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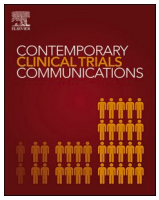

Detailed description of multidisciplinary prehabilitation in patients admitted to nerve sparring radical prostatectomy – A randomized feasibility study protocol

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ABSTRACT

Background: Localized prostate cancer treated with radical prostatectomy is highly effective, though severe side-effects are common after the surgery. Prehabilitation is an approach to optimize patient's physical and mental resources before surgery, to improve postoperative outcomes. The feasibility of a multi-modal home-based prehabilitation program, delivered using telehealth in patients awaiting radical prostatectomy is unknown. This paper describes the development of a prehabilitation program for patients awaiting radical prostatectomy.
Method: A model by The Medical Research Council for developing and evaluating complex interventions (MRC Framework) was used in the development process. The Template for Intervention Description and Replication (TIDieR) checklist was applied for ensuring sufficient description of the interventions. A total of 40 patients will be randomized to either intervention or control group. Patients in the control group will follow standard care. The 4-week prehabilitation programme consists of exercise, pelvic floor exercise, sexual counseling, stress management and nutritional support. The interventions are home-based and delivered using telehealth. Feasibility outcomes will include recruitment, attrition rates, adherence, safety and suitability.
Conclusion: We have developed a multimodal prehabilitation programme, which has the potential to bring tangible health benefits to men with prostate cancer awaiting radical prostatectomy. The results of the feasibility study will inform the design of a fully powered randomized controlled trial.

1. Introduction

Gold standard surgical treatment of localized prostate cancer is radical prostatectomy (RP). RP reduces the incidence of metastasis and significantly improves cancer survival. However, incontinence, erectile dysfunction, fatigue and reduced physical functioning are common side-effects, often resulting in decreased health-related quality of life [1–3]. To address these side effects, it is well-recognized that a biopsychosocial approach is needed, where all aspects and consequences of the disease are taken into account [4].

Prehabilitation aims to optimize the patient's physical and mental resources before surgery, in order to improve postoperative outcomes

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and avoid perioperative/postoperative complications, reduce readmissions and short-/longer-term impairments [5]. Over recent years, the literature on prehabilitation has grown, and although there has been much heterogeneity in prehabilitation strategies, it can be broadly divided into three sub-domains: psychosocial support, optimising nutrition and exercise to improve physical functioning [6,7]. A recent systematic review that evaluated the effect of prehabilitation in men affected by localized prostate cancer [10] showed that studies have generally used single modality interventions (i.e., psychosocial support, optimising nutrition or exercise). However, the authors argued that a combination of different interventions is needed in clinical practice to address the individual's person-centered care needs and that future studies should have multimodal designs to inform holistic models of care and address all patient care needs [8].

This is consistent with prehabilitation guidance from Macmillan Cancer Support in the UK [9] based on evidence that psychological-based prehabilitation, good nutrition and exercise when implemented as individual interventions alongside standard care before cancer surgery yield better outcomes than standard care alone. Therefore, multimodal prehabilitation involving all three intervention modalities is the recommended approach for people with cancer preparing for treatment [9]. By adopting a comprehensive approach that integrates these diverse modalities, not only can patients' physical preparedness for the surgery be optimised, but also resilience and well-being across the continuum of cancer care can be fostered. Despite the difficulty in isolating the specific contributions of each component to improved outcomes, the potential for synergistic effects, enhanced healthcare efficacy and implementation of a holistic patient-centered approach provide a strong rationale for the development of a multimodal home-based prehabilitation program [8].

Multimodal prehabilitation, which is likely to involve a multidisciplinary team of healthcare professionals, is recognized as a complex intervention [10]. Furthermore, where each sub-component of the prehabilitation intervention is carried out in a complex environment, the outcome is likely to be influenced by contextual factors [11]. Therefore, to improve patient care and outcomes throughout the continuum of the cancer pathway, including individualized patient tailored multimodal prehabilitation, it is essential that the development of prehabilitation interventions and context is described in detail [12]. In this way, the experiences and results gained can be used to identify any shortfalls to aid future intervention refinement and implementation within real-life cancer care settings [12].

