

Planning and Developing a Web-Based Intervention for Active Surveillance in Prostate Cancer; An Integrated Self-Care Programme for Managing Psychological Distress

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Abstract

Objectives:

To outline the planning, development and optimisation of a psycho-educational behavioural intervention for patients on active surveillance for prostate cancer. The intervention aimed to support men manage active surveillance related psychological distress.

Methods:

The person-based approach (PBA) was used as the overarching guiding methodological framework for intervention development. Evidence-based methods were incorporated to improve robustness. The process comprised of the following four components:

- A systematic review and meta-analysis of depression and anxiety in prostate cancer
- A cross-sectional survey on depression and anxiety in active surveillance
- A review of existing interventions in the field
- A qualitative study with the target audience

The purpose of this paper is to bring these components together and describe how they facilitated the establishment of key guiding principles and a logic model, which underpinned the first draft of the intervention.

Results:

The prototype intervention, named PROACTIVE, consists of six internet-based sessions run concurrently with three group support sessions. The sessions cover the following topics: lifestyle (diet and exercise), relaxation and resilience techniques, talking to friends and family, thoughts and feelings, daily life (money and work), and includes information about prostate cancer and active surveillance.

Conclusions:

The planning and development process is key to successful delivery of an appropriate, accessible and acceptable intervention. The PBA strengthened the intervention by drawing on target-user experiences to maximise acceptability and user engagement. This meticulous description in a clinical setting using this rigorous but flexible method is a useful demonstration for others developing similar interventions.

Trial registration and ethical approval:

NRES Committee South Central – Oxford A. REC reference: 11/SC/0355

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Key Messages Regarding Feasibility

- At the start of this process there were uncertainties around the feasibility of:
 - Reaching and recruiting the target group (men on active surveillance for prostate cancer)

- Creating an accessible and acceptable intervention
- Key feasibility findings:
 - Men on active surveillance for prostate cancer would like additional support, and are willing to take part in online and group-based sessions
- The research activities carried out in the intervention planning and development phases have optimised the acceptability of the proposed intervention.

Background

Prostate cancer prevalence is high in the UK(1), and affects around one in eight men(2). Treatment options include surgery, radiotherapy and hormone therapy, but for men with localised, low-risk prostate cancer, active surveillance (AS), a pathway that involves monitoring biological markers of the disease for progression, is also an option. AS aims to reduce overtreatment and comes without the unwanted side effects of interventional treatment, such as urinary incontinence and erectile dysfunction (3). However, research has shown AS may have a negative impact on psychological wellbeing with patients experiencing heightened levels of anxiety(4–6), illness uncertainty, hopelessness(7) and distress(8).

Few studies have explored the unmet psychological needs of men on AS and ways in which wellbeing could be improved(9), and to our knowledge there are no existing interventions available to support men on AS. The limited qualitative evidence suggests men on AS find AS related information inadequate and inconsistent(9), experience unmet psychological and emotional needs(9), and spousal support is important for AS acceptance(10). Furthermore, anxiety and uncertainty are two key reasons men choose to discontinue AS and pursue interventional treatments in the absence of changes to tumour status(11, 12), risking treatment side effects. Research in the area of AS related psychological wellbeing is vital to ensure patients have the information and tools that will allow them to better cope with this treatment pathway.

Best practice guidance recommends taking a ‘person-based’ approach (PBA) when developing behavioural interventions(13). The PBA is an established method used to optimise interventions, providing a clear process to ground interventions in the perspectives and psychosocial context of the target user group. The PBA recommends comprehensive qualitative research with the target user group to explore their experiences and create a picture of the challenges they face, and in turn the things that are likely to influence a target behaviour. Exploration of the key beliefs target users hold, for example, about their condition, its management or treatment, is important to gain an understanding of what might facilitate or prevent change. Taking this approach, the target users’ needs and preferences can influence the content, structure and overall design of the intervention, ultimately improving the intervention’s feasibility, acceptability and user engagement(14).

This paper describes four previously published research activities, bringing them together to demonstrate how they contributed to the planning and development process of PROACTIVE, a psycho-educational intervention for men with localised prostate cancer on active surveillance, consisting of parallel group-support and web-based sessions. It aims to describe the methodology needed to plan such an intervention, presenting a demonstration of how to develop an intervention using a PBA.

Using the Person-based approach to guide PROACTIVE planning

The PBA is flexible and non-prescriptive, and can be utilised alongside evidence-based approach methods and theory. The PBA provides an established methodological framework for the intervention planning process(13). The approach consists of two key stages. The first involves gathering information from the target audience to gain an insight into what is wanted and needed, giving the researchers a deeper appreciation of the psychosocial context of the audience. This is an iterative process used to continually refine the intervention to promote acceptability, and to encourage adherence and engagement.

The second stage is the creation of 'key guiding principles'. These consist of a) key intervention design objectives and b) key distinctive features of the intervention needed to achieve objectives. These principles aim to keep the design and development process on track by providing the research team with a summary of objectives to be referred to at each stage of the process.

The planning process commenced with a systematic review and meta-analysis of depression and anxiety in PCa. This was an evidence gathering activity aiming to improve understanding about the prevalence and magnitude of psychological distress in men with PCa (not specific to AS).

Using the PBA framework, the following activities were subsequently conducted to facilitate our understanding of: psychological distress specific to those on the AS pathway; the interventions that have been trialled previously; and the supportive care needs of the target audience:

- A cross-sectional survey on depression and anxiety in active surveillance
- A review of existing interventions in the field
- A qualitative study with the target audience

These components facilitated the creation of key guiding principles and a logic model to guide the intervention development.

Table 1 below shows the stages recommended by the PBA for intervention planning and development (columns 1 and 2) alongside an overview of the development of PROACTIVE (column 3) to show how the PBA process was implemented. Each activity will be described in depth in the next section.

