

ProtecT Study

(Prostate testing for cancer and Treatment)

Ten Year Anniversary Newsletter, Summer 2012

A Decade of ProtecT

This summer marks the ten year anniversary of the ProtecT study. The main trial began in 2002, although our centres in Sheffield, Newcastle and Bristol opened in 1999 to recruit men for the feasibility study.

The ProtecT study has never been more relevant as public interest in prostate cancer continues to grow. To reflect this interest, we have devoted a page of this newsletter to new developments in the treatment of prostate cancer. We have also created a ProtecT study timeline to illustrate important landmarks in the study.

The end of the study is now in sight, with an important baseline paper planned for publication later this year and the main analysis of results scheduled for 2016. For further information about both of these, please see the study update section.

We have also included more stories from you in this issue and hope you will find them entertaining.

Finally, we would like to thank all of you for your incredible support over the years. In this final stage of the study, please continue to fill in the questionnaires and attend appointments so that the ProtecT study is as successful as we all hope it will be.



ProtecT training meeting 2012 at Burwalls, Bristol.

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Timeline
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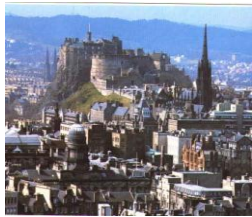
Protect Study Timeline 1999 - 2016



July 1999. Newcastle and Sheffield begin recruiting.



August 1999. First man seen in Bristol.



April 2002. Edinburgh starts recruitment.



February 2002. Cardiff starts recruiting patients.

April 2002. Birmingham joins study.



May 2003. Leicester centre opens.



October 2003. Cambridge centre opens.



Summer 2004. The CAP study - comparing ProtecT patients with the general population starts.



January 2004. The final ProtecT centre at Leeds begins to recruit.

May 2005. Progene study looking at patient family history started.

June 2006. Funding extension starts to recruit more patients.



Summer 2006. Probe study starts looking at the effects of prostate biopsy.



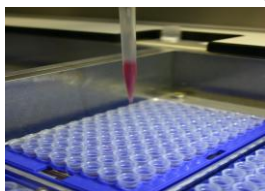
September 2009 Pro-diet study involving lycopene and green tea started.

July 2009. Last information appointment marks the end of study recruitment.

January 2009. Last man who consented to having a PSA test is seen at his GPs.



Winter 2012. ProtecT baseline paper planned for publication.



Jan 2011. HeLPP study starts to obtain consent from men to use their blood samples.

2016. Main analysis of ProtecT data planned.

Protect Study Update

Main analysis of ProtecT data planned for 2016.

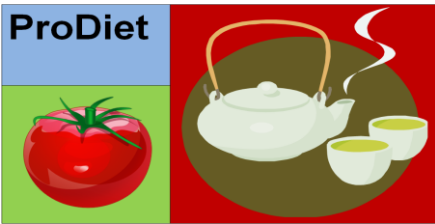
A question frequently asked of our research nurses is when results from the ProtecT study will be published. This is totally understandable given the effort that you all make in filling out questionnaires and attending appointments.

When ProtecT was originally given the green light, it was written into the study's protocol that researchers would not start analysing data until men had been taking part for an average of ten years. This means some of you will have been on the study for less than ten years, when the main analysis begins, whilst others considerably longer. This element of 'blindness' was incorporated to ensure that bias towards a particular treatment, which might have occurred if ProtecT researchers had been allowed to see interim results, was eliminated.

Ten years may seem like a long wait, but the key to assessing the treatments for prostate cancer are their effectiveness over time and how well patients cope with possible side-effects. The trend towards large scale randomised controlled trials for prostate cancer, including ProtecT, is a response to the medical profession's difficulty in evaluating the treatments available when patients are in their care or in short-term follow-up.

We appreciate your continued support and hope that you can be patient for just a few more years.

ProDiet



ProDiet study update

The ProDiet study, which ended in August 2010, examined the feasibility of asking men to take tomato and green tea products (both linked to improved prostate health) as part of a controlled trial.