The aim of this study was to develop and test the feasibility of a 4-week multimodal home-based prehabilitation program, consisting of psychological stress management, nutritional support and physical exercise (including pelvic floor exercise) delivered using telehealth, in prostate cancer patients awaiting nerve-sparing, robot-assisted RP. Herin, we describe the development of the multimodal prehabilitation intervention, using the Template for Intervention Description and Replication (TIDieR) checklist as a framework for ensuring that it is described in sufficient detail to allow replication and completeness of reporting [12].

2. Research design and methods

2.1. Study design

The design of the study is a single blinded, feasibility randomized controlled trial. The instructing therapist or the participants cannot be blinded to the group allocation, due to the nature of the intervention. The two assessors performing the clinical outcome assessment are blinded to the group allocation.

2.2. Study setting

After inclusion the participants are scheduled to attend for an introduction to the study, the online answering of questionnaires, obtaining of baseline information and to undergo physical tests. Randomization will be performed after obtainment of baseline information and the physical testing. The prehabilitation program is Home-based, meaning that all interventions will be performed in participants own homes. TeleHealth is used to deliver information and communicate with the participants throughout the prehabilitation period.

2.3. Participants

Patients referred to nerve sparing robot assisted RP due to adenocarcinoma of the prostate are eligible to participate in the study. Due to the rapid speed of the Danish clinical cancer pathway in prostate cancer, patients who are not recommended for nerve sparing RP are limited to a two-week window for surgery. Consequently, they are ineligible for a four-week prehabilitation program.

Eligible pt. will be recruited at the Urological Department, Regional Hospital Gødstrup i Denmark.

A total of 40 patients will be randomized 1:1 to either intervention group ($n = 20$) or control group ($n = 20$). The randomization will be conducted through REDCap (Research Electronic Data Capture), which is a secure web-based software platform for building and managing online surveys and databases [13]. A sample size of 40 participants is estimated to be appropriate to assess feasibility outcomes and estimate sample size for a definitive trial. This sample size is based on a hypothesis that 80 % of the participants will complete the full follow-up period.

2.4. Selection criteria

The inclusion criteria are: Male >18 years; diagnosed with PC and referred to robot assisted nerve sparing RP; adequacy in written and spoken Danish; cognitively well-functioning; able to understand the study procedures and willing to provide signed informed consent. The exclusion criteria are: severe comorbidities that would prevent the patient from exercising (e.g. recent fractures, severe heart disease or neurological disorders); no possibility to access a smart-phone or tablet; no sufficient ability to handle information in an App.

2.5. Outcome measurement

Outcomes will be measured at baseline, on the day of pre-surgery information and 6 weeks, 6 and 12 months postoperatively. Primary feasibility outcomes include recruitment rate, rates of attrition, adherence, and adverse events. Based on previous studies, we expect the feasibility outcomes will align with the following [14]. The expected recruitment rate is predefined as 55 %. The attrition rates will be evaluated as the percentage of included participants that leave the study before the 12-month of follow-up postoperatively. The predefined attrition goal is 5 % from baseline to the end of prehabilitation, and 20 % from baseline to 12-month follow-up.

Adherence to the home-based exercise interventions will be measured through an online logbook, completed by the participants at the end of every week of the PREHAB-program. Adherence to the exercise will be assessed by investigating how many patients complete the prescribed total exercise volume. This will be assessed by dividing the exercise volume completed, by the targeted exercise volume prescribed over the 4 weeks of prehabilitation. Participants are considered to adhere to interventions if they complete 75 % of the prescribed exercise volume. We expect that 80 % of the participants adhere to the exercise interventions.

