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Supporting self-management by an e-health application in men with prostate cancer who have had their prostate removed

Submission date
29/05/2018

Recruitment status
No longer recruiting

Registration date
07/06/2018

Overall study status
Completed

Last Edited
11/09/2024

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English Summary
Background and study aims
Prostate cancer is increasingly common and is the leading cause of cancer death in 24 countries. The most common treatment is surgery. However, after surgery many men are affected by urinary incontinence and problems maintaining an erection, which can affect their quality of life. These symptoms can be managed using self-care exercises, which means that cancer survivors should be encouraged to be active in self-care management. We designed an eHealth application (ePATH), based on a motivation theory, to support men after they have had their prostate removed. The application can be installed on the computer as well as on the smartphone. The aims of the study are to compare how well the eHealth-application works, compared with standard care on urinary incontinence and sexual functioning, and to test if ePATH affects the patient's activation, motivation, overall well-being and health literacy over time, compared to standard care.

Who can participate?
Men diagnosed with prostate cancer who are treated with surgical removal of the prostate (radical prostatectomy).

What does the study involve?
The participants will be randomly allocated to two groups. One group will receive the usual advice and follow-up at the clinic following prostate removal. The other will receive the usual care and be encouraged to use the ePATH app. The app contains information about the disease, treatment and self-care, suggested self-care activities, a messaging function to health care contacts and ability to rate symptoms, track activities and progress over time. The app also has an optional notification function, so that the user can get reminders to perform activities. Both groups will be followed up using interviews and questionnaires for a year after surgery.

What are the possible benefits and risks of participating?
Men who use the ePATH app might benefit from improved knowledge of their condition and self-care. There are no risks involved in participating in the study. All participants receive the usual follow-up.

Where is the study run from?
Linnaeus University (Sweden)

When is the study starting and how long is it expected to run for?
September 2015 to December 2021

Who is funding the study?
The Medical Research Council of Southeast Sweden, the Kamprad Family Foundation of Entrepeneurship, Research and Charity and the Swedish Cancer Society.

Who is the main contact?
1. Dr Amanda Hellström, Senior Lecturer at the Faculty of Health and Life Science, Linnaeus University
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2. Camilla Wennerberg, registered nurse, urotherapist and doctoral student in the project, Faculty of Health and Life Science, Linnaeus University
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Contact information

Type(s)
Scientific

Contact name
Prof Mirjam Ekstedt

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39234

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CAN 2017/748

Study information

Scientific Title

Enhanced patient activation in cancer care transitions – a randomized controlled trial of a tailored eHealth intervention for men with prostate cancer

Study hypothesis
1. ePATH will have greater effect on patient outcomes of UI and sexual health at 1, 3, 6 and 12 months in users compared to patients receiving standard care after radical prostatectomy
2. ePATH will have greater effect on patients level of activation, motivation, overall well-being and adherence and endurance to self-care at 1, 3, 6 and 12 months following radical prostatectomy in users compared to patients receiving standard care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional board of ethical review, Linköping, 23/03/2018, Dnr 2016/484-31

Study design
Pragmatic multi-center block-randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet in Swedish

Condition
Prostate cancer

Interventions
The study is a pragmatic multi-center block-randomized controlled trial (RCT) with two study arms: standard care (control arm) and an eHealth assisted standard care (Intervention) for patients undergoing radical prostatectomy. The intervention contains tailored comprehensive information about diagnosis and treatment, a standardized care plan, list of medications and self-care support. ePATH supports functions enabling the patient to communicate with his health care contacts and report self-care activities (e.g. pelvic floor muscle training or exercise), symptoms of relevance for diagnosis (e.g. urinary incontinence, sexual health, mood etc.) and follow reported data over time. Notifications of exercises or medication can be activated to support and remind the patient to do them.
A computer-generated block randomization list will be used. The sequence will be concealed from the researchers using sequentially numbered, opaque, sealed envelopes. Envelopes will be