Our Winter 2010 newsletter stated that the results would be reported in the following newsletter; unfortunately, due to the demands of the main ProtecT study, analysis of the ProDiet data was delayed. We apologise for not mentioning this in our Winter 2011 newsletter, but can confirm that a recent analysis has been accepted for presentation at the National Cancer Institute's conference in November. A full report will appear in a future newsletter.

ProtecT Baseline Record Paper

The publication of an important ProtecT paper is planned for later this year. The 'baseline paper' will show the stage in the study that was reached by each of the 200,000 plus men contacted by ProtecT.

It is good practice to publish the recruitment results of a study and ProtecT researchers working on the baseline paper are following internationally recognised guidelines provided by the CONSORT Group (Consolidated Standards of Reporting Trials.)

Because the ProtecT study's remit includes examining the possible value of a screening programme for prostate cancer, it is important that we also know how many men agreed to have a blood test and were found to have a raised PSA that eventually led to a diagnosis of prostate cancer. The ratio of prostate cancers discovered in the ProtecT population of men will be contrasted with the general public by using the results of the CAP study. This prostate cancer trial has been running concurrently with ProtecT; examining the health of a population of men the same size as the one you were recruited from.

The details of the baseline paper will be reported in a future newsletter.

Men make positive dietary changes after a diagnosis of prostate cancer: recent findings from the 'Dietary Change in ProtecT' Study

Page 4

Dr. Kerry Avery, ProtecT study Research Fellow and National Institute for Health Research Post-doctoral Award Holder, University of Bristol



Dr Kerry Avery

What were the aims of the study?

Dietary changes after a prostate cancer diagnosis may improve men's health and quality of life but studies of dietary modification are complex and have so far met with mixed success. In particular, we are uncertain which parts of men's diets to change and how best to initiate and maintain change. Men's attitudes towards dietary change and preferences for dietary information are also poorly understood. The purpose of the 'Dietary Change in ProtecT' study was to explore best methods for developing dietary interventions for prostate cancer within the ProtecT trial.

What did we do?

Firstly, we compared men's diets before and after diagnosis using food questionnaires completed by 678 men in the ProtecT study. Secondly, we interviewed 58 men diagnosed with or at risk of prostate cancer and 11 of their partners to explore motivations and obstacles to dietary changes and the role of dietary change in survivorship. We then undertook focus groups and interviews with five men diagnosed with prostate cancer, four of their partners, healthcare professionals and research specialists to investigate their attitudes towards routinely providing men with dietary advice. Finally, we reviewed the findings from existing dietary modification studies to see how behaviour change theory may be used to design dietary interventions for cancer.

What were the main findings?

Analysis of food questionnaires revealed that diagnosis of prostate cancer prompted around one third of men to adopt healthier diets (e.g. increased fruit and vegetables, decreased fat and red meat intake) and eat more 'prostate-healthy' foods (e.g. increased tomatoes and tomato products). Findings from both the food questionnaires and interviews revealed that men often made dietary changes to maintain their health and enhance their well-being and that men's partners were important in initiating and implementing change. Men's diets were also influenced by the treatment they received, with men undergoing active monitoring more likely to drink more fruit and vegetable juice than men who received radiotherapy or surgery.

Men also told us that they often made dietary changes to help them overcome uncertainty or anxiety, with one man saying *"I suppose it could be classified partly psychological, it's doing some good... it was just the hope it was all going to help"*.

Focus groups and interviews with men, their partners, health professionals and specialist researchers also confirmed that men were rarely given dietary advice but that interest in men receiving dietary advice was high. Finally, our review of dietary modification studies revealed that only a small number were designed using behaviour change theory but that these were more effective at improving diet than those that were not.

Where do we go from here?