Table 1
PBA implementation in PROACTIVE

Stage of intervention development and evaluation	Specific PBA activities useful at each stage	PROACTIVE planning, development and optimisation	Additional activities
1. Intervention planning	<ul style="list-style-type: none"> • Synthesise previous qualitative studies of user experiences of similar interventions • Carry out qualitative research to elicit user views of the planned behaviour changes and intervention (including relevant previous experience, barriers and facilitators) 	<ul style="list-style-type: none"> • Review of existing interventions in the field • Qualitative study 	<ul style="list-style-type: none"> • A systematic review and meta-analysis of depression and anxiety in prostate cancer (evidence-based approach activity)
2. Intervention design	<ul style="list-style-type: none"> • Use themes arising from the intervention planning stage to identify key issues, needs and challenges the intervention must address • Create guiding principles, comprising: a) Key intervention design objectives b) Key distinctive features of the intervention needed to achieve objectives 	<ul style="list-style-type: none"> • Use themes from qualitative study to identify key issues, needs and challenges Proactive must address • Create guiding principles 	
3. Intervention optimisation and evaluation of acceptability and feasibility	<ul style="list-style-type: none"> • Elicit and observe user reactions to every intervention element (e.g. using thinkaloud techniques), iteratively modifying intervention to optimise acceptability and feasibility • Carry out detailed longitudinal mixed methods case studies of independent intervention usage 	<ul style="list-style-type: none"> • Create Proactive prototype, conduct think aloud interviews and modify the intervention accordingly 	

Methods

Intervention Planning

Review of the literature

Systematic review and meta-analysis of depression and anxiety in prostate cancer

Aim:

An evidence-based approach activity to systematically review literature around depression and anxiety prevalence in patients with prostate cancer (published elsewhere)(4).

Methods:

Due to a lack of previous research about depression and anxiety in men specifically on the AS pathway this review included men on other PCa treatment pathways. After de-duplication, 1130 articles were screened for eligibility, and 27 full journal articles were included giving a total sample size of 4494 prostate cancer patients.

Results:

Anxiety and depression were highly prevalent, and levels varied throughout the course of the illness and according to treatment status. A pattern of depression and anxiety was identified showing rates were highest after diagnosis before treatment, (depression: 17.27% (95% CI 15.06% to 19.72%)), (anxiety: 27.04% (95% CI 24.26% to 30.01%)), lowered during treatment (depression: 14.70% (95% CI 11.92% to 17.99%)), (anxiety: 15.09% (95% CI 12.15% to 18.60%)), and then raised again when treatment was complete (depression: 18.44% (95% CI 15.18% to 22.22%)), (anxiety: 18.49% (95% CI 13.81% to 24.31%)).

Relevance to PROACTIVE planning:

Of the 27 articles included, only 4 involved AS patients(15-18). The upper depression and anxiety prevalence rates reported within these articles were high, 17% and 21% respectively, indicating the need for further research into the psychological impact of AS, and an investigation into the use of a support tool.

Cross-sectional survey study

Cross-sectional assessment of depression and anxiety prevalence in prostate cancer patients undergoing AS

Aim:

To further explore the issue of heightened anxiety and depression in men with PCa, and provide a broader picture specific to AS, the research team conducted a cross-sectional assessment aiming to explore depression and anxiety prevalence specifically in prostate cancer patients undergoing AS. The full study is published elsewhere(5).

Methods:

313 men being managed by AS for PCa across 7 UK urology centres were recruited. The primary outcome was the Hospital Anxiety and Depression Scale (HADS)(19). The survey collected demographic data (age, employment, relationship, ethnic and educational status), to allow for cross-tabulation with anxiety and depression scores.

Results:

Results from this survey indicated a clinical depression prevalence of 12.5%, and clinical anxiety prevalence of 23% measured by the HADS. The results show a more than doubled depression prevalence, and almost tripled anxiety prevalence in men on AS for prostate cancer compared to men of a similar age in the general population (6% and 8% respectively(20)). Divorce was the only demographic predictor of higher anxiety and depression(5), indicating the family environment may need further investigation also.

Implications for PROACTIVE:

With the combined results from the systematic review and cross-sectional assessment indicating elevated levels of anxiety and depression, the research team concluded the levels of distress in men on AS for PCa needs to be addressed.

Review of existing interventions in the field

To gain an insight into whether informational, psychological, emotional or cognitive interventions can positively impact men with prostate cancer, the research team conducted a narrative literature review of supportive psychological interventions within prostate cancer (published elsewhere)(21). Ideally this review would have focussed on AS patients, however, due to a paucity of interventions in this area, interventions for PCa not exclusive to AS were included. The interventions were categorised by delivery mode: delivered in a group-based environment, delivered over the phone, delivered over the internet or delivered by other means. Intervention components and intervention effectiveness were considered in tandem (listed below in *Table 2*) to enhance understanding of the components that may be effective in a new intervention. See *Table 2* for a summary of the self-care interventions and the implications for PROACTIVE.

Table 2: Self-care psychological interventions targeting prostate cancer patients

Author(s)	Mode of delivery	Intervention description	Intervention components	Results / Effectiveness / points of interest	Implications for PROACTIVE
Parker et al (2009) (22)	Group based environment	Pre-surgical stress management programme for men undergoing radical prostatectomy	<p>2 x 90 minute sessions that involved:</p> <ul style="list-style-type: none"> • Learning relaxation skills • Guided imaginary rehearsals of surgery day • Discussion about fears and implementation of coping strategies. <p>2x booster sessions: on the morning of surgery; and 48 hrs post surgery</p>	<p>Significantly less mood disturbance, cancer related worries and physical side effects than controls. Effects maintained at 12 months.</p> <p>221 potential participants approached, 159 took part.</p>	Level of uptake suggests PCa patients are willing to take part in self-care interventions to improve psychological wellbeing.
Penedo et al (2004 & 2006)(23, 24)	Group based environment	Cognitive behavioural stress management intervention with men who had received either radical prostatectomy or radiotherapy for PCa	<p>10 week intervention with 2 hour weekly sessions involving:</p> <ul style="list-style-type: none"> • Implementing relaxation techniques • Utilising techniques such as identifying distorted thoughts • Goal setting • Utilising social support. 	Significant improvements in both general and PCa specific quality of life compared to controls.	In PCa patients relaxation interventions are both well received and clinically effective.
Carlson et al (2003 & 2007)(25, 26)	Group based environment	Standardised Mindfulness Based Stress Reduction (MBSR) course	<p>8 weekly sessions incorporating:</p> <ul style="list-style-type: none"> • Relaxation • Meditation • Gently yoga • Daily home practice <p>(Note: Recruits not exclusively PCa).</p>	Significant improvements in sleep, stress, anxiety, mood and fatigue.	Results were not stratified by disease type, so hard to draw any strong implications for PROACTIVE, however, the study findings do support the notion of group-based support for cancer patients.
Templeton & Coates	Group based environment	Educational intervention	Brief, group-based, nurse-led single session for men	Compared to controls, significant improvements in	Intervention effectiveness may not be dose

