 2017, if you agree, the nurse will weigh you and measure your grip strength. We will send you a shorter questionnaire. **You will still be a ProtecT study participant for as long as you wish. We hope you will want to continue to participate in the study for very many more years as we evaluate your longer-term experiences.**

## What will happen to the study findings?

When the findings are published, they will be sent to NHS and government committees that set guidelines for screening and treatment of prostate cancer. These organisations know that the findings will be coming soon and they are prepared to consider policy changes when they have seen the results. The findings are likely to be used by NICE (the National Institute for Health and Care Excellence), the UK National Screening Committee, the British and European Associations of Urology and other relevant medical and nursing organisations. These organisations are also very interested to see the longer-term findings as more follow-up is completed. We will let you know in study newsletters of future announcements by these organisations.

## Can I get involved in how the findings are presented?

We are very interested to know what you think of the findings, and how we can best present them to you and other men considering testing or treatment. There will be a lot of detailed information, and communicating it to different groups and audiences can be challenging. We are particularly keen to seek your help with this. We also need to find out how the findings and your experiences can help men who are now considering whether to have a PSA test or, if they have prostate cancer, which treatment to have.

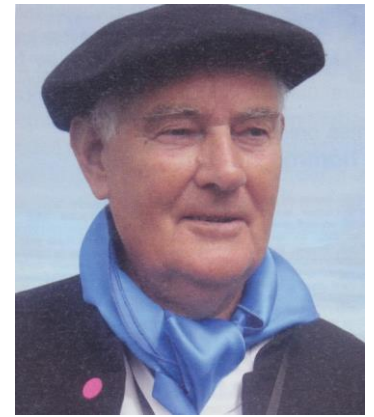
**If you are interested in getting involved further, please let us know. We would like to have a large number of ProtecT study participants who are interested in this. We need to include men with a wide range of experiences of each of the treatments. If you agree to take part in this aspect of the research, we would contact you only occasionally. You would be able to tell us how often we could contact you and how much time you could give. We would ask men to help us with the research in some of the following ways:**

- To be interviewed by researchers about their experiences and life-stories; some with their partners or a close relative
- To help us prepare newsletters, fact-sheets, web-posts and so on – by commenting on drafts by email, post or telephone
- To join a research advisory group to help plan future research within ProtecT. This might require coming to a meeting once or twice a year. Any expenses incurred would be reimbursed. This, and other opportunities, are explained in more detail at <http://www.nihr.ac.uk/get-involved/shape-research.htm>

**If you are interested in any of these opportunities to be involved, please contact the ProtecT administrative team on 0800 7833167 and ask for Nicholas Christoforou – or mention it to the lead nurse at your local clinical centre. We look forward to hearing from you.**

## Writer and *confrere* of the onion growers and sellers Gwyn Griffiths ....

“Most men die with prostate cancer, but few die of it”. This was one response I had from friends when they heard that I had the condition. Another typical comment was, “If you are going to have cancer, better that it should be prostate cancer.” Well meant, and generally reassuring. My view is that it is better to know that you have cancer than to remain in ignorance. Which is why I always urge friends to take the PSA blood test. Too many men I know, among them some very good friends, have died just because they did not know they had prostate cancer and the cancer had spread to other parts of the body by which time it was too late.



I was diagnosed with prostate cancer ten years ago, after I attended a clinic for a blood test. I came under the wing of the ProtecT Study project and my life has remained mostly unaffected by the condition. I had spent most of my working life with the BBC in Cardiff, had left the staff at the age of 50 but continued working for the corporation as a freelancer on and off until I was 61.

Writing has been my main interest, and the period since I found that I had prostate cancer has been quite productive. Over the last dozen years I have had eleven books published, all non-fiction. One was a history of the French – or more correctly Breton – men, known affectionately as the Onion Johnnies. They spent six months of every year, from August to February, selling their strings of onions which they carried around on bicycles and were once a familiar sight from Land’s End to John O’Groats. After the publication of my first book about these hardy and entrepreneurial characters I was hired to set-up a museum, *La Maison des Johnnies*, in the town of Roscoff, the centre of the onion growing area and their port of embarkation for Britain.

