

Efficacy, usage and acceptability of an online self-management intervention designed to maximise sexual wellbeing in men living with prostate cancer: a single-arm study

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Authors' contributions

EMcC, KP, RM, MS, ST, SJ and MK developed the original proposal for the study. EMcC, CF, NB and SOC drafted and revised additional versions of the intervention content. EMcC, CF, RM, JC and SOC conducted usability tests and think-aloud interviews during intervention development. SOC, CF and MS built and tested the final intervention version. SOC, CF and EMcC were responsible for data collection analysis and interpretation. SOC drafted the initial manuscript and all authors revised the manuscript for important intellectual content and approved the final version.

Conflict of interest

The authors declare they have no competing interests.

Abbreviations

Unified theory of acceptance and use of technology (UTAUT)

Abstract

Background:

Sexual dysfunction is a frequent side-effect associated with different prostate cancer treatment approaches. It can have a substantial impact on men and partners and is associated with increased psychological morbidity. Despite this, sexual concerns are often not adequately addressed in routine practice. Evidence-based online interventions have potential to provide ongoing information and sexual wellbeing support throughout all stages of care.

Objectives:

To examine the efficacy of an online self-management intervention designed to maximise sexual wellbeing in men living with prostate cancer and explore user perspectives on usability and acceptability.

Methods:

Using a single-arm study design, participants were provided with access to the five-step intervention for a period of 3 months. Intervention content was tailored based on responses to brief screening questions on treatment type, relationship status and sexual orientation. Efficacy was assessed using paired-sample t-tests comparing mean differences between pre and post intervention measurements exploring participant's self-reported knowledge and understanding, sexual satisfaction, and comfort discussing sexual issues. Usability and acceptability were determined based on programme usage data and a post intervention survey exploring perceived usefulness.

Results:

A total of 109 participants were recruited to the study. Significant post intervention improvements at follow-up were observed in overall survey scores (12.23/20 (SD: 2.46) versus 13.62/20 (SD: 2.31); $t = 9.570$; $P = 0.001$) as well as in individual item scores on the extent to which participants agreed that they had sufficient information to manage the impact of prostate cancer on their sex life (2.31/4 (SD: 0.86) versus 2.57/4 (SD: 0.85); $t = 3.660$; $P = 0.001$) and had the potential to have a satisfying sex life following treatment (2.38/4 (SD: 0.79) versus 3.17/4 (SD: 0.78); $t = 7.643$; $P = 0.001$). The median number of intervention sessions was 3.0 (Range 1 to 11 sessions) with a median duration of 22.0 minutes (Range: 8 to 77 minutes). Acceptable usability scores were reported with the highest result observed for the question on the extent to which the intervention provided relevant information.

Conclusions:

This study provides evidence for the efficacy of a tailored, online intervention to maximise sexual wellbeing in men living with prostate cancer. Results indicate that the intervention may improve self-perceived knowledge and understanding of how to manage sexual issues, and increase self-efficacy or a belief that a satisfactory sex life could be achieved following treatment. Findings will be used to refine the intervention content prior to testing as part of a larger longitudinal study examining its effectiveness.

KEYWORDS

prostate cancer, sexual wellbeing, digital interventions, self-management

Introduction

Prostate cancer is the single most common cancer among men accounting for around 25% of all cases [1,2]. While incidence rates are rising, partly associated with improved screening and changes in the population age profile [3], 5 and 10-year survival rates continue to improve [4]. Consequently, increasing numbers of men are living with significant, long-term side-effects associated with different treatment approaches [3]. Sexual challenges are the most frequently occurring sequelae [5, 6]. Rates of sexual dysfunction having a moderate to severe impact on quality of life of 31 to 64% have been reported after radical prostatectomy and external beam radiotherapy [7,8]. In a recent, large scale survey, 81% of men reported poor sexual function post-treatment, with approximately 56% not being offered any intervention to help manage these concerns [9]. Changes to sexual function are subsequently regarded as a major issue which can result be associated with increased psychological morbidity, including depression and relational dis-satisfaction, as well as reductions in self-efficacy and overall quality of life [10]. Sexual wellbeing can be described as a complex and highly individualised issue which encapsulates all aspects of sexuality, including physical, emotional, mental and social aspects [11,12]. Patients and their partners often have complex sexual health and wellbeing needs following diagnosis and treatment [13,14]. Effective, evidence-based care and support is therefore required to help manage these needs. Care and support aimed at maximising sexual wellbeing should not be restricted to purely biomedical approaches that focus on erectile dysfunction and physiologic penile rehabilitation [15]. These approaches do not address sexual wellbeing after prostate cancer in a biopsychosocial context [16].

While there is evidence examining relatively intensive couple-based counselling interventions delivered by health professionals [17,18], there is often limited access to such services. Current treatment guidelines [19,20] endorse delivery of psychosexual care for prostate cancer patients with recommendations made for the minimal level of support that should be provided. This includes provision of individualised information tailored to need, clear advice about potential long-term side-effects of treatment, and ensuring ongoing access to specialist care including erectile dysfunction clinics. Despite these recommendations, information provided varies greatly and is not available routinely across services [9]. Patients and partners frequently report that they do not receive adequate support to manage these concerns [21,22]. In a study of prostate cancer follow-up in urology and radiotherapy clinics, sexual aspects of recovery were not discussed in 46% and 48% of observed consultations respectively [23]. Despite the presence of partners in around half of consultations, their involvement was minimal and did not appear to influence whether or not any discussion of sexual concerns took place [23].

Discussing sexual health concerns in routine practice can be challenging, and there are a number of barriers to these conversations taking place [24,25]. Healthcare providers often feel unequipped to deal with sexual health issues and report a lack of resources to offer patients and their partners if they do identify a problem [26]. Patients may not spontaneously report sexual health issues and prefer health professionals to initiate the discussion [27]. These assumptions may be compounded when health professionals work with patients from minority groups, such as men who have sex with men. For example, many gay men report that health professionals often fail to ask about sexual orientation during initial consultations and assume they are heterosexual [28].