(2004) (27)			being treated with hormone therapy for PCa. Participants were provided with an information booklet.	general and PCa specific quality of life, PCa knowledge and satisfaction with care.	related, and short interventions may be as effective as more time consuming programmes. Information provision is valued by PCa patients. The participants in this trial were receiving hormone treatment and those on AS may feel differently.
Berglund et al (2007) (28)	Group based environment	Psychosocial rehabilitation	<p>7-week group based intervention. 3 arms; information arm, physical activity arm, combined arm, plus a control group.</p> <ul style="list-style-type: none"> • Information arm led by PCa nurse and participants received information about what PCa is, treatment options, side effects, and methods of dealing with urinary and erectile dysfunction. • Physical activity arm led by physiotherapist and focussed on increasing daily exercise. • Combined arm received both 	No significant improvements in anxiety, depression or quality of life.	Unclear why the intervention was unsuccessful, perhaps information needs to be combined with relaxation/stress management techniques.
Lepore et al (2003) (29)	Group based environment	Educational intervention	<p>3 groups, intervention, intervention plus discussion, control group.</p> <p>Intervention involved 6 1-hour weekly group sessions involving:</p>	Both intervention arms showed significant improvements in PCa knowledge and experienced less sexual dysfunction compared to the control group. No significant improvements in depression.	Depression baseline taken after treatment, low levels to start with so hard to draw conclusions for PROACTIVE from this.

			<ul style="list-style-type: none"> • Prostate cancer biology information • Treatment options • Managing side effects • Diet and nutrition • Stress, coping and relaxation. 		
Bailey et al (2004) (30)	Telephone	Intervention to manage uncertainty	<p>This was designed for men on watchful waiting. 5 brief telephone consultations with a male PCa nurse, with week-long intervals. Telephone consultations around:</p> <ul style="list-style-type: none"> • Re-framing negative thoughts • Managing uncertainty • Accepting watchful waiting 	Significant improvements in quality of life and uncertainty management compare to controls.	This study limited by high homogeneity in the sample, and watchful waiting patients may be different to AS patients.
Chambers et al (2013) (31)	Telephone	Psycho-educational intervention	<p>5 brief telephone consultations with PCa patients around:</p> <ul style="list-style-type: none"> • Cognitive reframing • PCa education • Management of side effects • Management of stress • Developing problem solving skills 	Significant improvements in mental health and cancer related distress in younger patients with higher levels of education and income, but not in the rest of the sample.	Heterogeneous sample compared to Bailey et al (2004), and large sample recruited from multiple centres. Indicates telephone support may not be effective for some groups of PCa patients.
Kazer et al (2011) (32)	Internet	Intervention to manage uncertainty	<p>5 week online intervention named "Alive and Well" for men on AS. Components included:</p> <ul style="list-style-type: none"> • Cognitive reframing of negative thoughts • PCa & AS information 	Significant improvement in 8 of the 12 quality of life subscales measured at the end of the intervention.	An online-only intervention improve quality of life in men on AS.

			<ul style="list-style-type: none"> • Lifestyle advice • Tailored emails 		
Osei et al (2013) (33)	Internet	Intervention to improve quality of life	6 week online intervention for men radically treated for PCa involving: <ul style="list-style-type: none"> • Online support forum • PCa information • Support managing side effects. 	Significant improvements in quality of life, but not maintained at follow-up.	Support may need to be more long term to improve outcomes beyond the study timeframe.
Weber et al (2004) (34)	Other – dyadic support	Social support intervention	Post-radical prostatectomy patients paired with men who had the same surgery 5 years previously. Men in the intervention arm met with long term survivors once a week for 8 weeks.	Men in intervention arm reported significantly lower levels of depression and significantly higher levels of self-efficacy compared to controls. High attrition rate – all 8 sessions attended by every intervention arm participant.	Dyadic support well adhered to. Support from men who have had similar experiences can be effective in improving psychological outcomes.

Qualitative study with a sample of the target audience

Aim:

The research team carried out a qualitative study with the aim of gaining a more in-depth and specific understanding of the supportive care requirements of prostate cancer patients being managed with AS. The full study is published elsewhere(8), and an overview is presented below.

Methods:

20 men on active surveillance were recruited from the prostate cancer clinic at Southampton General Hospital. Semi-structured qualitative interviews were conducted and analysed inductively using thematic analysis.

Results:

Table 3 shows the key findings that emerged from the data. In summary, the men reported high levels of emotional distress, a lack of knowledge about their condition or how to self-manage it, and a desire for more information and support(8).

Table 3: Key findings from the qualitative study

Theme	Description	Quote
Emotional Distress	All of the men interviewed showed increased levels of emotional distress to varying degrees due to being on active surveillance.	<i>"You are told that you have cancer but that it's nothing to worry about and that all they are going to do is watch it to see how it grows. That just doesn't make sense; if something can be done prior to it spreading, why isn't it being done? It freaks you out."</i> (Interviewee 5, aged 72)
Lack of information and knowledge	Part of the reason for the increased levels of emotional distress seemed to be attributed to a lack of understanding and lack of information received about active surveillance.	<i>"If they had said what active surveillance is then perhaps I might have understood it a bit better, but they just said we will keep an eye on it every 6 months. You know, keeping an eye on it could mean a blood test, a meeting with the consultant, another biopsy. I was in the dark and it is the not knowing, the lack of information, that is what worries you".</i> (Interviewee 13, aged 71)
The need for additional support in the form of a support group	The men interviewed explained their access to Prostate Cancer experts is limited and therefore access to a group of men also under active surveillance would be helpful.	<i>"You know, you see the hospital doctors very infrequently so for me I always viewed my GP, who I have known for years, as my first port of call when I needed to better understand things relating to active surveillance and my tests and stuff. But the problem I found was, and I don't mean to be rude, he [the GP] didn't know any more about active surveillance than me so you are kind of left in this horrible place where no one has the ability to answer your questions or fears so meeting up with other chaps on active surveillance in a confidential and educationally focused group would be a real coup for me"</i> (Interviewee 12, aged 58).
The need for additional support in the form of a website	Men wanted to play an active part in helping themselves and would value self-management information in the form of a website.	<i>"If prostate cancer specific information was available on the web, then that reassures people. Things like frequently asked questions, situations and symptoms to look out for, advice on what you can do to help manage it [prostate cancer], advice about diet, changes that I ought to be making. Things of that nature really, things to allow me to self-manage this [prostate cancer]"</i> (Interviewee 1, aged 71).