Because of the unique taste and appearance of the onion – it is grown on seaweed raked up from the beaches which accounts for its slightly reddish colour – it was awarded the coveted Appellation d’Origine Contrôlée status a few years ago. To be eligible for AOC status, which is usually associated with wines and cheese, a product has to be unique, of a high quality and have special history, hence my involvement. Three years ago I was honoured by the town of Roscoff and made a *confrere* of the onion growers and sellers, which was great fun. I am the only non-French citizen to receive the honour. The invitations to give talks to local history groups have increased and very recently I gave a paper at a three day international conference on ‘Minority’ Cultures and Travel organised by the University of Wales Centre for Advanced Welsh and Celtic Studies in Aberystwyth.



Gwyn with the people of Breton

My prostate condition has never stopped my wife and I from spending at least a month of every year in France, three or four weeks walking the mountains of Provence – I am a member of the local ramblers club - and a few days in Roscoff at the annual onion festival, another event which evolved out of the museum. Three years ago a nurse at my local GP practice referred me to a scheme to exercise at a local gym, partly funded by the NHS in Wales. Call it the zeal of the converted, but I feel better and I am fitter than I have been for years. Life is good, if hectic, but I would not have it any other way.

## John Prosser QC writes about his life and career .....

I was born on a mountain farm above Abercynon and spent the first years of my life there. Then my parents moved to a valley farm near Pontypridd where I lived until I left for university to read law. It was when I was eleven that I decided to become a barrister after reading a book about the life of Sir Edward Marshall-Hall KC. The stories about the criminal cases in which he acted for the Defence I found so enthralling that nothing would deter me from following the same profession.

So after Grammar School I went to King's College London University where I joined Gray's Inn as a student and then, following my Bar Finals examination I was called to the Bar in June 1956. However, before I could practice at the Bar I had to do my National Service which I did in the Royal Air Force. There I decided to take a Short Service Commission which enabled me to marry the girl I fell for in my school days – the local public librarian's daughter, Mary Cowdry. That was the best decision I ever made because she understood the difficulties facing a Barrister not only in the early years when trying to establish a practice but also in the busier years while trying to build on it. With her help, I succeeded at the Bar and went on to become a Queen's Counsel and after ten years in Silk – as a QC one wears a silk robe – I became a Circuit Judge.

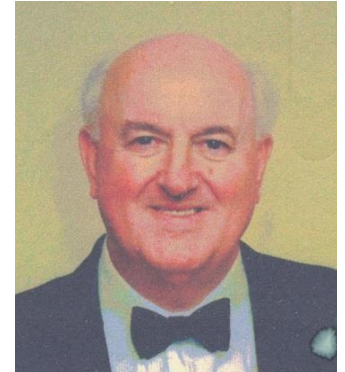
I started my practice in Cardiff on the Wales and Chester Circuit and was fortunate enough to succeed fairly quickly. Although I started my career handling criminal cases and progressing to a large divorce practice, I soon realised that my civil cases were accumulating. After ten years my practice was mainly involving civil claims in the High Court acting for insurance companies. I also handled a few murders, at first defending and then acting for the Director of Public Prosecutions.

In 1978 my application for Silk was accepted and as a QC I found a set of Chambers in the Temple, London. By now I had been a Recorder of the Crown Court for six years but before that I had sat as a Deputy Recorder for Merthyr and Cardiff. Another interesting job I did whilst in Cardiff was to act as a Deputy Chairman of the Industrial Tribunal, which lasted for six years. The other interesting appointment was to act as a Parliamentary Commissioner setting the boundaries. The last one I did was to set the Parliamentary Boundaries for Cardiff which are still in place today.

Practising in London was a great joy because I had the opportunity to act for the Plaintiffs and Defendants in large civil claims involving personal injuries as well as defending in murder cases in the Old Bailey. Being in London gave me the chance to work for solicitors all over the country, travelling to handle cases from Manchester to Exeter and Maidstone to Lincoln as well as on my own circuit, Wales and Chester.