Feasibility of the sexual health, nutrition, and mental health intervention will be described as how many participants received the interventions.

Additionally, secondary outcomes on physical activity performance, quality of life, urinary incontinency, erectile dysfunction, and

nutritional status will be collected.

2.6. Intervention

Details of the intervention and comparison elements of the feasibility study are presented below according to items of the TIDieR checklist [12].

2.6.1. Item 1. brief name

The TelePrehabTrial (Tele-Health prehabilitation trial).

Prehabilitation in prostate cancer patients undergoing nerve sparing robot assisted radical prostatectomy: a feasibility randomized controlled trial.

2.6.2. Item 2. why: describing the rationale and theory essential to the intervention

In the development of the prehabilitation intervention, we used a systematic iterative model developed by the British Medical Research Council for developing and evaluating complex interventions (MRC Framework) [11]. The core elements of the MRC framework includes the following, which should be taken into account in all steps of the development of complex interventions: consider context, engage stakeholders, identify key uncertainties, refine interventions, explore economic considerations and develop, refine and (re)test the programme theory [11]. All these elements were considered in our development process.

Patients, healthcare professionals, managers and administrators were involved in the development of the intervention and have an important role in implementing the prehabilitation program. Stakeholder involvement is detailed in Table 1.

To describe how the intervention is expected to lead to effectiveness, a programme theory was developed [11]. The programme theory is visualized in a logic model (Fig. 1) [15].

Based on the existing evidence-base, the following interventions are part of the prehabilitation program.

Exercise for improving physical function: In cancer populations, poor preoperative physical fitness is associated with increased complications, side-effects, hospital length of stay and readmission [16]. Prehabilitation, which includes exercise as a sub-component, has demonstrated efficacy and could lead to a better post-operative outcomes [6,16]. Physical exercise as part of prehabilitation mainly consists of aerobic and/or strength exercise, and aims to optimize physiological resilience to the surgical stressor [10]. For men awaiting surgery for prostate cancer, these exercise modalities have been shown to be feasible [17–20] and evidence suggest that pelvic floor exercise also has an important role to play. For men receiving RP, health related quality of life can be adversely affected by urinary incontinence after surgery [21]. However, engagement in pre-operative pelvic floor exercise can lead to improved recovery of this common surgical side-effect [21,22].

Nutritional support*:* Nutrition plays an essential role in prehabilitation, as numerous studies have demonstrated an association between preoperative malnutrition and poor surgical outcomes, including increased length of hospital stay, delayed wound healing and increased complications due to infection [23,24]. Patients are exposed to complex metabolic responses following surgical stress, and are prone to a delay in recovery [25]. In the preoperative period, the goal is to identify and optimize patients at nutritional risk due to the stress of surgery [25,26]. Malnutrition and poor diet could also play an important role in the progression of prostate cancer [27,28].

Psychosocial support*:* Mental health and psychological state before cancer surgery may influence postoperative recovery and long term wellbeing. Preoperative anxiety, depression and low self-efficacy have been consistently associated with worse physiological surgical outcomes and quality of life [29]. While anxiety and depression are distinct, both can be influenced by uncertainties. Uncertainty can worsen anxiety by triggering worries about negative outcomes, and it can contribute to feelings of hopelessness in depression. Moreover, uncertainties related to health conditions can impact quality of life. Stress management interventions should address the impact of uncertainties on both anxiety and depression, as well as their collective influence on quality of life. Targeted support for managing uncertainties can improve overall well-being and treatment outcomes [29]. To date, the evidence is insufficient to conclude that preoperative psychological interventions are effective, or which interventions are most effective [29]. It is generally recommended that prehabilitation should include a psychological component to identify and help the patient to manage anxiety and depression related to the impending surgery [29].