Implications for PROACTIVE development

The results from this qualitative study indicate that men being managed with active surveillance would welcome specific additional psycho-educational support to help them better cope and manage with the burden of living with untreated prostate cancer. According to the data, a mixture of web-based support and group session support would be most appropriate.

Intervention Design

Key guiding principles

Using the information gathered during the intervention planning phase, the research team developed a set of key guiding principles, in line with the PBA approach. The purpose of this is to summarise the design objectives and how these will be achieved, to facilitate quick and easy reference throughout the planning and development phase to guide and focus the decision making around intervention content and design(13). Table 4 outlines the three intervention design objectives along with the key features of the intervention designed to address each objective.

Table 4: Key Guiding Principles

Intervention design objective	Key features designed to address objective	Rationale for design objective and key features
<p>1. To support men to manage the anxiety they experience due to being on active surveillance.</p>	<p>The group sessions should provide support with anxiety by providing reassurance and normative information about others' experiences, and encouragement in the development of coping skills (for example, social support mobilisation). The web component should complement the group sessions, enabling men to learn self-management strategies to take control of their anxiety. The web component should also signpost men to further reliable information available online.</p>	<ul style="list-style-type: none"> • All research conducted in the planning phase indicated emotional distress. • The qualitative study with the target audience, and various previous interventions (22-27, 29) indicated group support may be beneficial. • The qualitative study indicated a lack of reliable PCa and AS related information.
<p>1. To encourage and support a healthy lifestyle.</p>	<p>The web component should provide information about diet, physical activity and stress management to encourage a healthy lifestyle. Asking the men to set weekly goals could encourage them to utilise the information and implement changes to benefit their health. Relaxation techniques to be demonstrated in the group sessions, and the lifestyle information reinforced.</p>	<ul style="list-style-type: none"> • Target audience in qualitative study requested self-management tools/advice.
<p>1. To maximise engagement in the programme.</p>	<p>In order to encourage participation from men who might usually feel uncomfortable participating, and to minimise withdrawal from the group sessions, the group sessions need to be facilitated in a way that encourages active participation, mutual understanding, respect and help-seeking behaviour (for example, demonstrating an interest for further information). To encourage men who might otherwise not participate the group facilitator needs to sensitively encourage patients to identify their emotional state and feelings.</p>	<ul style="list-style-type: none"> • Important to maximise engagement in the programme to maximise change / improvements.

Developing a logic model

The MRC complex intervention guidelines(35) recommend the development of a logic model to outline the hypothesized causal mechanisms involved in bringing about change in men on AS for PCa. The logic model (Figure 1) demonstrates how we anticipate the intervention will result in improved psychological wellbeing.

Figure 1: Logic Model

Public and patient involvement

Three Patient and Public Involvement (PPI) contributors with PCa were involved in the intervention planning and development process. The research team met with the contributors every 4-8 weeks to provide progress updates and gain feedback on ideas and written materials. PPI contributors reviewed and commented on the online and workshop content and were involved in all key decisions. The involvement of the PPI contributors ensured developing study materials were likely to be acceptable, understandable and relevant to the target audience.

Result

The PROACTIVE prototype

The prototype intervention was named PROACTIVE – ‘PROstate ACTIVE surveillance support’. The intervention consisted of two parts:

- 1.) An online programme consisting of six sessions designed to be completed on a weekly basis.
- 2.) A face-to-face group support programme with three sessions, spread across six weeks, held fortnightly and each lasting 60-90 minutes.

The web-based programme and the group support sessions interlink and are designed to run in parallel over 6 weeks, complementing each other; for example, the online sessions introduce topics that will be further discussed in the following group session, and the online sessions reinforce the information covered in previous group sessions. Figure 2 shows the intervention as a whole over the 6 week time period. See Table 5 for a detailed description of the session content.

Figure 2: The PROACTIVE Intervention

The intervention

Table 5 details the content of each of the web-based and face-to-face group sessions delivered over the 6-week period.

Table 5: The intervention

Week	Delivery mode	Session title	Content	Why was this included?	Target behaviour(s)
1	Web-based	Introduction and physical activity	<p>Introduction to the website.</p> <p>Information about active surveillance, Prostate Specific Antigen (PSA) testing, prostate cancer in general and prostate cancer statistics with printable information sheets.</p> <p>Section on physical activity providing information about the benefits of increasing physical activity and ways to go about it.</p>	<p>Target audience in qualitative study requested:</p> <ul style="list-style-type: none"> reliable information self-management tools/advice 	<ul style="list-style-type: none"> Engagement with the program Increased PCa knowledge Motivation to increase physical activity
1	Face-to-face group session	Information, reassurance and introduction to lifestyle information	<p>Provision of information to ensure patients are fully informed about their condition and treatment plan. Time for patients to ask questions included.</p> <p>Provision of reassurance and comfort by identifying areas of concern related to active surveillance, targeting possible frustration related to inadequate information.</p> <p>Introduction to lifestyle (diet and exercise) information.</p>	<p>Target audience in qualitative study requested:</p> <ul style="list-style-type: none"> reliable information self-management tools/advice social support from other men on the AS pathway 	<ul style="list-style-type: none"> Engagement with the program Increased PCa knowledge Motivation to improve lifestyle
2	Web-based	Foods to eat	Advice about foods to eat. General healthy eating advice, with some specific prostate cancer diet information.	Target audience in qualitative study requested self-management tools/advice.	<ul style="list-style-type: none"> Improved nutrition knowledge Motivation to improve diet
3	Web-based	Relaxation & Resilience techniques	Two relaxation techniques described with step-by-step instructions.	<p>Target audience reported:</p> <ul style="list-style-type: none"> emotional distress desire for self-management tools/advice <p>Relaxation techniques aim to provide men with self-management</p>	<ul style="list-style-type: none"> Improved confidence in the self-management of emotional distress Improved self-management of emotional distress

