

Title

The BeSpoke Decision Support decision aid for patients with newly diagnosed localised prostate cancer – a single-blind randomised controlled trial

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Background

Men diagnosed with localised prostate cancer (PCa) often face a choice between different management options, varying from monitoring to focal or radical treatment with prostatectomy or radiotherapy. For many, the choice is a patient-driven value-based decision. However, the information on which to base this can lack consistency and personalisation, and patient values are not always explored.

Decisional conflict arises when a patient feels uninformed, unclear about personal values, and unsupported in their decision.

We have designed a personalised web-based patient decision aid (PDA) called Bespoke Decision Support, for men with localised PCa. It provides up-to-date information on treatment options (including MRI-led active surveillance, focal therapy, robotic prostatectomy and modern radiotherapy), risk-stratified oncological and functional outcomes and a value-clarification exercise (Fig).

The aim of the trial is to evaluate the impact of BeSpoke Decision Support in men's decision-making experience.

Methods

The trial is a single-blind multisite interventional randomised control study comparing the addition of Bespoke Decision Support to standard of care (SOC) versus SOC alone, as usually provided by each site.

Men with newly diagnosed PCa who are clinically suitable for at least two treatment options are eligible for inclusion. Men unsuitable for active treatment, with either low-risk low-volume PCa or suspicion of metastatic disease, will be excluded.

The primary objective is to evaluate the impact of BeSpoke Decision Support on the decisional conflict score (DCS) at the time of a treatment decision for localised PCa, compared to SOC.

Secondary objectives include: post-decision making patient-reported experience measures (preparation for decision making, decisional self-efficacy); post-treatment satisfaction and regret with decision; satisfaction with information and PDA; health-economic impact; implementation outcomes; choice of treatment. A qualitative study involving patient and healthcare practitioners will investigate their experience with the PDA and of decision making and support during the trial.

DCS ranges from 0 (no conflict) to 100 (high conflict). A sample size of 346 participants has been calculated to detect a 5.5 absolute difference in DCS (SD 15), a significant level α of 0.05, a power of 90% and a correlation coefficient of 0.5.

Randomisation will be at participant level with 1:1 equal allocation to intervention and SOC arm using different size blocks and stratification at site level.

Patients will receive questionnaires at randomisation, after confirmation of treatment decision and at 3, 6 and 12 months after treatment.

Recruitment started in July 2026, with 10/346 participant recruited. Three sites are now open in London, with 8 more expected to open in England. Completion of recruitment is expected in October 2027.

ClinicalTrials.gov ID NCT07135271

Conclusions

The BeSpoke Decision Support trial seeks to improve men's experience in choosing the best prostate cancer treatment for them. The primary outcome will be reported after completion of trial recruitment.

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Conflicts of Interest Disclosure Statement

None of the authors have any relevant conflict of interest to disclose.

Need for additional prostate cancer treatment at 5 years ①

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The aim of treatment is to cure your cancer, but in some cases additional treatments are required during follow-up.

The following graph represents 100 men with a cancer like yours. The icon plot shows what happens to those men within 5 years from receiving a diagnosis of prostate cancer.

The data presented for active surveillance reflects MRI-led active surveillance at a single centre in London.

The data presented for re-treatment after surgery and focal therapy has been retrieved from a national database which reflects variations in practice across the UK.

For many people who need additional treatment after radiotherapy, this is done with hormone treatment. The data for this is not collected nationally, so the data used are from a large clinical trial where these data were carefully collected.

Other factors, such as how well the cancer responds to initial treatment, may be important in your likelihood of needing additional treatment. These figures are only an estimate and can't take all factors into account.

Your Clinical Parameters:

T Stage: T1 or T2

PSA: 6 ng/mL

Maximum Cancer Core Length: 11 mm

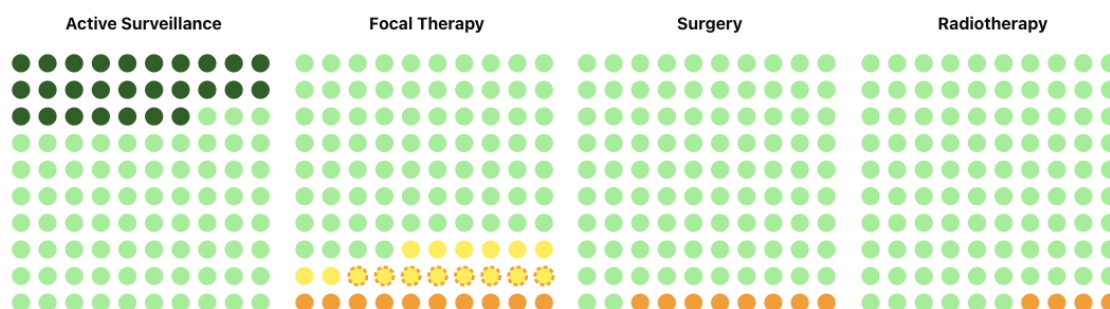
Gleason Score: 3+4

MRI Visibility: Yes (PI-RADS/Likert 4-5)

PSA Density: 0.12

What the icons mean

- No treatment (i.e. Active surveillance only)
- First treatment only (i.e. Focal therapy, Surgery, Radiotherapy)
- Second round of additional focal treatment
- ☼ Progressed to radiotherapy or surgery after a second round of additional focal therapy
- Progressed to different treatment (i.e. Radiotherapy or surgery after focal therapy; Salvage radiotherapy after surgery; Hormone treatment after radiotherapy)



Table

Outcome	Active Surveillance	Focal Therapy	Surgery	Radiotherapy
● No treatment (i.e. Active surveillance only)	27%	—	—	—
● First treatment only (i.e. Focal therapy, Surgery, Radiotherapy)	73%	74%	92%	96%
● Second round of additional focal treatment	—	8%	—	—
☼ Progressed to radiotherapy or surgery after a second round of additional focal therapy	—	8%	—	—
● Progressed to different treatment (i.e. Radiotherapy or surgery after focal therapy; Salvage radiotherapy after surgery; Hormone treatment after radiotherapy)	—	10%	8%	4%

Figure – “Need for additional prostate cancer treatment after 5 years” – personalised prediction of need for additional treatment based on baseline clinical parameters (shown in box) after starting active surveillance, focal therapy, surgery or radiotherapy.