Sexual health support*:* Radical prostatectomy can adversely impact relationship satisfaction and sexual satisfaction due to treatment-related erectile dysfunction [30]. This can be managed to some extent by a preoperative intervention consisting of strategies to improve post-operative communication regarding sex, realistic expectations regarding sexual activity, erectile dysfunction, and the use of aids [31].

On the basis of current evidence and the results of the stakeholder input, a prototype of the prehabilitation intervention was developed, and was subject to further discussion and refinement by members of the research team.

2.6.3. Item 3 and item 4: what (materials and procedures)

Prior to recruitment, patients will be provided with educational materials that describe the study, and what clinical outcomes will be assessed. All patients assigned to the study will wait 4 weeks before undergoing the surgery.

Patients in the control group will follow standard care, consisting of general information about mobilization, pelvic floor anatomy and muscle function provided by a physiotherapist approximately 1-week before the operation.

Patients in the intervention group will be introduced to the 4-week prehabilitation program and the intervention sub-domains will be adapted to individual patients. They will get access to an App containing the exercise program, which is illustrated through images, text and videos. The App also contains information on the clinical pathway prior to surgery. Patients will also receive instructions on how to install and use the App for access to exercise manuals, and how to use video calls for clinical consultations. Patients in the intervention group will hereafter follow the prehabilitation program in their own homes.

The intervention includes the following:

1) *Exercise:* Home-based individualized exercise consists of unsupervised cardio exercise (moderate intensity) and resistance exercise, i.e., 20 min of resistance exercise on 3 days per week and 30 min of aerobic exercise on 2 days per week.

Table 1
Stakeholders involved in the development of the TelePrehabTrial.

Involved partner	Methods of involvement
Patients, who had undergone surgery for prostate cancer.	Semi-structured group discussion including men affiliated with the Prostate Cancer Association. The themes for the discussion were challenges after the surgery, information and/or interventions deemed beneficial prior to surgery, and rehabilitation after surgery.
Health-care professionals: Doctors Physiotherapists Clinical Sexologist Dietitian Nurses	Group-meetings and workshops discussing ideas about the content of the prehabilitation interventions and organization of the different elements (sub-domains).
Managers	Meetings regarding the organization and booking of individual patients.
Administrators	Meetings regarding resources available.