				tools to address high levels of self-reported emotional distress.	
3	Face-to-face group session	Introduction to stress management and relaxation / resilience techniques	<ul style="list-style-type: none"> Identifying forms of coping. Presentation of 2 relaxation and resilience techniques. <p>Discussion of issues and concerns related to lifestyle and active surveillance related information.</p>	<p>Target audience reported:</p> <ul style="list-style-type: none"> emotional distress desire for self-management tools/advice social support from other men on the AS pathway 	<ul style="list-style-type: none"> Improved confidence in the self-management of emotional distress Improved self-management of emotional distress Improved confidence in improving lifestyle
4	Web-based	Talking to family / friends / professionals*	Advice and ideas about how to approach the subject of PCa and/or AS with friends and family. How to get the most out of specialist consultations.	<p>Target audience reported:</p> <ul style="list-style-type: none"> emotional distress lack of reliable information <p>Improved PCa / AS related communication with friends and family may reduce emotional distress.</p> <p>Improved communication in specialist consultations may help fill any gaps in knowledge or understanding.</p>	<ul style="list-style-type: none"> Improved PCa related communication with family and friends Improved communication in specialist consultations to ensure patient questions are answered adequately
5	Web-based	Thoughts and feelings*	Addresses distressing thoughts and feelings the men may be experiencing. Provides advice about how to manage and/or reduce these thoughts and feelings.	<p>Target audience reported:</p> <ul style="list-style-type: none"> emotional distress desire for self-management tools/advice 	<ul style="list-style-type: none"> Improved confidence in the self-management of emotional distress Improved self-management of emotional distress
5	Face-to-face group session Partners	Adapting stress management and relaxation techniques.	<ul style="list-style-type: none"> Opportunity for the partners of the participants to ask questions and share experiences. 	<p>Partners included to:</p> <ul style="list-style-type: none"> promote PCa/AS related communication 	<ul style="list-style-type: none"> Confidence in implementing self-management

	invited to the first 20 minutes of this session		<p>Partners to leave the session after 20 minutes.</p> <ul style="list-style-type: none"> Reinforcing and adapting relaxation and resilience techniques for future use. Discussion/feedback about the PROACTIVE programme. Opportunity for participants to gain clarity about anything covered in the programme. 	<ul style="list-style-type: none"> to ensure gaps in knowledge and understanding are filled for both the men and their partners <p>Reinforcement of all that has been learnt over the program to provide confidence in moving forward with self-management tools.</p> <p>Provision of social support from other men on the AS pathway.</p>	<p>tools moving forward</p> <ul style="list-style-type: none"> Confidence in PCA and AS knowledge and understanding
6	Web-based	Daily life; money and work*	Covers advice about practical issues (for example, paying for hospital parking), and provides information about dealing with work after receiving a diagnosis.	Practical advice to aid self-management.	<ul style="list-style-type: none"> Improved confidence in managing diagnosis in work
1-6		Goal and plan setting / Goal and plan reviewing	1-3 weekly goals, with a plan to go with each one. Goals and plans reviewed on a weekly basis.	Goal setting provides a way of self-monitoring progress and provides some accountability.	
1-6		Web links	Website links to useful resources related to each session.	Target audience reported a lack of reliable information. Links provide further information from credible sources.	

*These three online sessions could be completed in any order

Think aloud interviews to refine PROACTIVE

Identified by the PCaSO charity (Prostate Cancer Support Organisation), 2 men with prostate cancer took part in think aloud interviews. This process involved each participant working their way through the PROACTIVE prototype whilst simultaneously speaking aloud their thoughts about the programme. Statements such as ‘can you tell me what you think about this page?’ and ‘can you tell me why you chose that option?’ were used as prompts to elicit participants opinions on the intervention. Interviews were audio recorded, participant thoughts and opinions were collated and used to amend the prototype to be used in the pilot study. Table 6 provides a summary of these changes.

Table 6 Summary of changes from think aloud interviews

Comments from think aloud	Action
Various aesthetic suggestions were made, for example, removing/adding pictures, less information on each page, centralising headings.	All suggestions were discussed within the research team and the majority were implemented.
Suggestion to add in a quick summary of all sessions as part of the introduction.	Added as suggested.
Minor wording changes to information sheets and sessions suggested.	Implemented as suggested.
Physical activity section needs to be relevant to PCa.	Physical activity advice was included, and recommendations in line with NHS guidance. The research team added information to explain how improving physical activity can improve wellbeing and general health.
Physical activity session assumes all participants are unfit, amend wording to remove this assumption.	Implemented as suggested.
Add more examples of goals.	Added as suggested.
Add in the benefits of talking to others.	Added as suggested.
Section about talking to professionals implies there will be problems.	Wording adjusted to remove implication.
Add statement that doctors / nurses will not be embarrassed by certain topics.	Added as suggested.
Make goal page printable.	Actioned as suggested.

PROACTIVE ready for pilot study

The amended intervention became the final version for pilot. Figure 3 below shows some screenshots from the web-based sessions.

Figure 3 PROACTIVE Screenshots

Discussion

Summary

This paper demonstrates how we used the PBA to develop an internet and group based psycho-educational behavioural intervention for men on AS for PCa. The process of gathering, understanding and utilising target-user needs and perspectives has long been viewed as essential within the eHealth research community (36–38). Intervention developers in the area of eHealth have undertaken this task in a variety of ways(39, 40), however, until the publication of the PBA there was no standardised approach or process to follow. Guided by the PBA the researchers gained a context-specific understanding of the intervention elements likely to be needed to maximise participant acceptability and engagement.

Each component of our approach (see Table 1) added a valuable contribution to the development process. The systematic review and meta-analysis of depression and anxiety in prostate cancer provided a broad understanding of the prevalence of these conditions in PCa patients, and confirmed the dearth of literature specific to AS. Beginning to fill this gap in the literature, the cross-sectional survey on depression and anxiety in AS allowed us to narrow down the treatment pathway diversity in previous studies and focus on men on AS. Men in this survey displayed significant levels of distress, reinforcing the value of the proposed intervention. Reviewing existing interventions in the field provided a way of seeing what has and has not been successful in the past, and an understanding of the elements that may increase the success of the proposed intervention. The qualitative study gave us the opportunity to explore the supportive care needs of this user group in an in-depth way providing focussed direction for the intervention and a way of identifying any gaps.