Online or web-based interventions, provide access to ongoing, easily accessible and adaptable information and support to users at all stages of care [29]. There is evidence that tailoring, or personalisation of online information and support interventions is more effective, with increased user engagement when compared to standardised information [30]. In addition, tailored, self-management-based interventions are more able to alter determinants of individual beliefs and behaviours [31]. However, some barriers exist that can limit engagement with online resources including lack of time and usability issues [32]. Despite this, online interventions that specify and acknowledge the impact of treatment on sexual wellbeing of both men and their partners as well as providing appropriate support have potential to improve patient-important outcomes, including sexual wellbeing satisfaction and quality of life. Such interventions, aimed at supporting men, and partners, to cope with changes to sexual health and wellbeing after prostate cancer require further investigation.

This paper presents an evaluation of an online, self-management intervention designed to maximise sexual wellbeing in men living with prostate cancer. The programme provides tailored information and support based on user's treatment type, relationship status and sexual orientation. This aligns with existing guidelines that advocate tailored psychosexual interventions [19,20]. It is also in line with recommendations that emphasise early support, consisting of educational approaches and interventions to manage sexual side-effects of treatment, as well as minimise the impact of changes to sexual function on men and their partners [33].

Recent frameworks for developing and evaluating complex healthcare interventions emphasise a requirement for greater focus on initial development, since many fail to demonstrate effectiveness in real-world contexts [34]. Prior to conducting any larger studies exploring intervention effectiveness, this study was conducted to examine if the intervention had any effect on patient important outcomes, and to explore its acceptance to users. The primary

objective of the study was therefore to examine the efficacy of the intervention in terms of its impact on participant's understanding of how to manage sexual concerns, comfort discussing such issues with partners and health professionals, and overall satisfaction with their sex life. A secondary objective was to explore programme usage and user perspectives on usability and acceptability.

Methods

Study design

Results are presented here on a single-arm pilot study with pre-post intervention outcome assessments. Following enrolment, participants were given access to the intervention for a 3-month period. Where appropriate, the design and conduct of the study was conducted following the Consolidated Standards of Reporting Trials 2010 statement - extension to randomized pilot and feasibility trials [35].

Study setting and participants

The primary study recruitment methods were via health professionals sign-posting men to the study website who were attending routine prostate cancer appointments at two clinical sites (Northern Ireland Cancer Centre, Belfast City Hospital, UK and Ninewells Hospital, Dundee, UK) and via posters and leaflets placed in clinical areas within the same sites. In addition, a link to the programme was included on the patient information section of a national prostate cancer charity website. A minimum sample of 81 participants was determined based on paired sample t-testing and using an alpha value of 0.05 and a medium estimated effect size of 0.03 [36]. A planned sample size of 100 participants was therefore selected to allow for potential loss of data at follow-up. Following online registration with the site, potential participants were required to complete a screening questionnaire before a baseline assessment. To meet the study inclusion criteria, participants were required to be an adult male (aged 18 or over), diagnosed with prostate cancer, and due to start, or be currently receiving supportive care after radical prostatectomy, external beam radiotherapy, brachytherapy or androgen deprivation therapy (either alone or in combination). Exclusion criteria were: being on active surveillance or not being able understand instructions written in English.

Study procedures

Ethical approval for the study was provided via the Office for Research Ethics Committees Northern Ireland (OREN) (Reference number: 17/NI/014). Prior to completing the online screening questionnaire, participants were

provided with a study information sheet detailing the nature and purpose of the study. They were also given the opportunity to contact a member of the research team to ask any questions they might have about the study. All participants gave informed consent before participation. Participants then completed the baseline assessment which including demographic information and baseline outcomes. They then provided responses to the three questions which were used to allow the intervention to provide tailored information and support based on the responses given (See Table 1) . Participants were given access to the programme for a period of 3 months. The only contact participants received during the intervention period was via automated emails sent to confirm successful enrolment and to remind participants they had one week left to use the intervention. After the 3-month intervention period ended participants received email reminders asking them to login to the website and complete a follow-up assessment where baseline outcomes were repeated. They were also asked to complete a questionnaire on programme usability and acceptance.

Table 1. Questions asked at baseline to allow for tailored information to be provided by the intervention

Question	Response options
What treatment have you had?	- Surgery - Combined Radiotherapy & Hormone Therapy - Radiotherapy - Hormone Therapy
Are your sexual partners usually male or female?	- Female - Male
Do you currently have a partner?	- Yes - No

Intervention development, theory and description

Intervention development

A systematic, iterative and theory-based process modelled on the person-based approach was used to inform development, design and testing [37]. This method was primarily used to ensure development was in close collaboration with end users and to optimise intervention acceptability, feasibility, and engagement. This process included two phases; an intervention development and testing phase, followed by an evaluation and follow-up phase. The draft intervention content was modelled on an existing sexual wellbeing intervention [38]. In the first phase, evidence reviews and a qualitative synthesis of data from semi-structured interviews and focus group discussions with end users and field content experts were used to identify core or essential elements of the intervention. Additional interviews with both types of participant were then used to review and revise paper-based

versions of the content. This was to ensure it was relevant and meaningful to users. An initial prototype version of the intervention was subsequently built using LifeGuide software [39] which provides tools for developers to author, edit, deploy and trial interventions. Further modifications were then made based on usability testing and additional rounds of qualitative interviews. These steps were carried out prior to making further revisions and then building a final version for evaluation. In the second phase, evaluation of the intervention was conducted based on the quantitative and qualitative data exploring preliminary efficacy, usage and acceptability data which are presented in this paper.

Theoretical underpinning

Since the intervention was delivered in an online format, its theoretical underpinning was based on the unified theory of acceptance and use of technology (UTAUT), a widely used model of technology acceptance and usage intention [40]. This model integrates a number of relevant technology acceptance and behaviour change theories including self-efficacy, theory of reasoned action, technology acceptance, planned behaviour and social cognitive theory. Critical to the TAUT model are the concepts of perceived usefulness and ease of use. Central determinants of intentions and usage are performance and effort expectancy, social influences and facilitating conditions, with factors such as age, gender, prior experience and voluntariness to use assumed as moderators of these effects [41].