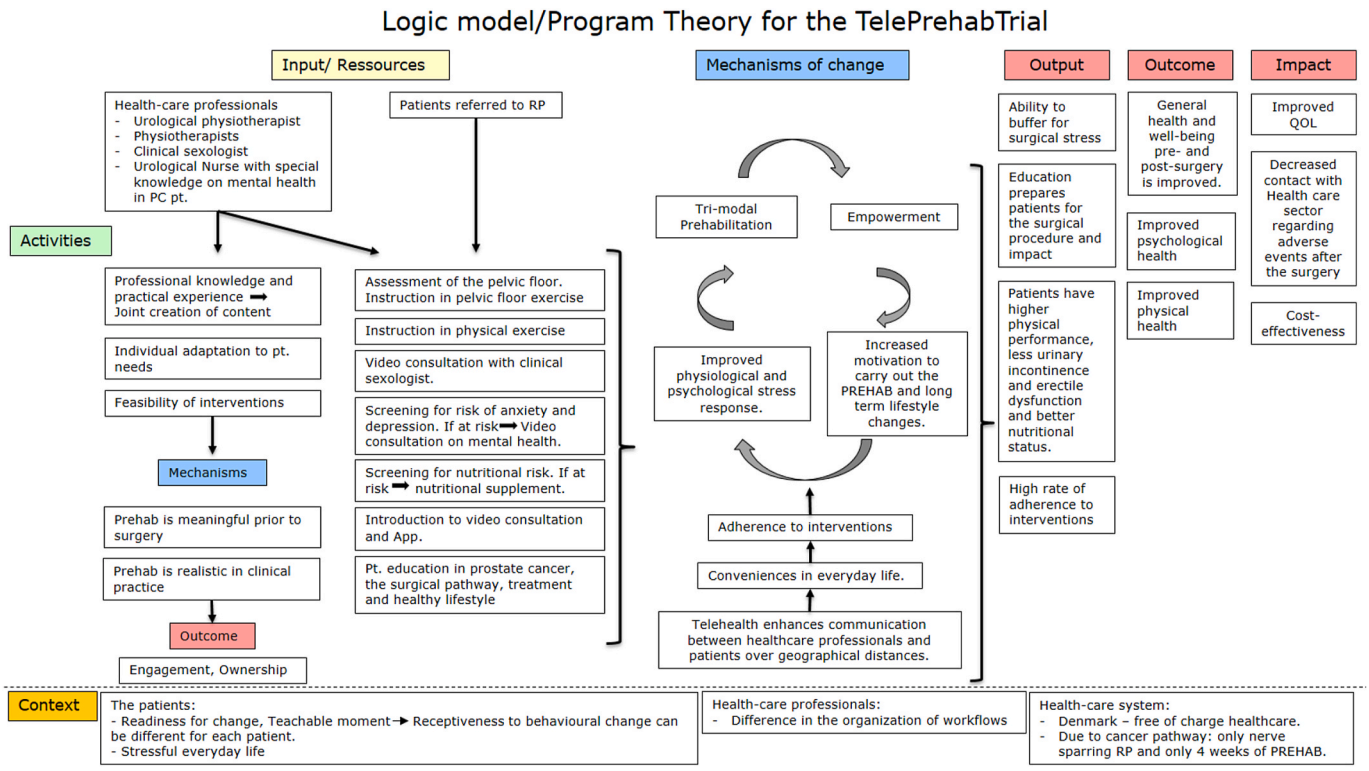

Fig. 1. Program Theory for the TelePrehabTrial.
The Program theory is illustrated using a Logic Model. The Program theory describes how the input/resources are expected to lead to effectiveness. The mechanisms of change may be affected by the context.

2) *Assessment of urination pattern, bladder control and pelvic floor exercise:* Patients will be assessed by a physiotherapist and receive instructions on a pelvic floor exercise program, accessed through the App. To facilitate the learning of how to perform relevant muscular contractions, the physiotherapists will use real time ultrasound guided pelvic floor muscle training. Patients will be instructed to perform pelvic floor exercise daily. Furthermore, the patients are provided with general information about pelvic floor anatomy and muscle function.
3) *Sexual counseling:* Patients will attend one video-consultation with a clinical sexologist, during the prehabilitation period. The consultation will be based on the patients' answers to the questionnaire *International Index of Erectile Function-5*. Patients will be instructed in strategies to improve postoperative communication regarding, sex, realistic expectations, erectile dysfunction and the use of aids.
4) *Stress management:* Patients will be systematically screened for anxiety, depression and health-related quality of life (Qol) using the Hospital Anxiety and Depression Scale (HADS). If patients are at risk of anxiety or depression (HADS >8), they will be referred on to a consultation with a nurse, who through a coaching approach, will provide information and strategies to handle the uncertainties they may experience during their treatment.
5) *Nutritional support:* Patients will be systematically screened for nutritional status and malnutrition. They will be provided with dietary advice via the App. Where a patient is at nutritional risk (NRS-2002 score ≥3) they will be provided with a nutritional supplement for 1-week pre-surgery, to increase protein and energy intake, according to recommendations from the ESPEN guidelines for clinical nutrition in surgery [16].

Standard care: The usual standard care regimen for pre-surgical preparation will be followed by participants in both the intervention and control group. This consists of information on how to prepare for surgery and details of the surgical pathway; anaesthesiological examination and preparation; general information about mobilization, pelvic floor anatomy and muscle function.

A diagram of the patient flow through the feasibility study is shown in Fig. 2.

