

# The PACE Trial

## Results of the long term side effects of prostate cancer treatment in PACE-B: conventional radiotherapy vs stereotactic radiotherapy

Thank you for participating in the PACE-B study, we are very grateful for your continued support. We have now analysed the information collected up to two years after completing radiotherapy on all 874 men who took part in this study and we would like to share the key results with you.<sup>1</sup>

### ***What is the study about?***

The aim of the PACE-B study is to see whether we can improve radiotherapy treatment for men with prostate cancer by giving fewer but larger radiotherapy doses at each visit, over a shorter period of time, so that radiotherapy is completed within 2 weeks rather than within 4 or 7-8 weeks. We want to achieve this by using advanced, more accurate radiotherapy technology (stereotactic body radiotherapy, SBRT).

SBRT allows your doctor to better focus the radiation on the tumour. This reduces the chance of damaging surrounding healthy tissue, which can cause side effects such as more frequent or urgent urination and diarrhoea.

### ***Background***

You were one of the 847 men with prostate cancer who joined the trial between August 2012 and January 2018. The trial was carried out in 40 hospitals in the UK, Ireland and Canada.

When you consented to take part in PACE-B you were allocated at random to one of the following radiotherapy treatment groups:

- 1) **Group 1 - Standard radiotherapy** - either 78 Gy\* in 39 fractions\*\* over 7-8 weeks, or 62 Gy\* in 20 fractions\*\* over 4 weeks (depending on what the standard treatment at your hospital was when you entered the trial).
- 2) **Group 2 - SBRT** - 36.25 Gy\* in 5 fractions\*\* over 1-2 weeks).

*\*Gray (Gy) is the units or amount of radiotherapy given*

*\*\* Fractions are the daily radiotherapy treatments*

Roughly half of the men in PACE-B had their radiotherapy over 4-8 weeks (“longer radiotherapy”) and half received their radiotherapy in 5 days (called “SBRT”).

---

<sup>1</sup> The full results were published in a medical journal in October 2022 so that doctors around the world can be made aware of the findings. You cannot be identified personally from any of the data used in any of the presentations or publications. The publication is called “Intensity-modulated radiotherapy versus stereotactic body radiotherapy for prostate cancer (PACE-B): 2-year toxicity results from an open-label, randomised, phase 3, non-inferiority trial” and is available at the following web address if you are interested: [https://doi.org/10.1016/S1470-2045\(22\)00517-4](https://doi.org/10.1016/S1470-2045(22)00517-4).

Any side effects that you experienced and how bad they were was assessed during and after your treatment, both by the cancer doctors at your hospital and by completing quality of life questionnaires. Our researchers have looked at assessments from the doctors and the questionnaires you completed.



### **Short-term effects of treatment**

The short-term (within 12 weeks of completing radiotherapy) bladder and bowel side effects were very similar for the men receiving longer radiotherapy and the men receiving SBRT.<sup>2</sup> Most men were feeling back to normal within 3 months of finishing their radiotherapy.



Overall, patients in both groups had **lower levels of side effects** than we expected.

### **Bowel effects of treatment**

We have looked at the data for how patients were feeling up to two years after radiotherapy treatment. We found that it was rare that patients in the PACE-B study had bowel symptoms bad enough to need any treatment to manage them. Only 3 men in every 100 experienced this type of bowel side effects after the longer schedule of radiotherapy treatments compared to 2 men in every 100 after the shorter 5 treatment schedule of SBRT. Severe side effects were rare, with fewer than 1 in 100 men experiencing these.

From the quality of life questionnaires you filled in, we found out that about a third of men could detect some change in their bowel function after longer radiotherapy but this was less (around a quarter of men) after SBRT.

**SBRT patients had slightly fewer bowel effects.**



<sup>2</sup> The full short term results were published in a medical journal in September 2019 so that doctors around the world can be made aware of the findings. You cannot be identified personally from any of the data used in any of the presentations or publications. The publication is called “Intensity-modulated fractionated radiotherapy versus stereotactic body radiotherapy for prostate cancer (PACE-B): acute toxicity findings from an international, randomised, open-label, phase 3, non-inferiority trial” and is available at the following web address if you are interested:

[https://doi.org/10.1016/S1470-2045\(19\)30569-8](https://doi.org/10.1016/S1470-2045(19)30569-8).

### ***Bladder effects of treatment***

At two years after radiotherapy, moderate bladder effects were rare in the PACE-B study. Only 2 men in every 100 experienced moderate bladder effects after the longer schedule of radiotherapy treatments compared to 3 men in every 100 after the shorter 5 treatment schedule of SBRT. Severe side effects were rare, with fewer than 1 in 100 men experiencing these.

From the quality of life questionnaires you filled in, we found out that about a quarter of men could detect some change in their bladder function after longer radiotherapy but about a third of men found this after SBRT.



### ***Sexual function***

Changes in sexual function were common in both treatment groups. Around 6 in every 10 men treated had some worsening in their erections after treatment and for around 3 in every 10 this required medication. About half of men said their quality of life, with respect to sexual function, had deteriorated. The number of patients having those side effects and how bad those side effects were was the same for both treatment groups.

### ***Summary***

Overall, fewer patients who took part in the PACE-B trial experienced side effects, less than we were expecting. There were no serious side effects.

On average, men who received SBRT had slightly more bladder side effects and slightly fewer bowel effects than men receiving longer radiotherapy.

### ***Conclusion***

SBRT would shorten the treatment time for patients having radiotherapy for localised prostate cancer without causing an increase in serious side effects.

### ***What will happen now?***

We still do not know whether the shorter SBRT treatment used in PACE-B will control cancer as well as standard longer radiotherapy and we will continue to collect data over the next few years to allow us to answer this question. Results comparing how well each treatment worked in controlling the cancer will not be available for a while. A separate information sheet will be made available when these results are known.

Thank you for taking part in PACE-B and for completing questionnaires. We would like to remind you of the importance of attending your clinic appointments; we would like to continue to follow you in the study for several more years. Without the contribution of people like you, this study would not be possible. If you have any questions about these side effect results from PACE-B, please discuss this information sheet with your local cancer doctor or a member of their team who will be happy to help you.

Local Consultants name:

Address:

Telephone:

---



## PACE-B Trial in prostate cancer - Two year results



874 men with low to medium risk prostate cancer were randomly assigned treatment.



Standard radiotherapy given over 20 or 39 visits.



SBRT, radiotherapy given in over 5 visits.



Overall, patients in both groups had lower levels of side effects than we expected.



SBRT patients had slightly more bladder side effects.

SBRT patients had slightly fewer bowel side effects.



SBRT would shorten the treatment time for patients significantly without causing an increase in serious side effects.