Intervention description

The finalised version of the intervention (prostate.lifeguidewebsites.org) consisted of a five-step programme designed to maximise sexual wellbeing in men living with prostate cancer. The five steps were as follows: i. Sexual wellbeing and prostate cancer. ii. Changes and coping with changes. iii. Maintaining and improving your sex life. iv. Exploring sexual pleasure. v. Facing the future. In addition, a user toolkit containing a series of quick guides was also included. Each step varied in length from 12 to approximately 40 web-pages. Information was also layered using page tabs meaning that while all participants were required to view core information, other information could be skipped or viewed at a later date. The intervention provided tailored information and support based on user's treatment type, relationship status and sexual orientation with the programming allowing different information to appear on screen based on the responses given to the brief tailoring questions participants completed during initial registration. Participants were encouraged to use the programme with their partner and specific, tailored information was included for partners. This included, for example, information for female partners on women's health, couple communication activities, as well as advice on talking to a partner's health

care team. It was recommended that users complete the steps in sequence over the 3-month intervention period. However, a key design feature of the intervention was that all steps were accessible from the start of the intervention period. It was also emphasised to participants that the intervention was designed as a resource which could be returned to at numerous times to revisit previously viewed sections or to view or complete unfinished steps. Participants received a tick mark over each step which could be seen each time they logged in. This was to indicate which steps they had already completed.

Each step consisted of a series of web-pages containing text-based information, infographics, videos highlighting patient experiences and instructional videos delivered by healthcare professionals. Some steps also included exercises, activities and other resources for participants. These included a couple’s communication activity and a printed checklist for participants to use when discussing sexual issues or concerns with their healthcare professional. The intervention content also included important behaviour change components and techniques including use of social support, information about health consequences, instruction on how to perform a behaviour, demonstration or modelling of behaviour and use of prompts, reminders and cues [42]. Key principles and characteristics of the final intervention version is shown in Table 2. A screenshot of the intervention homepage is shown in Figure 1.

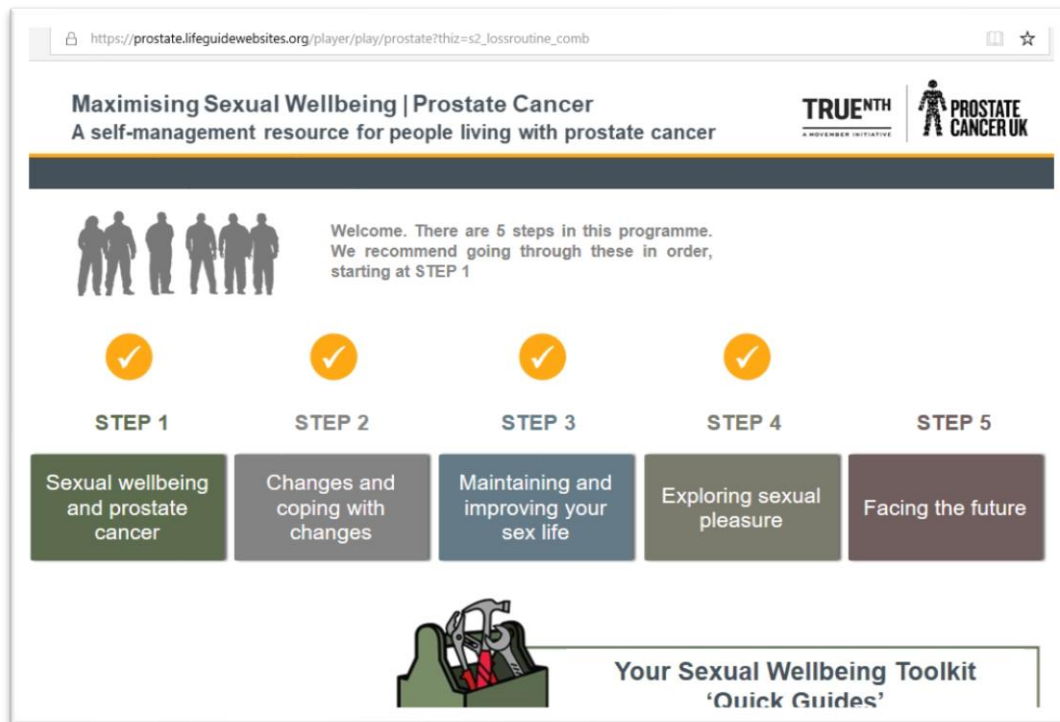
Table 2. Key principles and characteristics of the final intervention

Objectives of intervention	Key features of intervention included to meet objective
To normalise sexual concerns associated with prostate cancer and its treatment and address patient and partner expectations of potential sexual recovery	<ul style="list-style-type: none"> - Provide case based examples including patient experience videos. - Provide potential side-effect information including common methods of coping and managing individual side-effects.
To acknowledge changes or potential loss of sexual function and promote resilience and effective coping strategies	<ul style="list-style-type: none"> - Promote benefits of adapting to a “new sexual normal” and of adopting new approaches and working as a couple. - Provide instructional and demonstration videos presented by health professionals.
To provide personalised information and support based on need included treatment type, sexual orientation and partner status	<ul style="list-style-type: none"> - Provide layering of information and support based on need (ensuring intervention can be used briefly but can also facilitate more in-depth or intensive support based on user need).
To promote increased sexual wellbeing conversations between partners and health professionals	<ul style="list-style-type: none"> - Provide printable health professional communication aid. - Provide printable couple communication exercise. - Provide specific supportive information for partners to promote shared intervention usage.