opened consecutively by one researcher in our team, in order to allocated participants to one of the study arms. The researchers involved in the study are blinded to block size(s), if there is only one block size or different block sizes.
All study participants (both arms) will be followed using questionnaires before surgery (between being informed of the diagnosis and the date of surgery), 1 month, 3 months, 6 months and 12 months after surgery. We will collect data on health, symptoms specific for prostate cancer, self-efficacy, patient activation, health literacy, sleep, depression and fatigue. The participants will also be asked to participate in an interview approximately 6 months after surgery. The interviews will focus on how much ePATH was used, how the support given (standard care or standard care + ePATH) was experienced and how they cope with and handle symptoms and rehabilitation in their daily life.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome measure
1. Function assessed using Expanded Prostate Cancer Index Composite 26 (EPIC-26)
2. Physical activity assessed using Saltin–Grimby Physical Activity Level Scale (SGPALS)
3. Knowledge and confidence in managing condition assessed using Patient Activation Measure (PAM-13)
4. Basic needs satisfaction using Needs Satisfaction and Frustration Scale (NSFS)
Assessments will be carried out through a web-questionnaire at baseline (before surgery), 1 month, 3 months, 6 months and 12 months after surgery

Secondary outcome measures
1. Sleep Condition Indicator Short Form (SCI-2)
2. Patient Health Questionnaire (PHQ-9)
3. Japanese Communicative and Critical Health literacy scale
4. The Cancer Behavior Inventory – B
5. Fatigue Severity Scale (FSS)
Assessments will be carried out through a web-questionnaire at baseline (before surgery), 1 month, 3 months, 6 months and 12 months after surgery

Overall study start date
01/09/2015

Overall study end date
31/12/2021

Eligibility

Participant inclusion criteria
1. Able to speak, read and understand Swedish
2. Able to get a mobile ID for safe handling of information

3. Access to an email address
4. Computer literate
5. Diagnosis of prostate cancer
6. Suitable for surgical treatment

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
The anticipated number of participants is 242, 121 patients in each study arm. A computer-generated block randomization list will be produced by an independent statistician to allocate participants to the two study arms. The sequence and size of the blocks will be concealed from the researchers

Total final enrolment
170

Participant exclusion criteria
Does not meet inclusion criteria

Recruitment start date
02/01/2018

Recruitment end date
31/08/2019

Locations

Countries of recruitment
Sweden

Study participating centre
Kirurgkliniken, Länssjukhuset i Kalmar
Kalmar
Sweden
SE-39126

Study participating centre

Urologkliniken, Länssjukhus Ryhov
Jönköping
Sweden
SE-55185

Study participating centre
Urologkliniken, Centrallasarettet i Växjö
Växjö
Sweden
SE-35234

Sponsor information

Organisation
Linnaeus University

Sponsor details
Nygatan 18B
Kalmar
Sweden
SE-39234

Sponsor type
University/education

Website
http://lnu.se

ROR
https://ror.org/00j9qag85

Funder(s)

Funder type
Not defined

Funder Name
Forskningsrådet i Sydöstra Sverige (Medical Research Council of Southeast Sweden)

Funder Name

Familjen Kamprads Stiftelse (The Kamprad Family Foundation of Entrepeneurship, Research and Charity)

Funder Name
Cancerfonden (The Swedish Cancer Society)

Funder Name
Cancerstiftelsen i Kalmar län

Results and Publications

Publication and dissemination plan
In 2018, we intend to publish a paper about the development of the ePATH from a patient perspective. Qualitative data from interviews with participants will be submitted to high-impact peer-reviewed journals in 2019. In 2020 we aim to publish the first papers on the quantitative, longitudinal questionnaire data. We will also disseminate our research through conference proceedings and posters and at our website.

Intention to publish date
30/06/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Mirjam Ekstedt (mirjam.ekstedt@lnu.se). De-identified, quantitative will be available upon request from 2022. Data will be saved for 5 years after study completion, and then it will be destroyed. We do not intend to share data with third parties. Individual study participants are able to gain access to their personal data. For scientific review and the sake of transparency, we could provide de-identified data sets on request. However, that is only for critical appraisal of our findings and not for other researchers to publish.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	22/03/2019		Yes	No
Results article		06/09/2023	07/09/2023	Yes	No
Other publications	Patient experiences	05/01/2021	02/02/2024	Yes	No
Results article	Analysis of secondary outcome	10/09/2024	11/09/2024	Yes	No