2.6.4. Item 5. who provided

The multidisciplinary team consists of urologists, a physiotherapist, a physiotherapist specializing in urology and functioning of the pelvic floor, a clinical sexologist, two nurses specializing in urology and mental health for patients with prostate cancer, a nutritional counsellor, administrative staff and research team members. The outcome assessors will be blinded for randomization group.

2.6.5. Item 6. how: modes of delivery

Information about the study will be provided face-to-face by the treating urologist. Furthermore, written information will be provided to the participants. Thereafter, patients will be contacted by phone to arrange a date for enrolment, collections of baseline data and randomization. On the same day, patients in the intervention group will be introduced to the prehabilitation program.

2.6.6. Item 7. where: type of location

Eligible patients will be recruited from the Urological Department after referral for nerve sparing robot assisted RP. The interventions are home-based and will be delivered via App and video-consultations.

2.6.7. Item 8. when and how much

This is described in Item 4.

2.6.8. Item 9: tailoring

The prehabilitation program is partly standardized and partly individualized to individual patient needs. Individualization is applied: 1) in the exercise program, 2) through screening to assess whether the patient needs nutritional intervention or stress management support, and 3)

Timeline	Intervention Group	Control Group
Preliminary examination	Preliminary examination; biopsy, PSA, scanning. Medical conference and decision on treatment proposal for the patient. Diagnosis: Prostate cancer	Preliminary examination; biopsy, PSA, scanning. Medical conference and decision on treatment proposal for the patient. Diagnosis: Prostate cancer
Week 0	Preliminary consultation with patient and decision on treatment plan . If patient decides to have a nerve sparring radical prostatectomy: • Oral and written information about the study and patient rights.	Preliminary consultation with patient and decision on treatment plan. If patient decides to have a nerve sparring radical prostatectomy: • Oral and written information about the study and patient rights.
Week 1	Telephone call to ask the patient about inclusion in the study. If patient is included: • Patient is scheduled to physical attendance to be introduced to the study, have some physical test and answer questionnaire.	Telephone call to ask the patient about inclusion in the study. If patient is included: • Patient is scheduled to physical attendance to be introduced to the study, have some physical test and answer questionnaire.
Week 1	• Physical test: 6MWT, 30s STS, Grip strength test • Questionnaires: Baseline information, SF-12, IIEF-5, Physical activity, 24h Pad Weight test • Screening: NRS 2002, HADS • Randomization (After physical test and obtaining baseline information) • Introduction to and start of exercise and pelvic floor exercise (APP) • Examination by physiotherapist	• Physical test: 6MWT, 30s STS, Grip strength test • Questionnaires: Baseline information, SF-12, IIEF-5, Physical activity, 24h Pad Weight test • Screening: NRS 2002, HADS • Randomization (After physical test and obtaining baseline information)
Week 1-4	• Patient is exercising at home, using the app/program • Online consultation with clinical sexologist • If needed due to the screening: Online consultation regarding anxiety and stress	
Week 4	• Physical tests: 6MWT, 30s STS, Grip strength test • Questionnaires: SF-12, IIEF-5, Physical activity, HADS • Nutritional supplement if needed • Standard preoperative assessment and preparation by nurses	• Physical tests: 6MWT, 30s STS, Grip strength test • Questionnaires: SF-12, IIEF-5, Physical activity, HADS • Standard preoperative assessment and preparation by nurses and physiotherapist
SURGERY		
6 Weeks Post OP	• Physical tests: 6MWT, 30s STS, Grip strength test • Questionnaires: SF-12, IIEF-5, Physical activity, HADS, 24h Pad Weight test	• Physical tests: 6MWT, 30s STS, Grip strength test • Questionnaires: SF-12, IIEF-5, Physical activity, HADS, 24h Pad Weight test
6 Month Post OP	• Physical tests: 6MWT, 30s STS, Grip strength test • Questionnaires: SF-12, IIEF-5, Physical activity, HADS, 24h Pad Weight test	• Physical tests: 6MWT, 30s STS, Grip strength test • Questionnaires: SF-12, IIEF-5, Physical activity, HADS, 24h Pad Weight test
12 Month Post OP	• Physical tests: 6MWT, 30s STS, Grip strength test • Questionnaires: SF-12, IIEF-5, Physical activity, HADS, 24h Pad Weight test	• Physical tests: 6MWT, 30s STS, Grip strength test • Questionnaires: SF-12, IIEF-5, Physical activity, HADS, 24h Pad Weight test