To provide usable, easily accessible and relevant support available at all stages of care

- Include printable exercises and activities to be used as prompts or reminders of key points.
 - Provide information on appropriate support services based on need.
 - Use simple design interface with core information provided on main web-pages and selected additional information available based on user preference.
-

Figure 1. Intervention screen shot



Outcomes

Since the objectives of the study were to explore efficacy of the intervention and examine usage data and user perspectives on usability and acceptability, a 3-month pilot study was conducted. Efficacy was assessed using pre and post intervention measurements of a self-reported online survey that included a question exploring knowledge and understanding, two questions on sexual satisfaction and two questions on comfort discussing sexual issues (with healthcare professionals and with a partner). Participants were asked to rate how much they agreed with the five different statements using a 4-point Likert scale anchored with 'strongly disagree' and 'strongly agree' at either end. A composite efficacy score /20 was calculated by combining the scores for all five statements.

Intervention usage was determined by calculating the number of intervention sessions (logins) for each participant, as well as the duration of each session and the total time spent using the intervention over the 3-month evaluation phase. In addition, participants were classified as ‘completers’ or ‘non-completers’ based on whether or not they had completed at least four of the five intervention steps.

Usability and acceptability were determined based on different methods including a brief online survey and free text responses to two questions asked at the 3 month follow-up assessment. This survey was based on a modified and reduced version of the System Usability Scale [43]. Modifications were made to ensure the questions were relevant to assessment of intervention acceptability. This included the addition of questions on the look/design of the programme, as well as the relevance of the information provided. Participants were asked to rate how much they agreed with each of six statements using a 4-point Likert scale anchored with ‘strongly disagree’ and ‘strongly agree’ at either end. A composite usability score /24 was calculated by combining the scores for all six questions. Participants were also asked whether they would or would not recommend the intervention to others (yes, not sure, or no). Lastly, participants were asked to provide free text responses to the following questions: 1. Did you gain anything from using the intervention? And 2. Do you have any recommendations for how the intervention could be improved?

Data analysis

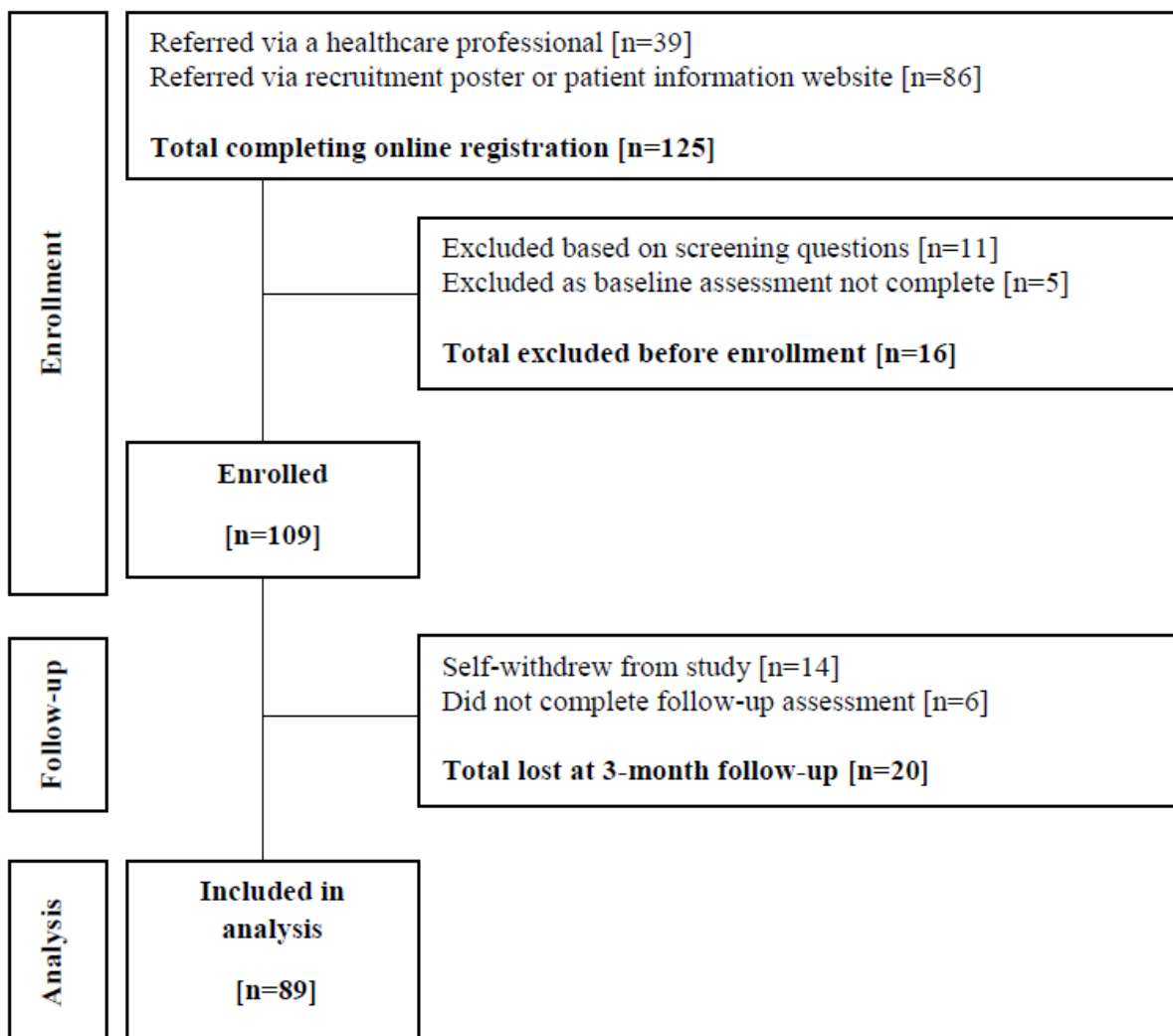
Data were exported into SPSS version 25.0 (SPSS, Chicago, IL) which was used to provide a descriptive analysis of demographic data, intervention usage data and usability ratings. To assess intervention efficacy paired sample t tests were used to compare mean pre and post intervention efficacy measures for the composite and individual question scores. Data were tested for normality of distribution and a Bonferroni adjusted p value of $p < 0.008$ (0.05/6) was used to allow for multiple comparisons. Estimated effects sizes for pre-post intervention effects were also calculated using the following criteria: 0.00-0.19: Insignificant; 0.20-0.49: Small; 0.50-0.79: Medium; 0.80+: Large [43]. Independent sample t tests were then used to test for any significant differences between composite and individual usability question scores between participants classified as ‘completers’ (those who accessed at least four of the five intervention steps) and those classified as ‘non-completers’.