Integrating the results from these 4 components we were able to create a set of key guiding principles. The key guiding principles summarised the design objectives and provided focus for decision making. Our logic model provided a visual representation of how the intervention might work, displaying the intervention ingredients and how these translate into the causal mechanisms likely to bring about change.

Armed with the understanding gained from the above mentioned processes we were able to create the prototype PROACTIVE intervention. The think-aloud interviews provided further clarity, and the minor changes made due to the results of these interviews improved our confidence in the intervention.

This methodological approach is rigorous but flexible. For other interventions the stages and processes may differ depending on the context of the intervention(41–45), for example, if there is already a large base of existing qualitative research, new qualitative research may not be necessary.

Strengths, limitations and future research

Treatment for PCa is a rapidly changing and advancing field, for example, medical technology and the accuracy of diagnostic tests continually being improved. For this reason PCa interventions (including PROACTIVE) would need to be updated regularly to stay current and accurate. The advantage of this development process is that it has produced a core product based on a rigorous transparent process with clear guiding principles that can easily be shared, adapted and updated, negating the need to repeatedly start from scratch.

The PBA recommends incorporating behavioural science into the development of interventions by integrating a ‘theory-based’ approach with the PBA processes as best practice. In this instance this was not possible due to time and resource constraints. Further research conducting theory-based processes, and mapping the findings to the intervention, identifying any gaps, would be beneficial to potentially strengthen the intervention.

Conclusion

This paper outlines the stages we followed using the PBA to develop the PROACTIVE intervention. The planning and development process is key to successful delivery of an appropriate accessible intervention. This meticulous description in a clinical setting using this rigorous but flexible method is a useful demonstration for others developing similar interventions.

Declarations

Availability of data and materials

The datasets supporting the conclusions of this article are included within the article and its additional files.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

SH: Part of the team that designed and developed PROACTIVE. Created the PROACTIVE prototype website. Drafted the paper.

AK: Part of the team that designed and developed PROACTIVE. Developed the content of the group sessions. Made substantial contributions to the paper with comments and advice.

HE: Made substantial contributions to the paper with comments and advice.

BS: Made substantial contributions to the paper with comments and advice.

BB: Made substantial contributions to the paper with comments and advice.

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References

1. Smittenaar CR, Petersen KA, Stewart K, Moitt N. Cancer incidence and mortality projections in the UK until 2035. *Br J Cancer*. 2016;115(9):1147–55.
2. Bray F, Ferlay J, Soerjomataram I, Siegel RL, Torre LA, Jemal A. Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA Cancer J Clin*. 2018;68(6):394–424.
3. Bellardita L, Valdagni R, van den Bergh R, Randsdorp H, Repetto C, Venderbos LD, et al. How does active surveillance for prostate cancer affect quality of life? A systematic review. *Eur Urol*. 2015;67(4):637–45.
4. Watts S, Leydon G, Birch B, Prescott P, Lai L, Eardley S, et al. Depression and anxiety in prostate cancer: a systematic review and meta-analysis of prevalence rates. *BMJ Open*. 2014;4(3):e003901.
5. Watts S, Leydon G, Eyles C, Moore CM, Richardson A, Birch B, et al. A quantitative analysis of the prevalence of clinical depression and anxiety in patients with prostate cancer undergoing active surveillance. *BMJ Open*.

2015;5(5):e006674.

6. Taylor KL, Hoffman RM, Davis KM, Luta G, Leimpeter A, Lobo T, et al. Treatment Preferences for Active Surveillance versus Active Treatment among Men with Low-Risk Prostate Cancer. *Cancer Epidemiology Biomarkers & Prevention*. 2016;25(8):1240.
7. Biddle S. The psychological impact of active surveillance in men with prostate cancer: implications for nursing care. *Br J Nurs*. 2021;30(10).
8. Watts S. "They say most men die with and not from prostate cancer, but how do you live with it?" A qualitative interview study of the supportive care needs of patients on active surveillance. *Patient Educ Couns*. 2015.
9. McIntosh M, Opozda MJ, Evans H, Finlay A, Galvao DA, Chambers SK, et al. A systematic review of the unmet supportive care needs of men on active surveillance for prostate cancer. *Psychooncology*. 2019;28(12):2307–22.
10. Donachie K, Cornel E, Adriaansen M, Mennes R, Oort I, Bakker E, et al. Optimizing psychosocial support in prostate cancer patients during active surveillance. *International Journal of Urological Nursing*. 2020;14(3):115–23.
11. Parker PA, Davis JW, Latini DM, Baum G, Wang X, Ward JF, et al. Relationship between illness uncertainty, anxiety, fear of progression and quality of life in men with favourable-risk prostate cancer undergoing active surveillance. *BJU Int*. 2016;117(3):469–77.
12. Latini DM, Hart SL, Knight SJ, Cowan JE, Ross PL, Duchane J, et al. The relationship between anxiety and time to treatment for patients with prostate cancer on surveillance. *J Urol*. 2007;178(3 Pt 1):826–31. discussion 31–2.
13. Yardley L, Morrison L, Bradbury K, Muller I. The person-based approach to intervention development: application to digital health-related behavior change interventions. *J Med Internet Res*. 2015;17(1):e30.
14. Yardley L, Ainsworth B, Arden-Close E, Muller I. The personbased approach to enhancing the acceptability and feasibility of interventions. 2015.
15. van den Bergh RC, Essink-Bot ML, Roobol MJ, Wolters T, Schroder FH, Bangma CH, et al. Anxiety and distress during active surveillance for early prostate cancer. *Cancer*. 2009;115(17):3868–78.
16. Van den Bergh R, Essink-Bot ML, Robol MJ, Schroder FH, Bangma C, Steyerberg EW. Do anxiety and distress increase during active surveillance for low risk prostate cancer? *J Urol*. 2010;183:1786–91.
17. Burnet KL, Parker C, Dearnaley D, Brewin CR, Watson M. Does active surveillance for men with localized prostate cancer carry psychological morbidity? *BJU Int*. 2007;100(3):540–3.
18. Steineck G, Helgesen F, Adolfsson J, Dickman PW, Johansson JE, Norlén BJ, et al. Quality of life after radical prostatectomy or watchful waiting. *N Engl J Med*. 2002;347(11):790–6.
19. Zigmond AS, Snaith RP. The Hospital Anxiety and Depression Scale. *Acta Psychiatr Scand*. 1982;67:361–70.
20. NHS. The Information Centre for Health and Social Care. Health Survey for England 2005: Health of Older People. 2007.
21. Watts S. The assessment and management of anxiety and depression in prostate cancer patients being managed with active surveillance. 2014.
22. Parker PA, Pettaway CA, Babaian RJ, Pisters LL, Miles B, Fortier A, et al. The effects of a presurgical stress management intervention for men with prostate cancer undergoing radical prostatectomy. *J Clin Oncol*. 2009;27(19):3169–76.