*Abbreviations: Hospital Anxiety and Depression Scale (HADS), 6-minute-walk-test (6MWT), 30 seconds sit-to-stand test (30s STS), 12-Item short form Health Survey (SF-12), 5-Item International Index of Erectile Function (IIEF-5), 24-hour Pad Weigh Test, Nutritional Risk Screening (NRS-2002)

Fig. 2. Diagram of the patient flow through the study.
*Abbreviations: Hospital Anxiety and Depression Scale (HADS), 6-min-walk-test (6MWT), 30 s sit-to-stand test (30s STS), 12-Item short form Health Survey (SF-12), 5-Item International Index of Erectile Function (IIEF-5), 24-h Pad Weigh Test, Nutritional Risk Screening (NRS-2002).

through information gleaned during individual patient consultations.

2.6.9. Item 10. Modifications during the course of the study

The prehabilitation intervention will not be modified during the course of the study. The patient's record side effects through the study. If side effects occur, they will be assessed by a doctor. Patients with side effects affecting the ability to complete the prehabilitation, will be withdrawn from the study.

The research team members will monitor the quality and completeness of the data throughout the study.

2.6.10. Item 11. How well (planned)

Participants will be reminded to complete the logbook weekly during the prehabilitation period. Qualitative interviews with participants in the intervention group will capture experiences of engaging with the telehealth prehabilitation intervention.

The secondary purpose of the study is to collect preliminary data on changes in patient-reported outcomes (PROs), physical performance and urinary incontinence. Outcomes will be measured at baseline (prior to randomization), 1 day prior to surgery and at 6 weeks, 6 and 12 months postoperatively. The following outcomes will be assessed: 6-min-walk-test (6MWT) [32], 30 s sit-to-stand test (30STS) [33], Grip strength test [34], Self-reported physical activity [35], Hospital Anxiety and Depression Scale (HADS) [36], 12-Item short form Health Survey (SF-12) [37,38], 5-Item International Index of Erectile Function (IIEF-5) [39,40], 24-h Pad Weigh Test [41,42], and Nutritional Risk Screening (NRS-2002) [43].

2.6.11. Item 12. How well (actual)

The feasibility of implementing the intervention within the RP clinical pathway will be reported in a published research output.

2.7. Statistics

Descriptive statistics will be used to describe the baseline characteristics for the intervention group and the control group. Data will be presented as mean scores and SD or number and percentages. The two groups will be compared and tested for significant differences at baseline using chi-square test, and Student's t-test for normally distributed continuous variables, and Wilcoxon rank sum test for nonparametric variables. The secondary analysis will use the intention-to-treat principle, including all randomized participants. Linear mixed-effect models will be used to estimate the adjusted sample mean scores.

Based on the potential differences in the outcomes between the intervention group and the control group, the main outcome will be identified, and a power calculation will be performed.

2.8. Ethics approval and consent to participate

The feasibility study will be carried out in accordance with the Helsinki Declaration and is registered at The Danish Data Protection Agency through the Central Denmark Region (reference number: 774676). The General Data Protection Regulation will be followed. All participants will provide informed, written consent before participating in the study, and all data will be anonymized to protect participant confidentiality. Only the research team members will have access to the final dataset.

The Regional committee on Health Research Ethics has approved this study (reference number: 1-10-72-103-22). Data will be collected and stored through RedCap.

Dissemination will include publications and presentations at national and international conferences.