Results

Participant flow and retention

Participants were recruited to the study between February and July 2019. A total of 125 potential participants completed the initial online registration, however, 16 of these were not enrolled on the basis of their responses to the screening questions or as they did not complete the baseline assessment questions. A total of 109 men were therefore enrolled to the study and provided informed consent to participate (Figure 2 includes a participant flow diagram). Of these, 20 were lost to follow-up at 3 months due to self-withdrawal (defined as no intervention usage or logins after initial registration) or non-completion of follow-up assessment questionnaires. This resulted in data from 89 participants being included in the final analysis.

Figure 2. Participant flow diagram



Participant demographics

Most men (n=66: 74%) were between 50-69 years of age and the majority (n=83: 93.3%) were from a white ethnic background. Surgical intervention alone (not in combination with any other form of treatment) was the single most common form of treatment received (n=53: 59.6%) with combined treatment (including radiotherapy and hormone therapy) was the second most common (n=20: 22.4%). Full demographic details of participants are shown in Table 3. There were no observable differences in demographics between the men included in the analysis and the 20 who were lost to follow-up.

Table 3. Demographic details of participants enrolled in the study

	Included in analysis (n=89) N (%)	Withdrawals (n=20) N (%)
Age category		
18-49 years	1 (1.1%)	0 (0.0%)
50-69 years	66 (74.2%)	16 (80.0%)
70+ years	22 (24.7%)	4 (20.0%)
Ethnicity		
White	83 (93.3%)	19 (95.0%)
Asian / Asian British	1 (1.1%)	0 (0.0%)
Black / African / Caribbean / Black British	4 (4.5%)	1 (5.0%)
Other	1 (1.1%)	0 (0.0%)
Previous sexual care or support received		
Yes	58 (65.2%)	9 (45.0%)
No	31 (34.8%)	11 (55.0%)
Timing of any previous sexual care or support received		
At diagnosis	16 (18.0%)	5 (55.5%)
During treatment	10 (11.2%)	4 (44.4%)
Both	32 (37.2%)	0 (0.0%)
Type of prostate cancer treatment received		
Surgery only	53 (59.6%)	17 (85.0%)
Radiotherapy only	9 (10.1%)	0 (0.0%)
Hormone therapy only	7 (7.9%)	0 (0.0%)
Combined therapy	20 (22.4%)	2 (10.0%)
Treatment phase		
Pre-treatment or on ongoing treatment	20 (22.5%)	16 (80.0%)
Within 6 months of completing treatment	37 (41.6%)	4 (20.0%)
More than 6 months after completing treatment	32 (35.9%)	0 (0.0%)
In a relationship		
Yes	82 (91.1%)	20 (100.0%)
No	7 (5.6%)	0 (0.0%)
Usual partner gender		
Female	81 (91.0%)	20 (100.0%)
Male	8 (8.9%)	0 (0.0%)

Efficacy data

Data were normally distributed. Based on the mean differences in pre and post intervention (3 month) self-reported measures, a significant improvement was observed in total composite efficacy scores ($t = 9.570$; $P = 0.001$) with a medium estimated effect size calculated (Cohen's $d = 0.577$) (See Table 4). For individual survey items, significant improvements were seen in mean scores for 1: Understanding of how to manage the impact of treatment ($t = 3.660$; $P = 0.001$) and 2: participant perceptions of their ability to maintain a satisfying sex life despite cancer treatment ($t = 7.643$; $P = 0.001$). No significant effects were found for participants mean current level of sexual satisfaction, or level of comfort with discussing sexual issues with a partner or a health professional.

Intervention usage data

Analysis of programme use during the 3-month intervention phase indicated that engagement with the intervention varied, suggesting that participants used the intervention differently based on their individual needs and preferences. Participants completed a median of 3.0 sessions (Range 1 to 11 sessions). The median session duration was 22.0 minutes (Range: 8 to 77 minutes) with an overall total usage time of 78.0 minutes (Range: 18.0 to 284.0 minutes) (See Table 5). 45 participants (50.6%) completed at least four of the five intervention steps and were subsequently classified as 'completers'. While the number of sessions and time of each session reduced each month over the duration of the intervention period (See Figure 3 and Figure 4), 85.4% ($n=76$) and 65.2% of participants ($n=58$) were still using the intervention in the second and third month of the intervention phase.

Usability and acceptability data

Based on the post intervention survey data, overall usability scores were found to be acceptable (total composite score /24: 19.68; SD: 0.56; percentage agreement 82.0%). The highest levels of agreement were observed for the questions on 'trust in the programme' (3.36/4; SD: SD=0.55; percentage agreement 93.3%) and if 'information included was useful to me' (3.77/4; SD: SD=0.53; percentage agreement 94.3%). The lowest agreement scores were found for the questions 'I liked the look of the programme' (2.87/4; SD: SD=0.47; percentage agreement 71.7%) and 'I found the programme easy to use' (3.03/4; SD: SD=0.69; percentage agreement 75.7%). Independent sample t tests identified there were no significant differences in composite or individual question scores on the usability survey between participants classified as 'completers' versus those classified as 'non-

completers' (See Table 6). 78.5% of participants agreed with the statement that they would recommend the intervention to others. Participant's responses to questions on what they gained from using the intervention and any recommendations for how it could be improved are summarised in Table 7.