The findings from this study provide some interesting areas for future research. We observed that many men are motivated and able to make healthy dietary changes after their prostate cancer diagnosis and that this may improve their wellbeing. Men, their partners and healthcare professionals are very interested in the provision of dietary advice and think that this would be feasible in routine practice. Men's willingness to change their diet also indicates that a successful trial of dietary modification may be possible, provided it is based on behaviour change theory. We are now outlining recommendations for the NHS and healthcare professionals for high quality studies of dietary modification and the routine provision of dietary information for men diagnosed with prostate cancer.

A word of thanks!

We would like to say a big THANK YOU to all of you who helped with the study, either by taking part in interviews or by completing the diet questionnaires – your help is very much appreciated.

Funding:

Kerry Avery was funded by a National Institute for Health Research (NIHR) post-doctoral fellowship award scheme between 2007 and 2012.

The 'Dietary Change in ProtecT' study was conducted by Dr. Kerry Avery, a ProtecT Study Research Fellow, and other members of the ProtecT team at the University of Bristol.

New prostate cancer results

Abiraterone now available on the NHS

The National Institute for Health and Clinical Excellence (NICE) has given the go ahead for Abiraterone to be available to NHS patients.

Used to treat advanced prostate cancer, Abiraterone can extend life by more than three months and allows patients to be treated at home because it can be taken as a pill.

It is estimated that 2500 men in England could benefit from taking Abiraterone - which was originally rejected by NICE on cost grounds before a reduced price could be negotiated with its manufacturer.

See British Medical Journal - 18th May 2012 - BMJ 2012; 344: e3520

New sound wave treatment for prostate cancer

According to UK researchers, a new sound wave treatment for specific types of prostate cancer may lead to fewer side effects.

Volunteers had small tumours within their prostates targeted with high-intensity focused ultrasound (HIFU) which heated tissue to a temperature of 80 degrees; killing cancerous cells whilst leaving healthy ones intact.

One year after treatment, none of the 41 patients treated with HIFU experienced incontinence, only one in ten complained of erectile dysfunction and 95% were cancer free. Study participants also had a nine in ten chance of achieving 'perfect outcome' one year after treatment (no urine leakage, functioning erections and cancer control.)

Dr Hashim Ahmed, who led the London based team, stated that: "Our results are very encouraging. We're optimistic that men diagnosed with prostate cancer may soon be able to undergo a day case surgical procedure, which can be safely repeated once or twice, to treat their condition with very few side-effects. This could mean a significant improvement in the quality of life."

Professor Malcolm Mason, Cancer Research UK's prostate cancer expert, has advised that a much larger clinical trial is required.

US task force advises against prostate cancer screening

The US Preventive Services Task Force (USPSTF) has reviewed the evidence for prostate cancer screening and advised against such programmes being introduced. USPSTF concluded that "there is moderate or high certainty that this service (screening) has no net benefit or that the harms outweigh the benefits."

In a recent article published in the Journal of Clinical Oncology, a group of prostate cancer researchers questioned whether USPSTF's recommendations were premature and made the following points:

- The largest prospective trial of PSA screening, the European Randomised Study of Screening for Prostate Cancer (ERSPC) had not reported its final results at that stage.
- The task force looked at overall survival when trial results so far only address cancer specific survival.
- USPSTF combined data from a number of incompatible trials.
- The task force claimed that no trials have examined the potential psychological impact of PSA screening.
- The task force overestimated the risks associated with radical prostatectomy because they used data from nearly 20 years ago collected from older men having surgery who were at greater risk anyway.

It seems the viability of prostate cancer screening remains an unanswered question and the Protect and CAP studies remain on course to help inform the debate.

PIVOT study update

In our last newsletter we mentioned that the US based Prostate Cancer Intervention Versus Observation Trial had presented its initial findings. We can now report that the PIVOT study has presented its full findings in the New England Journal of Medicine. If you would like to read their paper online, see:

<http://www.nejm.org/doi/full/10.1056/NEJMoa1113162>

In their own words.....men taking part in the ProtecT study

Stephen Billis from our Cambridge centre

It all started when I went into Addenbrooke's Hospital for my prostatectomy in February 2008. I took a book called "Downhill All The Way," written by Edward Enfield, the father of the comedian Harry Enfield.