Whilst in Silk I was asked to act as Deputy High Court Judge in London and elsewhere. But the icing on my career cake was being elected Leader of the Wales and Chester Circuit. As a Judge I was fortunate enough to sit in Cardiff, Newport and Swansea dealing with crime and for thirteen years I sat as a Deputy High Court Judge mainly in London.

All my life I have been blessed with good fortune. I retired in 2001 and within a year I had an operation to remove my prostate gland. More good fortune as I was in the hands of the Protect team at the University of Wales Hospital, Heath, Cardiff. I am still being monitored by the team led by Professor Kynaston. I bless the day I met them.



## A word from our nurses .....

Congratulations to Lynne Bradshaw, lead nurse at our Bristol centre, who was honoured at an awards ceremony organised by the North Bristol NHS Trust to mark International Nurses Day in May of this year. Lynne was named a Patient Experience Champion for the years of care she has provided to the four-hundred or so men recruited for the Protect Study by the nursing team based at Southmead Hospital. Lynne has supported some of her patients for over fourteen years and always treats them as individuals by remembering the details of their care and lives.



Not one to blow her own trumpet, Lynne agreed to have her award highlighted in this newsletter because she felt it represented the great work of all the Protect nurses, across our nine centres, and not just herself. In her own words:

"I think that the reason why we have retained patients for such a long time is because we are all Patient Experience Champions."

## Norma Lyons says goodbye

Having been in Nursing since 1977 the time has now come for me to hang up my fob.

I have been fortunate in that I have always loved my profession and never regretted my career choice whilst having met some kind and interesting people along the way.

As some of you will know the last 15 years have been spent working as Lead Nurse in the Protect study here in Edinburgh and the surrounding districts which has been a pleasure. I've had the opportunity to get lost on many occasions en-route to and from GP surgeries and I would bet a large proportion of the 146,000 miles on my old car was made up of getting lost on those trips (thank goodness for Sat Navs – though that's not to say they always guarantee you'll get to the correct destination; not in my case anyway).

I originally only agreed to help out with the Protect study temporarily until Mr Bollina found somebody to take it up full time as I had other commitments at the time, however I'm delighted to say that didn't happen and here I am still. I'm not too sure he looked for anyone else really and I would like to say thank you to him for that.

I would like to thank all of my Protect colleagues in all of the nine centres throughout the UK for all of their help and support over the years, especially Jan and Jackie here in Edinburgh who have become great friends. I would have been lost without them and will miss them dearly as I retire south of the border early next year.

Most of all thank you to all of "our men" in the study especially those here in Scotland for allowing me to be part of your lives for the last 15 years. As you all know the study is carrying on and I hope you all will continue to participate in the study once I am gone. I will think of you often and wish you well. I am sure that I will wish I was back with you all when I'm attempting to move house after 30 years.

Finally I'd like to leave you with one thought. There is only ever one of each of us, we are unique. We are neither better nor less than anybody else but rather the best or least of ourselves and I am still working on finding the best of me. It is an exciting on-going journey and I would like to thank you for being part of it. I am forever grateful for your stimulating company and the collection of experiences that we have shared.





## New ProtecT Study Research.

### Changes in levels of activity, alcohol, weight and smoking following diagnosis of prostate cancer.

Dr Lucy Hackshaw-McGeagh, Research Associate in Prostate Cancer at the University of Bristol.

It is still not clear whether behaviours such as poor diet and lack of physical activity, lead to an increased risk of prostate cancer, however there is some evidence to suggest that carrying on with 'unhealthy lifestyle behaviours', such as not being physically active, drinking high levels of alcohol and smoking after diagnosis can worsen prognosis. We know that some men make spontaneous positive changes to their behaviour after a diagnosis of prostate cancer, however this is not the case for all. Positive changes can benefit not only the prostate cancer, but general health overall.

We were interested in whether men with prostate cancer, in the ProtecT trial, made spontaneous changes to their levels of physical activity and alcohol intake, Body Mass Index (BMI) and smoking status, following a diagnosis of localised prostate cancer.

We looked at the data from men in the trial who had completed the Diet, Health and Lifestyle Questionnaire before their diagnosis of prostate cancer, and 9 months after their diagnosis. This was 511 men in total.

