# Development, validation and evaluation of an instrument for active monitoring of men with clinically localised prostate cancer: systematic review, cohort studies and qualitative study

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# **Plain English summary**

Active monitoring of men with clinically localised prostate cancer

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# **Plain English summary**

Active monitoring (AM) or active surveillance (AS) are management options for men with low-risk prostate cancer (PCa), consisting of regular blood tests measuring the level of prostate-specific antigen (PSA) and, sometimes, regular prostate biopsies. A rising PSA level can indicate worsening PCa, but PSA can also be raised for non-cancer-related reasons. A UK study [Prostate testing for cancer and Treatment (ProtecT)] will report results in 2016 that will provide clearer evidence about the best treatment (radiotherapy, AM or surgery) for low-risk PCa. Many research groups monitor PCa using PSA, but each uses different methods and there is much debate about the best method to use.

We developed a model for changes in PSA with age using data from men on AM in ProtecT. This model predicted PSA reasonably accurately in similar groups of men in the UK and USA. We developed software that shows the observed PSA data for a given patient in comparison with an average man's change in PSA and highlights an observed PSA in the predicted top 5%.

We interviewed patients and clinicians about current methods of AM/AS and the acceptability of our software. Patients and clinicians expressed reservations about whether or not the software would currently influence decision-making. Clinicians did not feel that they would make recommendations about stopping or continuing AM/AS based on PSA monitoring alone. Patients maintained that decision-making would ultimately be guided by their clinician.

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