When he retired at age 60, Edward Enfield decided to cycle the length of France - from Le Havre to the Mediterranean - and he wrote the book when he got back. Being a keen cyclist, the book grabbed my imagination and when I recovered from my operation, I decided I would do the same and help to raise money for the new Da Vinci Robot that Addenbrooke's desperately needs.

I retired in June 2011 and began planning the ride - along with two friends who were keen to go with me. To keep costs down, we decided to emulate Edward Enfield and camp along the way, which unfortunately meant we would be carrying a lot of luggage.

We set off from home in Saffron Walden, Essex on 31st May and travelled to Portsmouth by train. We then got the night boat to Le Havre and, after a good night's sleep, set off on French roads at 08.00 local time.

Our route took us across Normandy via Evreux into the Ile de France, then on to Burgundy, down to Lyon and then along the Rhone Valley to the Camargue and the Mediterranean. We used minor roads and dedicated cycle paths as much as possible and tried to follow river valleys to avoid hills, not always with success! My two companions needed to get back to the UK promptly, so they left me at the town of Orange. I stayed on and did some sightseeing in the south, arriving home on 18th June by the European Bike Express: a dedicated coach service for cyclists which carries bikes on a trailer.



We all carried lightweight tents, cooking utensils, stoves, sleeping bags, etc, as well as all our clothing in waterproof panniers. The weather had been pretty bad in the UK before we left, but it improved in France and we had some good cycling weather, apart from several severe thunderstorms and a tornado. The tornado struck while we were having lunch at a cafe in the Burgundy region. A big storm was brewing and it had started to rain, when all of a sudden it was as if an express train had gone past the front of the cafe. All the furniture, crockery and cutlery went flying down the street along with the awning and we got hit by what seemed like a wall of water, but was in fact the heaviest rain I have ever experienced. When we continued on our way about an hour later, our route was continuously blocked by fallen trees, many of which had been ripped up by the roots.

We had great fun along the way, cycling an average of 60 miles per day. The most we did on any one day was 73, between Etampes and Sens. There were, of course, highs and lows, but the highs always made up for the lows. One example was having to cycle up a huge hill for 7 miles with gradients up to 13%, in pouring rain and then arriving at probably the best campsite of the tour, with lovely hot showers and a restaurant.

The ProtecT team would like to congratulate Stephen on completing his journey and for raising an expected £4000.

Tony Rigby, originally from our Newcastle centre, now enjoying life across the channel

“Look Tony, you’re the right age group, even though you have no symptoms your data could be useful to this survey”. Probably the same sort of words we all heard from our GP when asking us to join the Protect Study.

Six months later, as I walked out of the Freeman Hospital following my brachytherapy, I realised how timely and fortunate that conversation had been for me.

There then followed a few months staying at a discreet distance from my pregnant daughter, and then from my new granddaughter, until the radiation period had passed.

During that time we finalised our plans to move to our house in France. My wife Carol was due to retire from University lecturing and, although I was three years from retirement, we decided to seize the day and make our move.

My last month or two at work at least kept my colleagues amused – following me as I set off to the loo armed with my tea strainer. I guess they wanted to see if I shed a piece of the Sizewell B reactor, which they fondly believed I carried inside me! Male bonding can take some strange forms!

In September 2002 we set sail for SW France – not for us the posh Provence beloved of Peter Mayle, nor yet “Dordogneshire” that piece of a foreign land which will be forever England. Our choice is rural Lot et Garonne, an area of hard-working farming folk.

Joining the French Health Service was an interesting experience. Administration and bureaucracy have been raised to an art form by the French, and one swiftly learns the only way to do things is by the book.

At first I couldn’t join because I was a non-earner of working age and the French aren’t about to give away their services to anyone who can’t contribute (Mr Cameron please note). However because Carol had a pension I was able to piggy-back on her rights – a kept man at last! Three years later I had membership in my own right.