The feasibility study was registered at ClinicalTrials.gov

(NCT05608746).

2.9. Dissemination

Study results will be published in a peer review journal and presented at relevant conferences.

3. Discussion

This multimodal telehealth prehabilitation program for patients awaiting nerve sparing robot assisted RP, comprises several interacting components having potential to influence the length and complexity of the causal chain (from intervention to outcome) and can therefore be described as a complex intervention [11]. The TIDieR checklist was used as a framework for transparently describing its development and improve the reporting of it, facilitating future evaluation and replication. In Item 4, we have described each sub-domain of the intervention, together with the intended feasibility and health outcomes to be used in a randomized controlled feasibility study, in accordance with the checklist [12]. We have also developed a program theory to show the proposed causal links between the multimodal prehabilitation intervention and output, outcome and impact. The expected mechanisms of change are illustrated, together with how context could influence the causal links between the interventions and the outcomes. Following on from the feasibility study, the program theory will be used to evaluate effectiveness and determine whether the interventions produce the intended outcomes in a fully powered randomized controlled trial. However, the results from the feasibility study may be used to adjust or refine components of the model, including mechanisms of change and contextual factors, prior to conducting the trial.

The process used to develop the multimodal prehabilitation intervention has some key strengths. The detailed description of the development of the prehabilitation program using the TIDieR checklist is considered to be an important strength, in terms of helping to ensure that the intervention is described in sufficient detail to enable replication and completeness of reporting. In addition, the development process included a high-level of engagement with different stakeholders. Patients and health-care professionals provided valuable insights into the barriers and facilitators of multimodal prehabilitation prior to RP. These insights helped to shape the content of the intervention and address the logistical challenges of implementation. The engagement of managers and administrators was also essential in helping to overcome challenges associated with implementation into clinical practice. Another strength of this study is that we have developed a comprehensive home-based multimodal prehabilitation program, which has much potential to address many of the health needs and concerns experienced by men with prostate cancer awaiting RP. The benefit of taking a multimodal prehabilitation approach was highlighted following a narrative review by Minnella et al. [20] and this study will be one of the first to evaluate the use of telehealth in home-based prehabilitation prior to RP [44]. Some key limitations of the proposed feasibility study and, more broadly, to the implementation of prehabilitation prior to RP, also warrant consideration. Due to the rapid speed of the Danish clinical prostate cancer pathway, patients referred to nerve sparing robot-assisted RP have only 42 days from treatment decision until the surgical procedure. This creates logistical challenges for prehabilitation research, in which patient recruitment, informed consent, collection of baseline and follow-up outcomes and implementation of the intervention all have to be undertaken within this timeframe. Patients where it is not possible to preserve the nerves during the RP, are not eligible for 4-weeks of prehabilitation, as they only have 14 days until the surgery must be completed. The proposed feasibility study also lacks blinding to group allocation, as in this type of study design, it is not possible to blind patients to whether they are in the intervention or control group.

In conclusion, we have developed a multimodal prehabilitation programme, which has much potential to bring tangible health benefits to men with prostate cancer awaiting RP. A randomized controlled feasibility study has been developed using the TiDier checklist and in consultation with key stakeholders. The results of the feasibility study will inform the design of a fully powered randomized controlled trial.

Declarations

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3.1. Availability of data materials

Not applicable.

CRediT authorship contribution statement

Malene Blumenau Pedersen: Writing – original draft, Resources, Project administration, Methodology, Investigation, Conceptualization. **John M. Saxton:** Writing – review & editing, Supervision, Methodology, Conceptualization. **Brigitta Rasmussen Villumsen:** Writing – review & editing, Supervision, Methodology, Conceptualization. **Jørgen Bjerggaard Jensen:** Writing – review & editing, Supervision, Methodology, Conceptualization. **Sara Birch:** Writing – review & editing, Supervision, Resources, Methodology, Investigation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

No data was used for the research described in the article.

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Not applicable.

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