23. Penedo FJ, Dahn JR, Molton I, Gonzalez JS, Kinsinger D, Roos BA, et al. Cognitive-behavioral stress management improves stress-management skills and quality of life in men recovering from treatment of prostate carcinoma. *Cancer*. 2004;100(1):192–200.
24. Penedo FJ, Molton I, Dahn JR, Shen BJ, Kinsinger D, Traeger L, et al. A randomized clinical trial of group-based cognitive-behavioral stress management in localized prostate cancer: development of stress management skills improves quality of life and benefit finding. *Ann Behav Med*. 2006;31(3):261–70.
25. Carlson LE, Speca M, Patel KD, Goodey E. Mindfulness-based stress reduction in relation to quality of life, mood, symptoms of stress, and immune parameters in breast and prostate cancer outpatients. *Psychosom Med*. 2003;65(4):571–81.
26. Carlson LE, Speca M, Faris P, Patel KD. One year pre-post intervention follow-up of psychological, immune, endocrine and blood pressure outcomes of mindfulness-based stress reduction (MBSR) in breast and prostate cancer outpatients. *Brain Behav Immun*. 2007;21(8):1038–49.
27. Templeton H, Coates V. Evaluation of an evidence-based education package for men with prostate cancer on hormonal manipulation therapy. *Patient Educ Couns*. 2004;55(1):55–61.
28. Berglund G, Petersson LM, Eriksson KC, Wallenius I, Roshanai A, Nordin KM, et al. "Between Men": a psychosocial rehabilitation programme for men with prostate cancer. *Acta Oncol*. 2007;46(1):83–9.
29. Lepore SJ, Helgeson VS, Eton DT, Schulz R. Improving quality of life in men with prostate cancer: a randomized controlled trial of group education interventions. *Health psychology: official journal of the Division of Health Psychology American Psychological Association*. 2003;22(5):443–52.
30. Bailey DE, Mishel MH, Belyea M, Stewart JL, Mohler J. Uncertainty intervention for watchful waiting in prostate cancer. *Cancer Nurs*. 2004;27(5):339–46.
31. Chambers SK, Ferguson M, Gardiner RA, Aitken J, Occhipinti S. Intervening to improve psychological outcomes for men with prostate cancer. *Psychooncology*. 2013;22(5):1025–34.
32. Kazer MW, Bailey DE Jr, Sanda M, Colberg J, Kelly WK. An Internet intervention for management of uncertainty during active surveillance for prostate cancer. *Oncol Nurs Forum*. 2011;38(5):561–8.
33. Osei DK, Lee JW, Modest NN, Pothier PK. Effects of an online support group for prostate cancer survivors: a randomized trial. *Urol Nurs*. 2013;33(3):123–33.
34. Weber BA, Roberts BL, Resnick M, Deimling G, Zauszniewski JA, Musil C, et al. The effect of dyadic intervention on self-efficacy, social support, and depression for men with prostate cancer. *Psychooncology*. 2004;13(1):47–60.
35. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *Int J Nurs Stud*. 2013;50(5):587–92.
36. Pagliari C. Design and Evaluation in eHealth: Challenges and Implications for an Interdisciplinary Field. *J Med Internet Res*. 2007;9(2):e15.
37. Baker TB, Gustafson DH, Shah D. How Can Research Keep Up With eHealth? Ten Strategies for Increasing the Timeliness and Usefulness of eHealth Research. *J Med Internet Res*. 2014;16(2):e36.
38. van Gemert-Pijnen JEW, Nijland N, van Limburg M, Ossebaard HC, Kelders SM, Eysenbach G, et al. A Holistic Framework to Improve the Uptake and Impact of eHealth Technologies. *J Med Internet Res*. 2011;13(4):e111.
39. Van Velsen L, Wentzel J, Van Gemert-Pijnen JEW. Designing eHealth that Matters via a Multidisciplinary Requirements Development Approach. *JMIR Res Protoc*. 2013;2(1):e21.

40. Yen P-Y, Bakken S. Review of health information technology usability study methodologies. J Am Med Inform Assoc. 2012;19(3):413–22.
41. Band R, Hinton L, Tucker KL, Chappell LC, Crawford C, Franssen M, et al. Intervention planning and modification of the BUMP intervention: a digital intervention for the early detection of raised blood pressure in pregnancy. Pilot Feasibility Stud. 2019;5:153.
42. Band R, Bradbury K, Morton K, May C, Michie S, Mair FS, et al. Intervention planning for a digital intervention for self-management of hypertension: a theory-, evidence- and person-based approach. Implement Sci. 2017;12(1):25.
43. Morton K, Ainsworth B, Miller S, Rice C, Bostock J, Denison-Day J, et al. Adapting Behavioral Interventions for a Changing Public Health Context: A Worked Example of Implementing a Digital Intervention During a Global Pandemic Using Rapid Optimisation Methods. Front Public Health. 2021;9:668197.
44. Muller I, Santer M, Morrison L, Morton K, Roberts A, Rice C, et al. Combining qualitative research with PPI: reflections on using the person-based approach for developing behavioural interventions. Res Involv Engagem. 2019;5:34.
45. Bradbury K, Steele M, Corbett T, Geraghty AWA, Krusche A, Heber E, et al. Developing a digital intervention for cancer survivors: an evidence-, theory- and person-based approach. NPJ Digit Med. 2019;2:85.