Tony Rigby's house in France.

Arranging for PSA tests was an amusing experience. Armed with all of my identity paperwork – but little else, other than a letter from consultant Ian Pedley outlining my treatment, I arrived at the GP’s surgery, only to be immediately sent home to collect an electricity bill. This we soon discovered is the most important document in your repertoire – better than a passport or even a letter from the President himself!

So to my first PSA test at the nurses’ clinic. Now, I may be built like an ox, but I am mortally afraid of needles. I explained this to the nurse who was highly amused and called one of her colleagues to tell her! Test duly completed, I handed over my (very small) fee and in return was given a sweet from the tin normally kept for children! I had been a “brave petit soldat”. Happily that little gift features at every PSA test now.

We’ve now settled down to a regular programme of PSA tests and their transmission to the Freeman. I try to see Teresa and my friends in the Study nursing team at the Freeman on my visits back to Newcastle to see our family. I will always be grateful for their support and encouragement, particularly when I have had black days (happily fewer nowadays.) As to life in France, do I miss anything about England? Oh yes! A Greggs’ mince & onion pie, or a stotty cake ham & pease pudding sandwich, or.....!

Life as a prostate cancer survivor is just dandy – and how to keep it that way! by Mr Gordon Hodgkin, ProtecT Study

I am one of the first guinea pigs enrolled on the ProtecT programme, and was treated with radiotherapy in 2000. I would like to reassure any newcomers to the programme that life post-treatment can get better and better, provided you just follow one simple rule: Don't act your age!

However, this year, for the first time ever, I was made to realise that where most insurance companies are concerned, I'm over the hill – practically dead in their eyes! I am now 76 years old (ooh, how did that happen?)

I was born in 1936, but have never been obsessed with my chronological age, still being a teenager on the inside, despite the occasional wrinkle or two that my mirror shows me when shaving. I do, of course, realise that I am lucky to have remained pretty fit for an Old Fart (as other people must see me), and still enjoy walks of up to 10-12 miles in the lovely Norfolk countryside, particularly when there is a great real-ale pub at the half-way point.

When seeking the usual travel insurance for my annual trip to the Med with Big Sis and bruvver-in-law (Menorca this year), I was surprised and perturbed to find that when I did identify on the internet companies grudgingly willing to insure me, some of them were asking an arm and two legs for the service.

Part of the premium can be explained by my two 'pre-existing medical conditions' (prostate cancer and angina, the latter having been sorted out with a clever little stent), but that can hardly justify the asking of £181 by the worst offender, closely followed by £164 by an anonymous company claiming to look after old folk. What I do want to share with you is my discovery of a very helpful provider, namely LV (Liverpool Victoria), who agreed to cover my week's holiday for £43. Another advantage of using this company is that they have no upper age limit for their travel insurance, so I will still be using them when I turn 100. Bet you didn't think you'd find anything that useful in the ProtecT study newsletter, did you! Just kidding – you editorial people! It's all fascinating, but my tip can help you save a bit of dosh, fellow patients. Look forward to seeing you all in the Med when I'm 100.



Useful Information

If you have moved.....or just need to contact us, you can by:

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

You can contact the **lead research nurse** at your local centre.

Birmingham: Pauline Thompson (0121 6272992)
 Bristol: Lynne Bradshaw (0117 3235080)
 Cambridge: Phillipa Herbert (01223 596225)
 Cardiff: Sarah Tidball (02920 746501)
 Edinburgh: Norma Lyons (0131 5372433)
 Leeds: Debbie Cooper (0113 2063509)
 Leicester: Sue Bonnington (0116 2588316)
 Newcastle: Teresa Lennon (0191 2231461)
 Sheffield: Joanne Howson (0114 2712791)

Editor's note:

If you would like to contribute to the next newsletter - whether by suggesting ways it could be improved or writing about your own experiences - please get in touch using the details above.

Finally, a very big thank you for all your help and support over the last ten years!