We were interested in whether they increased or decreased their levels of physical activity and the amount of alcohol they drank before and after diagnosis, any change to their BMI, calculated using their height and weight, and whether they smoked, or not, at diagnosis and 9 months afterwards. We also looked at data about age, marital status and social class at time of diagnosis, as well as clinical stage of prostate cancer at diagnosis.

Men included in this sub-study were an average of 62 years of age. Before diagnosis, the majority of men (65%) reported being sufficiently active. A relatively large amount (39%) were drinking more alcohol weekly than the recommended maximum levels prior to diagnosis, with only 55 men (11%) smoking. A third had a BMI within the recommended levels, with the majority having a BMI higher than this.

Nine months after diagnosis, there was some weak evidence that men increased their levels of physical activity overall, from pre to post diagnosis. This is especially evident in those classified as working class, who were twice as likely to increase their physical activity levels, compared to men in managerial and professional occupations. It was also noted that, men with T stage-2 who were insufficiently active pre-diagnosis were twice as likely to be sufficiently active post-diagnosis, compared with those with T stage-1.

There was weak evidence that men overall reduced their levels of alcohol consumption after diagnosis of prostate cancer. There was no overall change in BMI levels pre to post diagnosis. The data on changes on smoking levels were difficult to conclude as there were so few smokers to begin with.

We concluded that some men spontaneously change certain lifestyle behaviours on receiving a diagnosis of prostate cancer. For many men, however, additional support through lifestyle interventions is probably required to facilitate and maintain these changes.

This research has been published in an international peer reviewed journal 'International Journal of Cancer', the full reference is below.

*Full reference: Physical activity, alcohol consumption, BMI and smoking status before and after prostate cancer diagnosis in the ProtecT trial: Opportunities for lifestyle modification, International Journal of Cancer, Volume 137, Issue 6, pages 1509–1515, (2015). Lucy E. Hackshaw-McGeagh, Chris M. Penfold, Eleanor Walsh, Jenny L. Donovan, Freddie C. Hamdy, David E. Neal, Mona Jeffreys, Richard M. Martin, J. Athene Lane and the ProtecT Study Group.*



## New ProtecT Study Research continued .....

### Dr Julia Wade on nurse led active monitoring research.



Whilst many men on active surveillance or active monitoring will have PSA tests carried out at their GP practice, appointments to discuss results are usually with a urologist. It's now more common for specialist nurses to provide care for patients after surgery or radiotherapy and in cancer care generally. The model for active monitoring within the ProtecT study was designed to be a nurse-led (rather than the more common urologist-led) service. This study describes how nurse-led AM within ProtecT was designed by creating a detailed protocol for nurses to follow, which enabled them to refer men on for further tests and also gave them quick and easy access to support and advice from urologists when needed. There was flexibility in allowing men to influence timing, frequency and location of appointments for blood tests and to discuss results.

Men in ProtecT who are receiving or who have received active monitoring and who had agreed to take part in interviews about their experiences (24 men) were asked their views on nurse-led AM. These views were compared to views of 20 men receiving Active Surveillance (AS) outside the ProtecT study who were interviewed in a linked study (see link below). We also collected views of urologists and nurses outside ProtecT on urologist-led active surveillance and its alternatives using interviews. Finally we surveyed urologists and nurses within ProtecT about the pros and cons of nurse-led AM.

Nurse-led AM was valued by ProtecT study participants for its flexibility, accessibility and continuity of care and men felt confident about the quality of care. ProtecT consultant urologists and nurses also rated it highly, arguing it had advantages in terms of continuity of care and efficient use of resources. Clinicians and patients outside the ProtecT trial believed that nurse-led AM could reduce pressures on urology clinics without compromising quality of patient care and was a natural extension of current nurse roles. This study did not look at whether nurse-led AM as delivered in ProtecT is in fact cost-effective; more research would be needed to establish this.

**Thanks to all of you who took part in interviews!** We've included some of the views of ProtecT men about nurse-led AM below. If you want to read more you can access these articles free of charge using the weblinks given below.