Table 4. Mean differences in pre and post intervention (3 month) self-reported efficacy measures with estimated effect sizes

How much do you agree with each statement?	Mean baseline score (SD)	Mean score at 3 months (SD)	t	P^a (2-tailed)	Effect size (Cohen's <i>d</i>)	Effect size interpretation
I currently have a satisfying sex life	1.89 (0.92)	1.90 (0.94)	0.376	0.708	0.010	Insignificant
I have a good understanding of how to manage the impact of prostate cancer treatment on my sex life	2.31 (0.86)	2.57 (0.85)	3.660	0.001*	0.517	Medium
I can have a satisfying sex life despite prostate cancer treatment	2.38 (0.79)	3.17 (0.78)	7.643	0.001*	1.001	Large
I am comfortable discussing sexual issues with a partner	3.08 (0.72)	3.12 (0.70)	0.851	0.397	0.055	Insignificant
I am comfortable discussing sexual issues with a health professional	2.81 (0.74)	2.82 (0.71)	0.241	0.810	0.014	Insignificant
Total composite score /20	12.23 (2.46)	13.62 (2.31)	9.570	0.001*	0.577	Medium
^a Bonferroni adjusted p value for multiple comparisons: p<0.008. * Denotes a significant pre-post intervention effect. Effect size interpretation. 0.00-0.19: Insignificant; 0.20-0.49: Small; 0.50-0.79: Medium; 0.80+: Large. Statements scored /4 based on responses on a 4-point scale anchored with 'strongly disagree' and 'strongly agree' at either end. SD: Standard deviation						

Table 5. Median and mean values for programme usage data

Usage measure	Median (IQR ^a)	Mean (SD)
Number of sessions	3.0 (4.0)	3.8 (1.98)
Duration of each session	22.0 (18.0)	36.4 (16.7)
Duration of total usage time	78.0 (80.0)	115.2 (43.5)

^a Interquartile range.
SD: Standard deviation

Table 6. Mean and percentage agreement scores for usability survey data

How much do you agree with each statement?	Mean score (SD) N=89	% agreement	Mean score (SD) Completers** N=45	Mean score (SD) Non-completers N=44	P value (difference between completers and non-completers)
I was satisfied with the programme	3.16 (0.56)	79.0%	3.21 (0.68)	3.11 (0.71)	0.436
I found the programme easy to use	3.03 (0.69)	75.7%	3.15 (0.70)	2.91 (0.67)	0.096
I was able to move through the programme easily	3.49 (0.56)	87.3%	3.57 (0.56)	3.42 (0.61)	0.366
I liked the look of the programme	2.87 (0.47)	71.7%	2.89 (0.67)	2.85 (0.71)	0.446
I felt I could trust the programme	3.36 (0.55)	93.3%	3.26 (0.54)	3.47 (0.65)	0.342
The information included in the programme was useful to me	3.77 (0.53)	94.3%	3.84 (0.55)	3.71 (0.48)	0.632
Total composite score /24	19.68 (0.56)	82.0%	19.92 (0.61)	19.47 (0.63)	0.237

Statements scored /4 based on responses on a 4-point scale anchored with 'strongly disagree' and 'strongly agree' at either end.

** Completers were defined as participants who completed at least 4/5 steps of the online programme.

Table 7. Summary of participant views on what they gained from using the intervention and recommendations for how it could be improved

Views on what was gained from using intervention		
Explanation	N/141 comments (%)	Category
The programme provided information on issues not previously thought about	33 (23.4%)	Information
The programme provided useful warnings on possible effects of treatment	26 (18.4%)	Information
The programme helped to normalise sexual problems	22 (15.6%)	Information / Tone or language
The programme provided new information not previously discussed with health professionals	20 (14.2%)	Information
The programme provided information which was relevant and useful to me as an individual	11 (7.8%)	Information / Personalisation
The programme helped provide ideas for different approaches to manage sexual problems	9 (6.4%)	Information / Confidence or self-efficacy
The programme provided information that could be viewed and discussed with partner	9 (6.4%)	Information / Communication
The programme provided a positive tone and message which was reassuring	5 (3.5%)	Tone or language / Confidence or self-efficacy
The programme helped to increase my confidence	4 (2.8%)	Confidence or self-efficacy
The programme provided a reminder of information that was previously discussed with health professionals	2 (1.4%)	Information
Suggested improvements that could be made to the intervention		
Explanation	N/66 comments (%)	
Make intervention available to patients before treatment starts	32 (48.5%)	
Make intervention available as a mobile app	17 (25.7%)	
Include more support such as someone to contact for advice	14 (21.2%)	
Make intervention available in an offline or printed format	3 (4.5%)	

Figure 3. Box-plot showing number of sessions each month over the duration of the intervention period