Figures

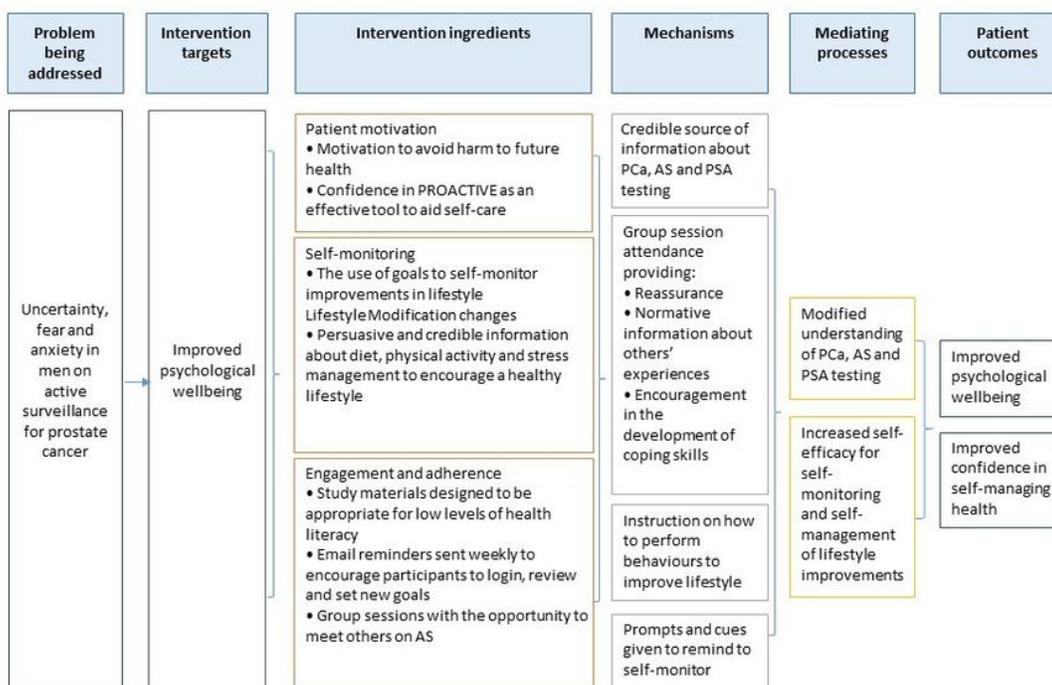


Figure 1

Logic Model

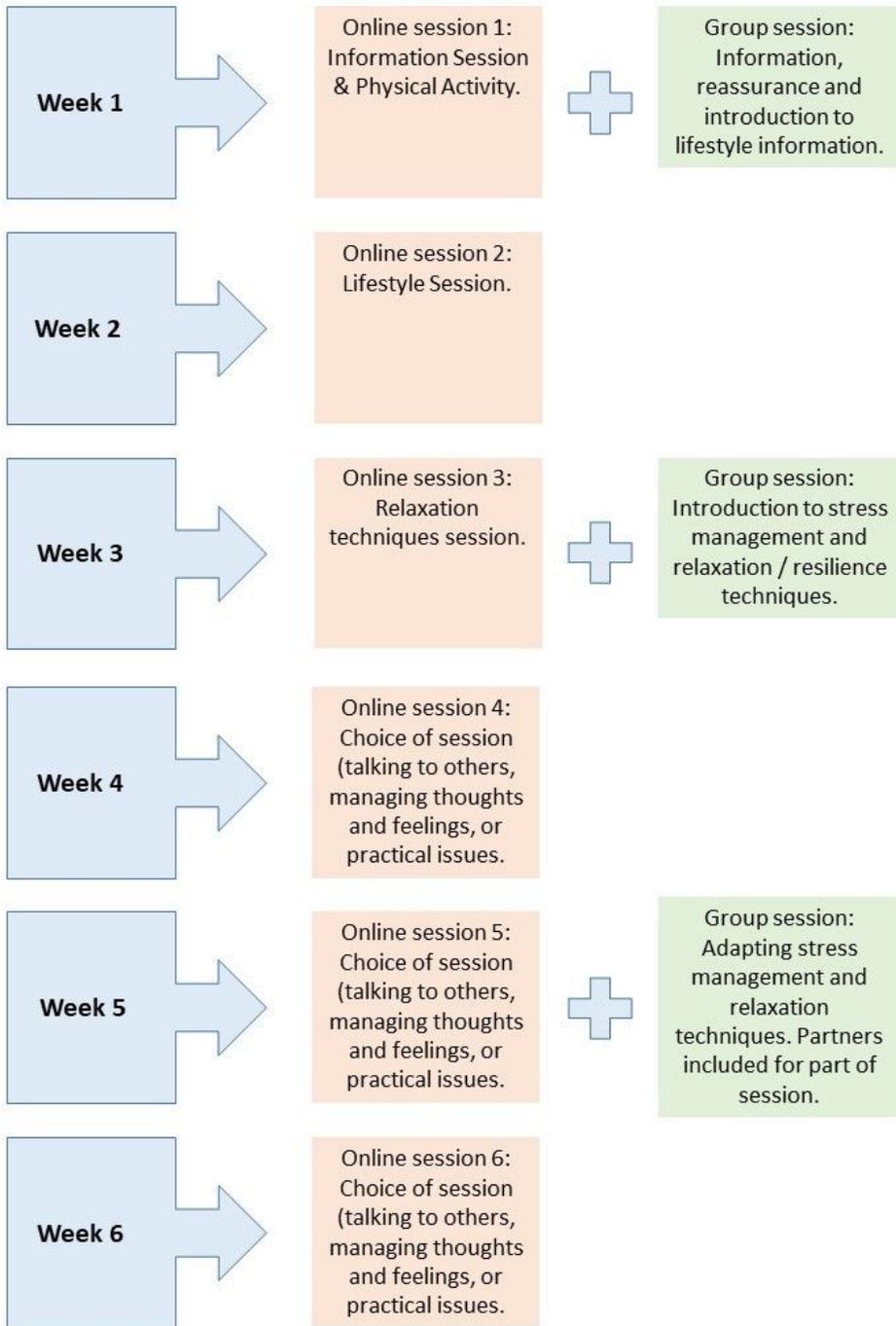


Figure 2

The PROACTIVE Intervention



Figure 3

PROACTIVE Screenshots