*Initially I was a bit concerned about it to be honest with you. As I say, initially—we're talking 2008 now—I was seeing a nurse rather than a urologist. But over the time and especially with [PROTECT NURSE NAME] I began to believe that they have such a base of knowledge that I have confidence in what they are saying.*

*Why bring him [urologist] in at enormous expense when he's far better cutting people up and sorting them out?*

*They do just ask how do you feel and whether it's giving you any trouble. When I do go over to [HOSPITAL NAME] if I am a little worried and I do talk to them, they put me at my ease.*

*I think it was interesting that it was a nurse-led study...consultants can be very focused on your specific condition and what they can do for that and I think that a nurse can be much more holistic.*

*As long as I'm happy to do the phone thing then that's fine, it suits me. Its 20 miles isn't it, it's not an easy place to get into town in the morning, for 9 o'clock or half past 9. It's better now because the car parking is a bit better than it was but initially it was a bit of a pain because I needed somewhere to park up. Yeah, so it's once a year going down and that's fine.*

If you would like to read academic papers on this subject then please use the internet addresses below:

Establishing nurse-led active surveillance for men with localised prostate cancer: development and formative evaluation of a model of care in the ProtecT trial

<http://bmjopen.bmj.com/content/5/9/e008953.abstract>

Development, validation and evaluation of an instrument for active monitoring of men with clinically localised prostate cancer: systematic review, cohort studies and qualitative study – please visit this internet address:

<http://www.journalslibrary.nihr.ac.uk/hsdr/volume-3/issue-30#abstract>

## Other news concerning the Protect Study .....

### The new ICEP Programme.

Blood samples provided by Protect study participants are to be used in a major new cancer programme funded by Cancer Research UK. The five-year, £4.1 million, Integrative Cancer Epidemiology Programme (ICEP) will examine various cancers, including prostate cancer, at a molecular level in order to better understand the biological mechanisms of the disease. An important objective of the researchers involved, including Professor Richard Martin, who sits on the Protect study's steering committee, is to identify unique biological markers which will help to determine which people are most at risk of developing aggressive cancers.

Whilst large population studies have shown an association between factors like diet and the possibility of developing cancer, there is little understanding of causation, or the risk to individuals of their lifestyle choices. If programmes like ICEP are successful then in the future it might be possible for GPs to tailor the health and lifestyle advice they give to their patients based on biological evidence obtained from physical samples such as blood and urine.

### Chief Medical Officer meets Protect researchers.

Since the last newsletter went into print, Professor Dame Sally Davies, the government's Chief Medical Officer, has visited Bristol University and spoken with Protect researchers.



Dame Sally Davies established the National Institute of Health Research (NIHR) in 2006 to enable research to be undertaken widely in the NHS. NIHR funds the Protect study through its Health Technology Assessment Programme.

Dr Athene Lane (Protect study co-ordinator) and Professor Jenny Donovan (principal investigator) met Dame Sally. Dr Lane had the opportunity to present the design and baseline data of the Protect study, which was greatly appreciated by Dame Sally.

Dame Sally was in Bristol to launch a large programme of work aiming to improve the health and well-being of people living in the West – CLAHRC West. She also delivered the inaugural Elizabeth Blackwell Institute lecture entitled: "The drugs don't work: the global threat of antibiotic resistance." This new institute has been named after Elizabeth Blackwell. She was born in Bristol but emigrated to the USA. She was the first woman to become a doctor in the USA. When Elizabeth Blackwell returned to the UK, she also practiced here as a doctor. She was alive around the same time as Florence Nightingale.



NIHR will be celebrating its 10-year anniversary next year all over the country – look out for events and opportunities to take part in research in your area!



***"It is not easy to be a pioneer - but oh, it is fascinating! I would not trade one moment, even the worst moment, for all the riches in the world."***

***Elizabeth Blackwell***

## The Scale of the ProtecT study .....



**109,000 men entered the ProtecT study – enough to fill the Michigan Stadium in the US.**

**And finally, another big thank you  
for all your help and support**

*'The ProtecT study is supported by the UK National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme, HTA 96/20/99; ISRCTN20141297. The funding source had no role in the design, conduct of the study, collection, management, analysis and interpretation or preparation, review, or approval of this newsletter'.*