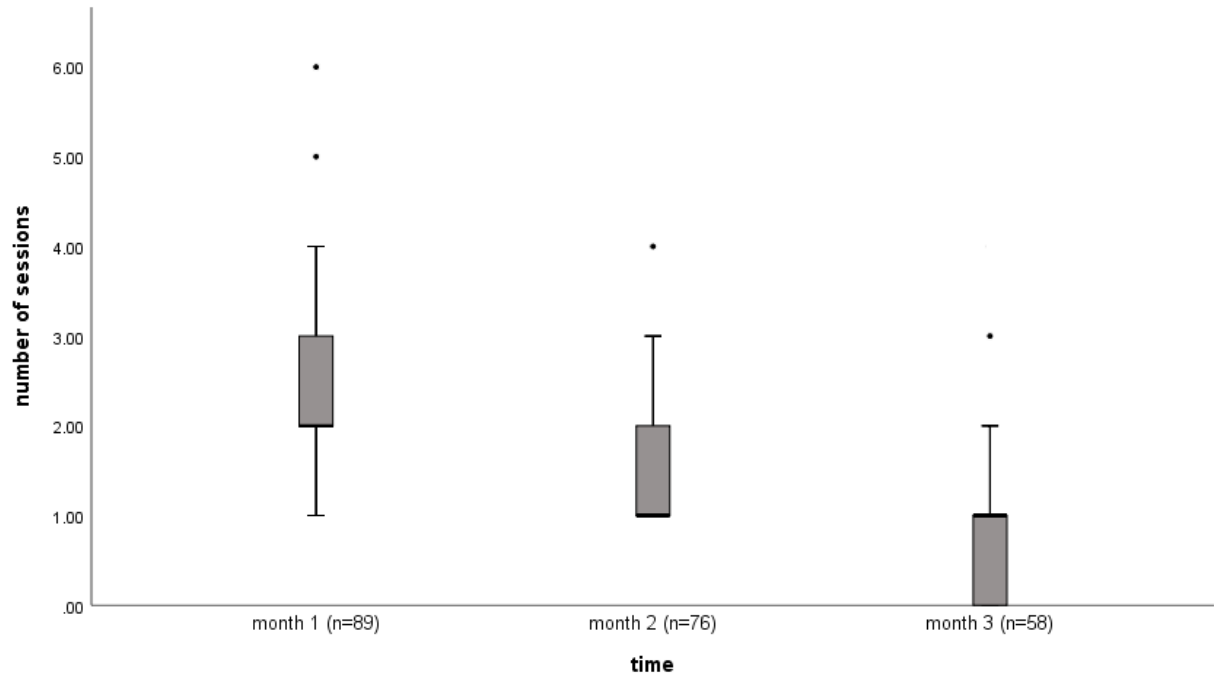
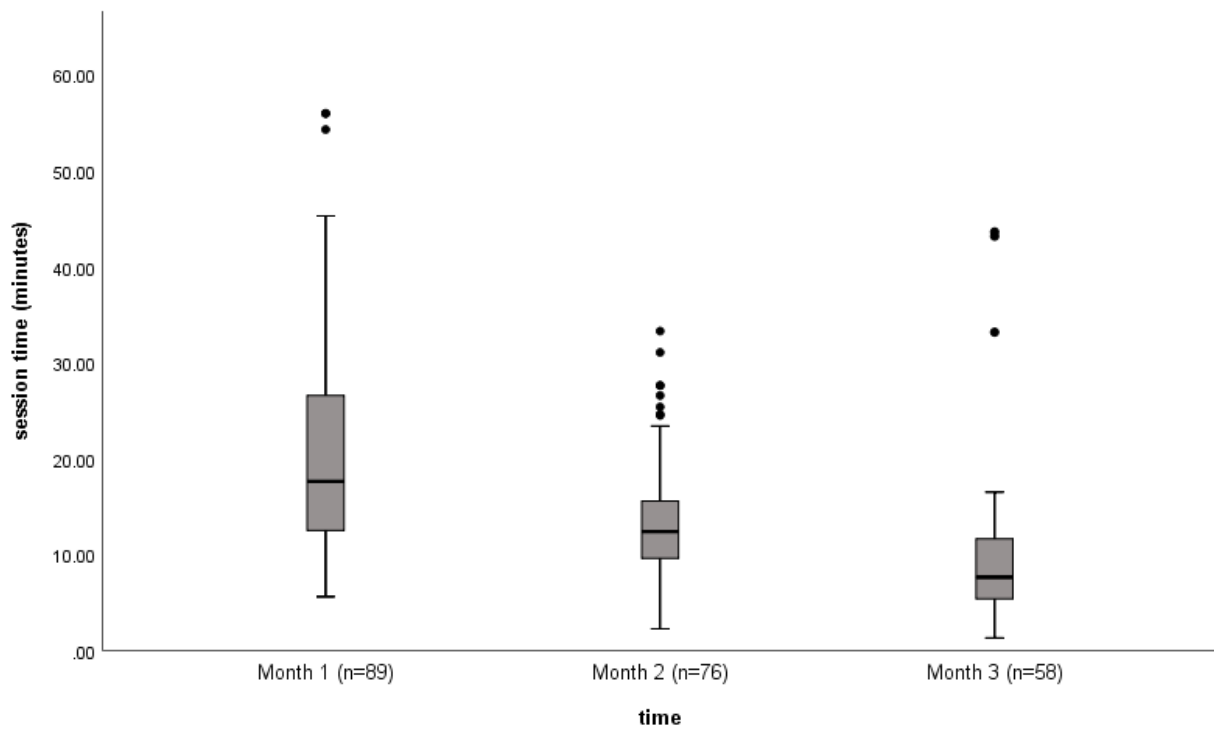


Figure 4. Box-plot showing time of each session over the duration of the intervention period



Discussion

Principal Findings

Findings from this study provide evidence for the efficacy of an online intervention designed to maximise sexual wellbeing in men living with prostate cancer. Analysis of self-reported outcome data found that the intervention resulted in significant improvements at 3 month follow-up in overall efficacy scores, as well as in participants understanding of how to manage the impact of sexual concerns, and their perceived ability to have a satisfying sex life despite prostate cancer treatment. Findings also indicated that the programme had good overall usability and acceptability. While participants utilised the online self-management intervention in markedly different ways, users typically engaged well, taking part in multiple sessions over the intervention period. This is one of the first studies to evaluate the potential effectiveness, and usage of a tailored, sexual wellbeing support for men and partners living with prostate cancer which is delivered using an online platform. A key strength of the intervention appears to be its flexibility with support able to be personalised based on user's needs and delivered at any stage of care.

Intervention efficacy

Self-reported measures at 3 month follow-up were used to evaluate intervention efficacy and demonstrated significant overall improvements in comparison to baseline scores. Improvements with a medium effect size were found in the extent to which participants agreed that they had sufficient information to manage the impact of prostate cancer on their sex life. In addition, the extent to which participants agreed there was potential for them to have to have a satisfying sex life following treatment also improved significantly. Findings indicate that the intervention had a positive influence on men's self-perceived knowledge and understanding of how to manage sexual issues, but more importantly, also appeared to contribute towards a substantial increase in self-efficacy or a belief that a satisfactory sex life could be achieved following treatment. This indicates a potentially important prerequisite for maintaining behavioural change. Higher coping self-efficacy can result in more effective responses to behavioural barriers or setbacks, with individuals more able to apply behaviour change maintenance strategies such as action planning [45,46].

Examination of individual survey item scores suggested that there were no effects of the intervention on participant's current level of satisfaction with their sex life; or on level of comfort discussing sexual issues with a partner or with a healthcare professional. The extent to which participants agreed that they were happy with their

current level of satisfaction was low at baseline and while this may have been a factor motivating potential participants to take part in the study; the intervention did not lead to improvements in this measure. This may have been due to the comparatively short timescale of the evaluation phase. Changes to sexual function post treatment are dependent on treatment type [9], with many effects having a long-term or persistent impact. Coping with these changes and adapting new practices as part of an individual's sex life can take time. It may be necessary to use longitudinal studies to evaluate interventions aimed at improving satisfaction with current sex life, which is a complex, multi-factorial concept closely related to overall quality of life [47] and potentially mediating factors such as relationship status and expectations of recovery. The extent to which participants agreed that they were comfortable discussing sexual issues also did not change, but these scores were relatively high at baseline. This supports findings from studies which have found level of comfort in men with prostate cancer is not a significant barrier to discussing sexual issues [21,48].

Usage, usability and acceptability

Findings indicated that while overall, participants accessed the intervention a median of 3 times, patterns of usage appeared to differ between participants. For example, engagement varied with some using the intervention more frequently over a number of shorter sessions throughout the intervention phase and others appearing to use it a limited number of times but with longer intervention sessions. This is reflected in the wide range of session numbers and session times of between 1 and 11 sessions and 8 and 77 minutes in duration. While usage reduced over the intervention period, around 65% of participants still showed engagement with the programme in the final month. Previous evidence has demonstrated levels of engagement with web-based interventions that are comparable to face-to-face delivery methods [49] and it has been suggested that online resources are viewed as an acceptable and widely used source of information on sexual concerns [50]. Various needs of web-based interventions have been identified including improving couple communication, as well as providing information on sexual side-effects, rehabilitation approaches and realistic expectations of recovery [51]. The reasons for the variation in user engagement in this study may be related to a number of factors, including that the intervention was intended to be used differently based on users individual needs and preferences. There is also evidence for an association between perceived usability or ease of use and engagement [52]. Usability and design issues could be additional reasons that may have accounted for different user engagement in this study. While no significant differences were found between users who completed at least four of the five intervention steps and those who did not, there was a slightly lower score in the non-completer group in terms of their agreement with the question on

ease of using the programme and some participants may have discontinued use of the intervention due to technical or usability issues. While overall, the intervention was seen as acceptable to participants with a good level of engagement observed, it is critical that any usability or acceptability issues are explored in detail and addressed in future re-designs of the intervention. This is important in order to maximise engagement since intention to use web-based interventions is mediated by perceived ease of use, usefulness as well as social determinants. Increased engagement may be related to behavioural or demographic characteristics including previous experience of using web-based programmes [40,53,54]. In addition, mode of intervention delivery may also have had an influence on engagement, particularly in terms of the number of recorded sessions. The intervention was designed for use on a laptop or desktop computer. These may be accessed less frequently than mobile devices so delivery of the intervention in a mobile app form might have increased the number of sessions completed by participants. This was reflected in some views on the intervention, with use of an app format the second highest suggested improvement that could be made (See Table 7).

Usage may also have been impacted by the behavioural components of the intervention. Although the intervention included common behaviour change techniques such as information on health consequences, social support and use of reminders and prompts; it did not include other methods commonly associated with sustained and repeated use of online programmes. For example, regular self-monitoring or use of goals setting. While the flexibility and open access of the intervention (i.e., not locking steps until completion of a previous step) may have increased initial engagement, it might also have been anticipated that this might make it less likely that participants would return to the intervention as frequently. However, this was not the case and a reason for this may have been that users returned to review previous information. This is evidenced by data from the usability survey which indicated that overall the intervention was seen as being usable, with tailored information provided regarded as useful and relevant (See Table 6). Another key reported benefits of the intervention were that participants reported a high level of trust in the information provided and reported that it helped to facilitate participants and partners to initiate conversations about sexual wellbeing that they might not otherwise have had (See Table 6). This was observed despite participants reporting relatively high levels of comfort discussing sexual issues with a partner (See Table 4). Couple communication about sexual wellbeing can be regarded as complex and often difficult to initiate [21]. However, such communication is important and is an essential step in managing concerns and supporting sexual wellbeing recovery.

Limitations

One limitation is that we were unable to explore in detail the reasons for withdrawal from the study or examine factors responsible for increased engagement with the intervention. The sample of participants was also relatively homogeneous which may limit generalisability of study findings. The assessment of usability was based on a modified version of the System Usability Scale [43] which limits the ability to compare findings on programme usability with those of other studies.

Conclusion

In this paper, efficacy, usage and acceptability data is presented for a tailored, online intervention designed to maximise sexual wellbeing in men living with prostate cancer. The study provides preliminary evidence for the efficacy of the intervention which was perceived as being usable and acceptable to participants with evidence of sustained usage. Digital interventions may provide access to low cost, scalable, updatable and evidence-based information to manage sexual concerns after prostate cancer treatment. By acknowledging the impact of treatment on sexual wellbeing and providing appropriate support at all stages of care, this intervention might have potential to improve patient-important outcomes and could easily be made available in routine practice. Further research will be conducted to explore factors associated with increased engagement and these findings will be used to refine content prior to testing as part of larger longitudinal and randomised controlled studies examining longer-term intervention effectiveness on a wider range of patient important outcomes, including symptom distress, self-efficacy, knowledge, couple communication, sexual satisfaction and overall quality of life. These studies will also be used to examine the influence of key demographic factors such as age profile, treatment type, relationship status and sexual orientation on these outcomes.

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